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The Honorable Henry A Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable John D. Dingell
House of Representatives

Subject: *Medicare Part D Formularies: CMS Conducts Oversight of Mid-Year Changes;
Most Mid-Year Changes Were Enhancements*

The Medicare voluntary outpatient prescription drug insurance program, known as Medicare Part D,¹ provided prescription drug coverage for about 23 million beneficiaries—eligible individuals 65 years and older and eligible individuals with disabilities—enrolled in the program in 2010.² Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private companies, known as sponsors, that contract with the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program.³ Sponsors may have multiple contracts with CMS to provide drug coverage, with each contract offering one or more distinct Part D plans.⁴ Sponsors compete for beneficiary enrollment on the basis of plan premiums and benefit designs. Sponsors also vary in the content of their formularies—the list of covered drugs and associated utilization management (UM) requirements. UM requirements include (1) step therapy, which requires that a beneficiary try lower-cost drugs before a sponsor will cover a more costly drug; (2) prior authorization, which requires a beneficiary to obtain the sponsor's approval before a drug is covered for that individual; and (3) quantity limits, which restrict

¹Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (2003) (codified, as amended, at 42 U.S.C. §§ 1395w-101—1395w-152).

²The number of total Medicare Part D enrollees excludes individuals enrolled in plans with restricted enrollment, i.e., employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans.

³Sponsors offer drug coverage either through stand-alone prescription drug plans (PDP), or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare Advantage, Medicare's managed care program—Medicare Part C.

⁴As of February 2009, Part D enrollment was concentrated in plans offered by a small number of sponsors. Medicare Payment Advisory Commission, *A Data Book: Healthcare Spending and the Medicare Program* (Washington, D.C: June 2009).

the dosage or number of units of a drug provided within a certain period of time. Sponsors may design their plans to use the same or different formularies. Sponsors may use their formulary structures to manage beneficiaries' drug spending and utilization, however, sponsors must adhere to a minimum set of formulary requirements established in statute and regulation.

In its administration of Part D, CMS is responsible for implementing program requirements and overseeing sponsors' compliance with these requirements. To do so, CMS issued regulations and program guidance addressing classes of drugs that must be covered on sponsors' plan formularies, classes of drugs that may not be covered by Part D, UM program requirements, and annual formulary submission time lines.^{5,6}

Medicare beneficiaries may choose to enroll in plans based, in part, on the formularies that sponsors establish for their plans at the beginning of each year.⁷ With few exceptions, once beneficiaries enroll in a sponsor's plan, they may not change plans until the next year. However, sponsors may make certain changes to their plans' formularies during the year, known as mid-year formulary changes, provided that their plans' formularies continue to meet certain minimum Part D formulary requirements including those that apply to mid-year changes. Mid-year formulary changes may enhance Part D formularies by adding drugs or removing or loosening UM requirements for drugs, or may restrict formularies by removing drugs or tightening UM requirements for drugs.

Mid-year changes affect sponsors' plan formularies and may disrupt beneficiaries' access to certain prescription drugs or make them responsible for new or unexpected costs. You asked us to review mid-year formulary changes in the context of CMS's oversight and the potential effect of mid-year changes on beneficiaries. In this report, we describe (1) the actions CMS has taken to oversee sponsors' compliance with mid-year formulary change requirements;

⁵42 C.F.R. § 423.120(b)(2010); CMS Medicare Prescription Drug Benefit Manual (CMS), chapter 6, Part D Drugs and Formulary Requirements, §§ 20.1, 30.1.5, 30.2.1, 30.2.8 (2008). The Medicare Prescription Drug Benefit Manual consists of multiple chapters related to various Part D program areas and outlines Part D requirements and CMS guidance.

⁶Drugs on formularies are grouped into categories and classes that treat the same condition or that work in a similar way. Sponsors generally must include at least two drugs within each therapeutic category and class of covered Part D drugs. Exceptions are allowed, for example, when there is only one drug in a particular category or class. In addition, CMS requires that formularies include "all or substantially all" drugs within six designated categories of clinical concern. 42 U.S.C. § 1395w-104(b)(3)(C)(i); 42 C.F.R. § 423.120(b)(2)(2010); CMS, chapter 6, § 30.2.5 (2008).

⁷The Part D program year is from January 1 through December 31. In June of the preceding year during the annual bid process, sponsors must submit separate bids for each plan, including any changes to formularies and plan benefit designs, to CMS. Sponsors must receive approval from CMS prior to implementing these changes for the next year. Beneficiaries may choose a drug plan during the Part D annual coordinated election period. Drug coverage under the elected new plan is effective on January 1 of the next year.

and (2) the mid-year formulary changes sponsors made for their plans in 2008 and 2009 and how many beneficiaries filled a prescription for a drug later affected by a negative mid-year formulary change in 2008.^{8,9}

To determine what actions CMS has taken to oversee sponsors' compliance with mid-year formulary change requirements we reviewed relevant laws, regulations, and CMS guidance. We also interviewed relevant CMS officials and examined previous GAO and HHS Office of Inspector General (OIG) reports related to CMS oversight of Medicare Part D sponsors.

To examine the mid-year formulary changes that sponsors made for their plans in 2008 and 2009, we obtained formulary files from CMS for prescription drug plans (PDP) and Medicare Advantage prescription drug (MA-PD) plans for years 2008 and 2009.¹⁰ To identify mid-year changes we compared the January and December formulary files for 2008 and 2009 and identified drugs and UM requirements that differed at the end of each of the two years.^{11,12}

For the purposes of this report, we categorized mid-year formulary changes as either enhancements or negative changes. We assigned mid-year formulary changes to these categories using a different basis than that used by CMS. CMS categorizes negative changes based on information sponsors submit when requesting approval to make negative formulary changes. However, our analysis indicated that some negative changes were implemented differently than requested.¹³ Therefore, we categorized mid-year formulary changes based on the plan's actual implementation of the change. In general, our "enhancement" and "negative" change categories correspond to CMS's "enhancement" and "negative" change categories, respectively. Specifically, we categorized two types of changes as enhancements to the formulary:

- when a drug was added to the formulary, which we refer to as "drug added"; or
- when any existing UM requirement for a drug on the formulary was removed or loosened, referred to as "removed UM requirements."

⁸CMS's prescription drug event data (PDE) data contain a record of each claim reimbursed under the Part D program. PDE data for 2008 were the most recent available at the time of our review.

⁹CMS refers to changes that enhance the formulary as "enhancements" and changes that restrict the formulary as "negative." CMS further categorizes negative changes as maintenance or non-maintenance changes. Maintenance changes include those involving generic substitution or modifying a formulary due to new information on a drug's safety or effectiveness. Non-maintenance changes include drug removals or tightening of UM requirements for reasons other than safety or generic substitution.

¹⁰To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1 of each year.

¹¹Sponsors upload formulary files—containing their approved formularies—to CMS's Health Plan Management System (HPMS). Sponsors may use the same uploaded formulary file for multiple plans.

¹²We counted the number of specific mid-year changes to a drug and multiplied each unique change by the number of plans for which the sponsor implemented the change. We summed these changes across plans to calculate the total number of mid-year changes.

¹³Sponsors are required to request approval from CMS prior to the implementation of most negative changes to their plans' formularies.

There were four types of changes that we categorized as negative changes:

- when a drug was removed from the formulary and another drug (known as an offset) was added,¹⁴ referred to as “removed drug, add offset drug”;
- when a drug was removed from the formulary, referred to as “removed drug without offset”;
- when any UM requirement was added to a drug and an offset drug was added, referred to as “tightened UM with offset drug”; and
- when any UM requirement was added to a drug, referred to as “tightened UM without offset.”

We completed additional analyses to determine the number of beneficiaries potentially affected by negative mid-year changes in 2008. To estimate the number of potentially affected beneficiaries for each of these changes, we identified 2008 Prescription Drug Event (PDE) claims for beneficiaries who filled a prescription for a drug affected by a negative change at any point from the beginning of the year up until the approved effective date of the change. To ensure the reliability of CMS data we reviewed data documentation; tested data elements for missing data, outliers, and errors; and discussed and resolved inconsistencies found in data elements with CMS officials responsible for data management. Based on these activities, we determined that the data were sufficiently reliable for our purposes. (See enclosure I for additional information on how we identified mid-year changes and potentially affected beneficiaries.)

We conducted this performance audit from July 2009 through June 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

CMS monitors—directly examines—certain requests for mid-year formulary changes prior to their implementation to ensure that formularies meet requirements including mid-year change requirements. CMS also conducts retrospective oversight activities of sponsors’ compliance with mid-year formulary change requirements. Specifically, CMS monitors agency data; conducts discussions with trade groups, advocates, and other patient representatives; and conducts targeted audit activities.

Our analysis of mid-year formulary changes in 2008 and 2009 indicated that sponsors implemented multiple mid-year changes for almost all plans in those years. Formulary enhancements, which added a drug to the formulary or removed or loosened restrictions on a drug, accounted for 87.4 percent of changes in 2008 and 88.6 percent in 2009. Negative changes, such as removing a drug from a formulary, accounted for 12.6 percent of changes in 2008 and 11.4 percent in 2009. In addition, we found that in 2008 about 5 percent of

¹⁴Hereafter, we refer to the addition of a drug such as a generic to offset a mid-year formulary change as an offset. According to CMS, an offset drug can be any FDA-defined therapeutic alternative to the drug being affected—for example, a lower-cost generic.

beneficiaries (over 1.1 million beneficiaries) filled a prescription for a drug that was later affected by a negative mid-year change.¹⁵

In its comments on a draft of this report, CMS generally agreed with our findings. CMS asked that we provide additional clarification on its oversight of sponsors' negative mid-year change requests and on our methodology for our analysis of mid-year changes. We have provided these clarifications as appropriate.

Background

Statute, regulation, and CMS policy established requirements for Part D formularies including requirements for mid-year changes.

Medicare Part D Formularies

Federal law requires that Medicare Part D formularies be based on scientific evidence and standards of practice and be developed and reviewed by a Pharmacy and Therapeutics Committee.¹⁶ Formularies must also include drug UM programs including incentives to reduce costs when medically appropriate.¹⁷ For drugs included on their formularies, sponsors may assign drugs to tiers that correspond to different levels of cost sharing. For example, sponsors may establish separate tiers for brand-name drugs and generic drugs—drugs that are therapeutically equivalent to brand-name drugs but cost less. In general, this type of structure encourages the use of less costly generic medications by putting them on a cost-sharing tier that requires the lowest out-of-pocket costs for beneficiaries. Sponsors submit formularies for their plans to CMS through CMS's Health Plan Management System (HPMS),¹⁸ and CMS reviews and approves formularies as part of the annual bid process.

Mid-Year Formulary Changes

Although formularies are reviewed and approved at the beginning of the year through the annual bid process, sponsors may make formulary enhancements and negative changes at certain times of the year. CMS established mid-year formulary change requirements that include timeframes in which each type of change can be made, as well as requirements for CMS approval and notification of beneficiaries.¹⁹ Specifically, sponsors may implement changes—that is, make changes to their plans' formularies in HPMS—that enhance the formulary at any time during the year, and are not required to seek CMS approval prior to implementation.²⁰ In contrast, sponsors must request and receive CMS approval prior to the

¹⁵According to CMS policy, beneficiaries currently taking prescription drugs affected by certain negative mid-year formulary changes are ensured continued access to those drugs for the remainder of the year.

¹⁶The Pharmacy and Therapeutics Committee must include at least one physician and one pharmacist with expertise in the care of elderly or disabled persons. 42 U.S.C. § 1395w-104(b)(3)(A), (B)(i).

¹⁷42 U.S.C. § 1395w-104(c)(1)(A).

¹⁸HPMS is the electronic information and communication system between CMS and sponsors participating in Medicare Parts C and D. HPMS collects data for and manages the following plan enrollment processes: application process, bid/benefit package submissions, formulary submissions, marketing material reviews, plan oversight, complaints tracking, survey data, operational data feeds for enrollment and payment, and data support for the www.medicare.gov Web site.

¹⁹42 C.F.R. § 423.120 (b)(4), (5), (6); CMS chapter 6, §§ 30.3 – 30.3.5.

²⁰CMS, chapter 6, § 30.3.3.1. CMS officials told us that they would retroactively deny a formulary enhancement that did not meet formulary requirements.

implementation of most negative changes that could restrict beneficiary access to drugs and are not permitted to implement most negative changes until 60 days after the beginning of the year.²¹

With the exception of certain safety related changes, CMS requires sponsors to request negative changes through an application in HPMS and CMS officials reported that they monitor these requests. The type of approval—implicit or explicit—needed for negative changes is dependent upon the sponsor’s justification for and categorization of the change. CMS generally implicitly approves changes that remove a brand name drug with the addition of a generic drug—known as brand to generic substitutions—that is, sponsors can assume these types of requests are approved if they do not receive disapproval from CMS through HPMS within 30 days of submitting the request. However, some negative changes such as, in some cases, the removal of a drug without the corresponding addition of an offset drug, require explicit pre-implementation approval from CMS.²² Also, because of the potential for these types of changes to adversely affect beneficiaries’ access to medications, CMS officials told us that the agency approves such changes on the condition that beneficiaries currently taking the affected drug are exempt from the change for the remainder of the year.²³ That is, for the remainder of the year the change can only apply to beneficiaries beginning to take that drug. CMS officials we spoke with referred to this conditional approval as the grandfathering policy.²⁴

Regardless of whether the type of change is an enhancement or negative, CMS requires sponsors to submit updated formularies—formularies that contain changes—through HPMS during the first 3 business days of any given month up until October of the year. Sponsors are also required to provide notice of negative formulary changes to, among others, beneficiaries currently taking the affected drug. However, because it is CMS policy to approve certain types of negative changes only when those currently taking the affected drug are exempted from the change, notice is not required for those beneficiaries.²⁵ In addition, sponsors must make information on negative changes available on their plan’s Web sites²⁶ and are

²¹CMS, chapter 6, § 30.3.2. Sponsors are not required to obtain pre-implementation approval from CMS to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer. 42 C.F.R. § 423.120(b)(5)(iii)(2010); CMS chapter 6, §30.3.3.1(2008). Sponsors must submit all change requests before July 31, and must upload new formularies containing approved changes to HPMS by October of the year.

²²CMS categorizes negative changes into two subgroups, called maintenance changes and non-maintenance changes. Maintenance changes include those involving generic substitution or modifying a formulary due to new information on a drug’s safety or effectiveness. Non-maintenance changes include drug removals or tightening of UM requirements for reasons other than safety or generic substitution. CMS’s implicit and explicit negative change approval policies are associated with the maintenance and non-maintenance change types, respectively.

²³See CMS chapter 6, §§ 30.3.3.1, 30.3.3.3. According to CMS officials, sponsors are responsible for defining which beneficiaries they consider “currently taking” the affected drug. For example, a sponsor could define beneficiaries “currently taking” an affected drug as any beneficiary who filled a prescription for the drug 2, 3, or 4 months prior to a mid-year change.

²⁴The grandfathering policy applies only to negative formulary changes that CMS categorizes as non-maintenance changes; the policy does not apply to changes that CMS categorizes as maintenance changes.

²⁵42 U.S.C. §§ 1395w-104(b)(3)(E); 42 C.F.R. § 423.120(b)(5)(2010); CMS chapter 6, § 30.3.4.1. Sponsors must provide written notice at least 60 days prior to the date the change becomes effective or provide a 60 day supply of the drug and written notice at the time an affected beneficiary requests a refill. Sponsors may immediately remove drugs deemed unsafe by the FDA or removed from the market by the manufacturer, but must provide retrospective notice to beneficiaries and others. 42 C.F.R. § 423.120(b)(5)(iii)(2010). CMS chapter 6, §§ 30.3.4.1, 30.3.4.3.

²⁶42 U.S.C. § 1395w-104(a)(3)(B).

responsible for ensuring that their marketed formularies, including those on their Web sites, are consistent with their approved formularies in HPMS.²⁷

CMS Conducts Prospective Reviews of Formularies and Some Retrospective Activities to Oversee Sponsors' Compliance with Mid-Year Formulary Change Requirements

CMS Prospectively Monitors Mid-Year Formulary Change Submissions to Ensure Formularies Meet Requirements

CMS officials stated that they monitor—directly examine—certain mid-year change requests submitted through HPMS and approve mid-year formulary changes that meet formulary requirements including mid-year change requirements. Specifically, in 2008 CMS began requiring sponsors to request approval for negative changes through the HPMS application.²⁸ Officials told us that they review sponsors' requests for negative changes in the context of each plan's full formulary to ensure that, if implemented, the changes would not result in substantial change to the plan's formulary and that the formulary would still meet the minimum Part D formulary requirements. For example, CMS would confirm that, even with the requested change, the sponsor's formulary would include at least two drugs in that drug class.²⁹ CMS officials reported that the number of negative mid-year change requests decreased by over 30 percent in 2008, when CMS made a number of policy changes including requiring that negative changes be requested through HPMS.³⁰

In addition to monitoring negative change requests, CMS also uses HPMS to ensure that certain mid-year formulary requirements are followed when sponsors submit requests for negative changes and when sponsors upload new plan formularies, that is, formularies that contain mid-year changes, to HPMS. For example, officials told us that HPMS ensures that all required fields are populated when sponsors submit requests for negative changes (e.g., required clinical justifications, offset drug information, etc.). In addition, HPMS only allows sponsors to submit change requests with permissible implementation dates and ensures that updated formularies contain only approved negative changes or changes that do not require pre-approval. CMS monitors HPMS formulary updates throughout the year and can retroactively deny a change, specifically a formulary enhancement,³¹ which does not meet formulary requirements, including applicable mid-year change requirements.

CMS's prospective oversight, including monitoring of HPMS, does not ensure that sponsors correctly implement approved changes and associated mid-year change policies intended to protect beneficiaries' access to medications. In order for beneficiaries to benefit from these protections, sponsors must administer approved changes accurately, such as by modifying their plans' Web sites to reflect plans' current formularies. In addition, sponsors must correctly apply relevant mid-year change requirements, such as providing sufficient notice of

²⁷In addition, sponsors must update the formularies maintained on their Web sites at least once per month. CMS chapter 3, Medicare Marketing Guidelines, §§ 60.5, 60.5.4.

²⁸Prior to 2008, CMS required Part D sponsors to submit change requests via a standardized template.

²⁹42 C.F.R. § 423.120(b)(2)(i).

³⁰CMS officials stated that they also monitor the number of negative changes sponsors request for their plans' formularies and follow up with sponsors that are outliers in the number of requests they submit.

³¹For example, CMS would retroactively deny the addition of a new drug to an incorrect formulary tier; however, CMS officials told us that they have never taken such action.

negative formulary changes to beneficiaries and ensuring that beneficiaries are exempted from changes if they are covered by the grandfathering policy.

CMS Conducts Some Retrospective Oversight Activities of Sponsors' Compliance with Mid-Year Formulary Change Requirements

CMS conducts some retrospective activities to oversee sponsor compliance with certain formulary requirements, including requirements specific to mid-year changes. Specifically, CMS officials told us that the agency monitors data from its complaint tracking module,³² appeals data from beneficiaries, and data from a CMS contractor (i.e., an independent review entity) to identify areas of noncompliance. In addition, CMS has discussions with trade groups, advocates, and other beneficiary representatives to determine if beneficiaries have been adversely affected by mid-year formulary changes which may indicate sponsors' noncompliance with mid-year formulary change requirements. CMS officials reported that these sources have not identified areas of noncompliance, nor does the agency have knowledge of any adversely affected beneficiaries. However, CMS officials acknowledged that the lack of complaints does not necessarily mean that beneficiaries have not been adversely affected.

CMS also conducts targeted audit activities to assess sponsors' compliance with certain formulary requirements, including requirements specific to mid-year changes. Specifically, in 2008 and 2009, CMS's program audits evaluated sponsors' compliance with mid-year formulary change beneficiary notification requirements. In addition, CMS completed selected reviews of sponsors' websites for their plans' formulary information in 2009 and 2010. In January 2011, CMS was preparing to conduct pilot audits to assess the accuracy of plan formulary information for a sample of sponsors' websites compared to these sponsors' CMS-approved plan formularies in HPMS. These audits would therefore determine the extent to which formularies marketed to beneficiaries match CMS approved formularies, including the appropriate inclusion of any mid-year formulary changes. Although CMS officials reported that selected reviews they completed in previous years had identified instances when a sponsor's posted formulary information for a plan included formulary enhancements that were not on the sponsor's approved plan formulary in HPMS, CMS did not view these discrepancies as a problem because formulary enhancements do not disadvantage beneficiaries.

³²The complaint tracking module (CTM) is CMS's centralized complaint system. Beneficiaries can express dissatisfaction with any aspect of the Part D program, other than coverage determinations, by filing a complaint with CMS which is logged into CMS's CTM system, or by filing a grievance directly with their respective sponsors. We have previously reported that while CMS developed a systematic oversight process that includes the CTM for tracking and resolving beneficiary complaints, CMS oversight of the grievance process was not as robust. GAO, *Medicare Part D: Complaint Rates Are Declining, but Operational and Oversight Challenges Remain*, [GAO-08-719](#) (Washington D.C.: June 27, 2008). Since that report, CMS indicated that the agency has implemented additional measures to improve the reliability and consistency of its grievance data and is developing plans to target audits to monitor sponsors' compliance with grievance requirements.

Most Mid-Year Formulary Changes Were Enhancements; about 5 Percent of Beneficiaries Were Potentially Affected by a Negative Change

Sponsors Implemented Multiple Mid-Year Formulary Changes for Almost all Plans in 2008 and 2009, the Majority of Which Added Drugs or Loosened Restrictions on Utilization

Sponsors implemented multiple mid-year changes for essentially all plans (see table 1), totaling over 446,000 changes in 2008 and over 475,000 changes in 2009.³³ Specifically, all but four of the 4,238 plans in 2008 had one or more mid-year changes and all 4,207 plans had 5 or more changes in 2009. Forty-seven percent of plans had more than 100 changes and a small number had more than 1,000 changes in 2008. Sixty percent of plans had more than 100 changes in 2009. More plans had a change that enhanced the formulary, such as adding a drug to the formulary or removing UM requirements from a drug, than had negative changes, such as removing a drug from the formulary.³⁴

Table 1: Percentage of All Plans With At Least One Mid-Year Formulary Change by Type of Change, 2008 and 2009

Type of change	2008 ^a	2009 ^a
Enhancements		
Drug Added	98.5	100.0
Removed UM	96.2	97.9
Negative		
Removed drug, add offset drug	46.4	40.0
Removed drug without offset	16.8	18.4
Tightened UM with offset drug	20.1	26.5
Tightened UM without offset	46.6	30.2
Plans with at least one mid-year change	99.9	100.0
Plans with more than 100 mid-year changes	46.9	59.6

Source: GAO analysis of CMS formulary data.

Note: Our analysis included negative mid-year changes for which sponsors requested approval through CMS’s Health Plan Management System (HPMS) and all enhancements. Sponsors are not required to obtain such approval to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer. The change types include changes to utilization management (UM) requirements.

^aOur analysis included the 4,238 total stand alone prescription drug plans (PDP) and Medicare Advantage prescription drug (MA-PD) plans operating as of January 1, 2008 and the 4,207 plans operating as of January 1, 2009. To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1 of each year.

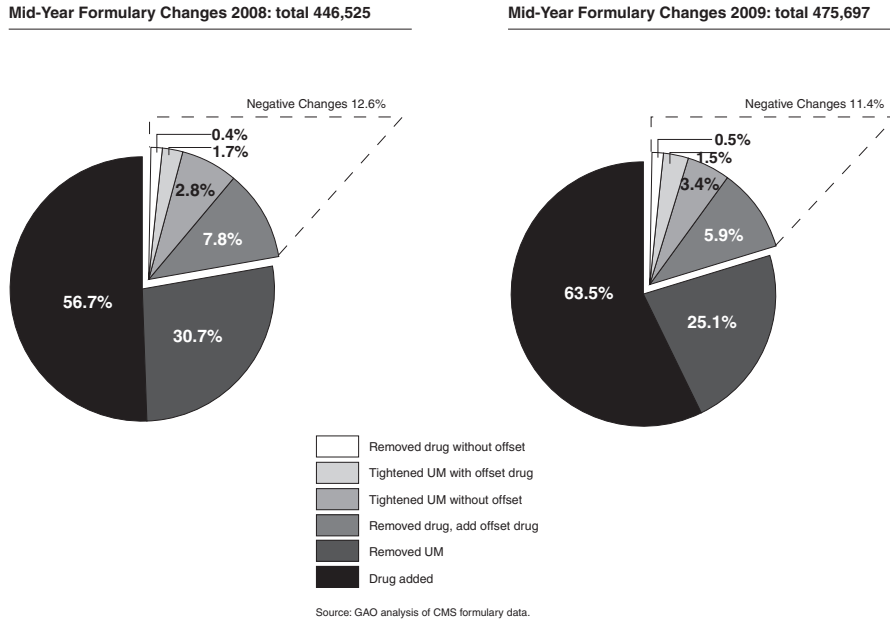
Formulary enhancements accounted for the majority of total changes in both years: 87.4 percent in 2008 and 88.6 percent in 2009 (see figure 1). Specifically, the addition of a drug to a plan’s formulary accounted for 56.7 percent of changes in 2008 and 63.5 percent in 2009. Changes that loosened restrictions on utilization by removing UM requirements from

³³We reported the total number of changes sponsors made across all plans. To arrive at the total number of changes, we counted the number of specific mid-year changes to a drug and multiplied each unique change by the number of plans for which the sponsor implemented the change. We summed these changes across plans to calculate the total number of mid-year changes.

³⁴For the purposes of this report we categorized types of mid-year changes based on the plan’s actual implementation of the change. Our analysis included negative mid-year changes for which sponsors requested approval through CMS’s HPMS and all enhancements. Sponsors are not required to obtain such approval to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer.

drugs on a plan's formulary comprised 30.7 percent of changes in 2008 and 25.1 percent of changes in 2009. Negative changes accounted for 12.6 percent of changes in 2008 and 11.4 percent in 2009. In both years, the most common negative change (7.8 percent of mid-year changes in 2008 and 5.9 percent in 2009) was removing a drug while adding an offset drug to the formulary, including changes such as substituting a brand name drug with a newly approved generic drug. Another common negative change was tightening UM requirements to a drug without adding an offset drug to the formulary, which accounted for 2.8 percent of mid-year changes in 2008 and increased to 3.4 percent in 2009. (See enclosure II for more information about the number of mid-year formulary changes implemented in 2008 and 2009.)

Figure 1: Distribution of Mid-Year Formulary Changes by Type of Change, 2008 and 2009



Note: Our analysis included negative mid-year changes for which sponsors requested approval through CMS's Health Plan Management System (HPMS) and all enhancements. Sponsors are not required to obtain such approval to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer. The change types include changes to utilization management (UM) requirements. Percentages do not add due to rounding.

To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1 of each year.

Mid-year formulary changes implemented in 2008 and 2009 affected a majority of Part D drugs, but the percentage of drugs affected by a mid-year change to any plan's formulary decreased from 88.2 percent in 2008 to 70.5 percent in 2009.³⁵ More drugs were affected by enhancements than negative changes in both years. For example, the number of drugs added to any plan's formulary was 1,335 in 2008 and 868 in 2009.³⁶ In contrast, the number of drugs affected by negative mid-year changes was smaller. For example, 101 drugs in 2008 and 87

³⁵There were 2,577 drug names—brand or generic name—in 2008 and 2,495 in 2009 that appeared on either a January or December formulary file.

³⁶To arrive at the number of drugs added to any plan's formulary, we counted the number of drug names added to each plan's formulary at the end of the year, irrespective of whether or not another plan's formulary included these drug names at the beginning of the year. We then summed the drug name additions across all plans.

drugs in 2009 were removed from any plan’s formulary in conjunction with the addition of an offset drug to the formulary.

About 5 Percent of Beneficiaries (over 1.1 Million) Filled a Prescription for a Drug in 2008 Later Affected by a Negative Mid-Year Formulary Change

In 2008, about 5 percent of beneficiaries (over 1.1 million) filled a prescription for a drug later affected by a negative mid-year formulary change (see table 2).³⁷ Sixty-eight percent of these beneficiaries, more than 755,000 (3.3 percent of all beneficiaries), had access to an offset drug, such as a generic, added as part of the formulary change that removed their drug from the formulary or tightened UM requirements for the drug. There were more than 375,000 beneficiaries (1.6 percent of all beneficiaries) who filled a prescription for a drug later affected by a mid-year formulary change that removed the drug or tightened UM requirements for the drug without adding an offset drug to the formulary. At least 5 percent of the 1.1 million beneficiaries were potentially affected by more than one negative mid-year change. However, CMS’s grandfathering policy is designed so that beneficiaries currently taking prescription drugs affected by certain negative mid-year formulary changes are ensured continued access to those drugs for the remainder of the year.

Table 2: Percentage of Beneficiaries Potentially Affected by Negative Mid-Year Formulary Changes, 2008

Type of change	2008	
	Number of beneficiaries	Percentage of all beneficiaries ^a
Removed drug, add offset drug	500,770	2.2
Removed drug without offset	23,928	0.1
Tightened UM with offset drug	256,413	1.1
Tightened UM without offset	352,652	1.5
Total beneficiaries that filled a prescription for at least one drug later affected by a negative mid-year change	1,109,180^b	4.9

Source: GAO analysis of CMS formulary and claims data.

Note: To estimate the number of beneficiaries potentially affected by negative mid-year changes, we counted the number of beneficiaries who filled a prescription for an affected drug up until the approved effective date of each mid-year change. CMS’s grandfathering policy is designed so that beneficiaries currently taking prescription drugs affected by certain negative mid-year formulary changes are ensured continued access to those drugs for the remainder of the year. Our analysis included negative mid-year changes for which sponsors requested approval through CMS’s Health Plan Management System (HPMS). Sponsors are not required to obtain such approval to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer. The change types include changes to utilization management (UM) requirements.

^aAs of January 1, 2008, there were 22,823,854 total beneficiaries enrolled in a stand alone prescription drug plan (PDP) or Medicare Advantage prescription drug (MA-PD) plan that we reviewed. To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1.

^bSome beneficiaries filled a prescription for more than one drug affected by a negative mid-year change; that is, were potentially affected by more than one change. Therefore the total number of beneficiaries that filled a prescription for at least one drug affected by a negative mid-year change is less than the sum of beneficiaries that filled a prescription for each type of change.

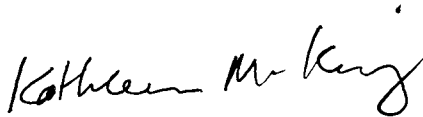
³⁷To estimate the number of beneficiaries potentially affected by negative mid-year changes, we counted the number of beneficiaries who filled a prescription for an affected drug up until the approved effective date of each mid-year change. Our analysis included negative mid-year changes for which sponsors requested approval through CMS’s Health Plan Management System (HPMS).

Agency Comments and Our Evaluation

CMS provided written comments on a draft of this report. CMS generally agreed with our findings. CMS noted that our characterization of the agency's implementation of the Negative Change Request module in 2008 may be misleading because we did not clearly state that sponsors were required to request negative changes prior to 2008. We have modified the draft to provide this clarification. In addition, CMS commented that we should add additional qualifications to the results of our estimate of the number of beneficiaries potentially affected by a negative mid-year change. Specifically, CMS stated that our methodology for identifying potentially affected beneficiaries could have resulted in an overestimate, as some beneficiaries who filled a single prescription early in the year may not have been taking the drug at the time the formulary change took effect. We agree that our methodology estimated the maximum number of beneficiaries that could have been potentially affected by a negative mid-year change and added language to note this in our methodology. CMS also asked that we take additional steps to highlight the agency's policy of approving certain negative changes on the condition that beneficiaries currently taking the affected drug should be exempt from the change for the remainder of the year. We modified the draft by providing additional references to this policy. Finally, CMS stated that we should clarify that our analysis included a certain type of mid-year formulary change. We included all requested negative mid-year changes in our analysis; a detailed explanation of our methods is provided in appendix I of the report.

As arranged with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of this report. At that time, we will send copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report will be available at no charge on the GAO Web site at <https://www.gao.gov>.

If you or your staff have any questions about this report please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure III.



Kathleen M. King
Director, Health Care

Enclosures – 3

Scope and Methodology

To examine the mid-year formulary changes that Part D sponsors made for their plans in 2008 and 2009, we obtained Health Plan Management System (HPMS) data files, including formulary files, from the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug (PDP) plans for years 2008 and 2009.¹ To identify mid-year changes for each year we compared the beginning of the year and end of the year formulary files (January and December, respectively) at the drug name level² and identified drugs and utilization management (UM) requirements that differed at the end of each year.³ For changes that involved a drug and a corresponding offset—a drug added to the formulary to offset the change—we counted a change to both drug names as a single change.⁴ Although we have identified all changes implemented as of the end of the year, we may not have identified formulary changes that were implemented and reversed through the course of the year.

For the purposes of this report, we categorized mid-year formulary changes as either enhancements or negative changes. CMS refers to changes that enhance the formulary as “enhancements” and changes that restrict the formulary as “negative.” CMS further categorizes negative changes as maintenance or non-maintenance based on information submitted by sponsors when requesting approval to make negative formulary changes through the Negative Change Request (NCR) module in HPMS.⁵ Therefore most “negative” mid-year changes have an associated NCR submission and we identified negative changes that sponsors requested for each year using the NCR file from HPMS. However, our analysis indicated that some negative changes were implemented differently than requested in the NCR file. Therefore we did not categorize implemented negative changes as maintenance or non-maintenance. Rather, we categorized types of mid-year formulary changes based on the

¹To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1 of each year. Sponsors upload formulary files—containing their approved formularies—to CMS’s HPMS. Sponsors may use the same uploaded formulary file for multiple plans.

²To develop a list of drugs for the 2008 and 2009 formularies we started with the reference National Drug Codes (NDC) included on the January and December CMS formulary reference files for each year. This file includes a set of reference (proxy) NDCs that may be included on Part D formularies. CMS began using a reference file in 2007. The codes on the reference file represent multiple forms and strengths of drugs, but not every manufacturer or package size for a particular drug. We generally grouped NDCs to identify changes at the drug name level—the brand or the generic names—because that is the level at which beneficiaries most likely identify a drug. We merged the beginning and end of year formulary files with data from *RED BOOK*TM—a drug pricing compendium published by Thomson Reuters—to obtain the drug name for each covered drug.

³We reported the total number of changes sponsors made across all plans. To arrive at the total number of changes, we counted the number of specific mid-year changes to a drug and multiplied each unique change by the number of plans for which the sponsor implemented the change. We summed these changes across plans to calculate the total number of mid-year changes made.

⁴According to CMS, an offset drug can be any Food and Drug Administration (FDA)-defined therapeutic alternative to the drug being affected—for example, a generic or multi-source brand name drug.

⁵Sponsors are required to request approval from CMS through HPMS prior to the implementation of negative changes to their plans’ formularies except for changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer.

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plan's actual implementation of the change.⁶ Specifically, we categorized two types of changes as enhancements to the formulary:

- when a drug was added to the formulary which we referred to as “drug added”; or
- when any existing UM requirement for a drug on the formulary was removed or loosened, referred to as “removed UM requirements.”

There were four types of changes that we categorized as negative changes, specifically:

- when a drug was removed from the formulary and an offset was added, referred to as “removed drug, add offset drug”;
- when a drug was removed from the formulary, referred to as “removed drug without offset”;
- when any UM requirement was added to a drug and an offset drug was added, referred to as “tightened UM with offset drug”; and
- when any UM requirement was added to a drug, referred to as “tightened UM without offset.”⁷

Our analysis included implemented negative mid-year changes for which sponsors requested approval through CMS's HPMS and all enhancements. We reported the number of implemented mid-year changes by type in each year. We determined the plans that had mid-year changes using CMS's plan information files for 2008 and 2009.⁸

To estimate the number of Part D beneficiaries who filled a prescription for a drug later affected by a negative mid-year change, we examined 2008 Prescription Drug Event (PDE) data.⁹ Specifically, for each implemented negative mid-year change with approval from CMS, we identified PDE claims for beneficiaries who filled a prescription for the drug affected by the change at any point from the beginning of the year up until the approved effective date of the change.¹⁰ For the purposes of this report, we used beneficiaries who filled a prescription for a drug later affected by a mid-year change up until the approved effective date of the change as a measure of beneficiaries potentially affected by negative mid-year changes. This approach includes all beneficiaries who filled a prescription for a drug prior to the mid-year

⁶In general, our “enhancement” and “negative” change categories correspond to CMS's “enhancement” and “negative” change categories respectively.

⁷In addition, less than one percent of mid-year changes in each year involved the removal and replacement of a UM requirement to a drug on the formulary with another UM requirement; we excluded these changes from our analysis.

⁸To determine the number of drugs added to any plan's formulary, we counted the number of drug names added to each plan's formulary at the end of the year, irrespective of whether or not another plan's formulary included these drug names at the beginning of the year. We then summed the drug name additions across all plans.

⁹CMS's PDE data contain a record of each claim reimbursed under the Part D program. PDE data for 2008 were the most recent available at the time of our review.

¹⁰Our count of beneficiaries who filled a prescription for a drug later affected by a negative mid-year change is an estimate, given that we used the approved effective date as a proxy for the mid-year change implementation date.

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change, some of whom may not have continued to require use of the drug at the time the mid-year change took effect. To calculate the percentage of the Part D population that filled a prescription for a drug affected by a negative mid-year change, we divided the number of beneficiaries who filled a prescription for a drug affected by these changes by the total number of Part D beneficiaries who were enrolled in a Part D plan included in our review as of January 1, 2008. We completed these analyses by mid-year change type and the number of changes by which a beneficiary was potentially affected.

To assess the reliability of CMS data we reviewed data documentation; tested data elements for missing data, outliers, and errors; and discussed and resolved inconsistencies found in data elements with CMS officials responsible for data management. Based on these activities we determined that the data were sufficiently reliable for our purposes.

**Number and Percent of Mid-Year Formulary Changes
across All Plans, 2008 and 2009**

Type of change	2008 ^a			2009 ^a			Percentage change 2008 to 2009
	Number changes ^b	Percentage of category	Percentage of all changes	Number changes ^b	Percentage of category	Percentage of all changes	
Enhancements	390,092	100.0	87.4	421,607	100.0	88.6	8
Drug Added	252,975	64.9	56.7	302,103	71.7	63.5	19
Removed UM	137,117	35.1	30.7	119,504	28.3	25.1	-13
Negative	56,433	100.0	12.6	54,090	100.0	11.4	-4
Removed drug, add offset drug	34,725	61.5	7.8	28,277	52.3	5.9	-19
Removed drug without offset	1,641	2.9	0.4	2,578	4.8	0.5	57
Tightened UM with offset drug	7,587	13.4	1.7	7,141	13.2	1.5	-6
Tightened UM without offset	12,480	22.1	2.8	16,094	29.8	3.4	29
Total mid-year changes across all plans	446,525	—	100.0	475,697	—	100.0	7

Source: GAO analysis of CMS formulary data.

Note: Our analysis included negative mid-year changes for which sponsors requested approval through CMS's Health Plan Management System (HPMS) and all enhancements. Sponsors are not required to obtain such approval to make mid-year formulary changes that remove a drug that has been deemed unsafe or withdrawn from the market by the FDA or a product manufacturer. The change types include changes to utilization management (UM) requirements. Percentages do not add due to rounding.

^aTo focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment—employer-sponsored, Demonstration, Cost, PACE, and religious fraternal benefit plans—and excluded plans with zero enrollment as of January 1 of each year.

^bWe reported the total number of changes sponsors made across all plans. To arrive at the total number of changes, we counted the number of specific mid-year changes to a drug and multiplied each unique change by the number of plans for which the sponsor implemented the change. We summed these changes across plans to calculate the total number of mid-year changes.

Enclosure III

GAO Contact and Staff Acknowledgments

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