**STATEMENT OF**

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**ON**

# OVERSIGHT CHALLENGES IN THE MEDICARE PRESCRIPTION DRUG PROGRAM

**BEFORE THE**

**U.S. SENATE COMMITTEE ON**
**HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS,**
**SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,**
**GOVERNMENT INFORMATION, FEDERAL SERVICES**
**AND INTERNATIONAL SECURITY**

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

**Testimony of**
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**Before the**

**U.S. Senate Committee on Homeland Security and Governmental Affairs,**
**Subcommittee on Federal Financial Management, Government Information,**
**Federal Services, and International Security**

**On**

**"Oversight Challenges in the Medicare Prescription Drug Program"**

**March 3, 2010**

Chairman Carper, Ranking Member McCain, and distinguished Subcommittee members, thank you for inviting me here to discuss the Centers for Medicare & Medicaid Services' (CMS) initiatives to improve the oversight of the Medicare Prescription Drug Program, also known as Part D.

Today, I would like to share with you the Administration and CMS's strategies to oversee and improve the Part D program. Launched in 2006, Part D has provided all Medicare beneficiaries access to prescription drug coverage, and today more than 90 percent of beneficiaries have some form of prescription drug coverage from either Part D or from other sources. We readily acknowledge we have only just begun. CMS has greatly improved and will continue to improve our multi-pronged strategy to oversee the Part D program, including the daily management of our Part D plan sponsors, new regulatory initiatives, and revised audit protocols and compliance review plans to hold Part D plan sponsors accountable to Medicare beneficiaries and tax payers and ultimately strengthen the Part D program and add value to beneficiaries.

CMS appreciates the thoughtful work of this Subcommittee, the Government Accountability Office, and the Department of Health and Human Services (HHS) Office of the Inspector General and the recommendations made to improve our program.

**CMS Part D Oversight Strategy: Day-to-Day Management of the Program**

Oversight of this program is complex. The Part D program is made up of a variety of different plans in different categories. There are also extra benefits for low-income beneficiaries, dual eligible Medicaid beneficiaries, and plans included in the Program of All-Inclusive Care for the Elderly (PACE). Today, hundreds of organizations offer Part D benefits to our beneficiaries through 1,576 standalone prescription drug plans and 2,358 Medicare Advantage Prescription Drug plans. Over the past year, CMS has made tremendous improvements in the day-to-day management of our Part D plan sponsors. This is our first-line strategy to improve compliance. To ensure the highest performance possible and to use our resources most efficiently, our efforts are data driven, proactive, and focused on key vulnerabilities.

In administering and monitoring Part D, we use a range of data to develop performance metrics and monitoring measures that inform us how our Part D plan sponsors are performing. These oversight activities are ongoing -- occurring prior to, during, and after the close of each contract year. Prior to the start of the plan year, CMS conducts a comprehensive review of all bids to verify compliance with a broad range of program and financial requirements. Each bid is subject to an actuarial benefit design analysis in order to address and resolve compliance issues.

Throughout the plan year, CMS collects and analyzes performance data submitted by plans, internal systems, and beneficiaries. Incoming data is continuously monitored, and organizations are immediately contacted when the data analysis reveals potential problems. While the

retrospective audits described below serve as an important oversight tool, our day-to-day monitoring and surveillance activities enable us to quickly identify and proactively resolve deficiencies throughout the program year. Additionally, on an ongoing basis, CMS investigates general grievances, appeals, and beneficiary complaints, monitors plan marketing efforts, monitors claims payment systems, reviews our centralized complaint tracking system, conducts weekly conversations with our appeals resolution contractors, analyzes plan reported data, and reviews the integrity of the prescription drug benefit available for our beneficiaries. Further, we incorporate feedback and lessons learned from this information to implement strategic improvements to the underlying program and our oversight efforts.

CMS conducts targeted audits to supplement the information collected from plans and other surveillance and monitoring activities. Program audits are designed to assess each sponsor's compliance with core program requirements, such as compliance plans, marketing and enrollment activities, and benefit delivery. CMS utilizes a targeted approach in selecting sponsors for audits. We target and apply more intensive staff resources – via account level management, program auditing, and compliance and enforcement actions – toward those organizations that present a statistically higher level of risk or vulnerability for the Agency, whether as a result of their size (large or small), anticipated significant growth in enrollment, or historical actions.

CMS also conducts extensive oversight of plan payment. Following the approval of plan bids, CMS collects prescription drug event (PDE) data, which is pharmacy level claims data on each filled Part D prescription. CMS uses this data along with plan-reported rebate and price concessions information to evaluate each plan's actual incurred drug costs. After the close of each plan year, Part D payments are subject to a reconciliation process. CMS follows statutorily

defined procedures to adjust bid-based prospective payments for discrepancies between anticipated and actual costs.

Finally, the independent Office of the Actuary at CMS conducts retrospective desk audits of the underlying methodology and assumptions of plan bids in order to improve the accuracy of the bidding process. Additionally, CMS conducts on-site financial audits that review Part D sponsors books. Both of these activities cannot take place until after a plan year is complete.

**New Regulatory Oversight Activities**

In October 2009, CMS proposed a new regulation (CMS 4085-P), intended to create a stronger oversight framework and improve performance of prescription drug and health plans by strengthening standards to participate in the Medicare program. This regulation builds on many of the administrative actions that we have pursued over the last year to improve our oversight capacity and ensure that sponsors are compliant with all program requirements. The proposed regulation contained approximately 70 proposed regulatory changes. If the rule is finalized, the proposed changes are intended to assist in simplifying and tightening management of the program.

The proposed enhancements are intended to strengthen Medicare Advantage (MA) and Part D performance requirements, extend greater beneficiary protections to people with Medicare, and ensure that companies offering more than one drug or health plan in the same geographic area offer meaningful differences between those plans. Specifically, among other things, CMS is proposing to:

- Strengthen CMS' ability to identify and approve qualified drug and health plans;

- Improve Medicare beneficiary protections from discriminatory cost-sharing by clarifying health plan requirements relating to out-of-pocket costs and cost-sharing; and

- Eliminate duplication in drug and health plan bids submitted by the same organization by requiring a meaningful difference between an organization's product offerings with regard to premiums, beneficiary out-of-pocket costs, plan types, and formulary offerings. While we support choice for beneficiaries, in terms of their ability to select the health care plan that best meets their unique needs, we want to ensure that distinctions among plans are clear and understandable for our Medicare beneficiaries.

Further, the proposed rule contains numerous provisions aimed at strengthening our oversight authority and improving our ability to act on the oversight and performance information that we collect. Among other things, we proposed to:

- Codify our recently implemented approach of considering sponsor past performance in our review of Part D sponsors and new Part D applications;

- Include a new methodology to assess performance, which would improve our ability to identify compliance issues and take appropriate oversight and enforcement actions; and

- Replace the existing corrective action plan process with an outcome-oriented reasonable period of time process to correct deficiencies as required by statute prior to plan termination.

Additional clarifications CMS is seeking in the proposed rule include a proposal to collect all PDE data elements for non-payment purposes, in order to provide accurate information for analysis of how people with Medicare are using their Part D plan benefits. The proposed rule

would also clarify that, by 2011, both MA and Part D plans will be expected to pay for the data collection costs associated with the annual Consumer Assessment of Healthcare Providers and Systems (CAHPS) enrollee satisfaction surveys performed by independent contractors. These important provisions will allow CMS to ensure proper day-to-day management of the program for our beneficiaries.

CMS is currently in the process of reviewing the comments on the proposed rule. The Agency is working towards finalizing these policies during 2010 to take effect in calendar year 2011.

**Audits and Reviews to Support the Program**

CMS' compliance plan activities are an integral part of the Agency's far reaching oversight functions. Strong rules and plan guidance provide the backbone of our oversight of Part D, further strengthened by the work of CMS' Medicare Drug Integrity Contractors (MEDICs) and our routine audits.

In response to concerns about the operation of our MEDICS, in November 2009, CMS restructured the way the Agency utilizes our MEDICs, moving from a regional-based MEDIC program to one that allows the MEDICs to develop efficiencies and expertise in their focus area. Given that many of our Part D sponsors operate across the country, CMS determined that a regional-based approach would duplicate our MEDICs work and impede coordination. Since that time, the Compliance and Enforcement MEDIC focuses on contract compliance activities for the Medicare Part C and Part D programs, including aggressive oversight of marketing activities, compliance plan audits, and serving as a liaison with the state departments of insurance. The Benefit Integrity MEDIC focuses on pursuing fraud, waste, and abuse activities and serves as a resource to law enforcement agencies.

This restructuring and redesign by workload should allow MEDICs to build on their already considerable successes. They have investigated thousands of complaints and referred nearly 300 cases to law enforcement. This has resulted in aiding prosecutions of rogue insurance agents, owners of fake infusion clinics responsible for billing Part C for millions of dollars in claims, and beneficiaries, healthcare providers, and physicians involved in forging prescriptions and overprescribing, selling, diverting, and trafficking Part D drugs. This past year, the MEDICs also initiated a Part D information sharing workgroup made up of plan sponsors, Pharmacy Benefit Managers (PBMs), and law enforcement representatives. This group has been instrumental in bringing together partners to communicate and share information to reduce pharmacy fraud in Part D.

Similarly, CMS has made significant changes to our compliance plan audits. After MEDICs conducted 16 desk review compliance plan audits, CMS determined that they were of limited value to our monitoring and oversight efforts. As a result, in 2009, CMS took the opportunity to significantly revise its original approach to conducting compliance audits. CMS determined it was necessary to change its approach from a desk review to an on-site review and to develop more comprehensive, meaningful, and robust compliance plan audit protocols focused on evaluating and validating the effectiveness of compliance programs, including the effectiveness of measures to prevent, detect, and correct fraud, waste, and abuse. With the assistance of the MEDICs, CMS piloted these new audit protocols by conducting an on-site compliance plan audit with the largest Medicare Advantage and Part D sponsoring organization in 2009, and with a smaller Medicare Advantage and Part D sponsoring organization in January 2010. CMS made changes to the protocols as a result of lessons learned during these initial audits and also

incorporated these audits into the October 2009 proposed rule. CMS fully expects the MEDICs to begin these more comprehensive on-site compliance plan audits in the spring of 2010.

As part of CMS' functions in administering the Part D program in line with statutory requirements, we conduct bid reviews, bid audits, and financial audits of plan submissions. These activities are done throughout the plan year, which begins January 1, and preparation begins months before a new contracting cycle. For instance, while the 2010 plan year for beneficiaries began two months ago, CMS is preparing to publish the final 2011 Medicare Advantage and Part D Rate Announcement/Call Letter on Monday, April 5 as required by statute, and staff has already begun working on guidelines for plan year 2012. Meanwhile, payment reconciliation will be conducted for plan year 2009 during this summer and fall. Reconciliation payments are calculated after the close of a plan year to ensure that the prospectively paid direct subsidy, reinsurance subsidy, and low-income cost-sharing subsidy match actual costs incurred by the sponsors. In addition, reconciliation examines whether plans are entitled to risk-sharing money based on unexpected losses or must share a portion of unexpected profit with Medicare.

Further, CMS performs financial audits of one-third of Medicare Advantage-Prescription Drug Plans and standalone prescription drug plans for each plan year. All financial audits performed include a prescription drug program review component. Independent auditing firms under contract with CMS perform these audits, after plan reconciliation is complete. Audit firms issue an opinion on the accuracy of selected financial data and sufficiency of internal controls.

CMS is on track to complete all plan year financial audits. Plan year 2006 includes 169 audits and plan year 2007 consists of 200 audits. Audit firms have completed 213 of the 369 audits for

these two years. CMS is currently in our procurement phase for plan year 2008, which will include 235 audits. The financial audits include a review of beneficiaries' True Out of Pocket cost calculations, Part D expenses and payments, and Part D direct/indirect remuneration. CMS is evaluating the results to determine meaningful and actionable measures that we should undertake in our effort to improve our programs.

Finally, CMS also conducts a number of other audits for sponsoring organizations, including:

- "LIS readiness" audits to determine a qualifying stand-alone prescription drug plan sponsor's ability to accept one-time annual and recurring monthly low-income premium subsidy (LIS) enrollments assignments from CMS;

- Annual on-site audits of selected sponsoring organizations and selected areas of compliance (e.g. enrollment operations, premium billing, communications to beneficiaries, appeals and grievances, and marketing); and

- Cost report audits for Cost Plan Sponsors.

The Administration is committed to using the lessons learned in our oversight activities and audits to inform the process of future year's bids. New plan expansions were not allowed this past year in certain cases due to past performance issues. This accountability action assures beneficiaries access to high quality plans and requires plan sponsors not meeting CMS standards to focus attention on their current plan areas before being eligible for expansion. We will continue to follow the bid reviews, bid audits, and financial audits that are called for in statute in administering the Part D prescription drug benefit.

**New Initiatives**

CMS recently announced a realignment plan that will strengthen our existing efforts to coordinate all Medicare programs and combat fraud and abuse.

The realignment includes the creation of a Center for Program Integrity, integrating similar functions from the Medicare and Medicaid programs to improve intra-agency coordination and deployment of resources to address fraud, waste, and abuse. By housing all Program Integrity efforts in one Center, CMS staff will gain valuable insights and share best practices, which allow the Agency to fulfill the mission of ensuring effective, up-to-date health care coverage and promoting high-value, quality care for our beneficiaries.

In addition, the Administration has made fighting health care fight fraud, waste, and abuse a central part of the FY 2011 Budget Request through an unprecedented increase in CMS program integrity funding and support for aggressive new authorities. The FY 2011 request includes a total of $561 million in discretionary Health Care Fraud and Abuse Control (HCFAC) resources and proposes a new package of legislative and administrative changes that will give CMS new tools that enhance program integrity, Part D oversight, and the important work done by CMS' MEDICs. This funding includes a total of $159 million to strengthen program integrity activities in Medicare Advantage and Medicare Part D. In particular, the Budget requests ongoing investments through MEDICs; Medicare C and D contract oversight; monitoring performance assessment and surveillance; program audits; and compliance and enforcement activities. Not only does this continued investment safeguard the program, it has been proven to save money.

The HCFAC Account has a return on investment average of 6 to 1 and returned over $13 billion to the Medicare trust funds between 1997 and 2008.[1]

In addition, the President has recently released a health insurance reform proposal that builds on provisions proposed by the House and the Senate health reform bills, as well as Republican bills, to crack down on fraud, waste, and abuse. These efforts include further authorities and initiatives at CMS and other federal agencies to provide proper oversight of Medicare. For example, the President's Proposal speeds access to claims data to identify potentially fraudulent payments more quickly. It also establishes a system for using technology to provide real-time data analysis of claims and payments under public programs to identify and stop fraud, waste, and abuse, among other efforts. It provides additional tools to reduce the number of individuals and agencies participating in Federal health programs that have a history of fraudulent activities. It improves coordination and information sharing in anti-fraud efforts. If adopted, we anticipate these efforts will improve our oversight efforts and stand ready to work with Congress to implement health insurance reform legislation.

**Further Concerns**

As I have already described, our efforts to deal with oversight challenge include a multi-faceted effort centered around day-to-day management, increased data utilization, proper use of MEDICs, and better targeting our compliance plan and program audits. As we look to future oversight efforts of Part D, CMS remains committed to finding the best methods and tools for oversight and development of our program.

[1] HHS Fiscal Year 2011Budget in Brief, 58.

However, as an Agency we remain concerned about numerous oversight challenges, including marketing and enrollment abuses, clinical access issues, and plans undergoing rapid expansions. We know that we need to work more closely with our partners to ensure that we share a common vision in serving Medicare beneficiaries, many of whom are vulnerable and sick, and help make choices and access to health care clear and easy. To that end, we are pursuing oversight and compliance efforts, like those in the recent proposed rule ensuring that high quality, strong prescription drug plans are available to our beneficiaries without causing confusion.

In the effort to ensure that CMS' payments to Part D sponsors are accurate, CMS has been developing payment error measures for the Part D program. We have developed and reported the following measures: 1) payment error originating from the Part D payment system, 2) payment error relating to low income payments and 3) payment error relating to incorrect Medicaid status. CMS is currently working on additional complex and elaborate measures that will better take into account claims data from plans and price concessions from manufacturers. In order to report publicly this information, we have needed time to put in place a more thoughtful and robust system to capture and better report Part D error; in the meantime, we are steadily pursuing the full range of our oversight and compliance activities.

**Conclusion**

CMS is strongly committed to maintaining and improving the health care benefits provided to beneficiaries of the Medicare Part D program and ensuring effective management and oversight of these plans. Since President Obama took office, the Agency has taken significant action to dedicate resources and attention to proper oversight and combating fraud, waste, and abuse. We are proud of the progress we have made. Yet, we know we have more work to do.

The Agency is committed to examining every part of our day-to-day operations to ensure effective oversight. When potential gaps in oversight or vulnerabilities are identified, we will examine potential regulatory or programmatic changes that will strengthen the program. Further, we will build upon the existing framework of MEDICs, financial audits, and compliance reviews to ensure this information is used in new, targeted, and more effective ways.

I look forward to working with the Congress and this Subcommittee to ensure a strong and effective Part D program and am happy to answer any questions you might have.