MIPPA: First Broad Changes to Medicare Part D Plan Operations

Jean D. LeMasurier; Babette Edgar, PharmD, MBA

In July 2008, as part of broad Medicare reform, Congress passed the first major legislative changes to Medicare Part D since its enactment in 2003—the Medicare Improvements for Patients and Providers Act. This new legislation has significant implications for how Part D plans can market and enroll Medicare beneficiaries. The new legislation also strengthened beneficiary protections, expanded the low-income subsidy provisions originally included in Part D, and expanded Part D coverage. These changes have significant implications for the operation of Part D plans and can affect those involved in benefit design, including specialty pharmacy coverage. This article discusses the major changes that took effect on January 1, 2009, and have immediate implications for Part D plan sponsors, including Medicare Advantage plans and stand-alone prescription drug plans. [AHDB. 2009;2(3):111-118.]

The Medicare Part D Prescription Drug Program was enacted on December 8, 2003, as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and was implemented on January 1, 2006. Because the program was the largest major enhancement of Medicare since its inception in 1965 and was controversial in its original design, Congress chose not to amend the legislation until last summer.

As part of a broad Medicare reform, on July 15, 2008, Congress overrode a Bush White House veto and passed new legislation—PL 110-275—the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA includes the first broad legislative changes to improve the Medicare Part D program, which are designed to strengthen beneficiary protections, help low-income beneficiaries, address marketing abuses, and enhance Part D coverage and transparency.

The new legislation codifies the elimination of the late-enrollment penalty for low-income subsidy (LIS) beneficiaries and the designation of protected drug categories for disease states for which interruption in drug therapy could have severe negative consequences on patients, all changes that will affect Part D plans and their members. Other changes affecting those in charge of Part D benefit design include greater compendia coverage to be consistent with Part B drug coverage. Table 1 provides a summary of the MIPPA provisions that affect Part D plans.

Most of these new Part D provisions were focused on strengthening beneficiary protections and correcting sales and marketing abuses. These changes were driven by Democrats who assumed the congressional majority in the 2006 midterm elections and were responding to remaining challenges in the program. The Government Accountability Office (GAO) documented some of the problems in its reports, for example, the report on beneficiaries filing grievances to plan sponsors. In addition, a series of GAO reports in 2007 and 2008—GAO-07-555, GAO-08-812T, and GAO-08-824—documented problems with the low-income subsidy provisions in the Part D program and helped drive the legislative agenda to expand federal subsidies to low-income Medicare beneficiaries and to strengthen protections for vulnerable beneficiaries, concerns that are now reflected in MIPPA.

Another goal was to improve Part D access and coverage to the extent possible under the congressional “pay for” rules. These rules say that when a bill expands benefit coverage, there is a new cost, which must be funded by reduced costs elsewhere in the program. For example, MIPPA added 2 new Part D drugs, but these could not be paid for until 2013.

The Centers for Medicare & Medicaid Services (CMS) provided the MIPPA provisions to Part D in 3
regulatory rules—(1) a final rule (CMS-4131-F) and (2) an interim final rule (CMS-4138-IFC), which were published on September 18, 2008; and (3) an interim and final rule with a comment period (CMS 4138-IFC4), published on January 16, 2009.

Marketing Changes
During the first 2 years of the Part D program, more than 17 million Medicare beneficiaries were enrolled in stand-alone Part D plans, and an additional 8 million beneficiaries were enrolled in Medicare Advantage plans that included Part D coverage. This was a phenomenal accomplishment in such a short amount of time and was largely made possible through plan use of contracted sales brokers and agents.

Before the introduction of the Medicare Part D program, Medicare Advantage plans primarily employed sales agents, and use of contracted sales agents was limited to the Medigap supplemental insurance market. With the establishment of the Medicare Part D program, many new plans entered the Medicare marketplace for the first time, and with them many new agents who were unfamiliar with selling managed care products. CMS's attempts at regulating the marketplace can be seen in the marketing guidelines issued in 2005 and revised in 2006. The sales agents for the new Part D plan had the task of selling more than 5000 plans nationwide, with multiple benefit designs and formulary structures that included a limited enrollment period of 45 days.

Inevitably, abuses occurred in the marketplace, including large commissions that encouraged churning, misunderstanding of complicated plan designs, and outright fraud and abuse, resulting in beneficiaries being enrolled in plans they did not choose, or plans that did not meet their needs. Information on CMS's corrective action plans and enforcement actions is open to the public and helps ensure that Medicare regulations of health plans are followed properly.

MIPPA imposes major changes in the marketing of Part D plans. The changes include a number of prohibitions and limitations on sales and marketing activities by Medicare Advantage and prescription drug plan (PDP) sponsors and their agents, brokers, or other third parties that represent them. Effective January 1, 2009, Medicare Part D plans and their representatives are prohibited from the following promotional activities:

- Unsolicited direct contact of prospective enrollees, such as door-to-door sales and cold calling (telemarketing)
- Selling non–health-related products (cross-selling)
- Providing meals at promotional and sales events
- Selling or marketing in healthcare settings and at educational events.

Other marketing requirements in MIPPA include:

- Advance agreement with a prospective enrollee on

### Table 1 MIPPA: Key Provisions Affecting Medicare Part D Plans

<table>
<thead>
<tr>
<th>Medicare Advantage</th>
<th>Marketing Reforms</th>
<th>Beneficiary Improvements</th>
<th>Low-Income Individuals</th>
<th>Part D Drug Benefit Improvements</th>
<th>Physician Services under Part B</th>
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<td>Reduces overpayments to private Medicare Advantage plans by phasing out an adjustment for indirect medical education</td>
<td>Prohibits and limits certain sales and marketing activities under Medicare Advantage and Part D prescription drug plans</td>
<td>Provides Medicare mental health parity</td>
<td>Extends the qualifying individual program</td>
<td>Requires Part D plans to cover benzodiazepines and barbiturates in 2013</td>
<td>Blocks the scheduled 10.6% cut to physician fees</td>
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<td>Requires private fee-for-service plans to establish provider networks and to measure and report on the quality of care they deliver</td>
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<td>Reduces money in the Medicare Advantage Stabilization Fund</td>
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<td>Codifies suspension of the late enrollment penalty for Part D beneficiaries who qualify for low-income subsidy</td>
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<td>Excludes the value of life insurance policies and in-kind support from resource calculations for low-income subsidy</td>
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the scope of products to be discussed during marketing appointments
• Limitations on the use of the name or logo of a network provider (co-branding)
• Limitation on gifts to prospective enrollees to nominal dollar value
• Compensation of brokers and agents: plans must comply with guidelines established by the Health and Human Services (HHS) Secretary that provide incentives to enroll individuals in plans that best meet their healthcare needs
• Annual training and testing of agents, brokers, and other parties
• Inclusion of plan type in plan name in 2010
• Plans can only use state licensed agents and brokers and must comply with state appointment laws and state investigations of agent, broker, or third-party conduct.

CMS did its utmost to publish regulations in time for the beneficiaries’ annual election period, leading up to the January 1, 2009, enrollment. However, the development of policy on the new commission structure proved difficult, and CMS’s policy on the interim final rule with comment (IFC) was modified twice after industry and consumer groups responded that the initial policy was unworkable or did not accomplish the objective to reduce churning. The final policy (in the final regulation) adopted a 6-year structure similar to the compensation structure used in the Medigap insurance industry.

It is too early to assess the impact of the new MIPPA requirements and regulations, because much activity during the 2008 selling season was delayed as a result of uncertainty on the commission requirements. To date, we are aware of only a few reports of potential abuses that are currently under investigation, as noted by CMS in the draft Call Letter for 2010. Overall, CMS oversight has been strengthened, and congressional scrutiny will certainly follow.

**Low-Income Subsidy**

One of the major changes introduced by the Medicare Part D program was to shift dual-eligible beneficiaries (ie, those eligible for Medicare and Medicaid) from drug coverage under state Medicaid programs to drug coverage under the Medicare Part D program with federal LIS.

A number of members of Congress were concerned that during the first 3 years of the Part D program, an estimated 3 million beneficiaries who had been expected to be eligible for LIS had not signed up. One of the problems that emerged was that LIS eligibility require-

**KEY POINTS**

- MIPPA offers the first broad legislative changes to the Medicare Part D program that are intended to increase beneficiary protections, provide subsidies to low-income beneficiaries, impose major changes to the marketing of Part D plans, and enhance coverage and transparency.
- Changes directly affecting drug benefit design include the coverage of all drugs in 6 protected classes, increased compendia coverage for Part D plans consistent with Part B, a new definition of medically accepted indications, and coverage of barbiturates and benzodiazepines.
- MIPPA imposes stringent prompt payment requirements to pharmacies, as well as regular updates of drug prices by Part D plans to their network pharmacies.
- Despite these changes, basic structural concerns with the Part D program—such as the coverage gap or a competing government drug program with governmental drug price negotiation authority—were not addressed by MIPPA.
Drug Coverage Changes

Formulary Protected Classes

When Medicare Part D was enacted, CMS identified drug categories for disease states in which interruption of drug therapy could have severe negative consequences for patients. Many of these disease states correlate directly with conditions that are prevalent among low-income beneficiaries. To ensure that therapies would not be interrupted and that vulnerable populations had the widest choice of plans, CMS included policy in subregulatory guidance that requires Part D plans to provide coverage substantially for all drugs within the 6 drug classes of clinical concern (Table 2). Because Congress was concerned that a future HHS Secretary could retrench on this coverage, it included a provision in MIPPA to codify the current policy on protected drug classes under the Medicare Part D program.

One of the surprising provisions in MIPPA is the establishment of a process to potentially expand the protected classes under Part D. MIPPA provides that the HHS Secretary, beginning in 2010, shall identify categories and classes of drugs that:

1. If restricted, would have a major or life-threatening clinical effect, and
2. Are needed by individuals who use multiple drugs in a drug category/class, because of the unique chemical actions and pharmacologic effects of those classes, such as cancer drugs.

According to the statute, the HHS Secretary must use a public rule-making process to identify protected classes that meet these criteria. When final rules are issued, Part D plan sponsors will be required to cover all drugs in the category/class that the HHS Secretary identifies for that purpose, unless there are exceptions based on scientific evidence and medical standards of practice.

The January 16, 2009, regulation identifies the process that will be used to implement this new provision, and indicates that there will be no changes in 2010. However, many observers believe that the clinical standards included in MIPPA are very stringent, and that combined with the public rule-making process, it will preclude broad expansion of the currently protected classes.

New Definition of Medically Accepted Indications

In 1994, Medicare Part B started to cover off-label indications for US Food and Drug Administration (FDA)-approved anticancer drugs, if those uses were published in specified compendia or in 1 or more approved peer-reviewed journals, provided that the carrier determined the unlabeled use to be medically accepted as safe and effective for the particular use. The list of Part B drug compendia was updated in 2008; it now includes the following 5 compendia:

- The American Hospital Formulary Service Drug Information (AHFS DI)
- The US Pharmacopeia Dispensing Information (USP DI), which is no longer published and which incorporates the also no-longer published American Medical Association Drug Evaluations (AMA-DE)
- The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- DRUGDEX
- Clinical Pharmacology.

An analysis conducted by the Agency for Healthcare Research and Quality (AHRQ) and published in May 2007 revealed 14 off-label uses for cancer treatment listed across all compendia. For example, the following 3 drugs—bevacizumab (Avastin), oxaliplatin (Eloxatin), and irinotecan (Comptosar)—at that time were not approved by the FDA for the treatment of breast cancer, but were listed by various compendia as off-label options for such use. (Bevacizumab has since received a new indication for the treatment of some forms of breast cancer.)

Expanded Oncology Compendia for Part D

Before MIPPA, the list of compendia for Part D coverage of drugs used off-label was more limited than the drug coverage under the Part B program. The regulations that implemented Part D prohibited coverage of off-label use of prescription drugs, unless the prescribed use was supported in 1 of 3 medical compendia used to define “medically accepted indications” in the Medicaid program. The 3 compendia that were accepted by the Part D program were AHFS DI, USP DI (or its successor), and DRUGDEX. If the drug was not listed in any of these 3 specified compendia, Part D plans could not cover the drugs, regardless of any medical necessity or

Table 2 MIPPA: The 6 Protected Drug Classes in Part D

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Uses covered</th>
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<tbody>
<tr>
<td>Anticonvulsants</td>
<td>Epilepsy, bipolar disorder, neuropathy</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Depressive disorders</td>
</tr>
<tr>
<td>Antineoplastics</td>
<td>Cancers (different types)</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>Psychotic disorders, schizophrenia</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>HIV infection/AIDS</td>
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<tr>
<td>Immunosuppressants</td>
<td>Organ transplant rejection prophylaxis</td>
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evidence of clinical effectiveness, including evidence from clinical research published in peer-reviewed medical journals.

Under MIPPA, Congress has expanded the Medicare Part D drug coverage to off-label uses of anticancer drugs, to be consistent with the compendia used for Part B coverage. The impetus for the change in Part D came from pressure from consumer groups that identified numerous circumstances where beneficiaries were better off with their drug coverage before Medicare Part D. For example, a report issued by the Medicare Rights Center in August 2007 on the exclusion of off-label use from Medicare Part D coverage points out that before Part D, many beneficiaries were prescribed medically necessary drugs for off-label uses.17 The report states that more than 20% of prescriptions written for the most often used drugs were for off-label uses, and such off-label uses were most prevalent for the treatment of patients with cancer or with HIV infection.17 The report also cites studies by the GAO and the American Cancer Society, showing that more than 50% of patients with cancer are prescribed at least 1 drug for an off-label use.17

The Medicare Rights Center recommended that Congress change the Part D statute to include medically necessary off-label prescriptions outside the then 3 compendia used for regulating Part D coverage, to improve the lives and health of Medicare beneficiaries. The Medicare Rights Center also argued that expansion of the compendia would be consistent with common medical practice and with the intent of the Part D statute.

Congress adopted part of the consumer group recommendations in MIPPA; effective January 1, 2009, Part D now covers off-label uses of drugs for the treatment of cancer if they are listed in any of the CMS-recognized compendia for determining coverage under the Part B program. But unlike Part B, MIPPA does not allow Medicare Advantage Part D plans or PDPs to use peer-reviewed studies as guidance for determining off-label uses.

The regulation implementing the new MIPPA provision does not impose significant changes under Part D, because most cancer-related drugs are covered under the Part B program. Coverage for off-label use of non-cancer-related drugs did not change under MIPPA. Effective in 2010, MIPPA requires all compendia to have a publicly transparent process for evaluating drug therapies, as well as disclose any conflicts of interest.

Coverage of Barbiturates and Benzodiazepines

MIPPA expands Part D coverage to include barbiturates and benzodiazepines if they are used for the treatment of epilepsy, cancer, or a chronic mental disorder. These 2 drug classes were excluded from Part D coverage before MIPPA, even though many older adults in nursing homes and in outpatient settings are prescribed these drugs. However, this new coverage does not go into effect until 2013, because of the associated increased cost anticipated to the Part D program.

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Prompt Payment to Pharmacies

With the implementation of Part D, some pharmacies, particularly community pharmacies, were concerned that Part D plans were paying claims for Part D drugs too slowly.18,19 Under the Part D rules, clean claims had to be paid within 30 days. Many pharmacies restocked their supplies every 2 weeks and received discounts from suppliers if their orders were paid quickly. According to the National Community Pharmacists Association (NCPA), the delays in Part D payments to local pharmacies presented severe financial difficulties and threatened the existence of many pharmacies.20 It is further believed that this delayed payment was a major contributor to the closing of many pharmacies during the first year of Medicare Part D. The NCPA lobbied hard for a prompt payment requirement similar to the commercial sector.20 Therefore, MIPPA includes a more stringent prompt payment requirement to pharmacies.

Effective in 2010, Part D plan sponsors will be required to pay clean claims from all pharmacies—except for mail order and long-term care (LTC) pharmacies (pharmacies located in or contracting with LTC facilities)—within 14 days after transmission if submitted electronically, or within 30 days if submitted otherwise, starting on the fifth day after the postmark or transmission date. If claims are not paid in a timely manner, Part D plan sponsors will pay interest to the pharmacy.

MIPPA does not include a prompt payment requirement for claims from LTC pharmacies; however, MIPPA establishes a time period for LTC pharmacies to submit claims to their Part D plan sponsors—not less than 30 days or more than 90 days.
Another change included in MIPPA is a requirement that Part D plans provide timely and regular updates of their drug prices to their pharmacies.

Updating Drug Pricing

Another change included in MIPPA is a requirement that Part D plans provide timely and regular updates of their drug prices to their pharmacies. Specifically, if plans pay pharmacies based on the cost of a drug, they must provide updates at least weekly, beginning with an initial annual update every January 1.

This new policy would affect payments on the basis of drug costs, such as the average wholesale price (AWP). The September 18, 2008, IFC rule clarifies that Part D plan sponsors that contract with pharmacies, providers, first-tier, downstream, and related entities must include provisions for regular drug pricing updates.7

Access to Part D Data

MIPPA includes a provision that Part D data may be used for research, to improve public health, and for congressional oversight. This provision codifies policy that was published in final regulations on May 28, 2008, which stipulates who can have the data and for what purposes (eg, for research or for congressional oversight, among other uses).21

Electronic Prescribing

For Part B covered drugs, MIPPA provides incentive payments for clinicians to use qualified electronic-prescribing (e-prescribing) systems in the coming years. The bonus payment schedule is:

- 2% in 2009 and 2010
- 1% in 2011 and 2012
- 0.5% in 2013.

Clinicians would be required to use qualified e-prescribing systems by 2011. Payments to clinicians who fail to e-prescribe will be reduced incrementally:

- 1% in 2012
- 1.5% in 2013
- 2% annually thereafter.

Currently, these incentive payments and penalties do not apply to Part D prescriptions (except for Medicare Advantage private fee-for-service plans, and providers who do not contract with Medicare Advantage plans). MIPPA includes an authority that allows the HHS Secretary to use Part D data in lieu of Part B claims data for e-prescribing reporting. It also authorizes the HHS Secretary to change the reporting requirements in the future, based on the number of Part D prescriptions. The regulations implementing the MIPPA e-prescribing provisions do not currently address the Part D program.

Conclusions

MIPPA includes the first extensive legislative changes to the Medicare Part D program. Nevertheless, these changes are relatively modest program improvements to strengthen beneficiary protections and low-income individuals, address marketing abuses, and enhance coverage and transparency. The basic structural concerns with the Part D program, such as the coverage gap, and the ideological issues, such as a competing government drug program with governmental drug price negotiation authority, were not addressed by MIPPA. We anticipate that these issues will be discussed vigorously during the 111th Congress. Indeed, during the first weeks of the session of the new Congress, bills have already been introduced to address these issues.

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Disclosure Statement

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References


**STAKEHOLDER PERSPECTIVE**

**Part D under the Medicare Improvements for Patients and Providers Act of 2008**

**PAYERS:** The Bush administration and the congressional Republican leadership went to extraordinary lengths to secure final passage of the Medicare Prescription Drug and Modernization Act of 2003 and the creation of the Medicare prescription drug benefit (Part D). That process—and the ongoing challenges involved in developing bipartisan consensus for major health reform efforts—led to immediate and vigorous criticisms of the Part D program from the left and from the right on issues ranging from the costs of the program to the now-infamous coverage gap in the benefit design, more often referred to as the “doughnut hole.”

However, facts on the ground often contrasted the politically driven criticisms. For example, Part D plan premium costs ended up being lower than projected, as the Centers for Medicare & Medicaid Services (CMS) announced (in a press release on August 13, 2007). Moreover, satisfaction rates have been very high, as reported in several surveys in 2006 and 2007 conducted by the AARP, JD Power and Associates, and others. These realities strengthened the Bush administration’s resolve in opposing any legislative reform efforts.

Concurrently, the natural operational challenges—such as the enrollment processing glitches in early 2006—associated with a new program of this size, helped to bolster the critics. Part D was lambasted in many congressional hearings held between 2006 and 2008. Ultimately, the momentum of these hearings resulted in a veto override of President Bush, leading to the first major legislative changes to

*Continued*
Part D in the third coverage year of the program in the form of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

With early-2008 passage and several legislatively mandated January 2009 deadlines, the implementation process of MIPPA was less than ideal for CMS and for Part D plan sponsors. CMS operates the Part D program in annual cycles that include plan bids, development of benefit designs, and approval of plan marketing materials. For operational reasons, these activities need to be completed in the spring and summer, before the start of a new coverage year. Ill-timed legislative mandates such as MIPPA put substantive operational strain on CMS and on Part D plan sponsors as they work through the rule-making and implementation-design processes.

MIPPA has had an immediate and profound effect on Part D plan marketing, while strengthening existing CMS policies around coverage and benefits administration. MIPPA represents the starting point for more intense CMS oversight of Part D plan sponsors. Indeed, in its annual 2010 Call Letter (released on March 30, 2009), CMS announced that it would perform “more targeted, data-driven and risk-based audits,” with the goal of the “earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors.”

MIPPA did not address, however, the more politicized reform proposals, including the public plan option, closing the doughnut hole, and government negotiation of drug prices. Plan sponsors can expect to see proposals debated through the legislative process in the immediate future.

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