

June 2008

MEDICARE PART D

Complaint Rates Are Declining, but Operational and Oversight Challenges Remain

This Report Is Temporarily Restricted Pending Official Public Release.

This report was changed as of 7/1/08 to add Appendix II, which is the agency comment letter that was inadvertently left out of the report.





Highlights of [GAO-08-719](#), a report to congressional requesters

Why GAO Did This Study

Medicare Part D coverage is provided through plan sponsors that contract with the Centers for Medicare & Medicaid Services (CMS). As of April 2008, about 26 million beneficiaries were enrolled in Part D. When beneficiaries encounter problems with Part D, they can either file a complaint with CMS or a grievance with their plan sponsors. CMS centrally tracks complaints data and plan sponsors must report summary data on grievances for each of their contracts. GAO provided information on (1) complaints and what they indicate about beneficiaries' experiences with Part D, (2) whether grievances data provide additional insight about beneficiaries' experiences, and (3) CMS's oversight of the complaints and grievances processes. To conduct its work, GAO reviewed CMS's complaints and grievances data and interviewed the plan sponsors of eight, judgmentally selected contracts, which accounted for 40 percent of 2006 enrollment.

What GAO Recommends

GAO recommends that CMS undertake efforts to improve the consistency, reliability, and usefulness of grievances data. Such efforts include enhancing existing guidance, requiring plan sponsors to report additional information, and conducting systematic oversight of these data. The agency concurred with the recommendation and highlighted steps it has implemented or will consider to improve the quality of grievances data.

To view the full product, including the scope and methodology, click on [GAO-08-719](#). For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

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Complaint Rates Are Declining, but Operational and Oversight Challenges Remain

What GAO Found

While the number of complaints filed with CMS and the time needed to resolve them has diminished as the Part D program has matured, complaints data indicate that ongoing challenges pose problems for some beneficiaries. From May 1, 2006, through October 31, 2007, about 630,000 complaints were filed; most complaints were related to problems in processing beneficiaries' enrollment and disenrollment requests. The monthly complaint rate declined by 74 percent over the period, and the average time needed to resolve complaints decreased from a peak of 33 days to 9 days. However, trends in the complaints data also indicate ongoing implementation issues, such as information-processing issues related to beneficiaries' requests for enrollment changes and automatic premium withholds from Social Security payments. In addition, CMS and plan sponsors did not resolve a significant proportion of complaints related to beneficiaries at risk of depleting their medications in accordance with applicable time frames.

Due to limitations and anomalies, the grievances data that plan sponsors reported for their contracts did not provide sufficient insight into beneficiaries' experiences with Part D. Specifically, these data did not include information about whether beneficiaries who filed grievances were at risk of depleting their medications or whether plan sponsors were resolving grievances in a timely manner. In addition, GAO identified a number of anomalies in the grievances data, raising questions about whether plan sponsors were reporting these data consistently and accurately. For example, reported grievances were concentrated in a small number of plan sponsors' contracts and at a rate that was significantly disproportionate to their respective enrollment levels; varied considerably among contracts with similar levels of enrollment; and increased from 2006 to 2007, in contrast to patterns in complaints data.

CMS's oversight efforts thus far have focused almost exclusively on resolving complaints with little attention devoted to plan sponsors' grievances processes. CMS routinely monitors the status of complaints and has taken actions against plan sponsors who failed to comply with requirements for the complaints process. In contrast, CMS oversight of plan sponsor grievances processes has been more limited. CMS provided plan sponsors with general guidance for classifying grievances and periodically reviewed these data. However, several plan sponsors indicated that the guidance was insufficient, increasing the likelihood that plan sponsors report erroneous and inconsistent information to CMS and that they rely on the wrong processes to address beneficiaries' concerns. Further, CMS could not explain many of the anomalies in the grievances data that GAO identified.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
CSR	customer service representative
CTM	Complaint Tracking Module
HHS	Department of Health and Human Services
MA-PD	Medicare Advantage prescription drug
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
OMO	Office of the Medicare Beneficiary Ombudsman
PBM	pharmacy benefit managers
PDP	prescription drug plan
SSA	Social Security Administration

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United States Government Accountability Office
Washington, DC 20548

June 27, 2008

Congressional Requesters

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a voluntary outpatient prescription drug benefit, known as Medicare Part D.¹ Considered the largest change to the Medicare program since 1965, the new benefit was intended to provide affordable prescription drug coverage to Medicare beneficiaries. Under the program, which began providing benefits on January 1, 2006, the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—contracts with private companies called plan sponsors to provide this benefit.² Through these contracts, plan sponsors offer prescription drug plans which may have different beneficiary cost-sharing arrangements (such as copayments and deductibles) and charge different monthly premiums.³ In addition, while each plan may vary in the specific drugs it covers, all must provide coverage for drugs within certain categories.⁴

To obtain the Medicare drug benefit, eligible beneficiaries enroll in a specific Part D plan offered by a plan sponsor.⁵ Approximately 21 million people enrolled in a Medicare Part D plan during the program’s initial enrollment period, which ran from November 15, 2005, through May 15,

¹Pub. L. No. 108-173, tit. I, § 101, *et seq.*, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101—1395w-152).

²Plan sponsors include health insurance companies and pharmacy benefit managers (PBMs). Although PBMs typically manage prescription drug benefits for third-party payers, some PBMs have contracted directly with Medicare to offer Part D plans.

³MMA requires that plan sponsors offer beneficiaries a standard benefit plan, which specifies deductible and coinsurance amounts, or a plan with benefits that are actuarially equivalent to the standard plan.

⁴Part D sponsors’ formularies—lists of plan-covered drugs—generally must cover at least two drugs in each drug category and class. CMS also requires formularies to cover “all or substantially all” drugs within six designated drug categories: antidepressants, antipsychotics, anticonvulsants, anticancer, immunosuppressants, and HIV/AIDS.

⁵In addition, beneficiaries who qualify for both Medicare and Medicaid—a jointly funded federal-state health care program that covers certain low-income families and other individuals—are known as full-benefit dual eligibles. If they do not independently enroll in a Part D plan, CMS must automatically enroll them in a prescription drug plan.

2006. Subsequent to the initial enrollment period, beneficiaries can enroll in a plan during the same time period when they become eligible for Medicare or change plans during the annual coordinated election period, which runs from November 15 through December 31 of each year. As of April 2008, nearly 26 million beneficiaries were enrolled in a Medicare Part D plan. As part of the enrollment process, beneficiaries can choose to pay for their share of premiums by having the Social Security Administration (SSA) automatically deduct them from their social security payments. CMS and SSA coordinate to ensure that this deduction occurs, and millions of beneficiaries have chosen this option.

Soon after the implementation of Part D in January 2006, the Secretary of Health and Human Services (HHS), as well as beneficiary advocacy groups and states, reported various difficulties beneficiaries experienced when obtaining and utilizing their Part D benefits.⁶ For example, there were reports that beneficiaries experienced problems enrolling in plans and being charged incorrect copayments at the pharmacy. As the primary federal oversight body for Medicare Part D, CMS is responsible for ensuring that plan sponsors meet applicable requirements, which include resolving these and other problems that could affect a beneficiary's ability to obtain Part D benefits.

Medicare beneficiaries who experience problems, such as difficulties in trying to enroll in a Part D plan, or cases when they were charged too much for their prescriptions, have two distinct processes through which they can pursue resolution. CMS has established a process through which a Medicare beneficiary can file a complaint directly with CMS, which will generally forward it to the appropriate plan sponsor for resolution, or a beneficiary has the right to file a complaint directly with the plan sponsor, in which case it is known as a grievance.⁷ Complaints are tracked and resolved through CMS's centralized complaints system, while grievances are tracked and resolved by each plan sponsor using its own systems. Through its outreach efforts, CMS encourages individuals to file grievances with their plan sponsors before pursuing a complaint with CMS; however, individuals can simultaneously file a complaint and

⁶See Mike Leavitt, *Secretary's One Month Progress Report on the Medicare Prescription Drug Benefit* (Washington, D.C.: Department of Health and Human Services, Feb. 1, 2006).

⁷Beneficiaries or their authorized representatives (including advocates and caregivers) can file complaints or grievances. In addition, providers and pharmacists can also file complaints.

grievance on the same issue. CMS's time frames for resolving complaints vary and depend on whether the complaint relates to a beneficiary's medication supply, that is, whether the beneficiary is at risk of exhausting his current medication supply unless the complaint is resolved. For example, CMS defines complaints as immediate need when a beneficiary has between 0-2 days of medication remaining, and according to its policy, plan sponsors must resolve such complaints within 2 calendar days of receiving them. In addition, it defines complaints as urgent when a beneficiary has between 3 and 14 days of medication remaining, and CMS officials encourage plan sponsors to resolve these complaints within 10 calendar days.⁸ Part D regulations generally require that plan sponsors resolve grievances within 30 days.⁹ Additionally, if beneficiaries experience problems obtaining coverage from their Part D plan sponsor for a drug that has been prescribed for them, they must pursue resolution through a separate process known as a coverage determination. Under this process, beneficiaries make a formal request to their plan for coverage, and if they receive an unfavorable coverage determination, they may appeal the decision.¹⁰

You expressed interest in the extent to which beneficiaries may have experienced problems obtaining and utilizing their benefits under Part D, and the extent to which CMS has assured the resolution of such problems. This report provides information on (1) complaints filed with CMS and what they indicate about beneficiaries' experiences with Part D, (2) the extent to which plan sponsor-reported grievances data provide insight about beneficiaries' experiences with Part D, and (3) CMS's oversight of the complaints and grievances processes.

To identify and analyze the Part D complaints reported to CMS, we obtained and analyzed data from CMS's Complaint Tracking Module (CTM) database on all complaints filed for the 18-month period from May 1, 2006, the point at which CMS first began centrally tracking

⁸CMS considers all other complaints "routine," and CMS officials encourage that routine complaints be resolved within 30 calendar days.

⁹Additionally, a 14-day extension may be granted at the beneficiary's request or if the sponsor justifies the need for additional time and indicates how the extension is in the interest of the beneficiary. However, certain types of grievances must be responded to within 24 hours. See 42 C.F.R. § 423.564(e),(f).

¹⁰For further information on the Part D coverage determinations and appeals processes, see GAO, *Medicare Part D: Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could be Improved*, [GAO-08-47](#) (Washington D.C.: Jan. 22, 2008).

complaints, through October 31, 2007, the date for which CMS had the most complete complaints data for our purposes at the time of our request.¹¹ For this same time period, we also obtained from CMS information on the number of beneficiaries enrolled under the plans of each Part D contract. Based on the information which CMS collected for each complaint, including its category, or type of issue, and its filing and resolution dates, we conducted a series of analyses which allowed us to determine aggregate monthly complaint rates and summary statistics on the types of issues which generated the complaints. Through these analyses, we also determined the extent to which complaints were related to beneficiaries' medication supplies, the proportion of complaints that were resolved and their resolution times, and various trends over the 18-month period.¹² We also interviewed CMS officials to obtain a more thorough understanding of the complaints data and to obtain their views regarding the trends our analyses identified. To assess the reliability of the complaints data, we reviewed CMS manuals and other policies for collecting, categorizing, and analyzing complaints, interviewed CMS officials responsible for collecting and analyzing the data, and conducted a series of electronic tests on the data file CMS provided. We determined that the data were sufficiently reliable for the purposes of this report.

To determine whether plan sponsor-reported grievances data provided insight about beneficiaries' experiences with Part D, we obtained plan sponsor-reported grievances data from CMS for each quarter of calendar year 2006 and for the first 3 quarters of calendar year 2007. As of December 2007, these data represented the universe of grievances reported to CMS by plan sponsors. These grievances data, which plan sponsors are contractually required to report to CMS, contained summary statistics on the number and type of grievances reported for each Part D contract. Based on these reported grievances and CMS enrollment data described above, we conducted a series of analyses to determine the number and grievance rates by quarter and the types of issues which generated the grievances. However, while conducting our analyses we

¹¹We determined that including complaints filed after October 31, 2007, could skew our analyses because CMS and plan sponsors may not have had sufficient time to resolve such complaints as of the time of our December 2007 data request. Specifically, including complaints filed after this date could have indicated that a disproportionate number of complaints remained unresolved.

¹²We did not report on complaint rates for individual Part D contracts because our initial analyses found that patterns in complaint rates for individual contracts were generally consistent with trends in the aggregate rates.

identified a number of limitations and anomalies, and thus we determined that the grievances data were too limited and not sufficiently reliable for us to draw conclusions regarding beneficiaries' experiences with Part D.

To determine how CMS oversees the complaints and grievances processes, we reviewed relevant federal statutes and regulations, as well as available CMS guidance, including standard operating procedures, for tracking, monitoring, and resolving complaints and grievances. We reviewed other CMS data, including information on compliance actions taken by the agency against certain plan sponsors and the reasons for these actions, and separately reviewed CMS's audit findings pertaining to grievances. In addition, we interviewed officials from CMS's central office responsible for collecting and monitoring CTM data and for reviewing plan sponsor-reported grievances data. We also interviewed CMS officials in each of its 10 regional offices responsible for ensuring that complaints were entered into the CTM and were appropriately resolved. Finally, to identify plan sponsors' views on the extent to which CMS provided guidance and oversight for their grievances processes, we interviewed officials from eight plan sponsors. We selected these plan sponsors based on a number of factors, including variation in enrollment levels and grievance rates for some of their specific contracts.¹³ The information we obtained from these plan sponsor interviews was not generalized to all plan sponsors.

In conducting our work we were unable to definitively determine the number of complaints and grievances filed since the inception of the Part D program, and thus assess the full range of implementation problems beneficiaries may have faced. CMS did not begin centrally collecting complaints until May 2006, and thus no information was readily available on complaints filed between January and April 2006. Further, because beneficiaries could have filed both a complaint and grievance on the same issue or filed more than one complaint or grievance on the same issue, complaints and grievances may be duplicative. In addition, for a variety of reasons, including the newness and uniqueness of the Part D program, we were unable to determine what an appropriate complaint rate should be. For example, CMS officials cautioned us about comparing the Part D complaint rate to that of the Medicare Part C program—which is designed to provide comprehensive medical coverage—because the Part D data reflect early implementation challenges, and because the goals of the two programs and thus, the nature of issues facing beneficiaries, differ.

¹³These eight contracts accounted for 40 percent of Part D enrollment in 2006.

We conducted this performance audit from December 2006 to June 2008 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

Most complaints were related to enrollment and disenrollment issues and both the number of complaints and time needed to resolve them have decreased as the Part D program has matured; however, ongoing issues continue to pose challenges for some beneficiaries. Of the nearly 630,000 complaints filed with CMS between May 1, 2006, and October 31, 2007, about 63 percent were related to problems processing beneficiaries' enrollment and disenrollment requests, such as when enrollment records between CMS and plan sponsors differed or contained errors. Another 21 percent of complaints were related to the pricing and coinsurance category of complaints, and included problems with automatic premium deductions from beneficiaries' social security payments. Most complaints did not involve cases where beneficiaries were at risk of exhausting their medications while their disputes were pending, and virtually all complaints were documented as resolved. Beneficiaries reported fewer problems over time and their problems were resolved more quickly, according to our review. For example, between May 2006 and October 2007, the monthly complaint rate declined by 74 percent, and from July 2006 to October 2007 the average resolution time decreased from a high of 33 days to 9 days. However, the complaints data also confirmed that information system coordination problems continue to pose challenges for some beneficiaries. For example, information processing issues between CMS and plan sponsors and between CMS and SSA contributed to spikes in the number of enrollment and premium withholding complaints during the months immediately following the end of the 2007 annual coordinated election period. Also, a substantial proportion of the most critical complaints—those filed when beneficiaries were at risk of exhausting their medications—were not resolved within CMS's applicable time frames.

Due to data limitations and anomalies, plan sponsor-reported grievances data did not provide sufficient insight into beneficiaries' experiences with Part D. For example, in contrast to the data available about complaints, the grievances data reported by plan sponsors for their contracts did not include information about whether a grievance was related to beneficiaries at risk of exhausting medications or whether it was ultimately resolved. Therefore, we were unable to determine the extent to which beneficiaries' grievances related to medication supply issues, whether plan sponsors resolved the grievances, or whether grievances were resolved in a timely manner. In addition to their limited nature, we identified a number of anomalies in the grievances data that raised questions about whether these data were reported consistently and accurately. For example, grievances were concentrated in a small number of contracts, and at a rate that was significantly disproportionate to their respective enrollments. Specifically, in 2006 plan sponsors reported grievances data for 522 contracts, 19 of which accounted for 80 percent of all grievances but only 49 percent of enrollment. The concentration was more pronounced in 2007, when 11 of the 604 contracts for which grievances data were reported accounted for 90 percent of all grievances but only 42 percent of enrollment. We also found significant variations in the number of grievances reported for contracts with similar levels of enrollment. For example, in 2006, the two largest contracts each averaged about 3 million enrollees; however, grievances data indicated that one contract had 35 times the number of grievances than the other contract.

CMS's oversight efforts thus far have focused almost exclusively on complaints, with little attention being paid to plan sponsors' grievances processes. Consequently, CMS has only partial assurance that beneficiaries' concerns have been addressed. To oversee complaints, CMS uses a structured framework that includes standard operating policies and procedures, a centralized repository of complaints data, and staff to review and assess trends in the complaints data. Through this framework, CMS routinely monitors the status of complaints and can take actions against plan sponsors who are noncompliant with process-related requirements. However, some gaps exist. For example, CMS does not verify, on a consistent basis, that plan sponsors have effectively resolved complaints, and in some cases, beneficiaries may deplete their medications before their complaints are resolved. In contrast, CMS oversight of plan sponsor grievances processes has been more limited. CMS provided plan sponsors with general guidance for classifying grievances, periodically reviewed plan sponsor grievances data, and audited some plan sponsors' grievances processes. However, several plan sponsors indicated that CMS's guidance for determining whether

beneficiaries' problems should be considered grievances was insufficient, increasing the likelihood that plan sponsors report erroneous or inconsistent information to CMS and that they rely on the wrong processes to address beneficiaries' concerns. Further, although we found significant anomalies in the grievances data, CMS officials could not explain many of the anomalies and acknowledged that they had not undertaken efforts to review the data in detail or to assess their overall reliability.

To improve oversight of the Medicare Part D grievances process, we recommend CMS take measures to enhance existing guidance, require plan sponsors to report additional information, and conduct systematic oversight of these data. In commenting on a draft of this report, the agency concurred with the recommendation and highlighted steps it has already taken to provide Part D sponsors with more comprehensive guidance for their grievances processes and to enhance its related oversight activities. CMS also stated that it would consider adding data elements related to plan sponsors' timeliness and quality of grievances resolution to its calendar year 2010 Reporting Requirements.

Background

The Medicare Part D program offers beneficiaries an outpatient prescription drug benefit through various plan sponsors who offer coverage through drug plans, which may vary in terms of their benefits and costs. Enrollment in Part D consists of several steps and requires coordination among various organizations, such as CMS, plan sponsors, and SSA. If beneficiaries are not satisfied with certain aspects of the Part D program, they may file a complaint with CMS, a grievance with their respective plan sponsors, or they can file with both. CMS oversees the complaints and grievances processes and may rely on complaints and grievances data to undertake compliance actions against specific plan sponsors.

The Medicare Part D Program

The Medicare Part D benefit is provided through private organizations—such as health insurance companies—that offer one or more drug plans with different levels of premiums, deductibles, and cost sharing. Part D plan sponsors offer outpatient prescription drug coverage either through stand-alone prescription drug plans (PDPs) for those in traditional fee-for-service Medicare, or through Medicare Advantage prescription drug (MA-PD) plans for beneficiaries enrolled in Medicare's managed care

program, known as Medicare Advantage.¹⁴ In 2007, CMS entered into more than 600 individual contracts with about 250 plan sponsors to provide Part D benefits.¹⁵ Under these contracts, PDP sponsors offered about 1,900 individual plan benefit packages and sponsors of MA-PDs offered about 1,700.¹⁶ The majority of Part D enrollees, about 70 percent, were enrolled in PDPs during this time. Enrollment across contracts varies widely, and is highly concentrated—the 4 largest contracts accounted for nearly 40 percent of total Part D enrollment in 2007.

Beneficiaries enroll in the Part D program when they first become eligible for Medicare or during an annual coordinated election period and, once enrolled in a drug plan, typically have one opportunity each year to change their plan selection.¹⁷ Processing a Part D enrollment involves multiple, timely, and accurate electronic data exchanges among federal agencies, private health plans, and pharmacies. For instance, data exchanges occur between plan sponsors and CMS to verify benefit eligibility. Pharmacies rely on this information to ensure that payments for beneficiaries filling their prescriptions are processed appropriately. During the enrollment process, beneficiaries choose one of three options for paying their share of their Part D premiums—direct billing, automated withdrawal from financial accounts, or automatic deductions from social security payments, called premium withholds. As of January 2008 about 20 percent of Part D enrollees—4.8 million beneficiaries—opted to have premiums withheld from their social security payments, which requires coordination among plan sponsors, CMS, and SSA. When a beneficiary elects this option, CMS provides enrollment and payment information it receives from plan sponsors to SSA for processing. SSA then deducts premium amounts from beneficiaries' monthly social security payments and

¹⁴Some employers also offer Part D plans, although such employer-sponsored plans represent a small percentage of all Part D plans.

¹⁵These contracts require plan sponsors to operate their plans in compliance with federal law and regulations and CMS guidance and policies.

¹⁶A plan sponsor may have one contract and offer multiple plans or have several contracts and offer multiple plans.

¹⁷The annual election period runs from November 15 to December 31 of each year. Beneficiaries may be able to change plans at other times depending on special circumstances. For example, beneficiaries may enroll in a new plan if they move to areas not served by their plan. In addition, beneficiaries enrolled in Medicare Advantage may change plans once from January 1 to March 31, and dual-eligible beneficiaries can enroll and switch plans monthly.

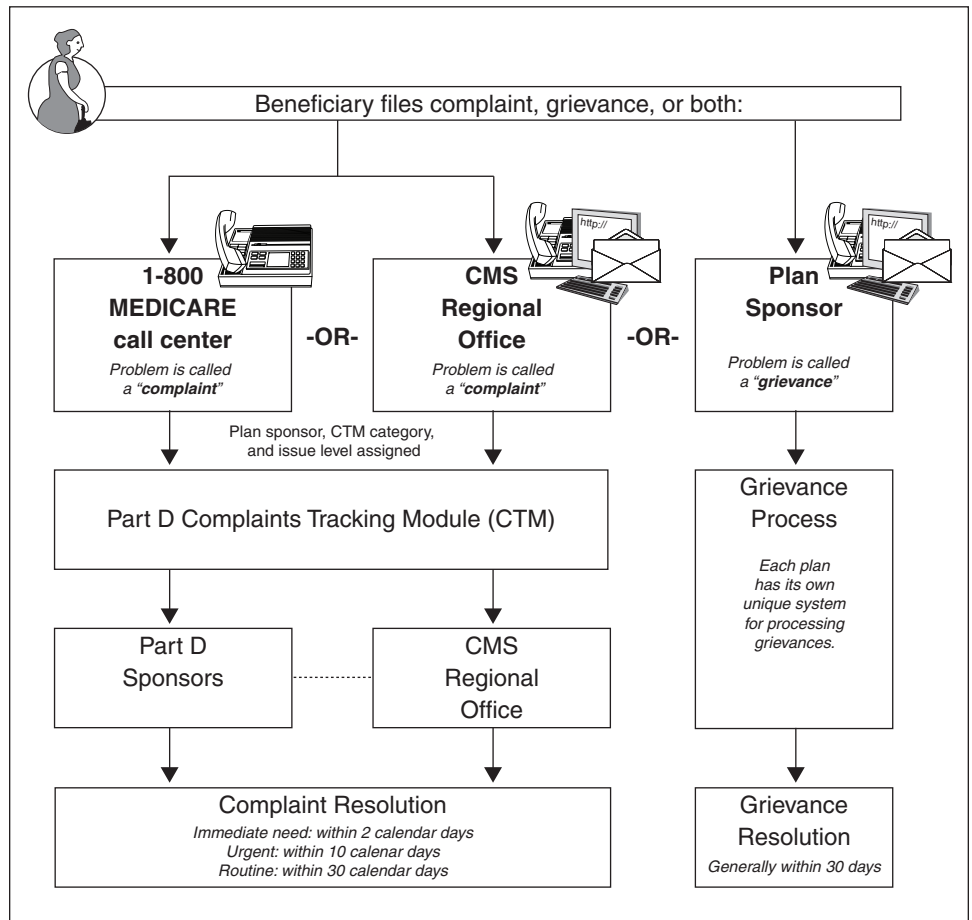
provides CMS with information on the amount of premiums it deducted in order for CMS to pay the appropriate plan sponsors.

Part D Complaints and Grievances Processes

Beneficiaries can express dissatisfaction with any aspect of the Part D program, other than coverage determinations, by filing a complaint with CMS or filing a grievance directly with their respective plan sponsors (see fig. 1).¹⁸ The processes for resolving complaints and grievances are independent of one another and the status of individual complaints and grievances is tracked separately. Although CMS encourages beneficiaries to first file a grievance with their respective plan sponsors, a beneficiary can choose to seek resolution by directly contacting CMS first to file a complaint or by filing a complaint and grievance simultaneously.

¹⁸Disputes involving quality of care under Part D may also be addressed through the Quality Improvement Organization dispute resolution process. *See* 42 C.F.R. § 423.564(e)(3)(iii).

Figure 1: Part D Complaints and Grievances Processes



Source: GAO, Art Explosion (graphics).

Beneficiaries typically file complaints by calling CMS’s 1-800-Medicare toll-free number or by contacting one of CMS’s 10 regional offices through telephone, fax, mail, or e-mail.¹⁹ For complaints filed through the toll-free number, customer service representatives (CSRs) enter details about the complaints into the 1-800-Medicare database, and assign the complaint to specific contracts administered by plan sponsors. CSRs also categorize the

¹⁹Although uncommon, beneficiaries may also file complaints directly with CMS’s central office.

complaint in several ways, including by (a) the nature of the complaint using 20 categories and over 180 subcategories, such as whether the complaint relates to enrollment, pricing, or customer service; and (b) the complaint's issue level or level of urgency, which corresponds to one of three issue levels—immediate need, urgent, or routine—depending on the beneficiary's risk of exhausting his or her medication supply while resolution of the complaint is pending.

The information included in the 1-800-Medicare database is uploaded each day into the CTM—CMS's centralized database of complaints information.²⁰ For complaints filed with the CMS regional offices, regional staff similarly categorize complaints by their nature and issue level and input them directly into the CTM. Most complaints in the CTM are assigned to specific contracts administered by plan sponsors who utilize their own staff to resolve beneficiaries' concerns.²¹ For complaints beyond the control of plan sponsors, such as those involving premium withholding and certain enrollment issues, plan sponsors request, through the CTM, that CMS resolve the complaint. Once complaints are resolved, the resolution date must be entered into the CTM. CMS requires that immediate need complaints be resolved within 2 calendar days, and encourages that urgent and routine complaints be resolved within 10 and 30 calendar days respectively.²² According to CMS policy, beneficiaries should be notified once their complaints are resolved.

Beneficiaries also have the right to express dissatisfaction by filing a grievance directly with their plan sponsors via telephone, fax, mail, or e-mail.²³ Plan sponsors enter information about the grievances in their internal tracking systems and assign individual grievances to their staff,

²⁰Complaints are not assigned a specific "filing date" until they are uploaded into the CTM. Complaints entered through 1-800-Medicare are uploaded into the CTM the next business day after they are received.

²¹For some enrollment complaints, such as those involving dissatisfaction with an enrollment decision, the CTM automatically flags them as a "CMS Issue" and CMS must resolve them.

²²According to CMS, while plan sponsors must resolve immediate need complaints within 2 calendar days, CMS caseworkers have 2 business days to resolve such complaints.

²³Under federal law, plan sponsors are required to provide meaningful procedures for hearing and resolving grievances between themselves and their enrollees. 42 U.S.C. § 1395w-104(f). Plan sponsors must also maintain records on grievances including the date of receipt, the date of final resolution, and the date the enrollee was notified of the resolution. 42 C.F.R. § 423.564(g).

who work to resolve them. Plan sponsors are required to resolve grievances within 30 days, but can allow for a 14-day extension in some cases.²⁴ Plan sponsors must inform beneficiaries of the outcome of the grievances process, and beneficiaries who are dissatisfied may choose to file a complaint with CMS on the same issue.

CMS Oversight of the Part D Complaints and Grievances Processes

CMS is responsible for overseeing the Part D program, which includes overseeing the complaints and grievances processes and ensuring that beneficiaries' problems are addressed. To oversee the complaints process, CMS staff monitor data within the CTM, including calculating complaint rates and resolution times for each Part D contract administered by a plan sponsor. Specifically, CMS monitors resolution time frames to determine whether plan sponsors resolve complaints assigned to their contracts within applicable time frames. To aid its oversight of the grievances process, CMS requires plan sponsors to categorize grievances into 1 of 11 categories,²⁵ which differ from CTM categories, and submit quarterly reports for each of their contracts on the number of grievances by category²⁶ (see app. I). CMS uses these data to calculate grievance rates to identify plan sponsors with outlier contracts.

According to CMS officials, the agency can initiate a range of actions against plan sponsors it determines have noncompliant processes (see fig. 2). For example, CMS can make a formal compliance call to plan sponsors to discuss identified issues. However, if CMS's monitoring indicates that plan sponsors are not taking corrective actions in response to the compliance call, CMS may pursue more stringent compliance actions.²⁷ For example, the agency may send formal written notices of noncompliance, which notify plan sponsors of their noncompliance and explicitly inform them that they must address the problems. For plan sponsors that remain noncompliant, CMS can send warning letters that

²⁴Expedited grievances—those which involve a sponsor's refusal to expedite a decision concerning payment for or provision of a drug—must be resolved within 24 hours.

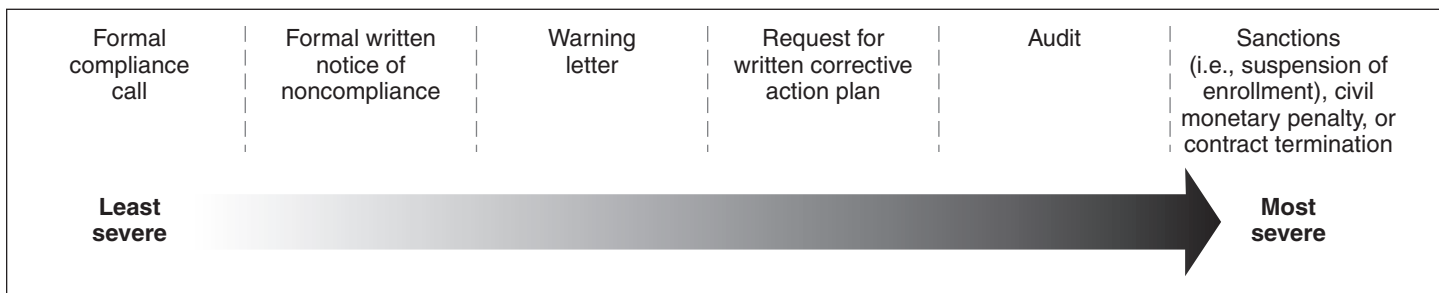
²⁵See CMS, *Medicare Part D Reporting Requirements, Contract Year 2007* (Baltimore, Md.: Updated Dec. 15, 2006).

²⁶Certain plan sponsors, which offer a comprehensive optional benefit under both Medicare and Medicaid through the Program of All-Inclusive Care for the Elderly, are not required to report grievance data.

²⁷According to CMS, the agency can initiate a formal compliance action at its discretion without first making a call to a sponsor.

notify plan sponsors that their performance is unacceptable; request that plan sponsors submit written corrective action plans that show formal plans to come into compliance; or audit the plan sponsors.²⁸ In the most extreme cases of noncompliance, CMS can impose intermediate sanctions, which include suspension of enrollment, payment, or marketing activities. CMS can also impose a civil monetary penalty or terminate or decline to renew a Part D contract.

Figure 2: Range of Actions to Address Noncompliance in Order of Severity



Source: CMS.

Complaints Data Highlight Beneficiaries' Enrollment Problems, Decline in Complaint Rates, and Ongoing Challenges

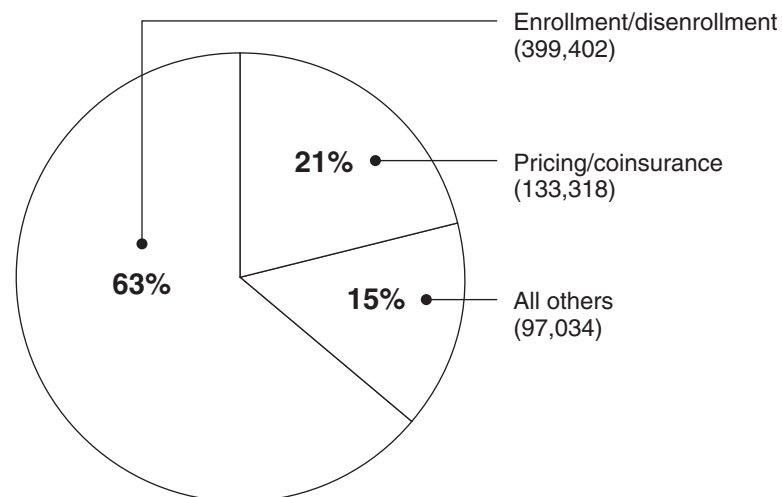
Most complaints related to enrollment issues and while both the number of complaints and the time needed to resolve them decreased as the Part D program matured, ongoing challenges continued to pose problems for some beneficiaries. The majority of complaints were related to delays and errors in processing beneficiaries' enrollment and disenrollment requests and were resolved. In addition, a small proportion of complaints involved cases where beneficiaries were at risk of depleting their medication supplies. Further, trends in complaints data suggest that beneficiaries reported fewer complaints over time and their problems were resolved more quickly as they, plan sponsors, and CMS gained experience with the Part D benefit. However, the complaints data also revealed some ongoing challenges facing the program, including problems related to data system coordination between CMS and plan sponsors and between CMS and SSA, which continued to present difficulties for some beneficiaries.

²⁸These corrective action plans are then monitored by CMS until the plan comes into compliance.

Most Complaints Were Related to Enrollment Issues and Were Resolved

During the 18-month period from May 1, 2006, through October 31, 2007, 629,792 complaints were filed with CMS—an average monthly complaint rate of 1.5 complaints per 1,000 beneficiaries.²⁹ The majority of complaints—about 63 percent—were related to problems beneficiaries experienced when trying to enroll in or disenroll from a plan, and about 21 percent were related to pricing and coinsurance issues. The remaining 15 percent of complaints were spread among the other 18 CTM categories, and included complaints related to customer service and marketing of plans (see fig. 3).

Figure 3: Proportion of Medicare Part D Complaints Filed by CTM Category, May 2006-October 2007



Source: GAO analyses of CTM complaints.

Note: 38 of the 629,792 complaints were not assigned to a CTM category.

Percentages may not sum to 100 because of rounding.

²⁹The average complaint rate is based on an average monthly enrollment of about 23.4 million enrollees over the 18-month period studied. We found no noticeable difference in aggregate complaint rates between PDPs and MA-PDs, which suggests that enrollment in either a PDP or MA-PD did not noticeably affect the likelihood that a beneficiary would file a complaint. In addition, we were unable to evaluate the magnitude of this complaint rate because we had no basis of comparison.

The vast majority—about 73 percent of the enrollment and disenrollment complaints, or 290,000 complaints—were assigned to five CTM subcategories and were related to delays and errors in processing beneficiaries’ enrollment or disenrollment requests.³⁰ According to CMS officials, such problems occurred when enrollment records between CMS and plan sponsors differed or contained errors, and thus extra time was needed for CMS and plan sponsors to identify and correct the errors and ensure beneficiaries were enrolled in their plans of choice.

Approximately 47,000 (or more than 35 percent) of the complaints that were categorized as pricing and coinsurance issues were related to beneficiaries who experienced problems having their premiums automatically deducted from their social security payments.³¹ Specifically, these complaints included cases in which the wrong amounts were deducted from beneficiaries’ social security payments, the correct amounts were being deducted but were not forwarded to the appropriate plan sponsor for payment, or premiums had not yet been deducted when beneficiaries expected otherwise.³² According to CMS officials, many of the complaints related to accurately deducting premiums and forwarding payments to plan sponsors were due to problems with data exchanges between CMS and SSA. In addition, CMS officials indicated that beneficiaries are not always aware that it can take several months for SSA to process a request for premium deductions; therefore, they may file complaints when premiums are not immediately deducted from their social security payments. Many of the remaining pricing and coinsurance complaints were filed because some beneficiaries complained they were charged too high of a coinsurance amount for their prescriptions.

³⁰Most enrollment and disenrollment complaints were assigned to five subcategories—delayed enrollment processing, inappropriate enrollment, inappropriate disenrollment, untimely processing of disenrollment requests, and other enrollment/disenrollment issues.

³¹CMS did not separately track premium withholding issues until February 2007, and CMS officials indicated that prior to that time such issues were typically placed into the “other pricing and co-insurance issues” subcategory. Therefore, the number of cases related to premium withholding issues during the period May 2006 through October 2007 was likely higher.

³²Ongoing GAO work is examining the process for withholding Medicare premiums from beneficiaries’ Social Security payments. This study, which is designed to provide information about the challenges CMS and SSA face in processing premium-withholding transactions, is estimated to be complete in summer 2008.

In addition to complaint categories, the CTM also contains information on the “issue level” of complaints (immediate need, urgent, routine), and the dates complaints were filed and resolved. We found that about 73 percent of complaints were unrelated to beneficiaries at risk of depleting their supplies of medication and were considered routine. About 20 percent of complaints were considered immediate need, meaning beneficiaries had between 0 and 2 days of medication remaining, and about 7 percent of complaints were considered urgent, meaning beneficiaries had 3 to 14 days of medication remaining. Further, using CTM dates, we found that 99 percent of all complaints filed between May 2006 and October 2007 were resolved, on average, in 25 days.³³ Although immediate need and urgent complaints were resolved, on average, much more quickly—12 days for immediate need complaints and 16 days for urgent complaints—these average resolution times still exceeded CMS’s resolution time frames.³⁴

Finally, we found that 44 percent of all complaints involved issues, such as those related to premium deductions from social security payments, which were beyond the control of plan sponsors, and thus required CMS intervention for resolution.³⁵ When compared to complaints that plan sponsors could resolve independently, these complaints took, on average, twice as long—34 days compared to 17 days—to resolve. According to CMS officials, the lengthier resolution times for complaints requiring CMS intervention reflected the fact that these complaints were often related to delays associated with reconciling data between the agency and plan sponsors or SSA.

³³For the purposes of this analysis, we measured resolution times for each complaint by subtracting the date the complaint was entered into the CTM—known as the “data entry date”—from the date the complaint was resolved. When conducting our analyses, we found that about 4 percent of the resolved complaints had either missing or invalid resolution dates, and thus, those complaints are excluded from our analysis.

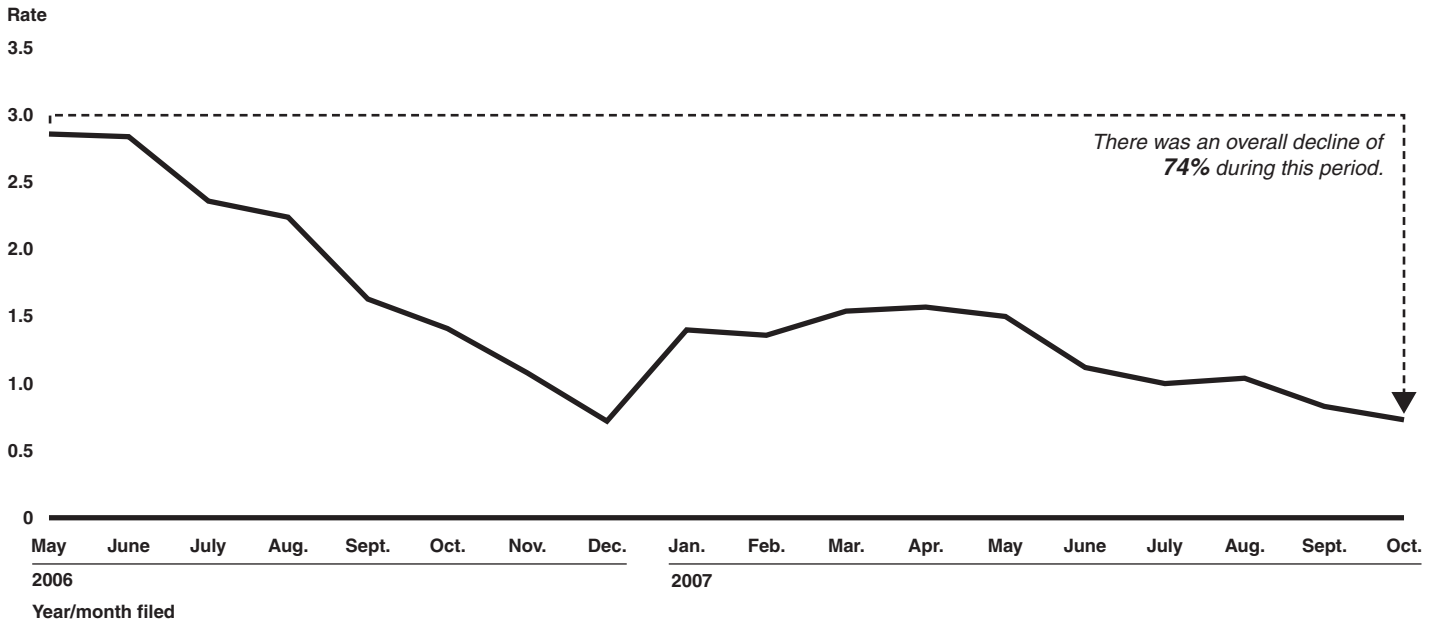
³⁴The average resolution time of 25 days reflects the fact that the vast majority of complaints were routine. For the 18-month period, routine complaints took an average of 29 days to resolve.

³⁵CMS utilizes a computer program, which analyzes CTM categories, subcategories, and word patterns to identify complaints that are beyond the control of plan sponsors to resolve. We used this computer program to determine the proportion of complaints, which required CMS’s intervention to resolve.

Trends in Complaints Data Indicate Beneficiaries Reported Fewer Problems, but Highlight Ongoing Challenges

Trends in the complaints data indicate that beneficiaries reported fewer problems and their problems were resolved more quickly. For example, while the average monthly complaint rate was 1.5 per 1,000 beneficiaries during the period, the monthly complaint rate declined by 74 percent from its peak of 2.86 complaints per 1,000 beneficiaries in May 2006 to .73 in October 2007 (see fig. 4).

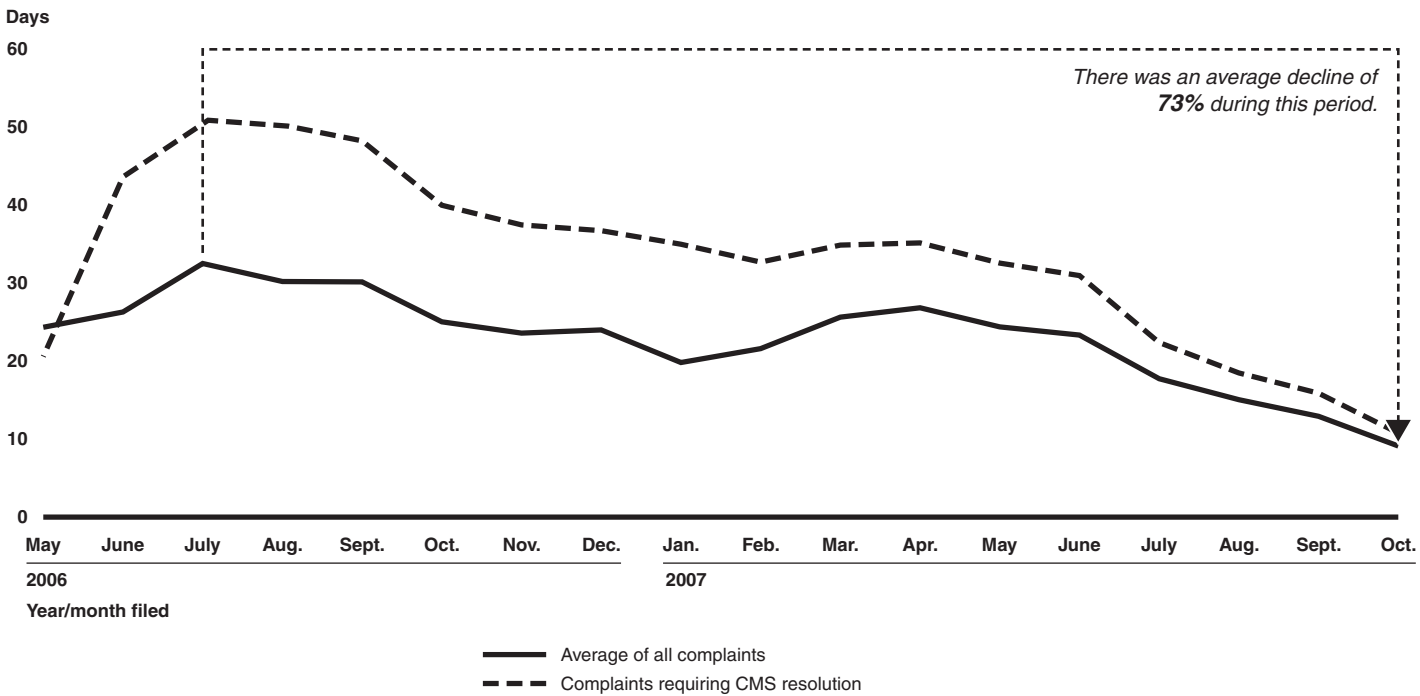
Figure 4: Medicare Part D Complaint Rates per 1,000 Beneficiaries, May 2006-October 2007



Source: GAO analysis of CTM data.

In addition, the average time needed to resolve beneficiaries' complaints declined by 73 percent, from a peak of 33 days in July 2006 to 9 days in October 2007 (see fig. 5). The decline in average resolution time for complaints CMS resolved during this period was even more pronounced, falling from 51 days to 11 days. According to CMS officials, the decline in monthly complaint rates and average resolution times reflected improved implementation of the Part D program since the initial election period, and improved familiarity of the program among beneficiaries, plan sponsors, and CMS itself.

Figure 5: Average Resolution Times for Closed Complaints, May 2006-October 2007



Source: GAO analysis of CTM data.

Note: Based on the 600,382 closed complaints with valid resolution dates over the period.

While trends in the complaints data highlighted declines in the monthly complaint rate and average resolution times, they also revealed some ongoing challenges facing the program. Specifically, the data confirmed information-processing issues related to beneficiaries' requests for enrollment changes and automatic premium withholds from their Social Security payments remained. For example, despite the trend in the overall complaint rate discussed earlier and as shown in figure 4, the complaint rate nearly doubled, from .72 in December 2006 to 1.40 in January 2007. This was due largely to a spike in the number of complaints related to delays or errors when CMS and plan sponsors processed beneficiaries' enrollment and disenrollment requests following the end of the 2007 annual coordinated election period.³⁶ More specifically, according to CMS officials this increased complaint rate was due largely to the sheer volume of transactions processed during this time each year. The officials told us that while they expect to continue to see an increase in complaints each year following the annual coordinated election period, they expect the magnitude of such increases to diminish as the program matures.

In addition, the general trend of increasing complaint rates from January 2007 through May 2007 reflected increasing numbers of complaints related to beneficiaries' requests for automatic withholding of premiums that can occur when beneficiaries elect to change plans. According to CMS officials, the timing of when SSA processes the premium withhold request may affect the accuracy of the deduction, and result in complaints. For example, as required by law, SSA must process cost-of-living adjustments for beneficiaries' social security payments on an annual basis, and according to SSA, they begin this processing in November of each year. To process these adjustments for recipients who are also enrolled in Part D and have chosen the premium withholding option, SSA must rely on CMS enrollment information to determine the amount to deduct for Part D premiums. However, because beneficiaries may have elected to change plans during the Part D annual coordinated election period, which runs from November 15 through December 31 of each year, SSA's calculations may not account for premium differences related to beneficiaries'

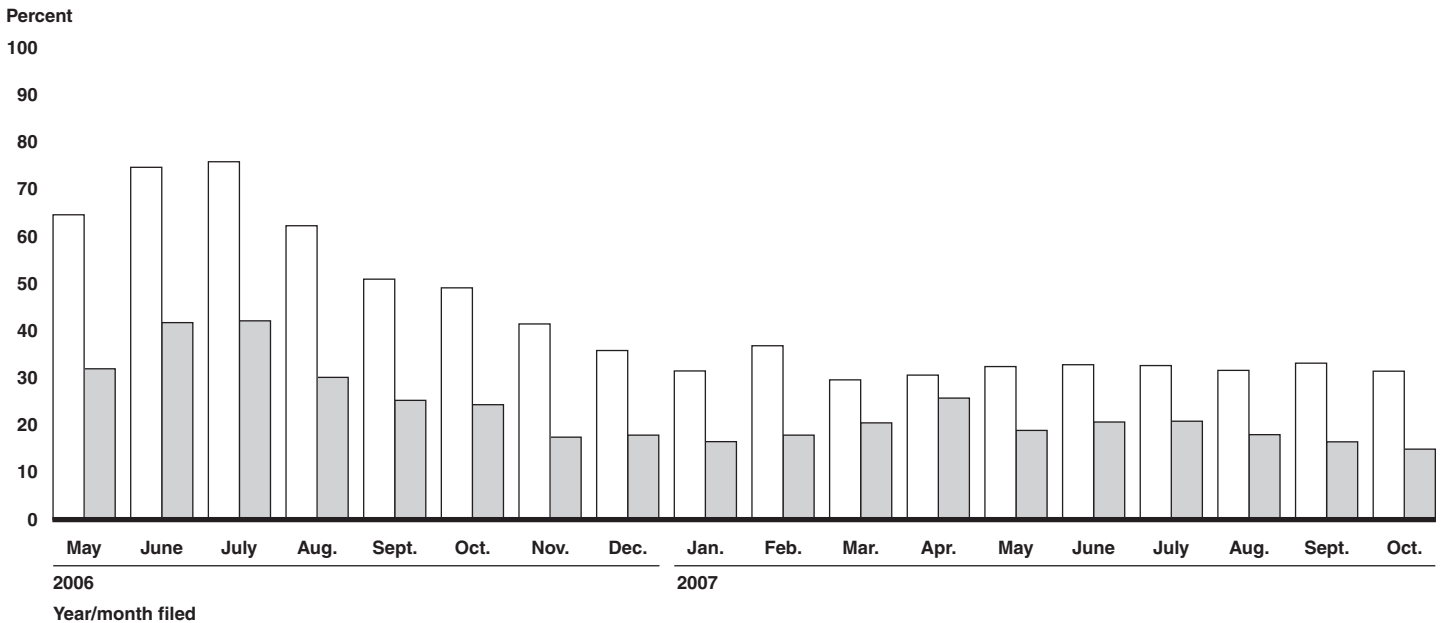
³⁶For example, while there were about 9,000 complaints related to enrollment/disenrollment issues filed in December 2006, there were more than 19,000 filed in January 2007.

subsequent enrollment changes.³⁷ CMS officials indicated that there is no easy solution to the data coordination and timing issues between CMS and SSA at the root of this problem. However, CMS and SSA have formed several work groups to identify improvements, including improved data system exchanges, which could help reduce complaints related to this issue. In the interim, CMS has undertaken outreach efforts to plan sponsors and beneficiaries to inform them of potential delays related to requests for automatic premium withholds, letting them know that such requests may take several months to process.

Finally, while we found that CMS and plan sponsors resolved complaints, including immediate need and urgent complaints, more quickly as the Part D program matured, a substantial percentage of such complaints were not resolved within CMS's time frames. Specifically, during the period from May 2006 through October 2007, 53 percent of immediate need complaints (66,001) and 27 percent of urgent need complaints (10,476) were not resolved within the applicable time frames. Further, progress in meeting the time frames, particularly for immediate need cases, largely stagnated from March 2007 to October 2007, as the proportion of cases not meeting the time frame hovered around 30 percent each month (see fig. 6).

³⁷CMS officials also indicated that beneficiaries are not always aware that it can take several months for SSA to process a request for premium deductions; therefore, they may file complaints when premiums are not immediately deducted from their social security payments.

Figure 6: Proportion of Immediate Need and Urgent Cases Closed but Not Meeting Time Frames



Immediate need
 Urgent

Source: GAO analysis of CTM complaints.

Limitations in Grievances Data Reported by Plan Sponsors for Their Contracts Prevent Reliable Assessment of Beneficiaries' Experiences with Part D

Grievances data reported by plan sponsors for their contracts contained limitations and anomalies and did not yield sufficient insight into beneficiaries' experiences with Part D. In contrast to the data CMS collects on complaints, CMS only requires plan sponsors to submit quarterly reports on the total number of grievances they received in 11 CMS-defined categories for each of their Part D contracts. Therefore, CMS does not have information about whether a grievance is related to a beneficiary's medication supply or whether it was ultimately resolved. As a result, we were unable to determine the extent to which beneficiaries' grievances related to medication supply issues, the extent to which plan sponsors were resolving grievances, or whether they were resolving them in a timely manner.

In addition to their limited nature, we identified a number of anomalies in the grievances data that raise questions about their accuracy and usefulness in drawing conclusions about beneficiaries' experiences with Part D. Among these anomalies, we found that grievances were concentrated in a small number of contracts, and at a rate that was significantly disproportionate to their respective enrollments, raising questions about whether plan sponsors were reporting grievances data for their contracts in a comprehensive and consistent manner. For example, in 2006 plan sponsors reported grievances data for 522 contracts, 19 of which accounted for 80 percent of all grievances but only 49 percent of enrollment. The concentration was more pronounced in 2007, when 11 of the 604 contracts for which grievances data were reported accounted for 90 percent of all grievances but only 42 percent of enrollment.³⁸

We also found significant variations in the number of grievances reported for contracts with similar levels of enrollment, and in the number of grievances filed between 2006 and 2007. For example, in 2006, while the two largest contracts each averaged about 3 million enrollees, one contract had more than 140,000 grievances, for an average monthly grievance rate of 4.22 per 1,000 beneficiaries, while the other contract had fewer than 4,000 grievances, for a grievance rate of .11 per 1,000 beneficiaries. In addition, in contrast to the decline in the monthly complaint rate that we identified, available data show an increase in the average monthly grievance rate between 2006 and 2007. Specifically, while a total of 310,215 grievances were reported in 2006, for an average monthly grievance rate of 1.23 per 1,000 beneficiaries, there were a total of 726,440 grievances reported for the first 3 quarters of 2007 alone, for a rate of 3.38 per 1,000 beneficiaries. We found that this variation was predominately due to differences in the number of grievances reported for three contracts, which had a total of 70 grievances for 2006, and 495,961 for the first 3 quarters of 2007, despite having nearly identical levels of total enrollment in each year.

Finally, the proportion of grievances assigned to categories varied significantly between 2006 and 2007, a change that is inconsistent with trends in the complaints data. For example, while over 60 percent of the 2006 grievances were assigned to the enrollment and disenrollment category—a percentage generally similar to the complaints data filed with

³⁸Plan sponsors reported zero grievances for over 70 contracts in 2006, and over 125 contracts for the first 3 quarters of 2007.

CMS—they assigned approximately 5 percent of the 2007 grievances to this category. In commenting on a draft of this report, CMS indicated that the variation between the two years was likely due to data collection issues that existed during the early implementation of Part D. For example, CMS suggested that the grievances data reported by plan sponsors in 2006 included nongrievances or erroneously categorized grievances in the enrollment and disenrollment category.

CMS's Oversight Focused on Complaints and Not Grievances, Leaving Oversight Gaps

While CMS has a systematic oversight process for complaints, it lacks a similar oversight framework for plan sponsor-reported grievance processes. To oversee the complaints process, CMS has established a framework consisting of several key elements, which include standard operating policies and procedures and a centralized repository of complaints data, and staff that routinely review and assess the complaints data and take actions against plan sponsors it determines have noncompliant processes. In contrast to complaints, CMS's oversight of plan sponsors' grievances processes has been more limited. CMS developed guidance for classifying grievances, required plan sponsors to report summary grievances data for each of their Part D contracts, and periodically reviewed these data. However, limitations in these oversight elements have resulted in plan sponsors reporting incomplete and inconsistent data to CMS, and there is little assurance that beneficiaries' grievances are resolved or that they are resolved in a consistent fashion.

To ensure a level of consistency in how complaints are tracked and resolved, CMS developed standard operating procedures for both its caseworkers and plan sponsors. These procedures provide guidance on how complaints should be entered into the CTM as well as how caseworkers and plan sponsors should resolve them. For example, CMS's guidance includes requirements to enter key dates for each complaint, such as the dates complaints were filed and resolved, and information about how individual complaints should be categorized by their nature and issue level.³⁹ Specifically, CMS's guidance to plan sponsors provides information about how they can utilize the CTM to access, review, and document case resolution, or request CMS assistance in the event they are unable to achieve resolution. Through its guidance, CMS has been able to ensure consistency in terms of the information the CTM contains about

³⁹In addition, CMS provides regular training opportunities and weekly calls for its staff so they can obtain clarification on confusing policies or procedures.

each complaint. Further, it has allowed the agency to create, through the CTM, a reliable source of data from which it can monitor the complaints process.

CMS also dedicated significant resources to ensure that beneficiaries' complaints are addressed. Specifically, CMS officials estimated that several hundred staff members throughout the agency have some responsibility for the oversight of the complaints process.⁴⁰ For example, some regional staff members are responsible for reviewing plan sponsors' case notes included in the CTM to verify their resolution of complaints or for directly resolving complaints beyond the control of plan sponsors. In addition, other CMS staff members routinely analyze CTM data to identify trends in complaint rates and track issues related to the performance of individual plan sponsors, such as resolution times. For example, on a quarterly basis, CMS staff members analyze complaint rates for individual contracts both by overall complaints and by three CTM categories, and then compare complaint rates among contracts.⁴¹ Based on this comparison, CMS staff assign a star rating to each contract.⁴² Further, CMS has dedicated staff in the Office of the Medicare Beneficiary Ombudsman (OMO) who utilize complaints data to identify systemic problems affecting the implementation of Part D.⁴³ When OMO staff identify problems, such as those related to delays in processing enrollment requests and withholding premiums from Social Security payments, they alert high-level CMS managers, who in turn are responsible for initiating corrective actions.

CMS officials informed us that the agency may rely on a variety of actions, ranging from formal compliance calls to the termination of a plan sponsor's Part D contract when it identifies a plan sponsor that is noncompliant with requirements for the complaints process. CMS officials

⁴⁰According to a CMS official, these staff have other responsibilities in addition to Part D casework, including conducting outreach to plan sponsors and beneficiaries.

⁴¹The three CTM categories include complaints about (1) benefits and access, (2) enrollment/disenrollment, and (3) pricing and coinsurance.

⁴²Contracts can receive a rating between one and five stars, and contracts with higher complaint rates receive lower star ratings. For example, contracts that are in the highest 14th percentile in terms of complaint rates receive one star. Contracts between the 15th and 34th percentile in terms of highest complaint rates receive two stars. The star ratings are published at www.medicare.gov. CMS indicated that it does not currently utilize plan sponsor-reported grievances data for generating star ratings.

⁴³As required by federal law, in 2005 HHS established the OMO, which assists beneficiaries with certain Medicare-related issues and acts as a liaison with Part D plan sponsors.

indicated that their use of such actions has been limited because informal conference calls with plan sponsors have frequently been sufficient to correct problems identified through complaints. For example, although CMS officials said that they would require plan sponsors with contracts that received a one or two star rating for 2 consecutive quarters to submit a business plan describing how they would improve their performance, they have never had to do so because their informal calls to such plan sponsors have thus far been sufficient to correct problems. However, in some cases, CMS has taken more stringent actions.⁴⁴ For example, as of February 2008, CMS had issued 144 notices of noncompliance and 22 warning letters, and initiated 3 audits against plan sponsors that did not meet their contractual performance requirement to resolve 95 percent of immediate need complaints within 2 days.^{45, 46} Additionally, CMS had not terminated any plan sponsors' Part D contract or levied civil monetary penalties in response to issues related to compliance with the complaints process.

While CMS has a framework in place for overseeing the complaints process, some opportunities for improvement exist. For example, despite the existence of CMS's performance requirement, plan sponsors and CMS itself failed to resolve a substantial number of immediate need complaints within 2 days. As a result, some beneficiaries might have exhausted their medication supplies while waiting for their complaints to be resolved. While CMS officials indicated that they expected pharmacists to provide a temporary medication supply to affected beneficiaries until their complaints were resolved, they acknowledged that no specific policy exists to ensure that all beneficiaries receive or continue to receive their

⁴⁴According to a CMS official responsible for plan sponsor compliance, CMS has made formal compliance calls but does not systematically track these calls and could not estimate how many it has made.

⁴⁵To determine compliance with the performance requirement, CMS measures the number of days that have elapsed between the date the complaint was assigned to the contract and when it was resolved.

⁴⁶CMS officials noted that they will consider developing additional performance requirements, such as a requirement related to complaint rates, in the future. However, the officials noted that they would want to examine data trends from at least a 3-year period before doing so.

medication.⁴⁷ CMS also does not have a mechanism to verify that plan sponsors have effectively resolved complaints. While CMS caseworkers review plan sponsors' notes in the CTM, they do not routinely take a sample of complaints and follow up with beneficiaries to validate the plan sponsors' resolution actions. CMS officials indicated that the agency does not have the resources to perform such a comprehensive check and stated that beneficiaries who are dissatisfied with their plan sponsor's resolution could file another complaint directly with CMS.

In contrast to complaints, CMS's oversight of plan sponsor grievances processes has been more limited. CMS provided plan sponsors with general guidance for determining whether beneficiaries' problems were grievances or coverage determinations, which are addressed through a separate process. CMS also provided plan sponsors with time frames for resolving grievances, periodically reviewed plan sponsor grievances data, and began auditing plan sponsors' grievances processes in 2007.⁴⁸ However, although CMS's guidance to plan sponsors included examples of how they could classify beneficiaries' problems, several plan sponsors we interviewed said that this guidance was not detailed enough and raised concerns about whether plan sponsors were accurately differentiating among inquiries (i.e., general questions about the Part D program), grievances, or coverage determinations. CMS officials acknowledged that some plan sponsors have incorrectly classified inquiries as grievances. Further, in its 2007 audits of plan sponsors' grievances processes, CMS found numerous cases where plan sponsors did not correctly differentiate between grievances and coverage determinations, supporting plan sponsors' concerns about the adequacy of the existing guidance. Such confusion about how to classify grievances increases the likelihood that plan sponsors report erroneous or inconsistent information to CMS and that they rely on the wrong processes to address beneficiaries' concerns.

⁴⁷CMS has implemented some policies to ensure that dual-eligible beneficiaries maintain access to medications for an interim period after beneficiaries are enrolled in a plan. For example, CMS requires plan sponsors to provide dual-eligible beneficiaries with a short-term supply of drugs if their prescribed drug was not on their plan sponsor's list of covered drugs. See *Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries*, GAO-07-272 (Washington, D.C.: May 4, 2007).

⁴⁸CMS did not conduct any audits of Part D grievances processes in 2006.

CMS does not require plan sponsors to report certain information on grievances for each of their Part D contracts, such as resolution dates, that is essential for determining whether beneficiaries' grievances are being resolved, and devotes few resources to reviewing what plan sponsors have reported for their contracts. Instead, on a quarterly basis, each plan sponsor reports the total number of grievances for 11 categories for each of its contracts. CMS officials also could not explain many of the anomalies we identified in the grievances data, such as substantial variation in the enrollment category from 2006 to 2007 and considerable variation in the grievance rates between contracts with similar levels of enrollment. Further, they acknowledged that they had not undertaken efforts to review the data in detail or to assess their overall reliability. In fact, more than a year into the program, CMS officials were still uncertain as to whether grievances had been reported for all contracts, and as of May 2008, agency analysis was limited to calculating annual grievance rates for each contract that did report grievances.⁴⁹

CMS officials recognized that their efforts to oversee the grievances process have been limited, as they have chosen to focus their attention on other oversight issues such as appeals and coverage determinations and have devoted resources to program implementation issues, such as enrollment of dual-eligible beneficiaries. In the event that plan sponsors are not properly responding to beneficiaries' grievances, CMS officials stated that the issues could be resolved through the complaints process. Therefore, by focusing its attention largely on complaints, the agency expressed confidence that plan sponsors are addressing beneficiaries' issues. While the agency strongly believes in providing plan sponsors the latitude to implement their individual grievances processes, CMS expects to devote more resources to the oversight of grievances processes as the program matures.

Conclusions

January 1, 2006, marked a new era in the Medicare program as the federal government began offering outpatient prescription drug coverage to eligible Medicare beneficiaries. The program is currently in its third year of operation, and millions of individuals have chosen to enroll. While trends in complaints data suggest that CMS and plan sponsors have

⁴⁹Based on its analyses of calendar year 2006 grievances data, CMS sent 18 formal compliance warning letters, which requested the submission of business plans, to plan sponsors it determined had high grievance rates.

improved program operations over time, lingering operational issues continue to pose challenges to some beneficiaries. This has hindered their ability to enroll in their plans of choice, have their premiums accurately deducted from their social security payments, or ensure that their problems related to critical medication supply issues are resolved in a timely manner. While CMS is taking action to address some of these operational issues related to complaints, its continued effort to address these operational challenges will be key to achieving further improvement. Furthermore, CMS does not have reliable grievances data to identify problems and needed improvements and ultimately ensure that beneficiaries' concerns are addressed. This is particularly important given that CMS encourages beneficiaries to utilize the grievances process as their first line of redress when trying to resolve problems. Without reliable grievances data, CMS cannot ensure that plan sponsors are fulfilling their obligations and provide a full assessment of beneficiaries' experiences with the program.

Recommendations

To improve oversight of the Medicare Part D grievances process, and provide added assurance that beneficiaries' grievances are being resolved, we recommend that CMS undertake efforts to improve the consistency, reliability, and usefulness of grievances data reported by plan sponsors for each of their contracts. Such efforts include enhancing its existing guidance for determining whether beneficiaries' problems are grievances, requiring plan sponsors to report information regarding the status and issue level of grievances, and conducting systematic oversight of these data.

Agency Comments

We provided a draft of this report for comment to the Administrator of CMS. In its written comments (see app. II.), CMS remarked that our report did an "impressive job" describing the complex processes employed to monitor complaints and grievances regarding Medicare Part D. The agency concurred with the report's recommendation to undertake efforts to improve the consistency, reliability, and usefulness of grievances data reported by plan sponsors for each of their contracts, and highlighted steps it already has taken to implement it. CMS took issue with the report's conclusion that its oversight activities were focused almost exclusively on resolving complaints with little attention devoted to plan sponsors' grievances processes, and noted that it felt some information, such as details concerning attestations made as part of sponsors' Part D applications, had been omitted from our report. In addition to these

comments, CMS provided detailed, technical comments that we incorporated as appropriate.

Consistent with the recommendation to improve the consistency, reliability, and usefulness of grievances data, CMS noted that it has been working to provide Part D sponsors with more comprehensive guidance, enhance its oversight activities, and undertake corrective actions as needed. CMS stated that it recently provided guidance to plan sponsors regarding statutory definitions of grievances, coverage determinations, and appeals to facilitate accurate reporting of these data to CMS. For example, CMS cited its 2008 Reporting Requirements Technical Specifications, released this spring, as part of its efforts to further educate plan sponsors about the differences between coverage determinations and grievances. CMS further stated that it would consider adding data elements related to plan sponsors' timeliness and quality of grievances resolution to its calendar year 2010 Reporting Requirements.

CMS took issue with the report's conclusion that its oversight activities were focused almost exclusively on resolving complaints with little attention devoted to plan sponsors' grievances processes. The agency noted that it considered this conclusion misleading and felt it did not appropriately weigh all components of CMS's oversight of plan sponsors' grievances processes, such as plan sponsor audits, which include a review of grievances processes. In addition, CMS noted that the report did not consider a component of the Part D application, in which sponsors must attest that they will establish and maintain grievances processes in accordance with federal regulations. Finally, while agreeing with the report's statement that the average resolution time for immediate need and urgent complaints exceeded CMS's required time frames, CMS noted that its analysis of more recent complaints data demonstrated that case resolution time frames had improved and were trending towards CMS's standard time frames.

We recognize that CMS has audited the grievances processes of some plan sponsors, and the report highlighted key findings from these audits. While we believe CMS can rely on such audits to improve its oversight in the future, the agency did not begin auditing plan sponsors until 2007, and has yet to audit a number of plan sponsors. Further, while we recognize the attestation component of the application requirement, we believe that such attestations provide only limited assurance that beneficiaries' grievances are being resolved appropriately. We do not believe CMS will be able to ensure that plan sponsors are abiding by their statements until CMS audits the grievances processes of all plan sponsors. Finally, we did

not evaluate CMS's findings on resolution time frames from its more recent data, because the data CMS used to conduct their analyses of resolution time frames were from a time frame beyond the scope of our work.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and Human Services and other interested parties. We will also make copies available to others upon request. In addition, this report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Kathleen King 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. Susan Anthony, Assistant Director; Jennie Apter; Shirin Hormozi; David Lichtenfeld; and Jennifer Whitworth made key contributions to this report.



Kathleen M. King
Director, Health Care

List of Requesters

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives

The Honorable Charles B. Rangel
Chairman
Committee on Ways and Means
House of Representatives

The Honorable Pete Stark
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

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

The Honorable Sherrod Brown
United States Senate

Appendix I: CMS Medicare Part D Complaint and Grievance Categories

Beneficiaries and providers (including pharmacies and physicians) can file complaints with the Centers for Medicare and Medicaid Services (CMS) regarding Medicare Part D. Within the Complaint Tracking Module (CTM), beneficiary complaints are assigned to 14 categories and provider complaints to 6 categories, which are further delineated into 186 subcategories. CMS requires that plan sponsors report grievances based on 11 CMS-defined categories, which are somewhat similar to the CTM categories, but do not include subcategories. A description of the complaints and grievances categories is listed below.

Table 1: CTM Complaints Categories

Complaints filed by beneficiaries		
Category	Includes complaints about	Number of subcategories
Benefits/Access	Benefits and access to prescription drugs	13
Confidentiality/Privacy	Release of information	2
Contractor/Partner Performance	CMS contractors/partners providing support to Part D	6
Customer Service	Quality of customer service	12
Enrollment/Disenrollment	Joining and leaving a plan	22
Exceptions/Appeals	Plans' exceptions and appeals processes	3
Formulary	Plans' coverage of needed drugs	7
Grievances	Plans' grievances processes	3
Marketing	Plans' marketing materials and practices	7
Medication Therapy Management	Plans' programs to ensure prescription drugs are used appropriately	13
Plan Administration	Administration of Part D program	8
Pricing/Co-Insurance/ Premiums ^a	Drug pricing, out of pocket costs, and premium withholds	8
Program Integrity Issues/Potential Fraud, Waste, and Abuse	Potential cases of fraud, waste, and abuse	26
Quality of Care/Clinical Issues	Quality of care and clinical issues	2
Complaints filed by providers		
Benefits/Access	Benefits and access to prescription drugs	3
Implementation	Implementation of Part D program	11
Marketing	Plans' marketing materials and practices	8
Pharmacies	Pharmacy payment issues	7
Program Integrity Issues/Potential Fraud, Waste, and Abuse	Potential cases of fraud, waste, and abuse	23
Quality of Care/Clinical Issues	Quality of care and clinical issues	2

Source: GAO analysis of CTM categories and subcategories.

^aIn March 2008 CMS provided this listing of CTM categories. The listing included the word "premiums," which was not present in the CTM categories at the time we ran our data analyses.

**Appendix I: CMS Medicare Part
D Complaint and Grievance
Categories**

Table 2: CMS Grievances Categories

Category	Includes grievances about
Appeals	Plans' appeals process
Benefit Package	Beneficiary cost sharing and coverage issues
Confidentiality/Privacy	Release of information by pharmacy or plans
Customer Service	Customer service of pharmacy, plan, or subcontractors
Enrollment/Disenrollment	Joining and leaving a plan
Exceptions	Plans' exceptions process
Fraud and Abuse	Potential cases of fraud and abuse
Marketing	Marketing materials and practices
Quality of Care	Quality of care issues
Pharmacy Access/Network	Pharmacies' filling of prescriptions
Other	Any grievance not included in other categories

Source: GAO analysis of Medicare Part D reporting requirements for contract year 2007.

Appendix II: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 12 2008

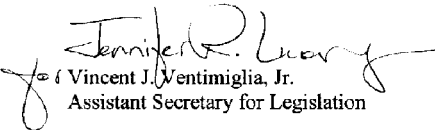
Ms. Kathleen King
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. King:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Medicare Part D: Complaint Rates are Declining but Operational and Oversight Challenges Remain" (GAO 08-719).

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,


Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation

Attachment

Appendix II: Comments from the Centers for Medicare & Medicaid Services



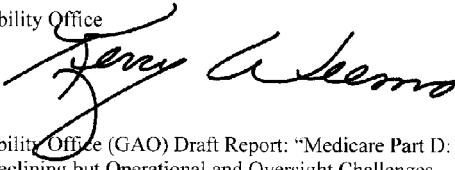
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: **JUN 11 2008**

TO: Kathleen M. King
Director, Health Care
Government Accountability Office

FROM: Kerry Weems 
Acting Administrator

SUBJECT: Government Accountability Office (GAO) Draft Report: "Medicare Part D: Complaint Rates are Declining but Operational and Oversight Challenges Remain" (GAO-08-719)

Thank you for the opportunity to review and comment on the above GAO draft report. The GAO's study focused on CMS' processes for collection and resolution of Medicare Part D complaints and grievances, trends in complaints and grievances data since the program's inception, as well as opportunities for improvement in CMS' oversight and enforcement actions.

We appreciate the GAO's thorough review of the issues involved, as well as the recommendation for fine-tuning CMS' procedures for improving oversight of the Medicare Part D grievance process and ensuring that beneficiary grievances are being resolved. In particular, the report does an impressive job of providing a solid background description of the complex processes employed to monitor complaints and grievances regarding Medicare Part D contracts. CMS appreciates suggestions on how to improve the collection and reporting of Part D complaint and grievance data, and has already implemented actions and enhancements recommended in the GAO report.

As you have observed in the course of conducting this study, the challenges associated with capturing complaints and grievances from the entire Medicare Part D-eligible population are vast and multi-faceted. Consistent with the draft report's recommendation, we have been working to improve the consistency, reliability, and usefulness of grievance data reported by Medicare Part D plan sponsors, and we continue to make refinements to our existing procedures related to Part D sponsor reporting requirements. As discussed further in our comments below, we have issued CY 2008 Technical Specifications to further clarify existing data definitions, and we will consider further refinements to data collection for the 2010 Part D reporting requirements. Thus, CMS believes it may be more constructive for the report to begin by acknowledging CMS' overall success in the collection and reporting of Part D complaint and grievance data processes over time since the establishment of the Part D program benefit.

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The report's main conclusion that CMS' oversight efforts thus far have focused almost exclusively on resolving complaints, with little attention devoted to plan sponsors' grievance processes, is misleading. The report's conclusion is largely based on CMS' analyses of plan reported grievance data, and does not consider other means by which CMS ensures plan sponsors are addressing grievances in a timely and appropriate manner. As a component of the Part D application, sponsors must attest that they will establish and maintain grievance processes that will ensure appropriate timelines and procedures in accordance with Federal Regulations at 42 CFR 423.564. Additionally, CMS' audit guides include review of sponsors' grievance processes and timeframes for resolution.

Utilizing complaints and grievance information, CMS has taken compliance actions against plan sponsors since the Part D program's implementation in 2006. For example, CMS has identified significant "star rating" outliers in complaint rates as a component of its comprehensive performance analyses. CMS has addressed poor plan performance by having formal executive-level compliance calls with those sponsors, as well as regular monitoring calls between account managers and plans. CMS is in the process of reviewing and identifying chronically poor plan performance across years, and we will issue warning letters as appropriate to those sponsors. Compliance actions have also been conducted based on outliers in grievance rates. These actions have included issuance of warning letters and requests of business plans from those identified sponsors.

GAO Recommendation

To improve oversight of the Medicare Part D grievance process, and provide added assurance that beneficiaries' grievances are being resolved, the GAO recommends that CMS undertake efforts to improve the consistency, reliability, and usefulness of grievance data reported by plan sponsors for each of their contracts. Such efforts include enhancing CMS' existing guidance for determining whether beneficiaries' problems are grievances, requiring plan sponsors to report information regarding the status and issue level of grievances, and conducting systematic oversight of these data.

CMS Response

CMS concurs with this recommendation, and notes that it has been working to provide Part D sponsors with more comprehensive guidance, enhance its oversight activities, and undertake corrective actions as needed. We have provided guidance to plan sponsors regarding statutory definitions of grievances, coverage determinations and appeals in order to facilitate accurate reporting of these data to CMS. One example of CMS' continued efforts to educate sponsors further on this issue is the 2008 Reporting Requirements Technical Specifications released this spring, which reiterate that an enrollee's request for a coverage determination or a redetermination regarding drug coverage is not considered a grievance, and refer Part D Plan Sponsors to Subpart M, section 423.564 of the regulations on the Voluntary Medicare Prescription Drug Benefit for more information about Part D grievances. In addition, the 2008 Reporting Requirements Technical Specifications instruct sponsors to exclude complaints received by 1-800-Medicare or recorded in the complaint Tracking Module from their grievance data.

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The CMS staff has also conducted compliance activities based on contracts identified to be outliers from their grievance data, including sending warning letters and requesting business plans. CMS continues to perform quality assurance, analyses, and oversight of plan reported data, including grievance data. These activities include identifying plans with high rates for grievance categories and total grievances by enrollment, as well as evaluating for correlations between grievances and complaints. CMS' continued collection and analyses of grievance data will ensure all sponsors' grievance data and processes are evaluated comprehensively.

With regard to requiring plan sponsors to report grievance status and issue level, CMS will consider the addition of data elements related to sponsors' timeliness and quality of grievance resolution in the new set of Reporting Requirements for calendar year (CY) 2010.

The CMS would also like to address the report's statement, "Although immediate need and urgent complaints were resolved, on average, much more quickly – 12 days for immediate need complaints and 16 days for urgent complaints, these average resolution times still exceeded CMS's resolution timeframes." While CMS agrees with the findings for the May 2006 – October 2007 time period of the report, analysis for a more recent time period (November 2007 – April 2008) demonstrates that case resolution timeframes are trending towards CMS' standard timeframes. For immediate need complaints (defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 2 or less days of medication left) the CMS standard for resolution is within 2 days. For urgent need complaints (defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 3 to 14 days of medication left) the CMS standard for resolution is within 10 days. Specifically, during the November 2007 – April 2008 time period, 32,819 immediate need and 11,105 urgent cases were processed. On average, immediate need complaints were resolved in less than 3 days and urgent complaints were resolved in 6 days—well within CMS' standard resolution timeframe.

In addition, there are a number of factual inaccuracies set forth in the report, as illustrated in our more detailed comments (attached). Some of these comments were previously provided by CMS in response to the GAO Draft Statement of Facts.

Again, we thank you for the opportunity to review and comment on this report.

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