



United States Government Accountability Office
Washington, DC 20548

October 28, 2005

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

Subject: *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*

Dear Mr. Waxman:

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added a prescription drug benefit to the Medicare program, to become effective January 1, 2006.¹ To assist Medicare beneficiaries with their prescription drug costs until the new benefit becomes available, the MMA also required the establishment of a temporary program, the Medicare Prescription Drug Discount Card and Transitional Assistance Program, which began in June 2004.² The drug card program is designed to offer Medicare beneficiaries access to discounts off the retail price of prescription drugs. All Medicare beneficiaries, except those receiving Medicaid drug coverage, are eligible to enroll in the drug card program. Certain low-income beneficiaries without other drug coverage qualify for an additional benefit, a transitional assistance (TA) subsidy,³ that can be applied toward the cost of drugs covered under the drug card program.

The Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services that administers the Medicare and Medicaid programs—administers and oversees the drug card program. The drug cards themselves are offered and managed by private organizations, known as drug card sponsors. There are different types of drug cards. General drug cards are available to all eligible beneficiaries living in a card's

¹Pub. L. No. 108-173, §101, 117 Stat. 2066, 2071, 2072.

²Pub. L. No. 108-173, §101, 117 Stat. 2066, 2071, 2131. Throughout this report, we refer to the Medicare Drug Discount Card and Transitional Assistance Program as the drug card program. Beneficiaries can enroll in the drug card program through December 2005. Beneficiaries can use their drug cards until the effective date of their enrollment in a Medicare prescription drug plan or until May 15, 2006, whichever comes first.

³For beneficiaries who qualify for TA, the program offers a subsidy of up to \$600 per year toward the cost of covered drugs. To qualify for TA, a beneficiary must have (1) an income at or below 135 percent of the federal poverty level and (2) with certain exceptions, not have other prescription drug coverage through Medicaid, an employer-sponsored group health insurance program, an individual health insurance policy, TRICARE (the Department of Defense health care program for active-duty personnel, retirees, and their dependents), or the Federal Employees Health Benefits Program. TA funds available to beneficiaries in 2004 and 2005 can be used until the effective date of their enrollment in a Medicare prescription drug plan or until May 15, 2006, whichever comes first.

service area; there are both national and regional general cards.⁴ Exclusive and special endorsement drug cards are available to specific beneficiary groups.⁵ Some drug card sponsors offer more than one drug card.

You asked us to examine CMS's implementation and oversight of the temporary drug card program. Specifically, we reviewed (1) the processes that CMS used to solicit, evaluate, and approve drug card sponsors; and (2) the processes that CMS uses to oversee drug card sponsors and the problems identified as a result of CMS oversight.⁶

To address these objectives, we focused our work on general drug cards; our work did not include exclusive or special endorsement cards. We interviewed CMS officials, staff from 6 CMS contractors that assist with key program oversight activities, and staff from 8 of 32 general drug card sponsors.⁷ The drug card sponsors we interviewed represented a mix of national and regional cards; varied in terms of total enrollment size, TA enrollment size, and number of beneficiary complaints received by CMS; reflected different organization types (for example, pharmacy benefit managers,⁸ managed care organizations, and health insurers); and included drug card sponsors whose applications were approved by CMS and those whose applications to offer drug cards were initially denied, but later approved. We also reviewed relevant CMS, CMS contractor, and drug card sponsor documents, such as CMS guidance, CMS contractor reports, and drug card sponsor applications. We targeted CMS's oversight of elements of five key program areas for more focused review—drug prices, sponsors' pharmacy networks, sponsor-provided beneficiary information, TA, and beneficiary complaints and grievances. We selected these areas based on their likelihood to influence beneficiaries' enrollment decisions and access to drugs, as well as their potential to pose problems or weaknesses for the program. When feasible, we validated the information CMS officials told us by reviewing program documents and interviewing officials from CMS contractors and drug card sponsors. We conducted our work from April 2005 through October 2005 in accordance with generally accepted government auditing standards.

We briefed your staff on the information contained in this report on September 23, 2005. As discussed with your staff at that time, we agreed to issue this report, which officially transmits the briefing slides (see enc. I) and expands on the information provided at the briefing.

⁴National cards provide beneficiaries access to discounts at pharmacies nationwide, while regional cards offer discounts at pharmacies within a smaller geographic area—an entire state at a minimum.

⁵Exclusive cards are cards that Medicare managed care plans offer only to their plan enrollees. (Some managed care plans offer general cards open to all eligible beneficiaries, not just those enrolled in their plan.) Special endorsement cards serve residents of long-term care facilities such as skilled nursing facilities; U.S. territory residents; and American Indians and Alaskan Natives who use Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization pharmacies.

⁶We are conducting other work related to this topic. See *Medicare: CMS's Beneficiary Education and Outreach Efforts for the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, [GAO-06-139R](#) (Washington, D.C.: forthcoming). We also plan to issue a report in 2005 on sponsors' processes related to the drug card program.

⁷Included in the 32 sponsoring organizations are affiliated organizations, such as 11 individual Blue Cross and Blue Shield entities that are counted as one organization.

⁸Pharmacy benefit managers manage prescription drug benefits for third-party payers, such as employer-sponsored health plans and other health insurers.

Background

CMS implemented the drug card program within a 6-month time frame. The MMA was enacted on December 8, 2003. The following week, CMS published an interim final rule that outlined the drug card program, including the requirements that organizations had to meet to become drug card sponsors.⁹ Interested organizations had to submit applications to CMS by January 30, 2004. Organizations that CMS approved as drug card sponsors could begin enrolling beneficiaries on May 3, 2004. The drug card program took effect on June 1, 2004.

Organizations had to meet certain requirements in order to be approved by CMS as drug card sponsors. For example, a drug card sponsor had to be a nongovernmental organization doing business in the United States, be financially stable and reputable, have at least 3 years of private-sector experience in pharmacy benefit management, and serve at least 1 million covered lives under a similar pharmacy benefit program. Drug card sponsors also had to agree to manage the enrollment and TA processes for their cards, offer customer service and beneficiary grievance programs, provide program information to beneficiaries, operate a toll-free customer call center, and report data about their drug cards—such as drug price and utilization data—to CMS.

Drug card sponsors also had to demonstrate their ability to meet requirements regarding drug prices and beneficiaries' access to pharmacies. One requirement of the program is that drug card sponsors must offer a negotiated price¹⁰ for at least one drug in each of over 200 drug classes that CMS identified as being commonly used by Medicare beneficiaries.¹¹ According to CMS, nearly all prescription drugs that can be purchased at retail pharmacies are eligible to be covered by sponsors' drug cards.¹² The MMA refers to 9 classes of drugs that drug card sponsors are not allowed to cover through their drug cards; the excluded classes include barbiturates and benzodiazepines, among others. While drug card sponsors may change the prices charged to beneficiaries, they must report all price increases to CMS and explain the rationale for price increases not attributable to published sources of information such as the Average Wholesale Price (AWP) of the drug.¹³ They must also contract with a sufficient

⁹Medicare Program; Medicare Prescription Drug Discount Card; Interim Rule and Notice, 68 *Fed. Reg.* 69840 (2003).

¹⁰The MMA specified that drug card sponsors shall provide access to “negotiated prices” on the drugs they cover. CMS regulations define negotiated price as the discounted price that takes into account negotiated price concessions such as discounts, rebates, and direct or indirect subsidies or remunerations. Drug card sponsors are required to obtain rebates, discounts, or other price concessions from drug manufacturers and to pass on a share of these concessions to card enrollees; neither the MMA nor CMS’s regulations specify any minimum amount that must be passed on to enrollees.

¹¹Drugs that possess similar chemical structures and similar therapeutic effects are grouped into classes. Most drugs within a class produce similar benefits, side effects, adverse reactions, and interactions with other drugs and substances.

¹²Covered drugs include prescription drugs, certain vaccines, insulin, and some medical supplies associated with the injection of insulin.

¹³AWP is a list price that a manufacturer suggests wholesalers charge pharmacies.

number of pharmacies to ensure that their pharmacy networks meet the program's network access requirements.¹⁴

After reviewing applications from interested organizations, CMS approved all but 1 general drug card.¹⁵ Two potential drug card sponsors withdrew their applications to offer a general drug card. The 71 approved general drug cards included 39 national drug cards and 32 regional drug cards. Because 5 approved national drug cards were never marketed, 66 general drug cards enrolled beneficiaries. These 66 active general drug cards are sponsored by 32 different organizations. Many general drug cards are sponsored by pharmacy benefit managers, managed care organizations, or health insurers. As of August 2005, there were nearly 3.8 million general drug card enrollees; about 44 percent were enrolled in both a drug card and TA, while about 56 percent were enrolled in a drug card only. About 87 percent of general drug card enrollees were enrolled in national drug cards, and about 13 percent were enrolled in regional drug cards.¹⁶

CMS has provided guidance to drug card sponsors through several means. The agency has conducted periodic conference calls available to all sponsors and has shared guidance through e-mail bulletins and "Questions and Answers" posted on the CMS Web site. It also has provided written guidance on topics such as sponsors' outreach activities and the drug card data that sponsors must report to CMS. In addition, CMS assigned staff to serve as the point of contact for each drug card sponsor to provide individual guidance and assistance.

Results in Brief

The processes CMS used to solicit, evaluate, and approve general drug card applications were geared to the 6-month time frame between the enactment of the MMA and the mandated start date for the drug card program. This included the type of solicitation CMS used, the design of the application, and the application evaluation and approval process.

- CMS used a noncompetitive solicitation process in which all qualified organizations could participate in the program. CMS officials told us they took this approach to encourage participation in the program, facilitate communication with and among potential drug card sponsors, and avoid the need to develop weighted criteria to evaluate the applications—which CMS officials said would have been required if a competitive solicitation was used.
- CMS developed the application for drug card sponsors before all of the program's operational guidelines had been completed. As a result, CMS officials said that open-ended questions were used to learn more about and evaluate potential sponsors' capabilities and for other reasons.

¹⁴By regulation, in urban areas, at least 90 percent of a card's enrollees must live within 2 miles of a contracted network pharmacy; in suburban areas, at least 90 percent must live within 5 miles of a contracted network pharmacy; and in rural areas, at least 70 percent must live within 15 miles of a contracted network pharmacy. These access standards are based on those used in the TRICARE Retail Pharmacy program, which provides prescription services for Department of Defense beneficiaries through a network of retail pharmacies.

¹⁵CMS denied one applicant due to what it considered a failure to respond substantively to the application requirements.

¹⁶As of August 2005, CMS reported 6.4 million enrollees across all types of drug cards.

- Based on its initial review of applicants, CMS approved only those that provided all of the information requested in the application. Initially denied applicants whose applications were missing minor information were allowed to provide the missing information through a redetermination process; those whose applications were missing significant information were allowed to appeal the denial through a reconsideration process. CMS announced its initial list of approved general drug card sponsors on March 25, 2004; that list did not include sponsors that had not completed the redetermination and reconsideration processes. The last sponsor was approved on May 7, 2004.

CMS's oversight of drug card sponsors has identified and corrected some problems, but has had some limitations with respect to the timeliness of oversight activities and the guidance provided to sponsors. CMS uses multiple methods to monitor drug card sponsors. CMS investigates the complaints it receives directly from 1-800-MEDICARE¹⁷ and other sources, and collects information about the complaints reported to sponsors, known as "grievances." CMS has collected other data from drug card sponsors regularly, including drug price and pharmacy information that it published on its Price Compare Web site,¹⁸ as well as information on manufacturer and pharmacy price concessions. CMS also uses contractors to assist with oversight activities, including conducting financial audits of drug card sponsors and analyzing sponsor-reported price data. With respect to CMS's oversight, we reviewed five key program areas: drug prices, sponsors' pharmacy networks, sponsor-provided beneficiary information, TA, and beneficiary complaints and grievances.

Drug Prices

- Early in the program, CMS identified problems such as inconsistencies in sponsors' reported unit prices for non-pill prescriptions—such as creams, powders, and sprays—and delays in drug card sponsors' reporting of data. CMS officials told us that, as a result, they worked with sponsors to standardize the reporting of non-pill prices, did not post some sponsors' data on the Price Compare Web site, and took compliance actions against sponsors with reporting delays.
- Work to determine if non-TA enrollees have been inappropriately charged more than the maximum drug price reported on the Price Compare Web site began in June 2005; results are expected in November 2005.
- CMS finalized guidance on how drug card sponsors should report data on price concessions from manufacturers and pharmacies in November 2004, about 5 months after the program began. According to CMS, as of August 2005, the overall quality of that data remained questionable, with problems such as outliers and missing data.

¹⁷ 1-800-MEDICARE is a CMS-administered nationwide toll-free telephone help line that beneficiaries, their families, and other members of the public can call to ask questions about program eligibility, enrollment, and benefits.

¹⁸ This Web site, with information for beneficiaries on available drug cards, was part of the "Prescription Drug and Other Assistance Programs" tool located at www.medicare.gov—a tool to help beneficiaries determine their eligibility for the drug card program, decide whether to enroll in the program, and select a drug card. CMS deactivated the component of the Web site with information about drug prices on September 30, 2005.

Sponsors' Pharmacy Networks

- CMS officials told us that they have followed up on complaints received from beneficiaries and pharmacists about the accuracy of the pharmacy participation information displayed on the Price Compare Web site. In reviewing reported problems, CMS found that most of the problems were due to pharmacies being unaware that they were participating in a drug card sponsor's network; sometimes pharmacies were not actually participating in a sponsor's network even though they were listed on the Price Compare Web site. CMS officials told us that they worked with drug card sponsors to improve pharmacy awareness about program participation. When warranted, CMS corrected the pharmacy participation information on the Price Compare Web site.
- A CMS contractor also surveyed a sample of pharmacies in February 2005 to determine if they were participating in sponsors' pharmacy networks, in accordance with what was shown on the Price Compare Web site. According to CMS officials, preliminary survey results as of August 2005 showed some disagreement between pharmacies' responses and the Price Compare Web site information, with the rate of disagreement higher for some drug card sponsors and in three states (North Dakota, Iowa, and Missouri). Although this survey did not assess the reason for the disagreement, in its comments on a draft of this report, CMS stated that the disagreement was likely due to problems with pharmacies' knowledge about program participation, rather than errors on the Web site. CMS officials said they began following up with sponsors identified as problematic in summer 2005. In its comments, CMS reported that it had conducted compliance conference calls with those sponsors and had encouraged them to re-educate their network pharmacies.

Sponsor-provided Beneficiary Information

- A CMS contractor conducted a limited retrospective review of drug card sponsors' marketing materials in March 2005. Two pre-enrollment packets were requested by phone from each of six general drug card sponsors. All the packets were noncompliant with program requirements. Most packets were missing materials required by CMS and some materials had not been previously approved for distribution by the CMS contractor. The contractor never received several requested packets. CMS officials said that they worked with the drug card sponsors reviewed to resolve these problems.
- CMS's primary method for monitoring information provided by drug card sponsor call centers was a contractor-conducted study in which callers posing as beneficiary caregivers used different scenarios to test customer service representatives' responses to questions. CMS officials told us about several problems, including the unavailability of representatives for non-English speaking callers, the unavailability of representatives able to respond to callers using telecommunications for the deaf, inappropriate handling of beneficiary complaints about pharmacies (in which callers were told to contact the pharmacies themselves rather than file a grievance with the sponsor), and customer service representatives' confusion about enrollment fees if their call centers were handling calls about multiple drug cards. Most of the contractors' calls were conducted from June through December 2004. CMS officials said that sponsors were contacted during this period if there were problems such as a wrong call center telephone number or a call center that was closed during the hours

it claimed to be open. CMS officials told us that their follow-up with sponsors for the other identified call center issues began in summer 2005.

Transitional Assistance

- Financial audits of sponsors conducted by a CMS contractor revealed that \$1.3 million in TA funds were inappropriately used by drug card sponsors to pay for excluded drugs, which sponsors are required to repay. While CMS had provided general guidance on excluded drug classes on several previous occasions, it did not issue a comprehensive list of excluded drugs until November 2004.
- Financial audits also revealed that several sponsors had allowed beneficiaries to receive subsidies that exceeded the subsidy of up to \$600 per year. CMS officials attributed this to issues such as problems when beneficiaries transferred among cards. Drug card sponsors are required to repay excess payments.

Beneficiary Complaints and Grievances

- Most complaints reported to CMS and grievances reported to sponsors related to enrollment and disenrollment issues. For example, some beneficiaries complained to CMS about delays in receiving drug cards from drug card sponsors. CMS staff told us they worked with beneficiaries and drug card sponsors to resolve complaints.

As a result of its oversight efforts, as of August 2005, CMS had taken 23 compliance actions against 15 drug card sponsors, most often in the form of warning letters or corrective action plans.

Agency Comments

We provided a draft of this report for comment to the Administrator of CMS, and we received written comments. (See enc. II.)

CMS commented that the draft report did not paint a full picture of the depth and breadth of the agency's monitoring and oversight activities conducted relative to the Medicare drug card program. As our draft report discussed, we examined CMS's oversight of elements of five key program areas: drug prices, sponsors' pharmacy networks, drug card sponsor-provided beneficiary information, TA, and beneficiary complaints and grievances. We targeted these specific program areas based on their likelihood to influence beneficiaries' enrollment decisions and access to drugs. Furthermore, because these targeted areas represented fundamental components of the drug card program, any problems or weaknesses posed a threat to the overall integrity of the program.

In commenting on our finding that there was a lack of reliable data on price concessions, CMS agreed that there were significant data quality issues relative to the information submitted by drug card sponsors. CMS noted, however, that despite these concerns, the initial data, as well as information from other sources, including some external to CMS, suggested that drug card sponsors are passing through to beneficiaries a substantial portion of their negotiated rebates, discounts, and other price concessions. CMS also stated that it has worked to resolve the data quality issues and that most price concession data submissions are now accurate. Our work focused on CMS's oversight of the price concession data reported by sponsors, not on the magnitude of price concessions passed on to beneficiaries. As noted in the draft report, the overall quality of that data as of August 2005

was questionable; we have not assessed or verified changes in the data's quality since that time. However, both CMS's comments and our findings in this area highlight the importance of CMS oversight of sponsor-reported data.

In response to our finding that CMS's oversight of drug card sponsors has had some limitations with respect to the timeliness of oversight activities and the guidance provided to sponsors, CMS noted that it implemented the drug card program and instituted a wide range of oversight activities for the program, which is temporary, within a short period of time. In the draft report, we acknowledged the limited time between the December 2003 enactment of the MMA (which established the drug card program) and the June 2004 implementation of the program, as well as the temporary nature of the program. We also acknowledged various oversight activities that CMS noted were conducted. However, as discussed in the draft report, we identified some limitations of CMS's oversight of sponsors. For example, we noted that in February 2005, a CMS contractor surveyed a sample of pharmacies to determine if they were participating in sponsors' pharmacy networks in accordance with what was shown on the Price Compare Web site. For some sponsors, there were high levels of disagreement between pharmacies and the Web site. As noted in the draft report, CMS officials said they began working with those sponsors in summer 2005. In commenting specifically on our findings about the pharmacy network issue, CMS provided further detail about the oversight activities that it has conducted.

In response to our finding that TA funds were used to pay for excluded drugs on some occasions and that some beneficiaries received subsidies that exceeded the subsidy of up to \$600 per year, CMS commented that the inappropriate payments were small in relation to the total services delivered over the duration of the program. CMS further stated that it was the responsibility of drug card sponsors to identify the drugs in the excluded classes and to ensure that these drugs were not covered under the program. CMS added that in July 2004 it had provided sponsors with a list of drugs for two of the excluded drug classes. As noted in the draft report, financial audits conducted by a CMS contractor for 15 drug cards revealed that the sponsors of all 15 cards had incorrectly used TA funds to cover excluded drugs. It was not until November 2004 that a comprehensive list of drugs covering all of the excluded classes was provided by CMS. CMS is responsible for ensuring that no program monies are inappropriately spent.

With regard to our statements about problems related to information provided by drug card sponsors' call centers, in its comments, CMS provided some additional details on related oversight activities that it has conducted. CMS noted, for example, that the CMS contractor-conducted study using test calls to call centers found that for Spanish language callers, there were problems obtaining information in Spanish 20 percent of the time; 80 percent of the time, information was provided in Spanish. The findings from CMS's oversight of sponsors' call centers highlight the need for monitoring of sponsor-provided beneficiary information and, when needed, corrective action.

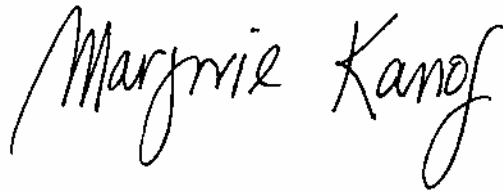
In its comments, CMS also noted that the agency has learned many valuable lessons as a result of its experience with the drug card program, and that those lessons will inform its future efforts as it moves forward with the implementation of the Medicare prescription drug benefit that is to become effective in 2006.

CMS also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this report. At that time, we will send copies to the Administrator of CMS and interested congressional committees. The report will also be available on GAO's home page at <http://www.gao.gov>.

If you or your staff have any questions or need additional information, please contact me at (202) 512-7114 or kanofm@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors are listed in enclosure III.

Sincerely yours,

A handwritten signature in black ink that reads "Marjorie Kanof". The signature is written in a cursive, flowing style.

Marjorie Kanof
Managing Director, Health Care

Enclosures – 3

GAO Briefing



CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program

Briefing for the Staff of
The Honorable Henry A. Waxman
Ranking Minority Member
House Committee on Government Reform

(Updated)



Briefing Overview

- Introduction
 - Objectives
 - Scope and Methodology
 - Background
 - Findings
-



Introduction

Medicare Drug Benefit

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established:

- A temporary program, the Medicare Prescription Drug Discount Card and Transitional Assistance (TA) Program, which began in June 2004.^a
- A Medicare prescription drug benefit, known as Medicare Part D, which begins in January 2006.

^a Throughout these slides, we refer to this program as the drug card program.



Introduction

Medicare Prescription Drug Cards

- The Centers for Medicare & Medicaid Services (CMS) administers and oversees the drug card program.
 - All Medicare beneficiaries, except those receiving Medicaid drug coverage, are eligible to enroll in the drug card program, which provides access to discounts off the retail price of prescription drugs.
 - TA offers eligible low-income beneficiaries without other drug coverage up to \$600 per year for prescription drugs covered under the drug card program.
- Drug cards are offered and managed by private organizations, known as drug card sponsors. Drug card sponsors also manage TA for eligible beneficiaries.



Objectives

1. To review the processes CMS used to solicit, evaluate, and approve drug card sponsors.
2. To review the processes CMS uses to oversee drug card sponsors and the problems identified as a result of CMS oversight.



Scope and Methodology

Scope

- Our work focused on general drug cards—cards offered on a national or regional basis to all eligible Medicare beneficiaries living in the cards' service areas.
- Our work did not include exclusive cards, which are cards that Medicare managed care plans offer only to their plan enrollees, or special endorsement cards, which serve residents of long-term care facilities such as skilled nursing facilities; residents of U.S. territories; and American Indians and Alaskan Natives who use Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization pharmacies.



Scope and Methodology

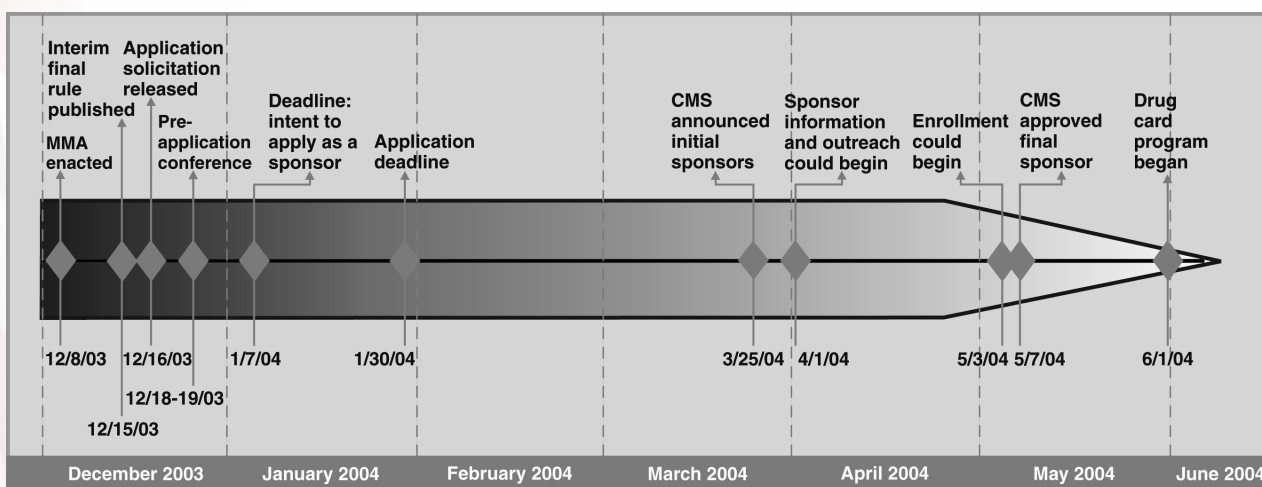
Methods

- Our methods included:
 - Interviews with CMS officials.
 - Interviews with staff of six contractors assisting CMS with key program oversight activities.
 - Interviews with staff from eight drug card sponsors.
 - Reviews of relevant documents.
 - Reviews of selected program areas.
- We performed our work in accordance with generally accepted government auditing standards from April 2005 through October 2005.



Background

Drug Card Program Implementation Timeline



Source: GAO analysis.



Background

Drug Card Sponsor Program Requirements

- Drug card sponsors had to demonstrate to CMS their ability to meet program requirements, including, for example:
 - Relevant organizational experience, including financial stability and at least 3 years of private-sector experience in pharmacy benefit management.
 - Beneficiary access to pharmacies.
 - Beneficiary access to discounts for covered drugs.
- Drug card sponsors are allowed to offer multiple drug cards, which are differentiated by factors such as the geographic locations in which they are offered and the level of discounts provided.



Background

Approved General Drug Cards

- CMS approved 71 general drug cards, including:
 - 39 national cards.
 - 32 regional cards.
- Five approved national cards were never marketed; there are 66 active general drug cards offered by 32 sponsoring organizations.^a

^aIncluded in the 32 sponsoring organizations are affiliated organizations, such as individual Blue Cross and Blue Shield entities that are counted as one organization.



Background

Types of Sponsoring Organizations

Active general cards by type of sponsoring organization, as of August 2005.

Type of sponsoring organization	National cards	Regional cards	Total general cards
Pharmacy benefit manager	18	12	30
Health insurer/managed care organization	3	18	21
Other	13	2	15
Total	34	32	66

Source: GAO analysis of CMS data and drug card sponsor information.

Note: Table does not reflect five approved national cards that were never marketed. "Other" includes an information technology company, a medical products company, and a claims processor, among others.



Background

General Drug Card and TA Enrollment

General drug card and TA enrollment as of August 2005.

General drug card type	Drug card and TA enrollment		Drug card only enrollment		Total general drug card enrollment
	<i>Number</i>	<i>Percentage</i>	<i>Number</i>	<i>Percentage</i>	
National	1,323,459	40.3	1,964,579	59.7	3,288,038
Regional	323,020	66.2	164,659	33.8	487,679
Total	1,646,479	43.6	2,129,238	56.4	3,775,717

Source: GAO analysis of CMS data.

Note: As of August 2005, CMS reported 6.4 million enrollees across all drug card types.



Background

CMS Guidance to Drug Card Sponsors

- CMS issued guidance to drug card sponsors using a number of mechanisms, including:
 - Periodic conference calls open to all sponsors.
 - Bulletins distributed via e-mail.
 - Electronic posting of “Questions and Answers.”
 - Other written guidance, such as information and outreach guidelines.
- CMS assigned staff to serve as a point of contact for each drug card sponsor to provide individual guidance and assistance.



Summary of Findings

- The processes CMS used to solicit, evaluate, and approve drug card sponsors were influenced by the 6-month implementation time frame.
- CMS's oversight of sponsors has identified and corrected some program problems, but has had some limitations with respect to the timeliness of oversight activities and the guidance provided to sponsors.



Objective 1

The Processes CMS Used to Solicit, Evaluate,
and Approve Drug Card Sponsors Were
Influenced by the 6-Month Implementation
Time Frame



Drug Card Sponsor Selection Overview

The 6-month implementation time frame influenced the:

- Solicitation type.
- Application design.
- Application evaluation and approval process.



Drug Card Sponsor Selection Noncompetitive Solicitation

CMS used a noncompetitive solicitation process in which all organizations meeting qualification requirements could participate in the program. CMS officials told us they took this approach to:

- Meet the 6-month implementation time frame.
- Encourage participation, given the uncertainty of industry interest in the program.
- Facilitate communication among and between drug card sponsor applicants and CMS.
- Avoid the need to develop weighted criteria to evaluate applications.



Drug Card Sponsor Selection Open-Ended Questions

- CMS used open-ended questions in the application it used to evaluate potential sponsors.
- CMS officials said that they took this approach because the short implementation time frame required that the application be designed before some of the program's operational guidelines had been developed.



Drug Card Sponsor Selection

Open-Ended Questions (cont.)

- CMS officials told us that the open-ended questions allowed them to learn about and evaluate applicants' capabilities by requiring detailed and descriptive responses.
- CMS officials said this would not have been possible using closed-ended questions that would have prompted, for example, a "yes" or "no" response. Each applicant was asked to describe, for example, how:
 - Its administrative infrastructure would interact with CMS.
 - It would manage the TA benefit.



Drug Card Sponsor Selection

Information Provided in the Application

- CMS officials told us that they did not use all of the information provided in the application to evaluate potential sponsors; they used some of this information to gain a better understanding of the industry. For example, they solicited information to better understand:
 - The frequency of price increases for drugs most commonly used by Medicare beneficiaries.
 - Educational efforts used by the industry pertaining to generic substitution.



Drug Card Sponsor Selection

Some Application Questions Problematic

CMS officials said that some of the application questions were problematic for applicants to answer due to:

- Short time frame—For example, sponsors' contractual relationships with drug manufacturers and pharmacies had not all been finalized, so reporting expected price concessions for beneficiaries was problematic for some sponsors.
- Lack of clarity about information to be provided—For example, applicants were asked to provide information on a few classes of drugs, such as antacids, for which only over-the-counter medications were available. Over-the-counter medications are not covered under the drug card program.



Drug Card Sponsor Selection Applicants' Attestations

- CMS officials told us, and our review of the application confirmed, that they often relied on applicants' attestations about their abilities to meet certain program requirements. For example:
 - Applicants were required to attest that they had contracts in place with drug manufacturers and pharmacies, but copies of executed contracts were not required to be submitted to CMS.
 - Applicants were required to attest that they would be ready to enroll beneficiaries and provide discounts and TA by May 3, 2004.



Drug Card Sponsor Selection Application Evaluation and Approval Process

- Based on its initial evaluation of applicants, CMS approved only those that provided all of the information requested in the application.
- For applicants that CMS initially denied:
 - Those with applications missing minor information were allowed to provide the missing information through a redetermination process.
 - Those with applications missing significant information could appeal the denial through a reconsideration process.



Drug Card Sponsor Selection Application Redetermination and Reconsideration

- Twelve potential sponsors (representing 18 general drug cards) supplied new information through the redetermination process.
- Four potential sponsors (representing 11 general drug cards) with applications denied due to missing significant information all notified CMS of the intent to appeal and requested a hearing through the reconsideration process outlined in the interim final rule for the drug card program.
- At the first hearing, the CMS hearing officer ruled that new information submitted by an applicant must be considered. This prompted CMS to allow other potential sponsors missing significant information to submit that information without going through a formal hearing.



Drug Card Sponsor Selection

Drug Card Sponsor Approval

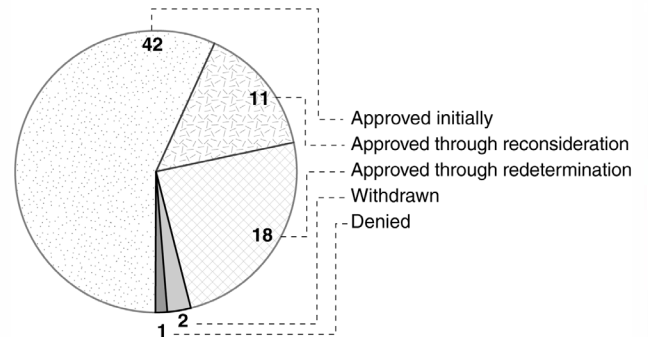
- CMS announced its initial list of approved general drug card sponsors on March 25, 2004.
- The initial list did not include sponsors that had not completed the redetermination and reconsideration processes.
- The final sponsor's application was approved on May 7, 2004.



Drug Card Sponsor Selection Application Approval Results

- CMS approved applications for 71 general drug cards.
- CMS denied one application.
- Two applications were withdrawn by the sponsoring organizations.

**Application Approval Results,
by Number of Drug Cards**



Source: GAO analysis of CMS data.



Objective 2

CMS's Oversight of Sponsors Has Identified and Corrected Some Program Problems, but Has Had Some Limitations with Respect to the Timeliness of Oversight Activities and the Guidance Provided to Sponsors



CMS's Oversight Approach

Multiple Methods

Methods CMS uses to monitor sponsors include:

- Reviews of complaints and grievances.
- Analyses of sponsor-reported data.
- Use of contractors to help perform oversight.



CMS's Oversight Approach

Complaints and Grievances

- CMS's regional offices investigate beneficiary complaints. CMS uses a Web-based tool to track and manage complaints it receives through:
 - 1-800-MEDICARE.
 - www.medicare.gov.
 - Written correspondence from beneficiaries.
 - Congressional correspondence.
- CMS requires sponsors to collect, track, resolve, and report beneficiary concerns reported to sponsors, known as "grievances."



CMS's Oversight Approach Data Sponsors Report to CMS

Frequency of reporting	Examples of type of information
Weekly	Drug prices and participating pharmacy information for CMS's Price Compare Web site^a
Monthly	- Number of grievances reported to sponsors - Prescription utilization
Quarterly	- Price concessions from manufacturers and pharmacies, amount of concessions passed on to beneficiaries - Number of dispensed prescriptions
As-needed	Material modifications to a sponsor's drug card

Source: GAO summary of CMS information.

^aThis Web site, located at www.medicare.gov, includes information for beneficiaries on available drug cards. CMS deactivated the component of the Web site with information about drug prices on September 30, 2005.



CMS's Oversight Approach

Contractor-Conducted Oversight Activities

Contractor	Key oversight activities
BearingPoint	Reviews of sponsors' beneficiary outreach materials; test calls to sponsor call centers; pharmacy participation survey
Booz Allen Hamilton	Analysis of sponsor self-reported data; development of metrics to measure sponsor performance and identify potential problems; development of sponsor report cards
IntegriGuard	Analysis of drug price data; audits of sponsor policies and procedures; referrals of potential fraud cases
Navigant Consulting, Inc.	Identification of errors in price data; analysis of price changes
MAXIMUS	Management of beneficiary requests for reconsideration of TA and eligibility decisions
DestinationRx	Collection, review, and posting of information for CMS's Price Compare Web site

Source: GAO summary of CMS and CMS contractor information.



CMS's Oversight of Selected Program Areas

Key Program Areas

We focused on CMS oversight of elements of the following key program areas:

- Drug prices.
- Sponsors' pharmacy networks.
- Beneficiary information (sponsor-provided).
- Transitional assistance.
- Complaints and grievances.

CMS's oversight has resulted in various formal compliance actions against sponsors.



CMS's Oversight of Selected Program Areas Drug Prices

- Sponsors' weekly price files are reviewed for outliers and other data concerns.
- CMS officials told us that early-reported data were sometimes problematic due to:
 - Incorrectly placed decimal points.
 - Inconsistent unit pricing of non-pill prescriptions (e.g., creams, sprays).
 - Delays in sponsors' reporting.
- CMS officials said that they took steps in response:
 - Some sponsors' data were not posted on the Price Compare Web site.
 - Warning letters were issued, which improved reporting.
- In June 2005, a CMS contractor began work to see if non-TA enrollees had been inappropriately charged more than the maximum price posted on the Web site. Results are expected in November 2005.



CMS's Oversight of Selected Program Areas

Drug Prices (cont.)

- The MMA required sponsors to pass price concessions from manufacturers to beneficiaries, and CMS requires sponsors to report price concessions from both manufacturers and pharmacies to CMS.
- CMS guidance about sponsors' reporting requirements, including the reporting of price concessions, was finalized in November 2004.
- Some sponsors said the guidance lacked clarity.
- According to CMS, as of August 2005, the overall quality of price concession data was questionable, with problems such as outliers and missing data. CMS officials said they were working with sponsors to resolve the problems.



CMS's Oversight of Selected Program Areas Sponsors' Pharmacy Networks

- According to CMS, some beneficiaries complained that pharmacies listed on the Price Compare Web site were not accepting their cards; some pharmacies complained that they were incorrectly listed as participating in a sponsor's network.
 - CMS found that most of the problems were due to pharmacies being unaware that they were participating in a sponsor's network.
 - CMS found that sometimes pharmacies were not actually participating in a sponsor's network.
 - CMS worked with sponsors to improve pharmacies' awareness about their participation in the program; when warranted, Web site information was corrected.
- Some participating pharmacies complained they were not listed on the Price Compare Web site. CMS officials told us that they worked to improve the accuracy of information in the national pharmacy database they used for the Web site.



CMS's Oversight of Selected Program Areas Sponsors' Pharmacy Networks (cont.)

In February 2005, a CMS contractor began a survey of a sample of 2,055 pharmacies listed on the Price Compare Web site to determine whether they were participating in sponsors' pharmacy networks, as shown on the Price Compare Web site.

- Surveys were sent to sampled pharmacies listed as participating in at least one general drug card.
- Pharmacy staff were asked which drug cards they accepted.
- Their responses were compared to information on the Price Compare Web site, to determine if there was agreement between pharmacies and the Web site about pharmacies' participation in sponsors' networks.



CMS's Oversight of Selected Program Areas Sponsors' Pharmacy Networks (cont.)

CMS officials told us that preliminary results, as of August 2005, showed that pharmacies' responses sometimes did not agree with what was shown on the Price Compare Web site.

- Nationally, there was about 80 percent agreement (and 20 percent disagreement) between pharmacies and the sponsor network information on the Price Compare Web site.
- North Dakota, Iowa, and Missouri pharmacies, which were oversampled due to a disproportionate number of complaints, had lower levels of agreement—between 63 and 74 percent.
- CMS identified some sponsors with particularly low levels of agreement between pharmacies and the Price Compare Web site information, and began following up with them during summer 2005.



CMS's Oversight of Selected Program Areas Beneficiary Information

- Sponsors' marketing materials were prospectively reviewed and approved by a CMS contractor prior to distribution to beneficiaries.
- Reviewers compared materials to criteria in CMS guidance and found common errors (such as missing forms) and incorporated their findings into sponsor training sessions.
- CMS staff examined some of the materials reviewed by the contractor and found that reviewers generally followed CMS guidance.
- CMS staff and several sponsors reported cases of inconsistency among the contractor's reviewers; CMS officials said that the contractor took steps to improve consistency.



CMS's Oversight of Selected Program Areas Beneficiary Information (cont.)

- In March 2005, the same contractor conducted a limited retrospective review to determine if materials sent to beneficiaries had been approved.
 - Two pre-enrollment packets were requested by phone from each of six general card sponsors.
- Reviewers noted whether packets had all required materials and if all materials had been prospectively approved.
 - All packets were noncompliant. Most packets were missing required materials, and some materials lacked required changes or had not been approved.
 - The contractor never received several requested packets.
- CMS officials told us they worked with the sponsors reviewed to resolve identified problems.



CMS's Oversight of Selected Program Areas Beneficiary Information (cont.)

- A contractor study using test calls was CMS's primary method for monitoring information provided by sponsor call centers.
 - Most calls were conducted from June through December 2004.
 - Callers posed as beneficiary caregivers.
 - Different scenarios were used to test customer service representatives' responses.
- CMS officials told us about several problems, such as:
 - Unavailability of representatives for non-English speaking callers and callers using telecommunications for the deaf.
 - Inappropriate handling of complaints about pharmacies.
 - Representatives' confusion about enrollment fees.
- CMS officials said they began contacting sponsors about these problems in summer 2005.



CMS's Oversight of Selected Program Areas Transitional Assistance

- Results from financial audits of 15 drug cards revealed that the sponsors of all 15 cards had incorrectly used TA funds to cover excluded drugs,^a totaling \$1.3 million in incorrect TA payments.
- CMS provided guidance on excluded drugs on several occasions but did not provide a specific list of excluded drugs for all drug classes until November 2004, about 5 months after the program began.
- Sponsors are required to repay CMS incorrect payments identified by CMS or through their own self-reporting.

^aThe MMA refers to nine drug classes, such as barbiturates and benzodiazepines, that sponsors were required to exclude from their drug cards.



CMS's Oversight of Selected Program Areas

Transitional Assistance (cont.)

- Results from the 15 financial audits revealed that the sponsors of five drug cards had allowed beneficiaries to receive subsidies that exceeded the subsidy of up to \$600 per year.
- CMS officials attributed this to issues such as problems when beneficiaries transferred among drug cards.
- Sponsors are required to repay excess payments identified by CMS or through their own self-reporting.

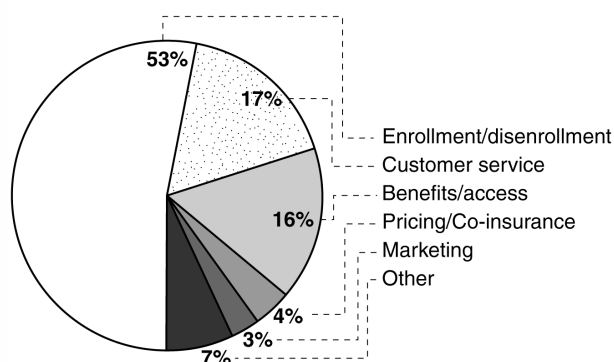


CMS's Oversight of Selected Program Areas

Complaints Received by CMS

- Nearly 11,000 complaints received by CMS about general drug cards.^a
- Most complaints related to enrollment and disenrollment.
- Some drug cards had less than 1 complaint per 1,000 enrollees; others had 15 or more complaints per 1,000 enrollees.

Complaints Received by CMS, by Type



Source: GAO analysis of CMS data.

^aReflects complaints received as of August 31, 2005.

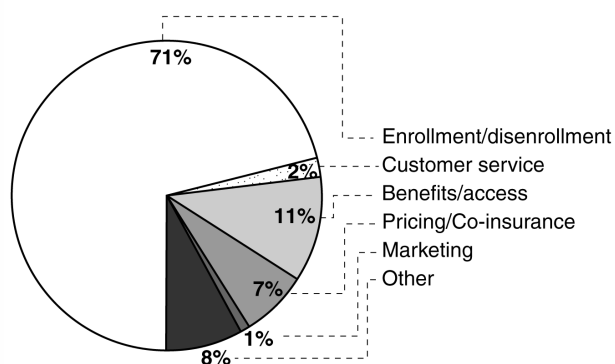


CMS's Oversight of Selected Program Areas

Grievances Reported by Sponsors

- Over 15,000 grievances reported by general drug card sponsors to CMS.^a
- Most grievances related to enrollment and disenrollment.
- Some drug cards had no reported grievances; others had 50 or more grievances per 1,000 enrollees.
- Sponsors are required to report the number of grievances in general categories and if they are resolved. They do not report information on the causes of grievances.

Grievances Reported by Sponsors, by Type



Source: GAO analysis of CMS data.

^aReflects grievances reported as of September 9, 2005.



CMS's Oversight of Selected Program Areas Formal Compliance Actions

As of August 2005, CMS had taken multiple actions against sponsors.

Type of action	Number of actions ^a	Example reasons for action
Educational call	1	Sponsor threatened to withdraw other lines of business from pharmacies unless they accepted its drug card
Warning letter	9	Sponsors did not report data for display on the Price Compare Web site
Corrective action plans	10	Improper inducements to pharmacists and beneficiaries; display of a Canadian pharmacy on a drug card Web page
Enrollment freeze	2 ^b	Improper payments to pharmacists, failure to grant audit access
Civil monetary penalty	1 ^c	Multiple compliance failures
Contract termination	0	Not applicable (no terminations)
Total	23	

Source: GAO summary of CMS information.

^aCMS took compliance actions against 15 sponsors; for 5 sponsors, CMS took more than one action.

^bFor one sponsor, a freeze was implemented. For the other sponsor, CMS proposed an enrollment freeze, but later withdrew the proposal because the sponsor corrected its compliance problem.

^cCMS proposed a civil monetary penalty for one sponsor; as of September 2005, the penalty was under appeal.

Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DATE: OCT 11 2005

TO: Marjorie Kanof
Managing Director, Health Care
U.S. Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Government Accountability Office's (GAO) Draft Report: *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program* (GAO-06-78R)

We appreciate having the opportunity to review and comment on the GAO draft report entitled, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*. While the report explored the findings that the Centers for Medicare & Medicaid Services' (CMS) oversight and monitoring produced, it did not paint a full picture of the depth and breadth of the actual monitoring and oversight activities, which was the intention of the study.

The most important aspect of the Drug Discount Card is whether the program provides discounts and access to prescription drugs. The answer is yes, immediately. Beneficiaries began using their discount cards on June 1, 2004, and millions of prescriptions have been filled, with only a tiny fraction of complaints or compliance issues. Another significant and successful undertaking of CMS was providing to the public an online Web tool so individuals could compare the costs of their drugs across all of our contracted sponsors—beneficiaries could find out and compare prices for every single covered drug, in every dosage available, located at any contracted brick and mortar or mail order pharmacy. This state-of-the-art approach publicly displayed drug prices for the first time and put choice in the hands of the beneficiaries. This online comparison tool will be carried through for the Drug Benefit.

The CMS has worked hard to help Medicare beneficiaries to obtain their prescription drugs at lower costs through the Medicare drug discount card program. The Drug Discount Card was our initial effort at implementing such a program. We have learned many valuable lessons that will inform our future efforts as we plan for the Drug Benefit in 2006. The new program required us to form new working relationships with drug card sponsors and other industry stakeholders in order to ensure that enrollment and payment systems ran smoothly. As part of that process, each sponsor has personalized access to CMS via a card manager, for both troubleshooting help and for larger policy issues. CMS has been working with these new partners on a consistent basis, via conferences, regular teleconferences, and daily card manager contact. We will implement similar communication structure for organizations offering the Medicare Drug Benefit, for example the recent Compliance Conference CMS held. CMS and our contractors have learned a tremendous amount about providing drug coverage through this program, and these lessons continue to help us with all of the up front work to prepare for 2006.

Page 2 - Marjorie Kanof

In spite of the short startup timeframe for the Drug Card and Transitional Assistance program, and the simultaneous development of and implementation of a functioning real-time monitoring system, there was much successful CMS action in a short period of time, including monitoring program integrity from the perspective of providers, consumers, and contractors, and enacting actions where necessary.

Since the inception of the Drug Card Program, which was implemented according to a statutorily established timeframe, CMS has conducted a wide range of oversight activities that were unprecedented for a program of limited duration. Moreover, all of our oversight activities were initiated in the first year of the program, another remarkable accomplishment. The GAO report primarily focuses on a snapshot that CMS conducted as part of its overall oversight activities, rather than the process. The report does not present the context of the larger oversight effort on the part of CMS, and thus presents only a small piece of the picture. We suggest that GAO include a comprehensive listing of our overall oversight activities, so that an accurate and full picture is presented.

As of August 2005, GAO reports that CMS had taken 23 compliance actions against 15 drug card sponsors, usually in the form of warning letters or corrective action plans. The 23 compliance actions were assessed for a variety of reasons such as: transitional assistance administration and system failures related to enrollment. Less than 25 percent of general card sponsors required compliance actions. It was our extensive compliance and oversight activities and diligence in our investigation of problems that led to the identification of these problems and the subsequent compliance actions.

We appreciate your willingness to incorporate information about CMS' implementation, monitoring, and compliance efforts into your final report, thereby giving readers and users of the report a complete picture and understanding of CMS' implementation of Part D in these areas.

Our specific and technical comments on the report are attached.

Attachment

Centers for Medicare & Medicaid Services' Comments to the Government Accountability Office's Draft Report: *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program* (GAO-06-78R)

I. GAO Finding: There was a lack of reliable drug card sponsor data on price concessions.

Card sponsors regularly report data to CMS on rebates, discounts, and other price concessions obtained from drug manufacturers and pharmacies, and the percentage passed through to beneficiaries.

There were significant data quality issues (including incomplete submissions and many obvious reporting errors), which CMS has worked to resolve. Most submissions are now accurate, although a few remain outstanding.

Despite these concerns, CMS is pleased that the initial data suggest that general card sponsors have been passing through a substantial portion of their negotiated rebates, discounts, and other price concessions to beneficiaries. These "pass-throughs" appear to be due to both negotiated manufacturer contracts and negotiated pharmacy contracts.

The CMS has done its own analysis of prices submitted by sponsors. An analysis of prices posted on the Price Compare Web site shows beneficiaries can obtain discounted prices that are about 12 to 21 percent less than the national average prices actually paid by Americans for commonly used brand-name drugs at retail pharmacies. Additionally, The Lewin Group, American Enterprise Institute, and Kaiser Family Foundation have conducted independent studies confirming savings in the same range.

The CMS finds these multiple analyses of the drug card data to validate sponsor prices.

II. GAO Finding: CMS has issues regarding timeliness of oversight activities and program guidance provided to sponsors.

Since the inception of the Drug Card Program, which was implemented according to a statutorily established timeframe, CMS has put into practice a wide range of oversight activities in a short period of time, which is unprecedented for a program of limited duration. Moreover, the expansive array of formal and systematized oversight and compliance activities were all initiated in the first year, which is a remarkable accomplishment considering the duration of the entire program, and the amount of time CMS had to implement it.

With only 6 months to implement the drug card program, CMS established several layers of oversight in order to ensure that sponsors met certain requirements, beneficiaries received meaningful discounts on commonly prescribed drugs, and specific customer service and grievance procedures were in place.

Attachment - 2

While planned oversight of the drug card program began well before May 2004, actual oversight of the Drug Card Program began on June 1, 2004, as soon as a beneficiary was unable to reach a sponsor phone number and called 1-800-MEDICARE, or called one of CMS' caseworkers because they had not received their drug card in the mail after applying weeks before. Prior to obtaining measurable data about these incidents, they were resolved and tracked, and dealt with at a sponsor/beneficiary level. If these problems occurred more than a few times, CMS would share the issue and resolution with sponsors on an all-sponsor teleconference. CMS acted swiftly and thoroughly to resolve potential problems through close oversight, even if it were at a beneficiary-per-beneficiary level.

Much of the information CMS utilizes to oversee the Drug Card program is gathered through beneficiary complaints that are generated either through 1-800- MEDICARE or the CMS Regional Office caseworkers. The receipt, tracking, and resolution of Medicare beneficiary complaints related to the Medicare-Approved Prescription Drug Card is a vital part of CMS' compliance process. These complaints are logged into a Web-based tracking tool, the Complaints Tracking Module (CTM). Complaints have been logged into the CTM since May 1, 2004. Since early May 2004, CMS has received 13,156 complaints related to various parts of the Drug Discount Program. CMS has resolved 12,688 (or 96 percent) of these complaints. Of these 7,331 (or 58 percent) have been validated and corrective actions have been taken. CMS determined that 4,221 (or 33 percent) were invalid. One thousand forty-seven (or 8 percent) of the complaints were withdrawn. Finally, 92 of the complaints, (or less than one percent) were forwarded to the MAXIMUS contractor, which handles eligibility reconsiderations, for action.

Taken into context, the overall number of valid complaints was quite small compared to the millions of prescriptions filled through this program and the more than one billion dollars of transitional assistance expended.

The Drug Card compliance program was intentionally structured to rely primarily on data and not on-site audits, given the short-term nature of the program. In addition, the compliance and oversight process was defined in detail in the Regulations, the Marketing and Outreach Guidelines, and the Office of the Inspector General (OIG) Guidance. Each of these documents was made available to sponsors well in advance of the start of the program. CMS issued an interim final rule on December 15, 2003, at 42 CFR Part 403 Section 101 "Medicare Program: Medicare Prescription Drug Discount Card." Section 403.820 of that regulation describes the sanctions, penalties, and termination actions that CMS may take in order to ensure compliance with the program requirements. Marketing and Outreach Guidelines were issued shortly after the regulations. CMS provided a regular forum for sponsors to receive guidance about certain operational or policy issues, and would allow sponsors to utilize the forum to raise concerns.

Specific CMS oversight activities have included:

- Initiating a series of recurring conference calls for sponsors – Most of the conference calls in the early stages of the program were held at least weekly, but most of the calls have now been cut back to about twice a month;
- Sponsor training on the drug card processes;

Attachment - 3

- CMS guidance for and review of sponsors' marketing materials;
- Retrospective audits of marketing materials;
- Independent evaluations of savings/satisfaction/compliance;
- Financial audits by contractors;
- Pharmacy survey;
- Pharmacy claims review;
- Mystery shopping;
- Weekly analysis of drug prices; and
- Analysis of reporting requirements.

In addition, the oversight program has included a Medicare program safeguard contractor (PSC-IntegriGuard).

The CMS' response to specific program violations has included: educational calls with sponsors, warning letters, imposition of corrective action plans, levying of civil money penalties, and imposition of intermediate sanctions.

III. GAO Finding: Transitional Assistance funds were used to pay for excluded drugs on some occasions and some beneficiaries were given more than \$600 per year.

The findings by GAO of inappropriate payments represent only a tiny fraction of the services delivered over the duration of the program.

Categories of excluded drugs are defined by statute and repeated in the drug card regulation and solicitation. From the very beginning of the program, CMS made it abundantly clear to sponsors that sponsors themselves – not CMS – were to identify drugs falling into excluded categories and ensure that they wouldn't be covered under the program. CMS repeatedly reminded sponsors of this obligation on sponsor conference calls beginning in January 2004. Written examples providing these reminders included a memo released on July 12, 2004 and other documents provided on August 30, 2004, November 4, 2004, and most recently on August 5, 2005 and August 30, 2005. CMS developed its own list of specific excluded drugs (i.e., those falling into the statutory categories) for oversight purposes, and provided this list to sponsors in November 2004. We believe that sponsors are well aware of their responsibility not to pay for these drugs. Therefore, we disagree with GAO's finding that guidance to sponsors was not provided in a timely manner (Finding II above).

On December 23, 2004, CMS sent out an "Overview of CMS' Drug Card Monitoring Activities" to all sponsors requesting each sponsor conduct a review of payments made for barbiturates and benzodiazepines using transitional assistance (TA) funds and repay improperly drawn funds through the payment management system. On August 30, 2005, CMS issued a memo to all drug card sponsors directing that sponsors conduct an internal review of their Medicare prescription drug discount card program data, books and records to identify all excluded drugs at the national drug code (NDC) level that have been paid for with Federal (TA) funds. Sponsors were directed to send a copy of their self-audit to their card managers by

Attachment - 4

September 30, 2005, and to repay improperly drawn funds through the payment management system.

If a sponsor disagrees with a medication on the CMS-issued excluded drug list, a CMS pharmacist will conduct a preliminary review of the sponsor's response and IntegriGuard will provide clinical and research support as needed. After IntegriGuard researches the issues and makes a recommendation to CMS a committee will review IntegriGuard's recommendation and make a recommendation to management. This committee will be staffed by CMS and will include clinicians and compliance, policy, and financial staff.

The CMS is requiring card sponsors to repay funds used to pay for excluded drugs.

Most inappropriate payments for transitional assistance in excess of the statutorily allotted \$600 per beneficiary occurred in instances where beneficiaries changed drug cards during the program. In February 2005, we instituted new transitional assistance systems processing rules in an attempt to reduce the time taken by sponsors to update beneficiary balances in CMS systems. This reduces the likelihood that a beneficiary would be allowed to overspend if they change drug cards because a more accurate balance would be passed from the CMS system to the new sponsor.

IV. GAO Finding: There is some disagreement between card sponsors and pharmacy networks in terms of participation in the drug card program.

Some beneficiaries complained to CMS that pharmacies listed on the Price Compare Web site were not accepting their drug cards and some pharmacies complained of being incorrectly listed as participating in a sponsor's network.

The CMS found that most of the problems were due to pharmacies being unaware that they were participating in a sponsor's network. CMS worked with sponsors to improve pharmacies' awareness about their participation in the program and Web site information was corrected as required. At our encouragement, sponsors conducted targeted outreach to their networks through blast faxes and conference calls with chain and independent pharmacy associations and calls with individual pharmacies. If there were targeted areas or pharmacies are found to be problematic, CMS would work individually with that sponsor.

A CMS contractor surveyed a sample of pharmacies listed on the Price Compare Web site to confirm participation in drug card programs as listed. Nationally, there was about 80 percent agreement between pharmacies and the sponsor network information on the Price Compare Web site. Many of the low congruence rates were for independent pharmacies. Findings were shared with CMS staff responsible for outreach to pharmacists and the Part D staff to determine how to best reach out to the independent pharmacies participating in the Part D program. CMS conducted compliance conference calls with sponsors exhibiting an exceptionally low agreement percentage, and encouraged these sponsors to undertake a re-education effort with their network pharmacies.

Attachment - 5

In February 2005, in a dialogue with the National Council of Prescription Drug Program (NCPDP), which creates and promotes standards for the transfer of data to and from the pharmacy services sector of the healthcare industry, we began work to assist them with updating inaccurate pharmacy addresses in their database. It was the inaccuracy of addresses we received from NCPDP that caused many of the problems with pharmacy listings in our price comparison system. A CMS contractor ran the NCPDP data file containing all pharmacies in the United States against address scrubbing software. The cleaned addresses were then sent to NCPDP for updating their database. We repeated this process again in April with NCPDP and achieved 98 percent accuracy in the NCPDP database. CMS will continue this process for future display of pharmacy information on www.medicare.gov, using NCPDP data.

V. GAO Finding: Beneficiaries occasionally received inaccurate information from drug card sponsors.

The CMS' mystery shopping contract, which randomly samples sponsor customer service lines, was a very informative source of information for CMS, and spurred actions early on in the program. CMS found that Customer Service Representative (CSR) training, education, and experience were all factors in beneficiary receipt of inaccurate information. Several sponsors included CSR trainings as part of the compliance plan.

For more oversight, a CMS contractor conducted a beneficiary call center study. This study found that for Spanish language calls the CSR had a difficult time obtaining information from card sponsors approximately 20 percent of the time. This means that 80 percent of the time a CSR was able to provide the requested information in Spanish. In addition, this study found that card sponsors abandoned or dropped very few calls and were able to answer most calls within the required 30 seconds. Most sponsors also successfully addressed the general aspects of transitional assistance and 80 percent of the general sponsor's CSRs mentioned the \$600 credit during the call. This study also found that sponsors who utilized third party translation services for language calls and relay services for TTY calls had better results. A briefing of the findings was conducted for the Part D implementation and marketing staff to describe the results and recommendations for Part D. CMS is contacting sponsors whose composite scores for the five scenarios shopped were exceptionally low.

Another significant and successful undertaking of sponsor information provided to beneficiaries was providing to every beneficiary free access to the cost of their drugs comparatively across all of our contracted sponsors—beneficiaries could find out and compare at the counter prices for every single covered drug, in every dosage available, located at any contracted brick and mortar or mail order pharmacy. This state-of-the-art approach put choice in the hands of the beneficiaries, and will be carried through for the Drug Benefit. This information was reviewed prior to it being loaded onto CMS' Web site, especially initially. The prices that were loaded and displayed via the CMS's "Prescription Drug Assistance and other Programs" Web page were honored by sponsors as the price that beneficiaries would find at the pharmacy, so the integrity of the prices was accurate and important.

Attachment – 6

The CMS developed a communications plan in order to provide accurate and reliable information about drug cards. The strategy included: conducting market research activities and paid advertising; providing information on 1-800-MEDICARE and www.Medicare.gov; providing uniform presentation and print materials; and promoting beneficiary awareness through both national and local outreach partners.

GAO Contact and Staff Acknowledgments

GAO Contact Marjorie Kanof (202) 512-7114 or kanofm@gao.gov

Acknowledgments In addition to the person named above, key contributors to this report were Debra Draper, Assistant Director; Lori Achman; Jennie Apter; Robin Burke; Meredith Kimball; Patricia Roy; and Syeda Uddin.

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