

GAO

Testimony

Before the Committee on Oversight and
Government Reform, House of
Representatives

For Release on Delivery
Expected at 10:00 a.m. EST
Friday, February 9, 2007

PRESCRIPTION DRUGS

Oversight of Drug Pricing in Federal Programs

Statement of John E. Dicken
Director, Health Care





Highlights of [GAO-07-481T](#), a testimony before the Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Several federal programs help pay for or reduce the costs of prescription drugs for eligible individuals and entities. Three examples are the Medicaid drug rebate program, part of the joint federal-state Medicaid program that finances medical services for certain low-income people; the 340B drug pricing program, which provides discounted drug prices to certain eligible entities such as community health centers; and the Medicare Part D program, which provides a Medicare drug benefit for the elderly and certain disabled people. The price information drug manufacturers report under these federal programs affects related federal spending. Spending is also affected by the extent to which federal oversight ensures the accuracy of this information.

GAO was asked to provide information related to the oversight of prescription drug pricing practices that affect these federal programs. This testimony focuses on the oversight of drug pricing related to the three programs and the implications for future congressional oversight. This testimony is based on recent GAO reports examining these programs and related work by the Department of Health and Human Services Office of Inspector General and others.

www.gao.gov/cgi-bin/getrpt?GAO-07-481T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Dicken at (202) 512-7119 or dickenj@gao.gov.

PRESCRIPTION DRUGS

Oversight of Drug Pricing in Federal Programs

What GAO Found

Regarding the Medicaid drug rebate program, GAO and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the prices manufacturers report to CMS to determine the statutorily required rebates owed to states. For example, GAO and others have reported a lack of clarity in CMS's guidance to manufacturers for calculating these prices. Several recent legal settlements under which manufacturers agreed to pay hundreds of millions of dollars to states because they were alleged to report inaccurate prices to CMS highlight the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report.

GAO and others have reported inadequacies in the Health Resources and Services Administration's (HRSA) oversight of the 340B drug pricing program and problems related to the lack of transparency in the maximum prices, called 340B prices, charged to eligible entities. GAO reported that HRSA did not routinely compare the prices actually paid by certain eligible entities with the 340B prices and that many of these eligible entities paid prices higher than the 340B prices. Because these prices are not disclosed to the entities, the entities are unable to determine whether the prices they pay are at or below these prices. In addition, because 340B prices are based on information reported by drug manufacturers for the Medicaid drug rebate program, inaccuracies under that program affect these prices. HRSA has made changes to its oversight of the program intended to address some of these concerns.

The Medicare Part D program shares in common with other federal programs certain features that led to federal agency oversight challenges. For example, Part D relies on multiple private organizations to report to CMS certain price concessions from manufacturers, similar to the Medicaid drug rebate program. Also, Part D relies on CMS's oversight to ensure that price information reported to it by private organizations are accurate, similar to the Medicaid drug rebate and 340B drug pricing programs. Other features of Part D, such as its reliance on contracts with private insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions with private entities, also suggest potential oversight challenges.

Oversight inadequacies, inaccurate prices, lack of price transparency, and the potential for abuse suggest areas the Committee may wish to consider as it develops its oversight agenda. The Committee may wish to consider the extent to which CMS and HRSA will systematically take steps to ensure the accuracy of prices reported and charged by private organizations that participate in federal programs. The Committee may also wish to consider the extent to which federal agencies will effectively monitor for and detect abuses in the reporting of drug price information that affect these three federal programs.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you examine prescription drug pricing practices that affect federal programs that help pay for or reduce the cost of prescription drugs, and the implications for future congressional oversight of the programs. Spending on prescription drugs in this country has risen by about 11 percent on average each year from 1998 through 2005 at retail outlets, faster than the average 7 percent yearly rate of increase in total U.S. health expenditures for health care services and supplies during the same period. Retail spending on prescription drugs from all sources in 2005 totaled about \$201 billion, of which the federal government spent about \$33 billion under various programs.¹ The federal spending amount precedes the 2006 introduction of the Medicare prescription drug benefit, known as Medicare Part D, which increased federal spending on prescription drugs.² The amount the federal government spends for prescription drugs is related in part to the price information drug manufacturers report to federal programs. In addition, federal oversight designed to ensure the accuracy of that price information is an important part of the effort to control federal spending.

To assist this committee as it develops its oversight agenda, you asked us for information pertaining to federal agency oversight of prescription drug pricing practices that affect the Medicaid drug rebate program, the 340B drug pricing program,³ and the Medicare Part D program. Accordingly, my

¹Centers for Medicare & Medicaid Services (CMS), Trustees, National Health Expenditure, Historical Data (Baltimore, Md: Centers for Medicare & Medicaid Services, 2007), http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp (accessed Jan. 9, 2007). The prescription drug spending figures reflect spending on prescription drugs through retail outlets, such as retail pharmacies, but do not account for spending through nonretail outlets, such as inpatient hospital or nursing home facility settings.

²The total federal contribution to Medicare Part D for 2006 is estimated at \$58.3 billion, rising to \$67.7 billion in 2007. See 2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Washington, D.C.: May 1, 2006).

³The joint federal-state Medicaid program finances medical services for certain low-income individuals. Within the Medicaid program, the Medicaid drug rebate program requires participating drug manufacturers to pay rebates to states as a condition of the federal contribution for covered outpatient prescription drugs. The Medicaid and Medicaid drug rebate programs are administered by the Centers for Medicare & Medicaid Services (CMS). Another federal program, the 340B drug pricing program, requires drug manufacturers that participate in the Medicaid program to provide drugs at discounted prices to eligible entities such as community health centers. The 340B drug pricing program is administered by the Health Resources and Services Administration (HRSA).

testimony today will focus on the oversight of drug pricing related to these three federal programs and the potential implications for future congressional oversight. My remarks today are based primarily on our 2005 and 2006 reports examining federal programs that help pay for or reduce the cost of prescription drugs, which were done in accordance with generally accepted government auditing standards.⁴ I will also refer to related work by the Department of Health and Human Services Office of Inspector General (OIG) and others.

In summary, oversight inadequacies by federal agencies and a lack of transparency in drug pricing practices that affect federal programs have important implications for federal spending on prescription drugs. Regarding the Medicaid drug rebate program, we and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the price information reported by manufacturers to determine the rebates owed to states, including a lack of clarity in CMS's guidance to manufacturers for calculating that price information. Recent litigation involving allegations that drug manufacturers reported inaccurate prices to CMS resulted in several manufacturers agreeing to pay about \$88 million, \$257 million, and \$345 million to states, thus highlighting the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report to CMS.

We and others have also reported inadequacies in the Health Resources and Services Administration's (HRSA) oversight of the 340B drug pricing program, a lack of transparency in the 340B prices, and overpayments to drug manufacturers. We reported in 2006 that HRSA did not routinely compare the prices actually paid by eligible entities with the 340B prices and that many entities we reviewed paid prices for drugs that were higher than the 340B prices. Because 340B prices are not disclosed to the eligible entities, the entities are unable to determine whether the prices they pay are at or below the 340B prices. In addition, because 340B prices are based on information reported by drug manufacturers for the Medicaid drug rebate program, inaccuracies in that information may affect 340B prices.

⁴See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States*, [GAO-05-102](#) (Washington, D.C.: Feb. 4, 2005); GAO, *Ryan White Care Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, [GAO-06-646](#) (Washington, D.C.: Apr. 26, 2006); and 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).

HRSA has made changes to its oversight of the 340B drug pricing program that are intended to address some of these concerns.

The Medicare Part D program shares in common with other federal programs certain features that led to federal agency oversight challenges related to the reporting of inaccurate price information in those programs. For example, the Medicare Part D program relies on private organizations that sponsor drug plans to calculate and report price information to CMS, much like the Medicaid drug rebate program relies on drug manufacturers to calculate and report drug pricing and price concession information to CMS. Also, the Medicare Part D program relies on CMS's oversight to ensure that price information reported to it by private organizations is accurate, similar to the Medicaid drug rebate and 340B pricing programs. Other features of the Medicare Part D program, such as its reliance on contracts with multiple private insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions with private entities, also suggest areas of potential oversight vulnerability.

Although actions taken by both CMS and HRSA may address some of the oversight inadequacies we and others have reported, it is too soon to know how effective these actions have been in improving program oversight. Thus concerns about oversight inadequacies, inaccurate price information, lack of price transparency, and the potential for abuse associated with federal programs that help pay for or reduce the cost of prescription drugs suggest areas the Committee may wish to consider as it develops its oversight agenda. For example, the Committee may wish to consider the extent to which CMS and HRSA will take steps to systematically ensure the accuracy of price information reported by private sector organizations that participate in federal programs, and the extent to which cognizant federal agencies will effectively monitor for and detect abuses in the reporting of drug price information that affects the Medicaid drug rebate, the 340B drug pricing, and the Medicare Part D programs.

Background

The Medicaid drug rebate program, the 340B drug pricing program, and the Medicare Part D program help pay for or reduce the costs of prescription drugs for eligible individuals and entities.

The Medicaid Drug Rebate Program

Medicaid is the joint federal-state program that finances medical services for certain low-income adults and children. CMS, an agency of the Department of Health And Human Services (HHS), administers and oversees the program. While some benefits are federally required, outpatient prescription drug coverage is an optional benefit that all states have elected to offer. State Medicaid programs, though varying in design, cover both brand and generic drugs. Retail pharmacies distribute drugs to Medicaid beneficiaries, then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. In 2004, Medicaid outpatient prescription drug spending reached \$31 billion, of which \$19 billion was paid by the federal government.

To help control Medicaid drug spending, federal law requires manufacturers to pay rebates to states as a condition for the federal contribution toward covered outpatient prescription drugs.⁵ Rebates manufacturers must pay states for brand drugs under the Medicaid drug rebate program are based on two prices that drug manufacturers must report to CMS: the average manufacturer price (AMP) (the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade) and best price (the lowest price available from the manufacturer to any purchaser with certain exceptions).⁶ Both amounts are to reflect certain financial concessions that are available to drug purchasers. The statute governing the program and the standard rebate agreement that CMS signs with each manufacturer define AMP and best price and specify how these prices are to be used to determine the rebates due to states. CMS provides additional guidance to manufacturers regarding the calculation of these amounts. After manufacturers report the required price information to CMS, CMS uses it to calculate the rebate due for each unit of a brand drug and reports this to the states. The state Medicaid programs use the information to determine the amount of rebates to which they are entitled from the manufacturers based on the volume of drugs paid for by the programs.

⁵See 42 U.S.C. § 1396r-8.

⁶The basic unit rebate amount for a brand name drug is the difference between best price and AMP or 15.1 percent of AMP, whichever is greater.

The 340B Drug Pricing Program

The 340B drug pricing program⁷ gives more than 12,000 eligible entities of various types—community health centers, disproportionate share hospitals, and AIDS Drug Assistance Programs (ADAP)⁸ among them—access to discounted drug prices, called 340B prices. To access these prices, entities must enroll in the program, which is administered by HRSA. Drug manufacturers must offer covered drugs to enrolled entities at or below 340B prices in order to have their drugs covered by Medicaid.⁹ Enrolled entities may generally purchase drugs in two ways. They may choose the direct purchase option to receive the 340B prices up front, or they may choose the rebate option, typically purchasing drugs through a vendor and later receiving a rebate from the manufacturer covering any amount they paid above the 340B prices. Enrolled entities spent an estimated \$3.4 billion on drugs in 2003.

To determine the 340B prices, HRSA uses a statutory formula that relies on AMP and Medicaid rebate data that it receives from CMS.¹⁰ Manufacturers separately calculate the 340B prices for their drugs using the statutory formula, and use these calculations as the basis for the prices they charge eligible entities. HRSA does not share the 340B prices with the eligible entities due to the statutory provisions regarding the confidentiality of information used to determine them.¹¹

⁷The 340B drug pricing program is named for the statutory provision authorizing it, section 340B of the Public Health Service Act (codified at 42 U.S.C. § 256b).

⁸Among other services, community health centers offer primary and preventive health services to low-income individuals. Disproportionate share hospitals are hospitals that serve a relatively large volume of low-income patients and are eligible for payment adjustments under Medicare or Medicaid. ADAPs purchase HIV/AIDS drugs for enrolled low-income people who are uninsured or underinsured.

⁹If a drug manufacturer fails to sell drugs at or below the 340B prices, it can be dropped as a participating drug provider in the 340B and Medicaid programs.

¹⁰In general, the 340B price for a covered outpatient drug is based on AMP and the total unit rebate amount for the drug. HRSA began calculating the 340B prices on October 1, 2005. Previously, CMS performed the calculations.

¹¹According to OIG, the confidentiality provision in the Medicaid drug rebate program statute related to AMP has been interpreted to mean that HRSA may not reveal the 340B prices to the entities. Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, December 15, 2005.

The Medicare Part D Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created a voluntary outpatient prescription drug benefit effective January 1, 2006, as Part D of the Medicare program.¹² Under Part D, Medicare beneficiaries may choose a prescription drug plan (PDP) from multiple competing PDPs offered by private organizations, often private insurers, that sponsor the plans. PDP sponsors enter into contracts with CMS, the agency that administers Medicare. PDPs may differ in the drugs they cover, the pharmacies they use, and the prices they negotiate with drug manufacturers and pharmacies. PDP sponsors may use pharmacy benefit managers (PBM) to negotiate with drug manufacturers and retail pharmacies for the prices of the drugs that each PDP covers.¹³⁻¹⁴ PDP sponsors are required to report to CMS the price concessions they negotiate; these price concessions include discounts, rebates, direct or indirect subsidies, and direct or indirect remunerations.

¹²Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101 to 1395w-152). MMA redesignated the previous Part D of title XVIII of the Social Security Act as Part E and inserted a new Part D after Part C.

¹³In the private health insurance market, health plans typically contract with PBMs to help manage their prescription drug benefits. PBMs negotiate rebates or payments with drug manufacturers, encourage substitution of generic drugs for therapeutically similar brand drugs, and negotiate discounted prices with networks of retail and mail-order pharmacies, passing along at least some of the savings to health plans and enrollees. PBMs influence price negotiations with manufacturers through formulary development and management and through the large market share they often represent.

¹⁴MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between PDP sponsors and drug manufacturers and pharmacies. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(i)).

Oversight Inadequacies in the Medicaid Drug Rebate Program Raise Concerns about the Accuracy of Rebates Paid to States

We and others have reported inadequacies in CMS's oversight of the price information reported by manufacturers under the Medicaid drug rebate program, including a lack of clarity in CMS's guidance to the manufacturers for calculating prices. We reported in 2005 that CMS conducted only limited checks for errors in manufacturer-reported drug prices and that it did not generally review the methods and underlying assumptions that manufacturers use to determine AMP and best prices.¹⁵ We also noted in that report that OIG found that CMS did not provide clear program guidance for manufacturers to follow when determining those prices—for example, how to treat sales to certain health maintenance organizations (HMO) and PBMs.¹⁶ OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, a lack of manufacturer documentation, or both. Our review also examined the pricing methodologies of several large drug manufacturers and found considerable variation in the methods they used to determine AMP and best price, and some of these differences could have affected the accuracy of these prices and thereby reduced or increased rebates to state Medicaid programs. OIG similarly identified problems with manufacturers' price determination methods and their reported prices in four reports issued from 1992 to 2001.¹⁷

Recent litigation has highlighted the importance of the accuracy of prices manufacturers report to CMS and the rebates they pay to states. For example, two drug manufacturers agreed to pay about \$88 million and \$257 million, respectively, to states in 2003 to settle allegations that they failed to include in their best price determinations certain sales to an HMO.¹⁸ Another manufacturer agreed to pay \$345 million to states in 2004

¹⁵See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, [GAO-05-102](#) (Washington, D.C.: Feb. 4, 2005).

¹⁶When the Medicaid drug rebate program began in 1991, PBMs played a much smaller role in the market.

¹⁷See Department of Health and Human Services, Office of Inspector General, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program*, A-06-91-00092 (Washington, D.C.: November 1992) and *Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056 (Washington, D.C.: March 2001). The other two reports focused on individual manufacturers and are not publicly available. Federal law permits the Secretary of Health and Human Services to verify manufacturer-reported prices, and the Secretary has delegated that authority to OIG. OIG regularly conducts audits, evaluations, and investigations pertaining to HHS programs.

¹⁸Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2003* (Washington, D.C.: 2004).

to settle several allegations, including that it did not account for drug discounts provided to two health care providers, resulting in an overstated best price for one of its top-selling drugs and reduced state rebates.¹⁹

CMS issued a proposed rule in December 2006²⁰ to, among other things, implement provisions of the Deficit Reduction Act of 2005²¹ (DRA) related to prescription drugs under the Medicaid program. This rule is intended to provide more clarity to manufacturers in determining AMPs reported to CMS, by indicating which sales, discounts, rebates, and price concessions are to be included or excluded. For example, it specifies that sales to PBMs and mail-order pharmacies must be included in AMP. The proposed rule also specifies that best price must include sales to all purchasers, including HMOs, that are not explicitly excluded and specifies the prices that must be included or excluded from those sales. Recognizing the evolving marketplace for the sale of prescription drugs, the proposed rule states that CMS plans to issue future clarifications of AMP and best price in an expeditious manner. In its notice of proposed rulemaking, CMS also referred to the DRA requirement that CMS disclose AMP data to states and post these data on a public Web site. AMP data are currently not made public. The changes represented by this proposed rule would likely affect the prices that manufacturers report to the federal government. Only after these regulations are finalized and implemented will there be an opportunity to assess the extent to which they improve the accuracy of prices reported and rebates paid by manufacturers.

¹⁹Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2004* (Washington, D.C.: September 2005).

²⁰71 Fed. Reg. 77174 (Dec. 22, 2006).

²¹Pub. L. No. 109-171, §§ 6001-6003, 120 Stat. 4, 54-61.

Oversight Inadequacies and Lack of Transparency in the 340B Drug Pricing Program Raise Concerns about Overpayments to Drug Manufacturers

We and others have reported inadequacies in HRSA's oversight of the 340B drug pricing program, problems related to the lack of transparency in the 340B prices, and overpayments to drug manufacturers. OIG recently reported that some of the 340B prices that HRSA calculated were inaccurate and that HRSA did not systematically compare the 340B prices with those that were separately calculated by drug manufacturers for consistency.²² In addition, we recently reported that HRSA did not routinely compare 340B prices with prices paid by certain eligible entities. We and OIG both found that many entities reviewed paid prices for drugs that were higher than the 340B prices.²³ OIG estimated that 14 percent of total drug purchases made by entities in June 2005 exceeded the 340B prices, resulting in \$3.9 million in overpayments. We also found that the prices of the eligible entities using the rebate option reported to HRSA did not reflect all rebates they later received from manufacturers, and thus we could not determine whether these entities paid prices that were at or below the ceiling established by the 340B prices. Because the 340B prices are not disclosed to eligible entities, the entities cannot know how the prices they pay compare with the 340B prices. Finally, because 340B prices are based on AMP and Medicaid drug rebate data, inaccuracies in those amounts affect the 340B drug pricing program.

Recent legal settlements related to drug manufacturers' overstatement of best prices used in the Medicaid rebate program also led to settlements related to the 340B program. This was because overstated best prices could affect rebates and result in inaccurate 340B prices.

HRSA has made changes to its oversight of the 340B drug pricing program that are intended to address some of the concerns we and OIG raised in our respective reports. For example, while manufacturers are not required to submit their calculated 340B prices to HRSA, the agency has requested that each manufacturer voluntarily submit its calculated 340B prices for comparison to the 340B prices calculated by HRSA.²⁴ It has also indicated

²²See Department of Health and Human Services, Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: October 2005), and *Review of 340B Prices*, OEI-05-02-00073 (Washington, D.C.: July 2006).

²³See GAO, *Ryan White Care Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, [GAO-06-646](#) (Washington, D.C.: Apr. 26, 2006). We found that in 2003, all of the ADAPs we reviewed that used the direct purchase option reported paying prices higher than the 340B prices for at least 1 of the top 10 HIV/AIDS drugs purchased in 2003.

²⁴HRSA indicated that as of July 2006, more than 50 manufacturers had submitted their data.

that it was planning to develop systems to allow eligible entities to check that the drug prices they are charged are appropriate while still maintaining the confidentiality of those prices. Because AMP is used to calculate 340B prices, the requirement under DRA that AMP become publicly available may enable HRSA to improve the transparency of these prices. However, the public reporting of AMP, which is only one element of the 340B price calculation, can only partially improve the transparency of 340B prices.

Medicare Part D Shares Features with Other Federal Programs and Has Certain Features That Suggest Potential Oversight Challenges

The Medicare Part D program shares in common certain features with other federal programs that help pay for or reduce the cost of prescription drugs. Because these features presented oversight challenges with other programs, they may also present challenges for Part D. Some of the common features include the following:

- Under Medicare Part D, PDP sponsors are required to calculate and report to CMS aggregate price concessions they negotiate. Similarly, the Medicaid drug rebate program requires manufacturers to calculate and report certain price information to CMS and to include various price concessions in the calculations.
- Medicare Part D relies on PDP sponsors to pass on to beneficiaries the benefit of price concessions they negotiate with drug manufacturers. Similarly, the Medicaid drug rebate and 340B drug pricing programs rely on manufacturers to pass on to states or eligible entities the rebates or discounted prices to which they are entitled under the programs.
- Medicare Part D relies on CMS to audit PDP sponsors to ensure proper disclosure of price concessions negotiated with manufacturers. Similarly, the Medicaid drug rebate and 340B drug pricing programs rely on federal audits of manufacturers to ensure that the prices reported and charged are appropriate.

Further, the Medicare Part D program shares in common with the Medicare prescription drug discount card program—which preceded Part D—features related to oversight inadequacies we identified with the discount card program. Under the discount card program, private sponsors negotiated drug discounts for beneficiaries and required the card sponsors to report price concessions they received for drugs and pass a share of these on to beneficiaries. We reported in 2005 that some card sponsors found that the guidance relating to the reporting of price concessions provided by CMS lacked clarity, and CMS reported that the

quality of price concession data provided by card sponsors was questionable, with problems such as missing data.²⁵

Two other features of the Medicare Part D program suggest potential oversight challenges. The first relates to the transition of the nearly 6 million typically high-cost individuals who qualify for both Medicaid and Medicare—referred to as dual eligibles—from Medicaid to Medicare Part D for prescription drug coverage. While the Medicaid drug rebate program is designed to help control prescription drug spending by requiring manufacturers to pay rebates to states, Medicare Part D relies on PDP sponsors to negotiate drug prices, including price concessions. Part D provides no assurance that the PDP sponsors will be able to negotiate price concessions that are as favorable as the rebates required under the Medicaid program. It is not yet known how the federal cost of prescription drug coverage for dual eligibles under Part D will compare with the costs incurred for these individuals under Medicaid.

The second feature relates to the Part D program's reliance on contracts with private PDP sponsors. The PDP sponsors provide prescription drug coverage to beneficiaries through a complex set of relationships and transactions among insurers, PBMs, and drug manufacturers. These relationships have similarities to the Federal Employees Health Benefits Program (FEHBP), the health care program for federal employees, in which the federal government contracts with private organizations to provide drug benefits, and these organizations often contract with PBMs to negotiate with manufacturers and provide other administrative and clinical services.²⁶ The relationships and transactions between PBMs and

²⁵See 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). To assist Medicare beneficiaries with their prescription drug costs before the new benefit became available, the MMA required the establishment of a temporary Medicare Prescription Drug Discount Card and Transitional Assistance Program, which began in June 2004. See Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2131. The drug discount card program offered Medicare beneficiaries access to discounts off the retail price of prescription drugs at the point of sale. The program was discontinued when the new Part D drug benefit became available in 2006.

²⁶FEHBP covers about 8 million federal employees, retirees, and their family members, making it the largest employer-based health insurance program in the country. In 2003 we reported on the relationships between the private insurers that provide coverage to federal employees under the FEHBP and the PBMs that administer the prescription drug benefit for most FEHBP enrollees. See GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, [GAO-03-196](#) (Washington, D.C.: Jan. 10, 2003).

drug manufacturers within FEHBP and other federal programs have been the subject of litigation. For example, a large PBM agreed to pay about \$138 million to the federal government in 2005, including about \$55 million to the FEHBP, to settle allegations that it had received payments from drug manufacturers in exchange for marketing certain drugs made by those manufacturers to providers who are reimbursed by federal programs.²⁷

Potential Areas for Future Congressional Oversight

Although actions taken by both CMS and HRSA may address some of the oversight inadequacies we and others have reported, it is too soon to know how effective these have been in improving program oversight. Thus, concerns about prescription drug pricing inaccuracies in the Medicaid drug rebate and 340B drug pricing programs and overpayments to drug manufacturers highlight the importance of federal oversight of prices reported by drug manufacturers under these programs. Because the new Medicare Part D program shares certain features in common with these programs, oversight of the price information reported under Part D is important as well. As the Committee develops its oversight agenda relating to federal programs that help pay for or lower the costs of prescription drugs, it may wish to consider the following areas.

- The extent to which federal agencies will take steps to systematically ensure the accuracy of price data associated with federal programs, specifically,
 - the extent to which CMS will ensure that AMP and best prices reported by manufacturers under the Medicaid drug rebate program include all appropriate transactions and price concessions—particularly once the proposed rule is finalized;
 - the extent to which HRSA will ensure the completeness and accuracy of the 340B prices it maintains, obtain final prices paid by all covered entities, and more systematically compare prices paid by entities with the 340B prices; and

²⁷Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for FY 2005* (Washington, D.C.: August 2006), and the Office of Personnel Management, Office of the Inspector General, *Semiannual Report to Congress* (Washington, D.C.: Nov. 1, 2005).

-
- the measures CMS will take to ensure that the price information Part D sponsors report to CMS include aggregate price concessions sponsors negotiate with PBMs and drug manufacturers.
 - Recognizing the evolving nature of purchasers and sellers in the prescription drug market, the extent to which CMS will be effective in updating and revising Medicaid drug rebate program pricing guidance for manufacturers as circumstances warrant.
 - The extent to which the transition of dual eligibles from Medicaid to Medicare Part D will affect federal spending.
 - The extent to which cognizant federal agencies will monitor for and detect abuses in the reporting of drug price information that affects federal programs.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Committee may have.

GAO Contacts and Acknowledgments

For future contacts regarding this testimony, please contact John Dicken at (202) 512-7119 or at dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Randy DiRosa, Assistant Director; Gerardine Brennan; Martha Kelly; Stephen Ulrich; and Timothy Walker made key contributions to this statement.

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548