Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MIDYEAR FORMULARY CHANGES IN MEDICARE PRESCRIPTION DRUG PLANS

Daniel R. Levinson
Inspector General

December 2009
OEI-01-08-00540

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVES

1. To describe the extent and nature of midyear formulary changes that Part D sponsors made in 2008.
2. To determine the extent to which sponsors adhered to the Centers for Medicare & Medicaid Services' (CMS) beneficiary notification requirements for negative midyear formulary changes in 2008.
3. To determine the extent to which CMS monitored Part D sponsors' midyear formulary changes in 2008.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide voluntary prescription drug coverage to beneficiaries. CMS contracts with private companies, called sponsors, to operate Part D prescription drug plans. Sponsors identify the complete list of drugs they cover in their formularies.

CMS sets guidelines for when and how sponsors may make changes to their formularies, referred to as positive and negative changes. Positive changes require no CMS approval and enhance the formulary by adding new drugs, reducing cost sharing, or removing utilization controls. Negative changes, which require CMS approval, restrict the formulary by removing drugs, increasing cost sharing, or adding utilization controls. Sponsors must provide written notice to beneficiaries currently taking affected drugs before implementing negative changes. CMS also requires sponsors to post updated formularies on their Web sites at least monthly and to list formulary changes 60 days before they take effect.

To conduct this study, we analyzed CMS data on formulary changes and interviewed CMS staff. We also drew a sample of 120 formularies for analysis, reviewed sponsors' notification letters, and reviewed 20 formularies posted on sponsors' Web sites.

FINDINGS

In 2008, all Part D sponsors made formulary changes. The majority of changes (64 percent) were positive. Thirty-six percent were negative,

and 62 percent of negative changes involved generic substitution. Other negative changes removed drugs without providing lower cost alternatives, added utilization controls without providing alternatives, or increased cost sharing.

With few exceptions, sponsors met beneficiary notification requirements for formulary changes. The notification letters we reviewed gave beneficiaries more advance notice than required, with a median of 74 days. Overall, 88 percent of the notification letters contained all six required elements—drug name, change type, reason for the change, alternative drugs, new cost sharing, and exceptions—while 12 percent of the letters contained five or fewer elements. In addition, we could not readily identify 60 percent of approved midyear changes on sponsors' Web sites.

CMS reviewed nearly all formulary changes listed in notification letters. CMS uses systematic checks to monitor formulary change requests and limits changes that restrict access to drugs without offering cost-saving alternatives or promoting drug safety. Even though these checks were in place, we detected some noncompliance whereby sponsors failed to seek approval for midyear changes. Only 1 percent of changes listed in notification letters required CMS approval but were not in the original change request file. Nearly all of these unapproved changes involved substituting or adding generic drugs.

CONCLUSION

This study found that sponsors and CMS are managing midyear formulary changes in compliance with Part D program requirements. Part D regulations require sponsors to promote cost-effective use of prescription drugs where medically appropriate, and it appears that sponsors adhered to these rules. CMS provides sponsors with various forms of guidance on formulary change requests and beneficiary notification. Although some sponsors may need more specific guidance on notification practices, we found that most complied with CMS regulations and provided even more advance notice than the 60-day standard requires. In addition, we found that sponsors' Web sites did not reflect all the changes approved by CMS. Further analysis may be warranted to determine the full extent of consistency between approved changes to sponsors' formularies and the changes that appear on their Web sites and to determine whether additional guidance is needed to address any inconsistencies.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally agreed with our findings. CMS requested that we specify that beneficiaries currently taking medications not subject to generic substitution are protected from disruptions in therapy. CMS also stated that it is working with a contractor to assess consistency between sponsors' Web versions of formularies and CMS's approved files. Based on the agency's comments, we made appropriate revisions to the report.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVES

1. To describe the extent and nature of midyear formulary changes that Part D sponsors made in 2008.
2. To determine the extent to which sponsors adhered to the Centers for Medicare & Medicaid Services' (CMS) beneficiary notification requirements for negative midyear formulary changes in 2008.
3. To determine the extent to which CMS monitored Part D sponsors' midyear formulary changes in 2008.

BACKGROUND

Medicare Part D

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide voluntary prescription drug coverage to beneficiaries.[1] CMS contracts with private companies, called sponsors, which operate Part D prescription drug plans. As of January 2008, over 25 million beneficiaries were enrolled in prescription drug plans.

A formulary is a complete list of the drugs that a drug plan covers, and it may change during the year.[2] However, the extent to which Part D sponsors alter their formularies during the year has been unknown. Midyear formulary changes can be advantageous for beneficiaries if they introduce new medications or promote cost savings. However, midyear changes can also adversely affect beneficiaries by restricting access to prescription drugs or increasing drug costs. Furthermore, CMS compliance audits of Part D sponsors suggest that sponsors did not fully comply with regulations regarding beneficiary notification for midyear formulary changes. Beginning in 2007, CMS audited sponsors' formulary change notification practices and found that 28 percent of sponsors had not notified beneficiaries of midyear formulary changes according to regulations.[3]

[1] P.L. No. 108-173.

[2] 42 CFR § 423.4.

[3] Office of Inspector General (OIG) analysis of CMS 2007–2008 compliance audit data.

Part D Formularies

Sponsors organize formularies into broad therapeutic categories (hereinafter, categories) and then into subsets called pharmacologic classes (hereinafter, classes). Formularies must include categories and classes that cover all disease states.[4]

In 2008, USP, a standard-setting authority for prescription drugs, defined 50 categories and 119 classes.[5] For example, USP defines blood glucose regulators as a category, with antidiabetic agents as a class within that category. Formularies must include at least two chemically distinct drugs in each category or class of drugs.[6]

CMS designates a subset of six classes (hereinafter, protected classes) for which substantially all available drugs must be covered in every formulary: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.[7]

Formulary Management

Sponsors may use various tools to control costs and ensure patient safety.[8] In addition to controlling the drugs they cover, sponsors may manage formularies by applying utilization controls and by setting cost sharing in a way that encourages beneficiaries to use lower cost drugs. Examples of utilization controls include:

- prior authorization, whereby a beneficiary must obtain explicit approval from the plan before it will cover a drug;
- step therapy, whereby a beneficiary must first try the most cost-effective and safest drugs, moving on to more expensive or risky drugs only if medically necessary; and
- quantity limits, whereby a beneficiary may obtain only a limited quantity of a prescription at one time, usually to ensure patient safety or encourage cost-effective use of the drug.

---

[4] Part D sponsors may use several classification systems to organize formularies, including the United States Pharmacopeia (USP) and the American Hospital Formulary Service. CMS must approve a sponsor's proposed classification system to ensure the formulary provides access to an acceptable range of Part D drug choices. CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.1, July 18, 2008.

[5] USP, *Model Guidelines and Formulary Key Drug Types*, Version 3.0. Available online at http://www.usp.org/pdf/EN/mmg/modelGuidelinesV3.0WithFKDTs.pdf. Accessed on October 1, 2008.

[6] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.1.

[7] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.5.

[8] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.1.5.

Sponsors typically establish differential cost sharing by dividing drugs into tiers that correspond to the amount the beneficiary will pay. Drugs in lower priced tiers are considered "preferred" drugs and those in higher priced tiers are considered "nonpreferred." For example, a Tier 1 drug is typically a low-cost generic drug for which a beneficiary might make a $5 or $10 copayment, while Tier 2 or Tier 3 drugs are likely to be more expensive brand-name drugs for which a beneficiary might make a $20 or $30 copayment.[9]

The ways in which sponsors manage their formularies can affect some beneficiaries' access to drugs. For example, beneficiaries who use multiple high-cost drugs may find that utilization controls create layers of administrative burden for both themselves and prescribers and, therefore, could make it difficult to obtain necessary drugs.[10] In addition, sponsors may increase the cost sharing on brand-name drugs during the year if a lower cost or generic drug is available. Beneficiaries who take these brand-name drugs could face unexpected increases in cost sharing.

Midyear Formulary Changes

Sponsors hold a 1-year contract with CMS for each plan they offer.[11] The contract year begins January 1 and ends December 31. CMS sets guidelines for when sponsors may make certain types of midyear formulary changes.

CMS refers to midyear formulary changes as either positive or negative changes.[12] Positive changes enhance the formulary by adding new drugs, reducing cost sharing, or removing utilization controls.[13] Sponsors may make positive formulary changes at any time during the contract year without CMS approval.[14]

Negative changes, which require CMS approval, restrict the formulary by removing drugs, increasing cost sharing, or adding utilization

---

[9] Copayments may vary substantially across plans and may be set as a fixed dollar amount or a percentage of the drug's negotiated price. Percentage copayments may fluctuate during the year if the drug manufacturer changes the drug's price. CMS does not require approval for these types of changes.

[10] Kaiser Family Foundation, *Medicare Part D 2008 Spotlight: Utilization Management*. Available online at http://kff.org/medicare/upload/7735.pdf. Accessed on October 1, 2008.

[11] 42 CFR § 423.506.

[12] CMS, Memorandum, "Calendar Year (CY) 2006 and CY 2007 Formulary Changes—New October Submission Window and Policy on Enhancements Added Between the October and February Submissions," October 5, 2006.

[13] CMS also refers to positive changes as "enhancements."

[14] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.3.1.

controls. Negative changes that remove drugs may simultaneously add replacement drugs. However, these are still considered negative changes. CMS categorizes negative changes according to their purposes. Sponsors may make routine negative changes that remove drugs or change utilization controls if the purpose is to promote cost savings or drug safety. For example, sponsors may remove a costly brand-name drug from the formulary when a lower cost generic version becomes available. In other cases, sponsors may place quantity limits on drugs because of new safety warnings. Other types of negative changes may remove drugs from the formulary or increase utilization controls without providing alternatives. For example, a sponsor may increase the cost sharing on an expensive brand-name drug but not offer a less expensive alternative drug in its place.

Sponsor Request and CMS Approval of Negative Midyear Formulary Changes

Sponsors must obtain CMS approval 60 days before they implement negative changes.[15] Only in cases in which the Food and Drug Administration has deemed a drug unsafe or manufacturers have withdrawn drugs from the market may sponsors remove drugs without CMS approval. Although sponsors may not make any negative changes during the first 60 days of the contract year, they may seek approval for them beginning in January. Sponsors may then implement negative changes between March 1 and July 31.[16] [17]

CMS generally approves routine negative changes and limits other negative changes.[18] Therefore, CMS guidance states that sponsors may assume CMS has approved routine change requests involving cost savings or drug safety if they do not hear from CMS within 30 days.[19]

Sponsors must wait for CMS approval before making other negative changes. For example, CMS may disapprove a change if it substantially discourages enrollment by certain beneficiary groups or means that the formulary would no longer include two drugs per category or class.[20]

---

[15] Ibid., §§ 30.3.3.1 and 30.3.4.1.

[16] Ibid., § 30.3.2.

[17] CMS, Memorandum, "Updating 2007 and CY 2008 Formularies," June 20, 2007.

[18] For more information on negative changes, see Appendix A.

[19] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.3.2.

[20] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.3.3.

Sponsor Notification to Beneficiaries

With few exceptions, sponsors must provide 60 days' written notice to beneficiaries currently taking affected drugs before implementing negative formulary changes.[21] Sponsors also have the option to provide written notice to all enrolled beneficiaries to meet the 60-day notification requirement.[22] CMS does not require sponsors to send notifications for positive formulary changes.[23] A written notification of a formulary change must include:

- the name of the drug,
- the type of change made to the formulary,
- the reason for the change,
- alternative drugs in the same class,
- expected cost sharing for alternative drugs, and
- information on obtaining a coverage determination or an exception for coverage of the affected drug.[24]

CMS requires sponsors to post updated formularies on their Web sites at least monthly and to list formulary changes 60 days before they take effect.[25] Sponsors may post formularies as PDF files, but may use other formats as well. In addition, online formularies must be accessible by a drug name search, and sponsors must include notice of any midyear changes on their Web sites.[26]

METHODOLOGY

Scope

This study analyzed the extent and nature of midyear formulary changes made by Medicare prescription drug sponsors in 2008 and CMS's monitoring of these changes. It also analyzed the extent to which sponsors complied with CMS notification requirements. It did not review year-to-year formulary changes or analyze specific types of drugs that sponsors included in their formularies.

---

[21] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, §§ 30.3.3.2 and 30.3.4.1.

[22] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.4.4.

[23] CMS, Memorandum, "Formulary Changes During the Plan Year: Operational Frequently Asked Questions," May 5, 2006.

[24] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.4.1.

[25] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 2, pp. 62 and 64, July 25, 2006.

[26] Ibid.

Data Sources

We used files from CMS's Health Plan Management System (HPMS) to create the universe of formularies that sponsors used in 2008. The universe contained 329 formularies and 204 sponsors.

We divided the list of 329 formularies into two strata: (1) those for which the sponsors did not request approval for negative changes and (2) those for which the sponsors requested approval for negative changes. Stratum 1 contained 94 formularies and stratum 2 contained 235 formularies. We then drew 50 formularies from stratum 1 and 70 formularies from stratum 2 for a total of 120 formularies. The formularies in our sample corresponded to 87 sponsors.

We used the following data sources to analyze changes to the sampled formularies in 2008:

1. Negative Change Request (NCR) file and Formulary Change Notification Report (FCR): We used the NCR and FCR files in HPMS to analyze positive changes and approved negative changes to the 120 sampled formularies. We used these files to analyze the extent and nature of formulary changes and to account for the changes listed in sponsors' notification letters. The 120 formularies in our stratified random sample had 4,333 negative change requests; CMS approved 3,425 of these requests. The FCR had 7,886 positive changes.

2. Sponsors' formulary change notification letters: We contacted 150 compliance officers from sponsors that used the sampled formularies to obtain notification letters for their formulary changes. We received a 100-percent response. However, 10 compliance officers referred us to another officer already in our sample. Therefore, we received final responses from 140 compliance officers. We later followed up with these compliance officers to collect more information on sponsors' notification policies.

   The responses included 853 notification letters covering 2,197 changes. Among negative changes listed in the letters, 484 had not been approved by CMS or did not require CMS approval. The 3,425 approved changes from the NCR file plus the 516 unapproved changes equaled all negative changes (3,941). We summed all negative (3,941) and positive (7,886) changes to get the total number of formulary changes (11,827).

3. Formularies from sponsors' Web sites: We selected a sample of 20 formularies based on convenience and availability from our

4. Interviews with CMS staff: We interviewed CMS staff responsible for reviewing and approving midyear formulary changes. We asked them about CMS processes to approve and track midyear changes.

Appendix B contains a full description of our methods.

Limitations

We could not assess whether sponsors sent a notification letter to every enrollee who should have received one. CMS requires sponsors to notify only those enrollees who are affected by negative formulary changes. However, we could not determine which enrollees were affected by each change and whether they received letters. Rather, we examined the content of the notification letters to see whether CMS had approved the negative changes listed in the letters.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

In 2008, all Part D sponsors made formulary changes

All sponsors that offered Part D plans in 2008 made some type of positive or negative change to their formularies. Seventy-six percent of sponsors requested at least one negative change from CMS in 2008. Sponsors must request approval for negative changes from CMS, but need not seek approval for positive changes. CMS approved 79 percent of the 4,333 negative change requests by sponsors in our sample.

Sixty-four percent of all formulary changes were positive

Positive formulary changes enhanced formularies by adding drugs, decreasing cost sharing, or deleting utilization controls. Among the 7,886 positive changes in our sample, 60 percent decreased cost sharing or removed utilization controls, such as step therapy, prior authorization, or quantity limits.

The remaining 40 percent of positive changes added drugs to the formulary. On average, positive formulary changes added twice as many drugs as negative changes removed (the average number of drugs added to each formulary was 46; the average number of drugs removed was 22).

Thirty-six percent of all formulary changes were negative, and most negative changes involved generic substitution

Negative changes involved removing drugs, moving drugs to higher cost-sharing tiers, or adding utilization controls. However, as Table 1 shows, 62 percent of negative changes involved substituting or adding generic drugs. Because generic drugs cost less than brand-name drugs, CMS considers sponsors' efforts to reduce beneficiaries' drug costs to be a part of routine formulary management.

Table 1: Formulary Changes, 2008

Type of Change	Percentage (n=11,827)	Percentage That Added or Substituted Generics
Positive changes	64%	N/A
Negative changes	36%	62%
Total changes	**100%**	

Sample includes positive and negative changes.

Source: Office of Inspector General (OIG) analysis of Medicare Part D 2008 midyear formulary changes.

Eighty-seven percent of changes that removed brand-name drugs from the formularies replaced them with generic versions. Among changes

that increased cost sharing for brand-name drugs, 78 percent added generic drugs to the formularies at the lowest cost-sharing tiers.

Medicare regulations require sponsors to promote cost savings by managing drug utilization in a medically appropriate manner.[27] Replacing brand-name drugs with less expensive generic drugs and placing generic drugs in the lowest cost-sharing tiers are two methods sponsors can use to meet this requirement. Thus, the focus on generic drugs in midyear changes reflects expectations in Medicare regulations.

Table 2 shows that removing drugs and moving drugs to higher cost-sharing tiers were the most common negative changes and that these changes also had the highest rates of generic drug substitution. Changes that added utilization controls, such as prior authorization, step therapy, and quantity limits, had lower rates of generic drug substitution. Rather, sponsors used these changes to adhere to new clinical guidelines or drug safety warnings.

Table 2: Negative Changes That Promoted Generic Drug Substitution, 2008

Type of Change	Type of Change as a Percentage of Negative Changes (n=3,941)	Percentage of This Change That Promoted Generic Substitution
Remove drugs	56%	87%
Move drugs to higher cost-sharing tiers	17%	78%
Add step therapy	7%	1%*
Add prior authorization	5%	1%*
Add quantity limit	4%	N/A
Other changes†	11%	N/A
Total negative changes	**100%**	

* We were unable to project these estimates to the population of negative changes. See Appendix C, Table C-9.

† Other changes include removing or discontinuing drugs or adding utilization controls to promote drug safety or to determine Part B vs. Part D reimbursement. Quantity limits and "other" changes generally do not involve generic substitution; therefore, we have no estimates on generic substitution for these changes.

Source: OIG analysis of Medicare Part D 2008 negative midyear formulary changes.

Forty-six percent of negative changes affected drugs most commonly prescribed to Medicare beneficiaries, as defined by CMS.[28] Sixty-nine

[27] 42 CFR § 423.153(b).

[28] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, Appendix D.

percent of these changes involved substituting generic drugs for brand-name drugs or altering cost sharing or utilization controls to encourage generic drug use. For example, Fosamax (alendronate sodium), a drug that treats osteoporosis, became available in generic form in 2008. Not surprisingly, because Fosamax was the second most commonly prescribed drug among Medicare beneficiaries in 2008, 53 percent of sponsors requested changes that added the generic version of Fosamax to their formularies or added utilization controls to encourage use of the generic form.[29]

Negative formulary changes that involved generic drugs also affected the six protected classes that sponsors must include in their formularies.[30] Thirty-nine percent of negative changes affected drugs in protected classes. Among these negative changes, 69 percent substituted generic drugs for brand-name drugs or altered cost sharing or utilization controls to encourage generic drug use.

Although most negative changes promoted generic substitution, more than a third did not

Thirty-eight percent of negative changes increased cost sharing, removed drugs without providing a lower cost alternative, or added utilization controls.[31] Forty-six percent of changes that did not involve generic substitution removed drugs from the formulary, and 17 percent added step therapy. Overall, these changes accounted for only 14 percent of all midyear formulary changes. Table 3 shows the types of changes that did not involve generic substitution.

[29] OIG analysis of CMS Prescription Drug Event Data, October 2008.

[30] The six protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.

[31] CMS refers to these changes as "nonmaintenance" changes. Beneficiaries who are taking drugs affected by these changes are exempt from the changes for the remainder of the plan year. See Appendix A for further details.

Table 3: Formulary Changes That Did Not Promote Generic Substitution, 2008

Type of Change	Percentage of Nongeneric Changes (n=1,572)
Remove drugs	46%
Add step therapy	17%
Add prior authorization	13%
Add quantity limit	11%
Move drugs to higher cost-sharing tiers	10%
Other changes*	3%
Total	**100%**

* Other changes include unapproved changes or those that did not require CMS approval.

Source: OIG analysis of Medicare Part D 2008 negative midyear formulary changes.

With few exceptions, sponsors met beneficiary notification requirements for formulary changes

Generally, sponsors used a combination of methods to notify beneficiaries of midyear changes. Sponsors used either form letters or explanation of benefits forms (EOBs) as written notice of formulary changes and also included formulary changes on their Web sites. CMS provides guidelines for notification letters and EOBs as forms of written notice.

Over half (59 percent) of the sponsors we spoke with have policies of sending written notices only to beneficiaries who are affected by changes, per CMS rules.[32] If no beneficiaries are taking the affected drugs, sponsors do not generate notification letters.

Notification letters largely met both timing and content requirements

CMS requires sponsors to provide 60 days' notice to beneficiaries for any negative changes. The notification letters we reviewed gave beneficiaries more advance notice than required, with a median of 74 days. This means that half of the changes in the letters gave more than 74 days' advance notice. Overall, 89 percent of the changes had notification times of 60 days or more. However, 9 percent of changes had between 30 and 59 days, and 2 percent had less than 30 days.

[32] 42 CFR § 423.120(b)(5)(A).

In addition to meeting timing requirements, notification letters must include six elements that describe upcoming formulary changes. Table 4 indicates the percentage of letters that contained each element. Overall, 88 percent of the notification letters contained all the required elements. However, 12 percent of the letters contained five or fewer elements.

Although notification letters contained the required elements nearly all of the time, information on cost sharing was missing in 5 percent of letters. Three sponsors submitted letters that did not contain information on the changes in cost sharing, but instead included statements directing enrollees to call the plans' customer service departments to find out the new cost.

Table 4: Percentage of Notification Letters Containing Required Elements, 2008

Element	Percentage of Letters Containing Element
Name of the affected drug	100%*
Type of change	100%*
Reason for the change	100%*
Alternative drugs in the same class	100%*
Information on obtaining a coverage determination or exception for coverage of the affected drug	100%*
New expected cost sharing	95%

* We were unable to produce confidence intervals for these elements because all sample letters contained the element. Therefore we cannot produce a measure of variability. We concluded that compliance with these requirements is very high.

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Among other issues with notification letters, two sponsors reported difficulties with subcontractors that produced their letters. Sponsors may contract with pharmacy benefit managers to send notification letters to beneficiaries on their behalf. However, one sponsor told us that its pharmacy benefit manager failed to send letters between August and October 2008 because of a data error; another sponsor's subcontracted mailing service went out of business, making it impossible for the sponsor to retrieve the letters for our request. Part D regulations state that sponsors are ultimately responsible for

downstream contractors, such as pharmacy benefit managers and their failure to send or retain notification letters.[33]

In a few instances, sponsors misinterpreted CMS guidance on which types of changes require approval. Two sponsors' responses suggested that they did not consider changes involving generic substitution or other routine negative changes to require CMS approval. However, in 2006, CMS issued guidance clarifying that these types of negative changes require approval.[34]

Web sites we reviewed did not consistently reflect midyear changes

We reviewed formularies posted on 20 sponsors' Web sites to identify midyear changes approved by CMS. None of the formularies reflected every change, and all online formularies varied in the extent to which they reflected changes. Overall, we could not readily identify 630 of 1,046 approved changes (60 percent) from the NCR file in the online formularies. For example, online formularies were available in PDF as suggested in CMS's guidelines, but they were not easily searchable or they listed drugs by generic rather than brand names that beneficiaries might recognize. CMS's guidelines for Part D marketing materials state that sponsors must update their online formularies at least monthly and that their Web sites must reflect midyear changes.

Although we found that midyear changes were not readily accessible on sponsors' Web sites, CMS lists formulary information on the Medicare Prescription Drug Plan Finder (hereinafter, Plan Finder) Web site. When sponsors update their formularies each month, CMS posts the formulary and pricing files to the Plan Finder. However, OIG has also raised concerns about the accuracy of pricing information on the Plan Finder.[35]

CMS reviewed nearly all formulary changes listed in notification letters

As stated previously, CMS approved 79 percent of sponsors' negative change requests. Sponsors withdrew 18 percent of change requests because they contained errors. CMS denied 3 percent of negative change requests.

---

[33] 42 CFR § 423.505(i)(4)(ii-iii).

[34] CMS, Memorandum, "CY 2006 and CY 2007 Formulary Changes—New October Submission Window and Policy on Enhancements Added Between the October and February Submissions," October 5, 2006.

[35] OIG, *Accuracy of Part D Plans' Drug Prices Provided on the Medicare Prescription Drug Plan Finder*, OEI-03-07-00600, July 2009.

In addition, CMS canceled less than 1 percent of change requests because they were incomplete or approval was not required.

CMS uses systematic checks to monitor sponsors' formulary change requests and monthly updates to formulary files. For example, CMS's Web-based file systems do not allow sponsors to obtain approval for new formulary files if those files contain unapproved negative changes. CMS staff also review all negative change requests by hand and deny changes that lack sufficient clinical justification. In addition, CMS uses its own threshold to limit changes that restrict access to certain drugs without offering cost-saving alternatives or promoting drug safety. If plans exceed this threshold, CMS denies the change requests and follows up with the plan.

Even though these checks were in place, we detected some noncompliance whereby sponsors failed to seek approval for midyear changes. Overall, only 1 percent of changes listed in the notification letters required CMS approval but were not in the original change request file. Nearly all (94 percent) of these unapproved changes involved substituting or adding generic drugs. The remaining 6 percent of unapproved changes involved moving drugs to higher cost-sharing tiers, adding utilization controls, or removing drugs from the formulary.

CONCLUSION

This study found that sponsors and CMS are managing midyear formulary changes in compliance with Part D program requirements. The data in this report show that 36 percent of 2008 midyear formulary changes restricted the formularies, but the majority of these changes also promoted cost savings through generic substitution. Part D regulations require sponsors to promote cost-effective use of prescription drugs where medically appropriate, and it appears that sponsors adhered to these rules.

CMS provides sponsors with various forms of guidance on formulary change requests and beneficiary notification. Although some sponsors may need more specific guidance on notification practices, we found that most sponsors complied with CMS regulations and provided even more advance notice than the 60-day standard requires. CMS could provide additional guidance to sponsors regarding cost sharing in notification letters and on managing subcontractors that provide notification services.

We reviewed a limited number of sponsors' Web sites to identify midyear changes and found that these Web sites did not reflect all the changes approved by CMS. These discrepancies are of concern because they deny beneficiaries accurate coverage information. CMS's guidance states that online formularies must reflect midyear changes. Beneficiaries should be able to rely on the formulary on a sponsor's Web site to reflect the drugs actually covered and the cost-sharing amount owed. Further analysis may be warranted to determine the full extent of consistency between approved changes to sponsors' formularies and the changes that appear on their Web sites and to determine whether additional guidance is needed to address any inconsistencies.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally agreed with our findings. It noted that it is working with a contractor to review sponsors' online formularies to assess consistency between their Web versions and CMS's approved formulary files. Also regarding sponsors' Web sites, CMS asked whether it is possible that sponsors' failure to implement negative changes could explain why we did not find those changes on the Web sites. We did not determine whether, in fact, sponsors implemented the changes that we could not find on their Web sites or whether sponsors sent notification letters for these specific changes.

We made two changes in response to CMS's comments. First, we clarified that beneficiaries taking medications subject to changes unrelated to generic substitution are protected from disruptions in therapy. We also corrected the text to show how we defined our sample strata.

Finally, we will provide to CMS, under separate cover, the names of sponsors we identified that either misinterpreted or appeared not to comply with formulary change notification requirements so that CMS can provide additional guidance to these sponsors.

The complete text of CMS's comments appears in Appendix D.

Maintenance and Nonmaintenance Changes in the Negative Change Request File

The Centers for Medicare & Medicaid Services (CMS) divides negative formulary changes into maintenance changes and nonmaintenance changes.[36] Sponsors notify CMS and request approval for these changes by uploading them into CMS's online Health Plan Management System (HPMS). CMS uses HPMS to review the proposed changes and communicate its approval or disapproval.

Maintenance changes. Sponsors make maintenance changes to encourage use of new, lower cost drugs or to restrict access to a drug because of safety concerns. Generally, maintenance changes provide alternatives for drugs that are removed or restricted. In cases in which maintenance changes do not provide alternatives or beneficiaries cannot take alternative drugs, sponsors must provide a process whereby beneficiaries may request coverage of the original drugs.[37] Examples of maintenance changes include:

- removal or placement in a less preferred tier of a brand-name drug because of the addition of a generic or brand-name equivalent at a lower tier or cost to the beneficiary;
- addition of utilization controls when the Food and Drug Administration issues a safety warning for the drug; and
- addition of utilization controls when necessary to effect other approved formulary changes (e.g., prior authorization for a brand-name drug when a generic becomes available on a formulary at a lower cost).[38]

Nonmaintenance changes. Nonmaintenance changes remove or restrict access to drugs without providing new alternatives. Sponsors make such changes to remove drugs from formularies, add utilization controls, or change cost-sharing tiers. CMS allows sponsors to make these changes only if beneficiaries currently taking the affected drugs are exempt from the changes for the remainder of the contract year. Nonmaintenance changes include, but are not limited to:

---

[36] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, §§ 30.3.3.2 and 30.3.3.3, July 18, 2008.

[37] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.4.1.

[38] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.3.3.2.

- changing preferred or nonpreferred formulary drugs, adding utilization controls, or increasing cost sharing on preferred drugs without the addition of a lower cost or generic drug; and
- removing dosage forms (e.g., removing the liquid form of a drug but keeping the tablet form).[39]

Because CMS generally approves maintenance changes, sponsors may send the 60-day notification to beneficiaries without waiting for CMS's explicit approval.[40] For nonmaintenance changes, sponsors must wait for explicit approval before sending the notification.[41]

[39] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, §30.3.4.2.

[40] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, §30.3.3.2.

[41] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, §30.3.3.3.

Detailed Methodology

Scope

This study analyzed the extent and nature of midyear formulary changes made by Medicare prescription drug sponsors in 2008 and the Centers for Medicare & Medicaid Services' (CMS) monitoring of these changes. It also analyzed the extent to which sponsors of prescription drug plans complied with CMS notification requirements. This study did not review year-to-year formulary changes or analyze specific types of drugs that sponsors included in their formularies.

Data Sources

We used a stratified random sample of 120 formularies to identify and analyze all midyear formulary changes (both positive and approved negative changes) and to identify sponsors that sent notification letters for negative changes to beneficiaries. From the sample of 120 formularies, we also drew a convenience sample of 20 formularies that we downloaded from sponsors' Web sites.

We used the Negative Change Request (NCR) file in CMS's Health Plan Management System (HPMS) to identify changes that sponsors requested. We also used the Formulary Change Notification Report in HPMS to identify positive formulary changes. In addition, we used the Approved Formulary file for 2008 to identify unique drug codes for drugs most commonly prescribed to Medicare beneficiaries as well as drugs in protected classes.

Methodology for Drawing a Stratified Random Sample of Formularies

Before drawing a stratified random sample of formularies, we created a file containing the universe of all Part D formularies in 2008 using the following files from HPMS:

- *2008 Approved Contracts*: This file contains approved 2008 contract numbers and sponsor information.
- *2008 Approved Plan Information*: This file contains plan-level data for each approved 2008 contract, including a formulary identification number for plans that offer prescription drug coverage.
- *2008 Plan Enrollment Information*: This file contains enrollment data for plans offered under each 2008 Part D contract.

Calculating the Total Number of Sponsors and Formularies in 2008.
We used information from two CMS data files to create a complete list of all Part D formularies. Because these files serve different purposes

and because CMS updates them during different periods, the number of observations in each file did not always match.

The Plan Enrollment file had 6,010 unique plans and 821 unique contracts. The file was current as of October 2008. We removed union-only plans, plans with no enrollment, and plans that did not offer Part D benefits. This left 723 contracts and 4,986 plans with total enrollment of 25,886,069.

The Approved Plan Information file contained 6,874 plans and 809 unique contracts. The file was current as of October 2008. Once again, we removed inactive contracts, union-only contracts, and those that did not offer Part D benefits. This left 5,609 plans, 769 contracts, and 342 formularies.

We merged the Plan Enrollment file with the Approved Plan Information file by unique plan identifiers. This produced our population file of 329 eligible formularies from which we selected our random sample. This file has 329 unique formularies associated with 4,906 unique plans, 671 unique contracts, and 204 unique sponsors.

The number of unique formularies dropped from 342 on the Plan Enrollment file to 329 because approved plans associated with 13 formularies had no enrollment. The number of unique plans decreased from 4,986 to 4,906 because 2 plans with a total enrollment of 3 people were not on the Approved Contracts file and 78 plans had no formulary identification information available. Together these 80 plans consisted of less than 0.05 percent of total enrollment.

These 329 formularies are associated with plans having total enrollment of 25,874,153, which is over 99.95 percent of total enrollment.

Drawing a Stratified Random Sample of Formularies. We used SAS to merge the list of sponsors with the NCR file to determine which sponsors had submitted negative changes in 2008.[42] To select our sample, we used a simple one-stage cluster sampling plan with changes clustered within formularies.

We used the list of 329 formularies eligible for the study and then divided these formularies into two strata: those that did not appear in the NCR file and those that did. Stratum 1 contained 94 formularies

[42] Copyright, SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

and stratum 2 contained 235 formularies. We then drew 50 formularies from stratum 1 and 70 formularies from stratum 2.

We chose this sampling design to enable us to make ratio estimates of the number of changes with certain characteristics over the number of all changes for key areas of interest with expected absolute precision of +/-10 percent at the 95-percent confidence level when expressing the ratios as percentages.

Methodology for Analysis of Negative Formulary Changes

We used SAS to analyze the NCR file, which contains changes that sponsors requested between January 1 and July 31, 2008. The NCR system allows sponsors to choose from 25 types of changes. We categorized these types of changes according to whether they added or substituted generic drugs, added utilization management to encourage generic drug use, and other types. The entire NCR file contained 14,991 negative change requests. The 120 formularies in our stratified random sample had 4,333 negative change requests, 3,425 of which CMS approved. We identified an additional 516 negative changes from sponsors' letters that CMS did not approve or that did not require CMS approval, as explained below. Together, approved NCR changes and unapproved changes from the letters accounted for all negative changes (3,941).

To identify drugs in protected classes, we used the 2008 Approved Formulary file. We created a list of the unique drug codes for drugs that fell into the classes that covered anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. We compared this list to the NCR file to identify requested changes that involved protected drugs.

Similarly, we identified drugs most commonly prescribed for Medicare beneficiaries using the list of classes from the *Medicare Prescription Drug Benefit Manual*, chapter 6, Appendix D. We used the 2008 Approved Formulary file to create a list of the unique drug codes for drugs that fell into these classes. We then compared this list to the NCR file to identify requested changes that involved drugs most commonly prescribed to Medicare beneficiaries.

Methodology for Analysis of Positive Formulary Changes

To analyze positive changes to formularies in 2008, we used data from the Formulary Change Notification Report (hereinafter, the report) in HPMS. Sponsors may submit new versions of their formularies each month, and HPMS assigns a new version number to the formulary each

time sponsors resubmit it. For each formulary in our sample, we used the report to compare drugs included in the first approved formulary version in or around the end of October 2007 with drugs in the last approved version in 2008. CMS aims to approve all formularies by this time each year so sponsors may post them on their Web sites prior to the Annual Election Period, which begins November 15. CMS first approved the majority of formularies in our sample on or around October 29, 2007. The 120 formularies in our sample had 7,886 positive changes.

We also used the report to identify changes that added new drugs to the formulary, reduced cost sharing, or removed utilization controls. Because that report does not assign a type to each change, we looked at the differences between the formulary versions and assigned positive change types, as shown in Table B-1. We added positive changes to the file of negative changes to create a file of all formulary changes.

Table B-1: Types of Positive Changes

Type of Change	Description
Decrease quantity limit day	The sponsor decreased the number of days before a beneficiary may obtain a refill on the drug
Decrease step group	The sponsor decreased the number of drugs that must be tried in step therapy before the beneficiary can obtain this drug
Move drug to lower cost-sharing tier	The sponsor placed the drug in a tier with a lower copayment
Delete prior authorization	The sponsor removed prior authorization for the drug
Delete quantity limit	The sponsor removed the quantity limit on the drug
Delete step therapy	The sponsor removed step therapy for the drug
Increase quantity limit	The sponsor increased the quantity of drugs that may be dispensed at one time

Source: Office of Inspector General analysis of Medicare Part D 2008 midyear formulary changes.

Methodology for Notification Letter Request and Analysis

We used a file of compliance officer contacts to identify 150 compliance officers associated with the formularies within our sample. The number of compliance officers is greater than the sample of formularies because some sponsors had more than one compliance officer. We sent letters to the compliance officers requesting copies of letters they sent to their enrollees notifying them of negative midyear formulary changes in 2008. To avoid duplicative letters, we did not request a copy of every

letter sent to every enrollee; rather, we asked for letters that covered all negative changes. We achieved a 100-percent response. However, 10 compliance officers told us that they no longer oversaw the formularies we referenced in our request. Therefore, we obtained all the required letters and information on the sampled formularies from 140 compliance officers. We later followed up with these compliance officers to collect more information on sponsors' notification policies.

Sixty percent of respondents included notification letters, while 40 percent said that they did not make any negative changes to their formularies or did not send letters because none of their enrollees was affected by the negative changes.

CMS does not require sponsors to send notification letters to beneficiaries who are not taking the affected drugs, and sponsors do not send letters for changes that CMS disapproves. Thus, sponsors could not send us notification letters covering every approved negative change they made. The letters we received covered 55 percent of requested changes.

We reviewed 853 letters covering 2,197 formulary changes. Of these changes, 516 were not approved by CMS or did not require CMS approval. We calculated the total number of formulary changes by adding unapproved changes (516) to the total positive changes (7,886) and total approved changes from the NCR file (3,425). This summed to 11,827.

To analyze changes listed in sponsors' letters, we first determined whether the changes were in the NCR file and then determined the presence or absence of each of the six required elements in the letters, the date the letter was sent, and the date the change became effective. Some letters lacked dates because sponsors redacted parts of the letters to protect enrollees' privacy. Therefore, we omitted these letters when analyzing notification time. For letters that did not appear in the NCR file, we also determined whether the changes required CMS approval.

Methodology for Analysis of Sponsors' Web Sites

We selected a convenience sample of 20 formularies from our stratified random sample of 120 formularies. We identified the sponsors that used those formularies using our list of 2008 sponsors. In December 2008, we went to each sponsors' Web site and downloaded the PDF version of each formulary.

Using data from the report, we identified negative changes that CMS had approved for the 20 formularies. We reviewed each online

formulary, focusing on four negative changes: (1) added prior authorizations, (2) drugs moved to higher cost-sharing tiers, (3) added step therapy, and (4) added quantity limits. We searched the 20 formularies for the brand and the generic names to determine whether the changes were accurately reflected in the formularies.

Methodology for Analysis of CMS Staff Interviews

We interviewed CMS staff responsible for monitoring and approving midyear formulary change requests and updates. We asked them for detailed information on the databases they use to track formularies, and we clarified technical aspects of our data collection to ensure we analyzed midyear changes appropriately. We also collected descriptive data from members on the processes they use to review change requests and the criteria they used to approve or disapprove changes.

Limitations

We could not assess whether sponsors sent a notification letter to every enrollee who should have received one. CMS requires sponsors to notify only those enrollees affected by negative formulary changes. However, we could not determine which enrollees were affected by each change and whether they received letters. Rather, we examined the content of the notification letters and checked to see whether CMS had approved negative changes for the drugs listed in the letters.

APPENDIX ~ C

Data Tables

Table C-1: Population Counts of 2008 Part D Sponsors

Population of Part D Sponsors	Sponsors That Requested Negative Changes	Sponsors of Sampled Formularies
204	156 (76%)	87

Source: Office of Inspector General (OIG) analysis of Medicare Part D 2008 midyear formulary changes.

Table C-2: Sample Design Information, 2008 Part D Formularies

Stratum	Population Size	Sample Size
1 – Formularies without negative change requests	94	50
2 – Formularies with negative change requests	235	70
Total	**329**	**120**

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-3: Percentage of Requested Negative Changes by CMS* Approval Status, 2008

Approval Status	Point Estimate (n=4,333)	95% Confidence Interval
Approved	79.0%	68.8%–89.2%
Denied	2.7%	1.4%–4.0%
Withdrawn	17.9%	7.3%–28.5%
Total	**100%**	

*Centers for Medicare & Medicaid Services (CMS).

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-4: Percentage of Positive and Negative Formulary Changes, 2008

Type of Change	Point Estimate (n=11,827)	95% Confidence Interval
Positive	63.6%	59.4%–67.7%
Negative	36.3%	32.2%–40.5%
Total	**100%**	

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-5: Percentage of Positive Changes by Type, 2008

Type of Positive Change	Point Estimate (n=7,886)	95% Confidence Interval
Decreased cost-sharing or removed utilization management	59.9%	55.4%–64.3%
Added drugs to the formulary	40.0%	35.6%–44.5%
Total	**100%**	

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-6: Mean Number of Drugs Added to or Removed From Formularies, 2008

Type of Change	Point Estimate	95% Confidence Interval
Added drugs to formularies	46.0	41.5–50.4
Removed drugs from formularies	22.1	17.5–26.6
Ratio of drugs added to drugs removed	2.1	1.8–2.4

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-7: Percentage of Negative Changes by Type, 2008

Type of Negative Change	Point Estimate (n=3,941)	95% Confidence Interval
Remove drugs	56.1%	47.8%–64.4%
Move drugs to higher cost-sharing tiers	17.2%	10.4%–23.9%
Add step therapy	6.6%	3.1%–10.0%
Add prior authorization	5.0%	3.4%–6.6%
Add quantity limit	4.2%	2.5%–5.8%
Other changes*	11.1%	8.9%–13.4%
Total	**100%**	

* Other changes include removing discontinued drugs or adding utilization controls to promote drug safety or to determine Part B vs. Part D reimbursement.

Source: OIG analysis of Medicare Part D 2008 negative midyear formulary changes.

Table C-8: Percentage of Negative Changes That Promoted Generic Substitution, 2008

Type of Negative Change	Point Estimate (n=3,941)	95% Confidence Interval
Negative changes that promoted generic substitution	62.2%	57.4%–66.9%

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-9: Percentage of Negative Changes Promoting Generic Substitution by Negative Change Type, 2008

Type of Change	Percentage of This Change That Promoted Generic Substitution	Sample Size	95% Confidence Interval
Remove drugs/substitute generics	86.7%	2,169	81.5%–91.9%
Move drugs to higher cost-sharing tiers	77.9%	668	65.8%–90.0%
Add step therapy	0.7%*	259	N/A
Add prior authorization	0.5%*	199	N/A
Add quantity limit	0%*	162	N/A
Other changes	11.2%	516	8.9%–13.5%

* We did not project this estimate because the confidence interval contains zero. While we cannot quantify the error in this estimate, the fairly large sample size and low incidence rate indicate that this change probably did not promote generic substitution very often in the population.

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-10: Negative Changes and Generic Substitution Among Drugs Most Commonly Prescribed to Medicare Beneficiaries, 2008

Type of Negative Change	Point Estimate	Sample Size	95% Confidence Interval
Negative changes affecting drugs most commonly prescribed to Medicare beneficiaries	46.3%	3,941	43.0%–49.7%
Percentage of these changes that involved generic drugs	69.3%	1,747	63.0%–75.6%

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-11: Negative Changes and Generic Substitution Among Drugs in Protected Classes, 2008

Type of Negative Change	Point Estimate	Sample Size	95% Confidence Interval
Negative changes affecting drugs in protected classes	39.2%	3,941	37.6%–40.8%
Percentage of these changes that involved generic drugs	69.0%	1,475	64.9%–73.0%

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-12: Percentage of Changes Not Promoting Generic Substitution by Change Type, 2008

Type of Change	Point Estimate	Sample Size	95% Confidence Interval
Negative changes that did not promote generic substitution	38.2%	3,941	33.5%–42.9%
All changes that did not promote generic substitution	13.9%	11,827	12.2%–15.6%

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-13: Percentage and Number of Sample Sponsors by Midyear Formulary Changes Notification Policies, 2008

Notification Policy	Percentage (n=140)	Count
Notify only affected beneficiaries	58.5%	82
Notify all beneficiaries	37.1%	52
Do not make any negative changes	4.2%	6

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-14: Sponsors' Notification Time for Negative Formulary Changes, 2008

Notice	Sample Median
Days' notice for midyear formulary changes	74

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-15: Percentage of Negative Formulary Change Letters by Timing of Notification, 2008

Timing of Notification	Percentage (n=1,557)
> 60 days	89.4%
≤ 59 days ≥ 30 days	8.7%
< 30 days	1.9%

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-16: Percentage of Changes With Notification Letters Containing Required Elements, 2008

Element	Percentage of Changes With Letters That Contained This Element (n=2,197)	95% Confidence Interval
All six required elements	87.5%	86.1%–88.9%
Five or fewer required elements	12.5%	11.1%–3.8%
Total	**100%**	

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-17: Percentage of Negative Formulary Changes That Did Not Promote Generic Substitution, 2008

Type of Change	Percentage of Negative Changes Not Promoting Generic Substitution (n=1,572)	Sample Size	95% Confidence Interval
Remove drugs	45.7%	741	37.7%–53.8%
Add step therapy	17.1%	257	8.8%–25.5%
Add prior authorization	13.3%	200	9.1%–17.5%
Add quantity limit	10.9%	162	7.2%–14.7%
Move drugs to higher cost-sharing tiers	10.1%	153	4.5%–15.7%
Other changes*	3.0%	65	2.3%–4.0%
Total	**100%**		

* Other changes include unapproved changes or those that did not require CMS approval.

Source: OIG analysis of Medicare Part D 2008 negative midyear formulary changes.

Table C-18: Percentage of Changes With Notification Letters Containing Six Required Elements, 2008

Element	Percentage of Changes With Letters That Contained This Element	95% Confidence Interval
Name of the affected drug	100.0%*	N/A
Type of change made to the affected drug	100.0%*	N/A
Reason for the change	100.0%*	N/A
Alternative drugs in the same class	100.0%*	N/A
Information on obtaining a coverage determination or exception for coverage of the affected drug	100.0%*	N/A
New expected cost-sharing	94.5%	93.9% - 95.2%

* We were unable to produce confidence intervals for these elements because all sample letters contained the element. Therefore we cannot produce a measure of variability. We concluded that compliance with these requirements is very high.

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

Table C-19: Unapproved Implemented Changes, 2008

Type of Unapproved Change	Point Estimate	Sample Size	95% Confidence Interval
Changes that required a letter	0.8%	11,827	0.5% - 1.2%
Changes that required a letter and involved generic substitution	93.5%*	117	86.3% - 100.0%
Changes that required a letter and involved increased cost sharing or added utilization controls	5.4%**	117	N/A

* The confidence interval for this estimate contains 100. Therefore, we cannot produce a measure of variability.

** We were unable to produce confidence intervals for these estimates because of small sample size.

Source: OIG analysis of Medicare Part D 2008 midyear formulary changes.

APPENDIX - D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 29 2008

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Midyear Formulary Changes in Medicare Prescription Drug Plans," (OEI-01-08-00540)

Thank you for the opportunity to comment on the OIG Draft Report: "Midyear Formulary Changes in Medicare Prescription Drug Plans," OEI-01-08-00540. The Centers for Medicare & Medicaid Services (CMS) recognizes the importance of close oversight of the midyear formulary change process. CMS has developed a midyear formulary change policy and implemented a standardized process that not only enables Part D sponsors to continue to offer cost-effective prescription drug coverage, but also ensures that Medicare beneficiaries continue to receive their necessary medications without disruption in therapy or changes in coverage.

The OIG developed a sound study methodology to research the degree to which Part D formularies change and Part D sponsors' compliance with CMS formulary change notification requirements. CMS generally concurs with the OIG regarding its findings. Please note that the current draft of the report still contains an error in the *Data Sources* section on page 6. The numbers for stratum 1 and stratum 2 are reversed. Based on the OIG report and our own internal numbers, the majority of formularies made midyear changes, and we thus believe stratum 1 contained 235 formularies and stratum 2 contained 94 formularies.

Based on the sampling method utilized in the study, OIG found that 38 percent of midyear formulary changes were not related to generic substitution. Other formulary changes that CMS also considers best practice are included in the report. The addition of prior authorization (PA) based upon a new United States Food and Drug Administration boxed warning or clinical guidelines recognized by CMS, for example, protects the interests of Medicare beneficiaries. As currently written, the finding that 38 percent of changes were unrelated to generic substitution suggests that these types of changes are not important formulary management techniques. Thus, this finding appears to overstate the number of non-maintenance formulary changes. Upon clarification of this finding in the report, we also respectfully request restatement in this section that beneficiaries currently taking drugs that are subject to a non-maintenance change are exempt from that change. CMS feels that this "grandfathering" requirement protects the beneficiary from disruptions in therapy.

The OIG found that the majority of Part D sponsors met CMS' beneficiary notice requirements. However, a small number of sponsors failed to include all necessary requirements on the notice, failed to meet required timeframes, or had difficulty producing notices. We would like to request that the OIG inform CMS of who these sponsors are so that CMS account managers can work with them to ensure that all requirements are met. Similarly, the report notes that one sponsor misinterpreted CMS guidance on midyear formulary changes and failed to submit brand-generic substitution change requests for CMS review. We would also request that the OIG identify this sponsor for CMS so we can provide further targeted education regarding this topic.

The CMS is concerned with the OIG's sample finding that 60 percent of negative changes identified in CMS' review file were not found on sponsors' Web sites. It is unclear whether only changes for which beneficiary notification was provided were sampled. If not, it is possible that sponsors submitted a negative change request for approval but failed to implement the change. Currently, CMS is working with a contractor to perform an extensive review of Part D sponsors' formulary Web sites to ensure consistency between the Web version and CMS' approved files.

Thank you again for the opportunity to comment on this thorough report on the midyear formulary change process.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Russell Hereford, Deputy Regional Inspector General.

Maria Maddaloni served as the team leader for this study, and Melissa Hafner served as the lead analyst. Other principal Office of Evaluation and Inspections staff from the Boston regional office who contributed to this report include Tim Chettiath; central office staff who contributed include Kevin Farber and Kevin Manley.