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United States Government Accountability Office
Washington, DC 20548

January 13, 2006

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

Subject: *Medicare: Sponsors' Management of the Prescription Drug Discount Card and Transitional Assistance Benefit*

Dear Mr. Waxman:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a prescription drug benefit to the Medicare program, which became effective January 1, 2006.¹ To assist Medicare beneficiaries with their prescription drug costs until the new benefit became 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 offers Medicare beneficiaries access to discounts off the retail price of prescription drugs at the point of sale. All Medicare beneficiaries, except those receiving Medicaid drug coverage, were eligible to enroll in the drug card program.³ Certain low-income beneficiaries without other drug coverage qualified for an additional benefit, a transitional assistance (TA) subsidy that can be applied toward the cost of drugs covered under the drug card program.⁴

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 Prescription Drug Discount Card and Transitional Assistance Program as the drug card program. Beneficiaries could 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.

³Not all applicants were eligible to enroll in the drug card program. CMS established an appeal process for those initially denied eligibility.

⁴For beneficiaries who qualify for TA, the program offered a subsidy of up to \$600 per year toward the cost of covered drugs. To qualify for TA, a beneficiary must (1) have had an income at or below 135 percent of the federal poverty level (FPL) and (2) with certain exceptions, not have had 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.

Drug cards were offered and are managed by private organizations, known as drug card sponsors. General drug cards were available to all eligible beneficiaries living in a card's service area; there are both national and regional general cards.⁵ Exclusive and special endorsement drug cards were available to specific beneficiary groups.⁶ Some drug card sponsors offered more than one drug card. The Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that manages the Medicare and Medicaid programs—administers and oversees the drug card program.

In response to your request, we examined drug card sponsors' management of the drug card and TA benefit and any challenges that sponsors experienced in meeting program requirements. Specifically, we (1) identified how drug card sponsors provided beneficiaries access to discounted drugs and the discounts obtained through these arrangements; (2) reviewed how drug card sponsors managed the TA benefit, including the enrollment of low-income beneficiaries and management of the TA subsidies; and (3) identified any benefits other than discounts on prescription drugs that drug card sponsors provided to beneficiaries.⁷

To address these objectives, we focused our work on general drug cards; our work did not include exclusive or special endorsement cards. We interviewed staff from 7 of 32 general drug card sponsors.⁸ We judgmentally selected the drug card sponsors we interviewed. They represented a mix of national and regional cards; varied in terms of total enrollment, TA enrollment, and number of beneficiary complaints received by CMS; and reflected different organization types (for example, pharmacy benefit managers (PBM),⁹ health insurers, and managed care organizations). We also interviewed CMS officials, staff from six CMS contractors that have assisted with key program oversight activities, officials from HHS's Office of Inspector General (OIG),

⁵National 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.

⁶Exclusive cards are cards that Medicare managed care plans offered only to their plan enrollees. (Some Medicare managed care plans also offered general cards open to all eligible beneficiaries, not just those enrolled in their plans.) 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.

⁷We have conducted other work related to this topic. See GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, [GAO-06-78R](#) (Washington, D.C.: Oct. 28, 2005) and *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.: Nov. 18, 2005).

⁸Included in the 32 sponsoring organizations are affiliated organizations, such as 11 individual Blue Cross and Blue Shield entities that are counted as one organization.

⁹Pharmacy benefit managers manage prescription drug benefits for third-party payers, such as employer-sponsored health plans and other health insurers.

and staff from selected pharmacy and pharmacist associations.¹⁰ Additionally, we reviewed relevant documents from drug card sponsors, CMS, and CMS contractors, such as drug card sponsor applications, CMS guidance, and CMS contractor reports. Data from CMS and CMS contractors reflected the most recent available as of November 2005. We conducted our work from April 2005 through January 2006 in accordance with generally accepted government auditing standards.

Results in Brief

Drug card sponsors generally built on existing arrangements that they, or their partner PBMs, had with drug manufacturers and pharmacies to provide beneficiaries access to discounted drugs. Drug card sponsors we interviewed generally reported little difficulty obtaining discounts for beneficiaries and meeting CMS's requirements to provide pharmacy access for beneficiaries. Analyses conducted by CMS found that beneficiaries enrolled in the drug card program could obtain prices that were 12 to 25 percent less than the average retail prices of brand-name drugs.¹¹ Analyses by other research organizations found similar results. Some program requirements, however, were new and challenging for some drug card sponsors, or their partner PBMs, to implement. These included providing drug manufacturer discounts to beneficiaries at the point of sale and meeting CMS's requirements for reporting detailed data on discounts obtained from drug manufacturers and pharmacies. To manage the TA benefit, drug card sponsors generally relied on their prior experience in administering insurance coverage. Drug card sponsors that we interviewed reported some challenges with beneficiary enrollment for TA, reconciling TA subsidy balances with CMS, or both. Drug card sponsors' records of TA enrollment did not always agree with enrollment data from CMS's eligibility files, and some sponsors had difficulty maintaining accurate TA account balances. All of the drug card sponsors we interviewed told us they provided beneficiaries with at least one additional benefit beyond discounts on covered drugs, such as mail-order dispensing to lower drug costs and drug interaction monitoring programs to promote quality and safety. However, little is known about the extent to which drug card sponsors overall provided these additional benefits because sponsors were not required to report to CMS on the extent to which they provided these added benefits.

We received comments on a draft of this report from CMS. CMS commented that despite the short implementation period, the drug card program was successfully implemented. CMS stated that the concern we raised in the draft report that the agency's use of multiple data systems created challenges for some drug card sponsors in maintaining accurate TA balances was unclear. We revised the draft report to clarify that sponsors' concerns related to a specific CMS data system. We identified that system and provided examples of the concerns.

¹⁰We interviewed staff of the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the Arkansas Pharmacists Association.

¹¹The national average retail price used by CMS represents the average price paid to pharmacies by both insured and cash-paying customers. Prices paid by insured customers are typically less than those paid by cash-paying customers due to discounts negotiated by insurers. Data on these prices were obtained by CMS from Verispan, a health care information firm that collects and reports data on retail pharmacy transactions.

Background

The MMA was enacted on December 8, 2003, and shortly thereafter, by January 30, 2004, interested organizations were required to submit their completed applications to become drug card sponsors to CMS. Organizations that CMS approved as drug card sponsors could begin enrolling beneficiaries as of May 3, 2004, and the drug card program took effect on June 1, 2004. As of November 2005, there were 66 active general drug cards sponsored by 32 different sponsoring organizations. (See table 1.) Many general drug cards are sponsored by PBMs, health insurers, or managed care organizations.

Table 1: Active General Drug Cards by Type of Sponsoring Organization, November 2005

Type of sponsoring organization	Number of national cards ^a	Number of regional cards	Total general cards
PBM	18	12	30
Health insurer/managed care organization	3	18	21
Other ^b	13	2	15
Total	34	32	66

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

^aTable does not reflect five approved national cards that were never marketed.

^bOther includes an information technology company, a medical products company, and a claims processor, among others.

There were nearly 3.8 million Medicare beneficiaries enrolled in general drug cards as of October 2005;¹² about 44 percent were enrolled in both a drug card and TA, while about 56 percent were enrolled in a drug card only. (See table 2.) About 87 percent of general drug card enrollees were enrolled in national drug cards, and about 13 percent were enrolled in regional drug cards.

Table 2: General Drug Card and TA Enrollment, October 2005

General drug card type	Drug card and TA enrollment		Drug card only enrollment		Total enrollment
	Number	Percentage	Number	Percentage	
National	1,334,895	40.7	1,946,065	59.3	3,280,960
Regional	322,779	66.2	164,531	33.8	487,310
Total	1,657,674	44.0	2,110,596	56.0	3,768,270

Source: GAO analysis of CMS data.

Organizations had to meet certain requirements 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 have served at least 1 million covered lives in a similar pharmacy benefit program. Drug card sponsors that did not have sufficient experience with pharmacy benefit management were allowed to partner with PBMs to meet the drug card program requirements.

¹²As of October 2005, CMS reported 6.4 million enrollees across all drug card types, including general and exclusive cards.

Access to Negotiated Discounts and Pharmacies

Drug card sponsors had to demonstrate their ability to meet various program requirements such as providing Medicare beneficiaries access to discounted drugs and a network of pharmacies, and must continue to show they are meeting these requirements. One requirement of the program is that drug card sponsors must offer a negotiated price¹³ for at least one drug in each of more than 200 drug classes that CMS identified as being commonly used by Medicare beneficiaries.¹⁴ According to CMS, nearly all prescription drugs that can be purchased at retail pharmacies are eligible to be covered by sponsors' drug cards.¹⁵ The MMA specifies 9 classes of drugs that sponsors are not allowed to cover through their drug cards; the excluded classes include barbiturates and benzodiazepines, among others. Drug card sponsors must also contract with a sufficient number of pharmacies to ensure that their pharmacy networks meet the program's network access requirements.¹⁶ On a weekly basis, drug card sponsors are required to report to CMS drug prices available at participating pharmacies.¹⁷ They also are required by CMS to report price concession information (which could include discounts, rebates, and other price concessions) from both drug manufacturers and pharmacies to CMS on a quarterly basis.¹⁸

¹³The 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. Sponsors are also required to guarantee that pharmacies provide the lower of the negotiated price or the usual and customary price for a covered drug. Neither the MMA nor CMS's regulations specify any minimum price concession that must be passed on to enrollees.

¹⁴Drugs 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.

¹⁵Covered drugs include prescription drugs, certain vaccines, insulin, and some medical supplies associated with the injection of insulin.

¹⁶By 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.

¹⁷The drug prices reported by drug card sponsors were posted on CMS's Price Compare Web site until September 30, 2005, when CMS deactivated this component of the Web site.

¹⁸The CMS reporting requirement includes the total dollar amount of discounts obtained, the percentage of discounts passed through to beneficiaries, and the average dollar discount per prescription.

Management of TA Benefit

Participating drug card sponsors are required by CMS to manage the TA benefit, including obtaining funds (TA subsidies) from CMS to reimburse pharmacies for covered drugs dispensed to TA beneficiaries. Sponsors must establish and use appropriate accounting procedures and controls to track TA spending for each enrollee and protect against misuse of TA funds, including the inappropriate use of these funds to pay for excluded drugs. In addition, drug card sponsors are required to manage the enrollment of TA beneficiaries, submit monthly TA expenditure reconciliation reports to CMS, and update CMS's enrollment database with beneficiary-level enrollment, utilization, and expenditure data.

Drug Card Sponsors Generally Built on Existing Arrangements to Provide Beneficiaries Access to Discounted Drugs

Drug card sponsors generally built on arrangements that they, or their partner PBMs, had for existing business to provide Medicare beneficiaries access to discounted drugs. Some drug card sponsors incorporated drug manufacturer assistance programs for low-income individuals into the drug card program as a way to provide additional discounts to beneficiaries beyond those required by the MMA. While sponsors generally reported little difficulty obtaining discounts for beneficiaries and meeting pharmacy access requirements, providing drug manufacturer discounts to beneficiaries at the point of sale and reporting detailed data to CMS on the discounts obtained were new and challenging for some sponsors.

Drug card sponsors that we interviewed, or their partner PBMs, generally relied on their existing business relationships for the drug card program. They did not provide detailed information to CMS about their arrangements with drug manufacturers and pharmacies because the agency did not require sponsors to disclose proprietary information about these relationships. According to the drug card sponsors that we interviewed, they sometimes sought arrangements with additional drug manufacturers to include a broader array of drugs, and one drug card sponsor also reported seeking agreements with additional pharmacies to meet program access requirements.

Some drug card sponsors also built on existing drug manufacturer assistance programs for low-income individuals to provide additional discounts to beneficiaries beyond those required by the MMA. According to CMS data, eight drug manufacturers have agreements with sponsors of some drug cards to provide additional discounts to TA beneficiaries who have exhausted their TA benefit, referred to as wrap-around coverage.¹⁹ (See table 3.) Four of these drug manufacturers also have agreements to provide additional discounts to low-income beneficiaries above the TA income limit.²⁰

¹⁹Most of these drug manufacturers provided discounted drugs to low-income individuals prior to the Medicare drug card program.

²⁰The TA income limit for 2005 was \$1,077 per month for a single individual in the 48 contiguous states. The income limit was higher in Alaska (\$1,345 per month) and Hawaii (\$1,239 per month).

Table 3: Drug Manufacturers with Wrap-around Coverage for TA Beneficiaries, September 2005

Drug manufacturer	Number of drug cards with wrap-around coverage ^a	Number of drugs covered ^b
Abbott	44	5
AstraZeneca ^c	13	19
Eli Lilly ^d	45	15
Genzyme	5	1
Johnson & Johnson	22	44
Merck	49	39
Novartis ^d	48	27
Pfizer ^e	24	55

Source: GAO analysis of CMS data from www.cms.hhs.gov/medicarereform/drugcard/mfagreements.asp (accessed on Sept. 22, 2005).

^aWrap-around coverage is for TA beneficiaries who have exhausted their TA benefit.

^bNumber of drugs covered may include multiple formulations of a single drug.

^cThe drug manufacturer offered discounts to low-income beneficiaries above the TA income limit, but only to enrollees of United HealthCare Insurance Company's U Share Prescription Drug Discount Card.

^dThe drug manufacturer offered discounts to low-income beneficiaries above the TA income limit for any drug card willing to participate.

While drug card sponsors that we interviewed told us that they generally experienced little difficulty obtaining discounts for beneficiaries and meeting pharmacy access requirements, there were some challenges. For example, drug card sponsors said that they, or their partner PBMs, often had to develop new processes to pass drug manufacturer discounts to Medicare beneficiaries at the point of sale. Some drug card sponsors volunteered that drug discount card programs managed by PBMs prior to the drug card program did not typically include drug manufacturer discounts, relying instead on discounts negotiated with pharmacies. In the drug card program, the price paid by beneficiaries at the point of sale reflects both drug manufacturer and pharmacy discounts.²¹ Providing drug manufacturer discounts to beneficiaries at the point of sale was a new process for many drug card sponsors and PBMs because these discounts are typically processed after the point of sale for their existing lines of business such as commercial insurance.²²

Several drug card sponsors we interviewed also told us of additional challenges they faced. For example, some drug card sponsors said their use of open rather than more restrictive formularies in the drug card program limited their ability to negotiate larger discounts with drug manufacturers because they were unable to increase the

²¹CMS officials estimated that the majority of discounts came from pharmacies rather than from drug manufacturers.

²²For other programs managed by PBMs, the manufacturer discount is typically not applied at the point of sale, but instead is often provided in the form of a rebate to the insurer or insured group on an established schedule after the transaction is completed. In the drug card program, according to the sponsors we interviewed, PBMs periodically reimburse pharmacies for the drug manufacturer portion of the discounts from drug card sales, typically on a weekly or biweekly basis. On a less frequent basis, generally monthly or quarterly, PBMs receive payments from drug manufacturers for the manufacturers' portion of the discounts on drug sales to beneficiaries.

market share of manufacturers' products sold to beneficiaries.²³ In addition, some drug card sponsors that we interviewed indicated that pharmacies sometimes declined to participate in the drug card program because they considered the level of discounts to be too high or because the pharmacy was sponsoring its own card. Further, pharmacies that did not have separate executed contractual agreements with PBMs specifically for the drug cards may have been unaware that they were participating in the drug card program, which created problems for beneficiaries when they tried to purchase drugs at those pharmacies. Finally, one drug card sponsor told us that some independent pharmacies that used Pharmacy Service Administrative Organizations (PSAO) to contract with PBMs did not always know they were participating with a particular drug card. This occurred because the individual pharmacies did not always recognize that the PSAO had contracted with a drug card sponsor on their behalf.²⁴

As of November 2005, the overall quality of the quarterly price concession data submitted to CMS by drug card sponsors was poor, with problems such as outliers and missing data.²⁵ This precluded CMS from compiling a detailed accounting of the amount and source of discounts and other price concessions for the drug card program. Some drug card sponsors that we interviewed told us that CMS's guidance for reporting price concession data was unclear and not timely, and that reporting the data in the form required by CMS was complex. CMS officials reported that as of November 2005 they were continuing to work with drug card sponsors to resolve the problems.²⁶

Although drug card sponsors' reporting of quarterly price concession data has been problematic, CMS and other research organizations have conducted analyses of drug prices using data reported weekly to CMS for posting on the Price Compare Web site,

²³A formulary is a list of approved drugs that a plan will cover. An open formulary contains no restrictions on what drugs are covered. The drug card program did not require open formularies, but most drug card sponsors offered them through their PBMs. For example, one drug card sponsor told us that the complexity involved in using a restricted formulary would not have been practical given the short duration of the drug card program.

²⁴PSAOs are organizations that sometimes represent independent pharmacies in contractual negotiations with entities such as PBMs or managed care organizations.

²⁵These data include the total dollar amount of discounts obtained by sponsors, the proportion of discounts coming from manufacturers versus pharmacies for each sponsor, and the amount of discounts obtained for beneficiaries with wrap-around coverage. This information on drug card sponsors' price concession data was also discussed in a previous report. See GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, [GAO-06-78R](#) (Washington, D.C.: Oct. 28, 2005).

²⁶As of October 2005, for the drug cards where CMS identified problems, incorrect data had been removed from the system into which drug card sponsors reported their data. However, not all of the sponsors have provided corrected information.

which identified discounts available to drug card beneficiaries.²⁷ A CMS analysis found that beneficiaries enrolled in drug cards could obtain prices as of September 2004 that were approximately 12 to 21 percent less than the national average retail price for selected brand-name drugs. This analysis also found that low-income beneficiaries who used the TA benefit had the potential to save between 44 and 92 percent compared to national average retail prices. A second analysis conducted by CMS found that beneficiaries enrolled in the drug cards could obtain prices as of February 2005 that were approximately 14 to 25 percent less than the national average retail price for cash-paying customers. Other analyses conducted by research organizations such as the Lewin Group and the Henry J. Kaiser Family Foundation found similar results.²⁸

Drug Card Sponsors Generally Used Prior Experience Administering Insurance Coverage to Manage the TA Benefit

Drug card sponsors, or their partner PBMs, generally relied on their prior experience administering insurance coverage to manage the TA benefit. Some of the drug card sponsors we interviewed reported challenges with managing the enrollment of low-income beneficiaries, reconciling TA subsidy balances with CMS, or both. Audits conducted by a CMS contractor, IntegriGuard, found that drug card sponsors' TA reports of enrollment did not always agree with enrollment data from CMS's eligibility files, and some sponsors did not properly document changes they made to TA applications after they were signed by the Medicare beneficiary and submitted to the sponsor.²⁹ Additionally, some drug card sponsors had difficulty maintaining accurate TA subsidy balances, particularly when beneficiaries transferred between drug cards or disenrolled from a drug card. Further, some drug card sponsors we interviewed reported confusion about which drugs were to be excluded from coverage. Audits conducted by IntegriGuard found that drug card sponsors had made approximately \$1.9 million in incorrect TA payments for excluded drugs.

Drug card sponsors were required to obtain completed TA enrollment applications from Medicare beneficiaries and perform an initial eligibility screen before submitting the applications to CMS for eligibility verification. Following CMS's eligibility verification, drug card sponsors were required to notify beneficiaries of their

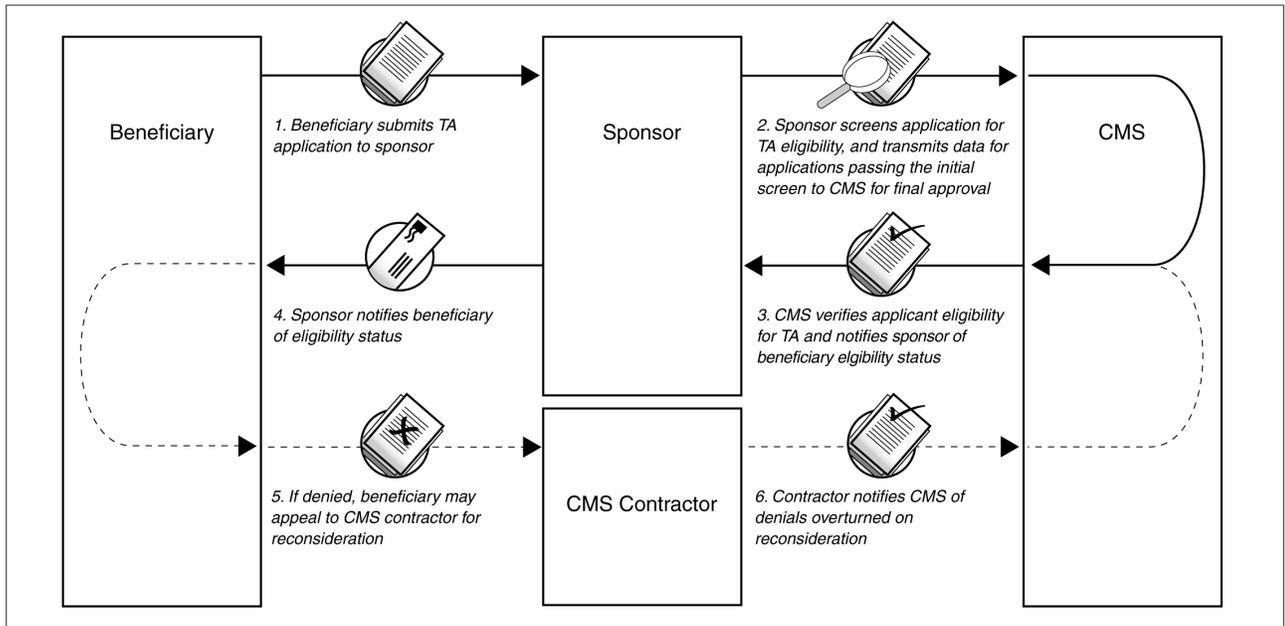
²⁷Early in the program, some drug card sponsors experienced problems with reporting drug pricing data for the Price Compare Web site. CMS identified problems such as inconsistencies in sponsors' reported unit prices for non-pill prescriptions—such as creams and sprays—and delays in drug card sponsors' reporting of data. CMS officials reported that they worked with sponsors to standardize their reporting of non-pill prices, did not post some sponsors' data on the Price Compare Web site, and took actions to address reporting problems. CMS officials stated that the quality of the Price Compare Web site data improved after the first 2 to 3 months of the drug card program.

²⁸See the Lewin Group, *Assessment of Beneficiary Savings in the Medicare Drug Discount Card Program* (Falls Church, Va.: August 2004) and Henry J. Kaiser Family Foundation, *Medicare Drug Discount Cards: A Work in Progress* (Menlo Park, Calif.: July 2004).

²⁹CMS contracted with IntegriGuard, a Medicare program integrity contractor, to conduct audits of drug cards.

eligibility status and right to appeal, as well as to determine the beneficiary's required coinsurance amount.³⁰ See figure 1 for an overview of the TA enrollment process.

Figure 1: Medicare Beneficiary Enrollment Process for TA



Source: GAO analysis of CMS information.

Notes: CMS contracted with MAXIMUS, an organization with experience in enrollment and eligibility issues for state Medicaid programs, to manage beneficiary appeals of TA eligibility denials. Enrollment of new beneficiaries ended December 31, 2005.

CMS established a process for Medicare beneficiaries who were initially denied eligibility for the TA subsidy to appeal the decision. As of August 2005, approximately 76,000 TA eligibility denials were appealed and adjudicated;³¹ 58 percent of these were reversed during reconsideration.³² Reasons for the initial denials varied, but most often it was because the beneficiary appeared to fail the TA income requirements (41 percent), be enrolled in another Medicare drug card (25 percent), or have other prescription drug coverage (22 percent).

Several drug card sponsors we interviewed told us they experienced problems with the TA enrollment process, including reconciling enrollment and eligibility data with CMS. For example, one drug card sponsor told us that when coverage changes in one state's Medicaid program led to the loss of Medicaid prescription drug coverage for some low-income Medicare beneficiaries in the state, there were delays in enrolling these individuals in the drug card program. The delays resulted because the CMS eligibility verification system continued to reflect these individuals as having

³⁰The MMA established the following coinsurance amounts for TA beneficiaries: 5 percent of the drug price for beneficiaries at or below 100 percent of the FPL, and 10 percent for beneficiaries above 100 percent and up to and including 135 percent of the FPL.

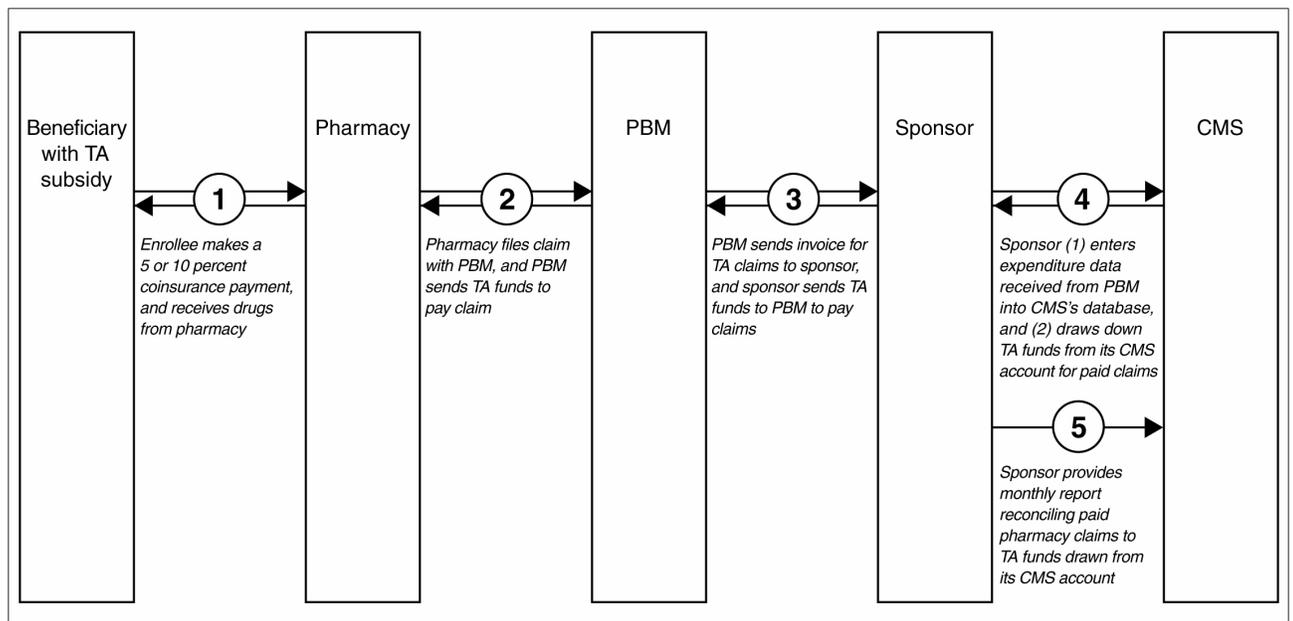
³¹There were 1.6 million Medicare beneficiaries enrolled in general drug cards and TA as of August 2005.

³²Of the reversed denials, 61 percent were initially denied by CMS; 39 percent by drug card sponsors.

Medicaid drug coverage, which would have made them ineligible for enrollment in a drug card. In addition, 8 of 23 audits conducted by IntegriGuard found that TA enrollment data as reported on drug card sponsors' monthly TA reports did not always agree with CMS's eligibility data files for the same period of time. Further, 10 of the 23 IntegriGuard audits found that drug card sponsors did not always properly document changes they made to TA applications after they were signed by beneficiaries and initially submitted to the sponsor. For example, when drug card sponsors followed up with beneficiaries about missing or incorrect information on applications, they did not always document why or on what date they made changes to the applications.

Drug card sponsors generally managed TA funds as they, or their partner PBMs, managed insurance benefits for their existing lines of business. This included operating a real-time claims adjudication system that facilitates the reimbursement of pharmacies for drugs purchased by TA beneficiaries and applies the correct beneficiary coinsurance at the point of sale. As shown in figure 2, once the TA beneficiary pays the 5 or 10 percent coinsurance and receives drugs at the pharmacy, the pharmacy files a claim, which is paid by the PBM. The PBM, if it is not the sponsoring organization, then sends an invoice for TA claims to the drug card sponsor. The drug card sponsor, in turn, draws down TA funds from its CMS account for claims paid to the PBM. To account for the TA funds expended, drug card sponsors are required to enter beneficiary-level expenditure data into CMS's enrollment database and provide a monthly report to CMS reconciling their paid pharmacy claims to TA funds drawn from the sponsor's CMS account.

Figure 2: Flow of Funds and Reporting for TA



Source: GAO.

Note: Step 3 in the figure would not apply if the sponsoring organization is a PBM itself.

According to audits conducted by IntegriGuard and discussed by some drug card sponsors we interviewed, some sponsors had difficulty maintaining accurate TA subsidy balances for beneficiaries who transferred between cards or disenrolled from the program. IntegriGuard audits of 23 drug cards found that sponsors of 11 of these cards had allowed some beneficiaries to receive subsidies that exceeded their TA limit. CMS officials largely attributed the problem to beneficiaries transferring between cards. Some drug card sponsors told us that CMS's Enrollment and Eligibility Verification Systems (EEVS) contributed to these difficulties, pointing to problems they experienced when they attempted to reconcile their enrollment data with CMS. For example, one drug card sponsor told us that it did not have the ability to check enrollment information in EEVS in real time. Another drug card sponsor reported that its TA claims payment system operated in real-time, but that it relied on TA eligibility data updates from CMS that were provided in periodic batch files.

Several drug card sponsors we interviewed also reported confusion about drugs that were to be excluded from coverage through the drug cards, citing inadequate guidance from CMS. While CMS provided general guidance on classes of excluded drugs on previous occasions beginning in June 2004, it did not issue a comprehensive list of excluded drugs until November 2004. IntegriGuard audits of 23 drug cards found that for each, the sponsor had incorrectly used TA funds to pay for at least some excluded drugs. This resulted in approximately \$1.9 million of incorrect TA payments as of November 2005, which drug card sponsors are required to repay to CMS.³³

Drug Card Sponsors Provided Beneficiaries with Some Additional Benefits Beyond Discounts on Covered Drugs

All seven drug card sponsors we interviewed said that they provided at least one benefit to Medicare beneficiaries in addition to the discounts on covered drugs. They extended existing PBM programs designed to lower costs and promote quality and safety to beneficiaries. These programs included mail-order options, efforts to increase the use of lower-cost generic drugs, and programs to detect potential problems such as allergy risks and adverse drug interactions. CMS guidance to drug card sponsors permitted them to provide additional products or services to beneficiaries, such as discounts on over-the-counter drugs at no additional cost to beneficiaries. However, there is little information available on the extent that these additional services or discounts are offered by drug card sponsors overall because they are not required by the drug card program, and sponsors are not required to report this information.

Medicare beneficiaries could achieve additional savings over discounted retail prices if they used a drug card sponsor's mail-order option or substituted lower-cost generics for brand-name drugs when offered. For example, one drug card sponsor we

³³See GAO, *Medicare: CMS's Implementation and Oversight of the Medicare Prescription Drug Discount Card and Transitional Assistance Program*, [GAO-06-78R](#) (Washington, D.C.: Oct. 28, 2005) for information on overpayments as a result of 15 of these IntegriGuard audits that were finalized by October 2005.

interviewed estimated that beneficiaries could achieve an additional 5 percent savings on mail-order purchases of brand-name drugs. According to the sponsor, however, savings from the use of the mail-order option may be limited to beneficiaries who could afford to purchase a 3-month supply of drugs at one time, a typical requirement for purchases made through mail-order pharmacies. This drug card sponsor also reported having a program that automatically substituted generic drugs where allowed. Another drug card sponsor reported providing educational materials to beneficiaries on the savings associated with using generics. Drug card sponsors that we interviewed also said that they, or their partner PBMs, often had a variety of quality and safety programs, which they sometimes extended to drug card beneficiaries. For example, six of the seven drug card sponsors we interviewed had drug safety edits that allowed pharmacists to identify potential adverse drug interactions or drug allergies at the point of sale. Further, four of the drug card sponsors said that they conducted some form of drug utilization review, and one offered a program of medication therapy management.³⁴

Agency Comments

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

In responding to our draft report, CMS had several general comments. First, CMS reiterated our finding that drug card sponsors largely built off of existing industry practices to manage the drug card and TA benefit. CMS stated that the drug card program's short implementation period was possible because of sponsors' reliance on existing practices. Second, CMS stated that the provision of both pharmacy and manufacturer discounts at the point of sale, which we discussed in our draft report, distinguished the drug card program from other discount cards on the market. CMS added that a September 2004 analysis conducted by the agency, which we also described in our draft report, found that beneficiaries enrolled in approved drug cards could obtain discounts of approximately 12 to 21 percent off the national average retail price of common brand-name drugs at the point of sale, with the potential for even higher discounts for low-income beneficiaries who used their TA benefit. Third, CMS commented that a recent evaluation conducted of the drug card program found that most drug card enrollees who were surveyed expressed overall satisfaction with their cards, especially with the breadth of the pharmacy networks, the enrollment process, and savings achieved. Fourth, CMS highlighted the value of the structure it established for the drug card program to communicate with sponsors and stated that it planned to operate a similar communication structure for the new Medicare prescription drug benefit that became effective on January 1, 2006. Finally, CMS noted that the agency and its contractors learned a tremendous amount about providing drug coverage through the drug card program, and that these lessons were helpful in preparing for the implementation of the Medicare prescription drug benefit that is currently underway.

³⁴Drug utilization review programs assist with preventing and detecting inappropriate drug use such as over- or underutilization of medications. Medication therapy management programs are designed to ensure that drugs prescribed for persons taking medications for multiple chronic conditions are appropriately used to optimize therapeutic outcomes and reduce the risk of adverse events.

In addition to these general comments, CMS provided several more specific comments. With respect to our finding that the overall quality of the price concession data reported to CMS by drug card sponsors was poor, CMS stated that it has worked to resolve significant quality issues. CMS said that most submissions are now accurate. As noted in the draft report, the overall quality of that data as of November 2005 was poor, and we have not assessed or verified any changes in the data's quality since that time. Our finding, however, highlights the importance of CMS oversight of sponsor-reported data.

In our draft report, we stated that CMS's multiple data systems created problems for some drug card sponsors in managing the TA subsidies. CMS said it was unable to interpret this concern because we did not indicate the specific systems in question or the actual nature of the problem. Further, CMS stated that it appeared that we simply repeated a concern raised by a sponsor. In response, we revised our report to clarify that sponsors' concerns related to CMS's EEVS system. Additionally, as more than one drug card sponsor raised concerns, we provided specific examples.

Regarding our finding that some drug card sponsors reported confusion about which drugs were to be excluded from coverage, CMS stated that the categories of excluded drugs are defined by statute and are repeated in the drug card regulation and solicitation. CMS added that it was the responsibility of drug card sponsors to identify the specific drugs in the excluded classes and ensure that these drugs were not covered. As we noted in our draft report, audits of 23 drug cards conducted for CMS by IntegriGuard found that the sponsors of all 23 cards had incorrectly used TA funds to cover excluded drugs totaling \$1.9 million. CMS noted in its comments that it provided guidance on excluded drug classes on several occasions, but acknowledged that it did not provide sponsors with a list of specific drugs that were to be excluded from coverage until November 2004, 5 months after the program began. However, CMS stated that it has continued to remind sponsors of their obligation. In its comments, CMS stated that on August 30, 2005, for example, it issued a memo to all drug card sponsors directing each sponsor to conduct an internal review of its drug card data, books, and records to identify all excluded drugs that were paid for with TA funds. CMS required drug card sponsors to repay TA funds that were identified through the internal reviews as having been improperly paid. While drug card sponsors are responsible for the correct use of TA funds, CMS is ultimately accountable for ensuring that no program monies are inappropriately spent.

With respect to our report of delays in beneficiary enrollment caused by changes in a state's Medicaid program, CMS acknowledged that it was possible for delays in state reporting to have led to delays in drug card enrollment. It added that the reconsideration process, which we discussed in our draft report, was established to consider different evidence regarding program eligibility and enroll beneficiaries affected by such concerns.

In response to our discussion of data discrepancies between sponsors' monthly TA reports and CMS's eligibility data files for the same time period, CMS stated that this occurred in a small number of instances. As we discussed in our draft report, however, discrepancies were identified in 8 of 23 audits conducted for CMS by

IntegriGuard. CMS said that it has worked with drug card sponsors to identify and correct these deficiencies.

Finally, CMS also provided technical comments, which we have addressed 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. We will also provide copies to others upon request. The report will also be available on GAO's home page at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7119 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. Key contributors are listed in enclosure II.

Sincerely yours,

A handwritten signature in black ink that reads "Kathleen M. King". The signature is written in a cursive style with a small dash above the final letter of the last name.

Kathleen King
Director, Health Care

Enclosures—2

Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JAN - 6 2006

TO: Kathleen M. King
Director, Health Care

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

SUBJECT: Government Accountability Office's (GAO) Draft Report: *Medicare: Sponsors' Management of the Prescription Drug Discount Card and Transitional Assistance Benefit* (GAO-06-299R)

We appreciate having the opportunity to review and comment on the GAO draft report entitled, *Medicare: Sponsors' Management of the Prescription Drug Discount Card and Transitional Assistance Benefit*. We note that the report did not offer any specified findings, recommendations, or implications for the Centers for Medicare & Medicaid Services' (CMS) consideration for the Medicare Prescription Drug Benefit starting January 1, 2006. Sponsor management of the Prescription Drug Discount Card and Transitional Assistance (TA) worked as intended, building off of existing industry practices, and providing significant discounts and savings. The exceptionally short implementation period (only 6 months) was possible because of the reliance on existing practices. The primary difference from those industry practices was providing discounts at the point of sale, as noted in the report.

The provision of both pharmacy and manufacturer discounts at the point of sale was groundbreaking, and the distinction that set the Medicare-Approved Prescription Drug Discount Card Program apart from other discount cards on the market. While this aspect of the program may have represented a new approach for sponsors, the results of the program strongly indicate the overwhelming success of the initiative and sponsor management of the program. CMS found, that as of September 2004, beneficiaries enrolled in approved drug cards could obtain prices that were approximately 12 to 21 percent less than the national average prices paid by Americans for commonly used brand-name drugs at retail pharmacies. The same analysis also found that low-income beneficiaries who used the TA benefit had the potential to save between 44 and 92 percent, compared to national average retail prices. Studies by independent organizations confirmed these findings.

Another indication of the successful management of the program is beneficiary satisfaction levels. An October 2005 evaluation of the Drug Card Program commissioned by CMS and conducted by an independent research firm, ABT Associates, found that card enrollees participating in focus groups reported no difficulties with enrollment, and non-enrollees did not report perceived difficulty of enrollment as a reason for not enrolling. Most survey respondents expressed overall satisfaction with their cards, especially with the breadth of the pharmacy

Page 2 – Kathleen M. King

networks, the enrollment process, and savings achieved with their cards. Finally, transitional assistance survey respondents and those with higher prescription drug utilization were especially satisfied, both overall and, more specifically, with their savings.

It is also worth mentioning that as part of that process of managing the Drug Discount Card and TA benefit, 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 have implemented 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 have helped us with all of the up front work to prepare for 2006, as well as the implementation underway currently.

While GAO did not offer specified findings or recommendations in the report, we have compiled several comments and technical points we wish to convey. These comments are attached.

Attachment

Centers for Medicare & Medicaid Services' (CMS) Comments to the Government Accountability Office's (GAO) Draft Report: *Medicare: Sponsors' Management of the Prescription Drug Discount Card and Transitional Assistance Benefit* (GAO-06-299R)

I. GAO Comment: The overall quality of the quarterly price concession data submitted to CMS by drug card sponsors was poor.

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.

II. GAO Comment: CMS' use of multiple data systems ... created problems for some drug card sponsors in maintaining accurate TA subsidy balances, particularly when beneficiaries transferred between drug cards or disenrolled from a drug card.

In multiple instances throughout the report (for instance, see pages 4, 11, and 14), the GAO noted that CMS' use of multiple data systems created challenges. We are unable to interpret this concern because the GAO specifies neither 1) the specific systems it is referring to, nor 2) the actual nature of the problem. Rather, the GAO simply repeats the statement that CMS' use of multiple data systems created problems for sponsors regarding their ability to maintain accurate Transitional Assistance (TA) subsidy balances. It would appear that the GAO repeated verbatim a statement raised by a sponsor, without clarifying or confirming the issue.

In fact, one single system at CMS housed TA subsidy balances – the Enrollment and Eligibility Verification System (EEVS). Moreover, this is the only CMS system with which sponsors interact for the entire drug discount card program. Therefore, we are particularly puzzled by this comment.

Now on pp. 3, 9 and 12.

With regard to transferring TA balances when a beneficiary switched from one drug card sponsor to another, CMS reported to the gaining sponsor, through EEVS, the transferring transitional assistance balance as well as any updates to that amount. To mitigate balance transfer problems, we instituted constraints on the period of a time the former sponsor was able to claim utilization past the beneficiary's disenrollment date.

III. GAO Comment: Some drug card sponsors reported confusion about which drugs were to be excluded from coverage.

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 that guidance to sponsors was not provided in a timely manner.

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 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 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.

IV. GAO Comment: One sponsor reported delays in the enrollment of beneficiaries when the state's Medicaid program led to the loss of Medicaid prescription drug coverage for some low-income Medicare beneficiaries in the state.

CMS relied on the States to report to us on a monthly basis the names of beneficiaries enrolled in Medicaid prescription drug coverage. It is possible that delays in State reporting occasionally led to delays in drug card enrollment. However, our reconsideration process was established to quickly consider different evidence regarding eligibility for the program and enroll beneficiaries affected by such concerns.

V. GAO Comment: Ten of 23 IntegriGuard audits found that drug card sponsors' monthly TA reports did not always agree with CMS' eligibility data files for the same period of time.

The EEVS system reflects the official, correct enrollment and eligibility information for the program. In a very small number of instances, information about certain beneficiaries listed in sponsor systems were out of sync with EEVS. To address these discrepancies, EEVS provides a monthly membership file with accurate enrollment and eligibility information which sponsors use to reconcile their internal membership lists. Card managers and the EEVS help desk work with sponsors to identify and correct these discrepancies. The IntegriGuard audits assisted CMS and sponsors further identify and correct discrepancies, and to ensure that benefits are appropriately applied.

GAO Contact and Staff Acknowledgments

GAO Contact Kathleen King, (202) 512-7119 or kingk@gao.gov

Acknowledgments In addition to the contact named above, Debra Draper, Assistant Director; Lori Achman; Eric Anderson; Jennie Apter; Robin Burke; Ann Tynan; and Syeda Uddin made key contributions to this report.

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