STATEMENT OF
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ON

COST OF PRESCRIPTION DRUG ABUSE IN THE MEDICARE PART D PROGRAM

BEFORE THE

U.S. SENATE COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES
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Chairman Carper, Ranking Member Brown, and distinguished Subcommittee members, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) initiatives to improve the oversight of prescription drug utilization in the Medicare Prescription Drug Program, also known as Medicare Part D.

The Administration is committed to reducing prescription drug abuse, as well as reducing waste, fraud, and abuse in Federal programs. Complementing those efforts, CMS is protecting our health care programs from waste, fraud, and abuse through new programs and technologies, such as enhanced Drug Utilization Review (DUR) procedures, increased use of health information technology (HIT), and improved collaboration between Medicare Part D stakeholders. We strongly believe that paying for prescription drugs that are not medically necessary is unacceptable and CMS is working aggressively to reduce abusive or fraudulent uses of the Part D benefit.

Prescription drug abuse is the nation's fastest-growing drug problem, and the Centers for Disease Control and Prevention has classified prescription drug abuse as an epidemic. Prescription medications have great potential for relieving suffering as well as great potential for abuse. For example, acute medical pain treatment for cancer patients would be impossible without prescription opioids; at the same time, opiate overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers.[1] These realities demand action, but we must approach any policy response thoughtfully, acknowledging that the policy must balance

[1] *Unintentional Drug Poisoning in the United States,* National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, July 2010.

our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use.

On April 25, 2011, President Obama outlined an action plan to reduce prescription abuse, titled "Epidemic: Responding to America's Prescription Drug Abuse Crisis."[2] A dramatic increase in prescription opioid use has occurred in recent years. From 1997 to 2007, the milligram per person use of prescription opioids in the U.S. increased from 74 milligrams to 369 milligrams, an increase of 402 percent.[3] In addition, in 2000, retail pharmacies dispensed 174 million prescriptions for opioids; by 2009, 257 million prescriptions were dispensed, an increase of 48 percent.[4] The Medicare program has felt this increase as well. In 2007, Part D sponsors provided nearly 46 million opiate prescriptions; by 2010, Part D sponsors provided nearly 57 million opiate prescriptions, an increase of 24 percent. As frequently abused drugs such as hydrocodone and oxycodone become more commonly prescribed, the likelihood that Medicare beneficiaries could abuse those drugs increases. As this crisis grows in size and scope, CMS is investigating the potential problem of Medicare beneficiaries obtaining frequently abused drugs through fraudulent means and determining the best policy to discourage abuse.

CMS appreciates the thoughtful work of this Subcommittee and the Government Accountability Office (GAO) who have provided information and recommendations to help CMS address this serious health problem.[5] Based on the information the GAO provided, CMS is undertaking an additional evaluation of our Medicare Drug Integrity Contractor's (MEDIC) data on potential prescription drug overutilization to identify policy solutions. Further, CMS issued program guidance to Part D sponsors on September 28, 2011 soliciting comments on how the Medicare Part D program can successfully exert control over payment for inappropriate overutilization of drugs. CMS is also helping Part D sponsors to use the wide variety of tools currently available

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[2] http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf

[3] Manchikanti L, Fellow B, Ailinani H, Pampati V. Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective. *Pain Physician.* 13:401-435. 2010.

[4] Based on data from SDI, Vector One: National. Years 2000-2009. Extracted June 2010. Available at http://www.fda.downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM217510.pdf

[5] GAO, *Medicare Part D: Instance of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: October 4, 2011). This GAO report found indications that doctor shopping could be occurring in the Medicare Part D program. The GAO recommended that CMS review GAO's findings, consider steps such as a restricted recipient program for identified doctor shoppers, and seek Congressional authority, as appropriate.

to them to ensure Medicare does not subsidize addiction to, or diversion of, prescription drugs. CMS is taking action to address the identified issues found in the GAO study.

Background on Medicare Part D

The Medicare Part D prescription drug benefit program was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173). Launched in 2006, Part D is designed to provide beneficiaries with drug coverage through private prescription drug plans. Unlike Parts A and B of the Medicare program, where Medicare acts as the payer and insurer and generally pays for items and services on a fee-for-service basis, the prescription drug benefit is based on a private market model. Under this model, CMS contracts with private entities—prescription drug plan (PDP) sponsors, Medicare Advantage (MA) organizations, as well as other types of Medicare health organizations—who then act as the payers and insurers for prescription drug benefits. These private entities are generally referred to as "Part D sponsors." CMS pays sponsors on a per enrollee basis, otherwise known as capitation, and the sponsors compete for enrollees based on premiums and coverage. In general, Medicare subsidizes about 75 percent of the average cost for basic coverage, with beneficiaries who choose to enroll in the voluntary Part D benefit paying the balance through monthly plan premiums.

Medicare beneficiaries who have limited income and resources may qualify for extra help to pay for prescription drugs costs. This low-income subsidy (LIS) Medicare program provides financial assistance for beneficiaries who have limited income and resources. Those who are eligible for the LIS program will get help paying for their monthly premium, yearly deductible, prescription coinsurance, and copayments, with no gap in coverage. Full benefit dual eligibles, Supplemental Security Income recipients with Medicare, and Medicare Savings Programs participants are automatically eligible for the LIS program. Other people almost always apply for the LIS program through the U.S. Social Security Administration (SSA) or through their State Medicaid programs.

Medicare Drug Integrity Contractors (MEDICs)

To discourage waste, fraud, and abuse in the Part D program, CMS contracts with private organizations, called Medicare Drug Integrity Contractors (MEDICs), to assist in the management of CMS' audit, oversight, and anti-fraud efforts in the Part D benefit. The main functions of the MEDICs include identifying and investigating potential Part D fraud and abuse, developing potential Part D fraud or abuse cases for referral to law enforcement agencies, acting as a liaison to law enforcement, collaborating with Part D sponsors on identification of potentially fraudulent schemes, and serving as an auditor of Part D sponsors' operations. MEDICs are also responsible for auditing the anti-waste, fraud, and abuse compliance programs detailed below that are a requirement for participation as a Part D sponsor in the Medicare program.

Medicare Prescription Drug Benefit: Program Integrity Regulations

On January 28, 2005, CMS published the final rule (CMS-4068-F) implementing the provisions of the Social Security Act that establish and regulate Medicare Part D. The regulation requires all Part D sponsors to have a comprehensive plan to detect, correct, and prevent waste, fraud, and abuse. The plan consists of written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards related to fraud and abuse. Sponsors must have a properly trained, effective compliance officer, and provisions for internal monitoring and auditing, as well as other requirements. These requirements help ensure that sponsors track and identify potential beneficiary or provider abuse. Chapter 9 of CMS' Prescription Drug Benefit Manual recommends that Part D sponsors generate and review reports, such as the following:

- **Payment Reports** which detail the amount paid by the Part D sponsor, the pharmacy provider, and the beneficiary, and a description of the drug provided, including dosage and amount. Part D sponsors use these reports to identify over- and under-payments, duplicate payments, timely payments, and pricing aberrances, and, also, to help verify correct pricing.
- **Drug Utilization Reports** which identify the number of prescriptions filled by a particular enrollee, and in particular numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by an enrollee.

Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs can be identified in reports and the enrollee and their prescribing providers should be contacted and explanations for use should be received by the Part D plan sponsor.

- **Prescribing Patterns by Physician Reports** which identify the number of prescriptions written by a particular provider and typically focus on a class or particular type of drug such as narcotics. Part D sponsors generate these reports to identify possible prescriber, provider, or pharmacy fraud.
- **Geographic Zip Reports** which identify possible doctor shopping schemes or script mills by comparing the geographic location (zip code) of the patient to the location of the provider that wrote the prescription, and should also include the location of the dispensing pharmacy. These reports generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (i.e., 30 miles). "Normal distance" should take into account where the beneficiary resides (i.e., beneficiaries in rural areas would typically have longer trips to a doctor or pharmacy than beneficiaries living in urban areas).

Medicare Prescription Drug Benefit Program Integrity Activities

To combat prescription drug waste, fraud, and abuse more effectively, CMS evaluates Part D sponsors' operations to ensure that they are compliant with the regulations detailed above, as well as aware of the recommendations in the Prescription Drug Benefit Manual. CMS also develops new methods and technologies designed to get ahead of people who would abuse the Part D program and identify their patterns of behavior early. CMS takes a variety of specific actions to identify, stop, and prevent drug abuse, which are detailed below.

Drug Utilization Review Reports

As mentioned earlier, CMS believes that drug monitoring and drug utilization reviews are effective in preserving program integrity, promoting safety, providing quality care, and preventing prescription errors. Part D plan sponsors must have concurrent and retrospective DUR programs in place. Concurrent DUR programs ensure that a Part D sponsor performs a review of the prescribed drug therapy at point-of-sale. Retrospective DUR programs ensure that Part D plan sponsors conduct ongoing periodic examination of claims data, to identify patterns of

inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs. A concurrent DUR program must include the following checks each time a prescription is dispensed:

- Screening for potential drug therapy problems due to therapeutic duplication,
- Over-utilization and under-utilization,
- Incorrect drug dosage or duration of drug therapy, and
- Clinical abuse/misuse.

The DUR programs generally produce online edits to perform the checks listed above and/or reports to describe the data found through the reviews. These online edits and/or reports provide an excellent measurement tool to assess efforts to fix patient safety and provider prescribing issues. In addition, the DUR reports identify dollars saved by avoidance of problems, such as drug-drug interactions, drug-disease interactions, therapeutic duplication, and over-prescribing by providers.

Prescriptions undergo DUR-related analysis both before they are dispensed (concurrent DUR reports) and after they are dispensed (retrospective DUR reports). Concurrent DUR reports take place by automatically prescreening the prescription prior to its being approved and dispensed. The retrospective DUR program is a broader analysis of prescribing patterns and may focus on a specific provider or specific drug use in individual patients. The Part D sponsor could examine DUR-related analysis, claims data, and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicare recipients. The Part D sponsors can also look for suspicious patterns associated with specific drugs or groups of drugs. This examination could involve pattern analysis, using predetermined standards of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies.

The GAO report provided an example of the DUR process preventing potential prescription drug abuse. Two physicians received alert letters from a Part D sponsor listing all of the medications that were dispensed to a beneficiary over a 9-month period. Both physicians no longer prescribed narcotics to the beneficiary after they became aware that the beneficiary saw multiple

doctors and obtained additional narcotics. Part D sponsors regularly send alert letters to providers when they identify, usually through retrospective DUR analysis, suspicious patterns of drug-seeking behavior. The GAO report also identified some cases where DUR procedures did not appear to work. CMS is working with Part D sponsors to implement best practices so that all sponsors become more effective at identifying and preventing fraud and abuse.

Health Information Technology and Electronic Health Records

The Obama Administration is supportive of information technology (IT) efforts and the use of IT to improve quality of care and clinical outcomes. CMS strongly supports Part D sponsors' anti-waste, fraud, and abuse measures and wants sponsors and providers to be aware that e-prescribing can reduce instances of unauthorized, improperly altered, and counterfeit prescriptions. Part D sponsors must establish and maintain an electronic prescription drug program that is consistent with the uniform e-prescribing standards adopted in the E-Prescribing and the Prescription Drug Program final rule (CMS-0011-F).

E-prescribing is an effective tool to detect and prevent fraud and abuse. For example, in the Medicare Part D program, an e-prescribing system could show the clinician the patient's real-time medication history across all providers. The e-prescribing tool may indicate if a prescription was filled, what the dosage was, who prescribed it and when. This data may indicate if the patient is doctor shopping for pain medications or other misused drugs. Hospital emergency department doctors appreciate e-prescribing for this reason, as they often struggle to identify what is an attempt to get medications fraudulently, versus what is a true medical complaint.

E-prescribing is a function of an electronic health record (EHR) being meaningfully used. An EHR with an e-prescribing function provides a more complete picture because it offers the service utilization history, diagnoses, lab results, and other data that can help clinicians determine the best course of treatment and if there is potential fraud or abuse involved. E-prescribing of controlled substances is under the purview of the Drug Enforcement Administration (DEA). CMS worked with the DEA on their proposed rulemaking and adjudicating the public comments. On March 31, 2010, DEA published an Interim Final Rule in

the Federal Register. This interim rule allows for the utilization of e-prescribing for controlled substances.

Sharing Data to Fight Abuse

The Affordable Care Act requires the centralization of certain claims data from Medicare, Medicaid and CHIP; the Department of Veterans Affairs; the Department of Defense; the Old-Age, Survivors, and Disability Insurance program; and the Indian Health Service. Sharing data makes it easier for agency and law enforcement officials to coordinate and identify criminals and prevent fraud on a system-wide basis. CMS is building the Integrated Data Repository (IDR), a data warehouse to integrate Medicare and Medicaid data so CMS and our partners can access data from a single source. The IDR provides a comprehensive view of Medicare and Medicaid data including claims, beneficiary, and drug information. The IDR provides greater information sharing, broader and easier access to data, enhanced data integration, and increased security and privacy of data, while strengthening our analytical capabilities. The IDR makes fraud prevention and detection efforts more effective by eliminating duplicative efforts to identify and prevent waste, fraud, and abuse by agency and law enforcement officials.

The IDR is currently populated with five years of historical Medicare Parts A, B, and D paid claims, and CMS is actively inputting pre-payment claims data. This additional data may allow us to analyze previously undetected indicators of aberrant activity throughout the claims process. Along with the IDR, the One Program Integrity (PI) web-based portal shares data with our contractors and law enforcement. The portal provides a single access point to the data within the IDR, as well as analytic tools to review the data. CMS is working closely with law enforcement to provide training and support in the use of One PI for their needs.

In their report, the GAO recommended that CMS consider facilitating the sharing of information on identified doctor shoppers among the Part D drug plan sponsors. In CMS' recently issued guidance, we ask Part D sponsors to provide suggestions on what would be required in terms of resources to address excessive utilization. We will consider the GAO recommendations, along with the Part D sponsors' responses to our guidance, when exploring approaches that could help

Part D sponsors monitor beneficiary-level utilization reports and the beneficiaries' medication histories in order to identify unusual patterns of drug use.

Collaborating with Part D Sponsors

CMS shares the best practices Part D sponsors have cultivated to address prescription drug abuse in the Part D program. CMS is distributing the GAO report to Part D sponsors and issuing guidance to address the problem of beneficiaries abusing the Part D program. CMS regularly promotes best practices and information sharing among the Part D sponsors. For example, on August 2 and 3, 2011, CMS hosted the "Part C and Part D Program Integrity National Conference" with the following goals:

- Enhancing stakeholders' understanding of MEDICs' roles, responsibilities, and capabilities;
- Discussing best practices in preventing, deterring, and detecting waste, fraud, and abuse in the Part C and Part D programs; and
- Providing opportunities for collaboration between CMS, the MEDIC team, and other key stakeholders, including Part D sponsors, in combating waste, fraud, and abuse.

Part D sponsors such as Humana, Cigna, and CVS Caremark hosted panels dedicated to sharing best practices for preventing and reducing waste, fraud, and abuse. CMS and the MEDICs also host quarterly Part C and Part D Working Groups during which sponsors share their experiences with fraud schemes.

For example, one case discussed at the August workgroup showed the value of information sharing and collaboration between Part D sponsors, pharmacies, the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services (HHS), and MEDICs. Teamwork between those groups led to an invoice and billing audit focused on the purchase and distribution of 40 high-dollar medications in six pharmacies across various States. This example showed how comparing claims and billing information across several purchasers could uncover fraudulent activities, even if the pharmacy's claims under one plan may not seem suspicious. CMS continues to bring these stakeholder communities together to conduct this important dialogue and strengthen our cooperative efforts across the Federal government and with the private sector.

CMS also sends letters to Part D sponsors about fraud schemes that are being perpetrated across the country. The letters summarize the schemes and explain how they are perpetrated, and encourage Part D sponsors to contact the appropriate MEDIC if they have encountered a similar scheme. This collaboration and information sharing allows CMS, Part D sponsors, and MEDICs to identify potential fraud and stop it before payment is made.

Collaborating with the States

States began to address the issue of prescription misuse and abuse more than 60 years ago by creating programs to monitor the dispensing of prescription drugs. Many States have established State Prescription Drug Monitoring Programs (PDMPs) and they are quite diverse in features.[6] The Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS actively collaborates with the States and communities on the prevention and treatment of prescription drug abuse and specifically with States and the Department of Justice (DOJ) on implementing and improving PDMPs.

Beginning in fiscal year 2002, Congress appropriated funding to the DOJ to support the Harold Rogers Prescription Drug Monitoring Program (U.S. Department of Justice Appropriations Act; P.L. 107-77). The purpose of the program is to provide support to States in an effort to enhance regulatory agencies and health care providers' capacity to collect and analyze controlled substance prescription data. The program focuses on providing help for States that want to establish new or enhance existing programs.[7] Currently, 48 States have enacted legislation that authorizes PDMPs, and 36 States have operational PDMPs. PDMPs aim to detect and prevent the diversion and abuse of prescription drugs at the retail level by tracking controlled substances prescribed by authorized practitioners and dispensed by pharmacies. To improve State PDMPs, the Administration and CMS are evaluating the utility of State PDMPs for reducing Medicare and Medicaid fraud. This step is called for in President Obama's prescription drug abuse prevention action plan mentioned previously. To build on these State efforts, the President's Fiscal Year 2012 Budget Request includes a proposal to require States to monitor high-risk

[6] www.dpt.samhsa.gov/doc/NASPER%2009142007.doc
[7] www.dpt.samhsa.gov/doc/NASPER%2009142007.doc

billing activity in the Medicaid program to identify prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs. This proposal, if enacted, would ensure that all States have efforts in place to track high utilizers, and is estimated to save $3.45 billion over 10 years.

Restricted Recipient Program

CMS agrees with the GAO that we must address the problems of excessive drug use and doctor shopping in the Part D program. CMS is improving and increasing efforts to curb overutilization in Part D. We are implementing solutions that curb not only the Federal costs of excessive prescription drug use, but improve the overall health and safety of Medicare beneficiaries taking Part D prescription drugs. CMS is undertaking a thoughtful approach that balances the need to combat waste, fraud, and abuse and the need to ensure our beneficiaries have adequate access to medically necessary prescription drugs. We recognize that one potential way to address the problem of drug abuse is to restrict a beneficiary's access to only certain providers, as the GAO recommends to CMS to consider. However, this approach is problematic in the Part D program because the Part D program is statutorily designed such that beneficiaries choose their drug coverage from a market of multiple private prescription drug plans. This multipayer design creates some challenges for implementing a traditional restricted recipient program model. For example, individuals in the Part D LIS program are permitted to change plans at any time. Further, a restricted recipient program may also create a barrier between a beneficiary and needed care. CMS is unsure that a restricted recipient program would be more effective in preventing prescription drug abuse than the enhanced DUR procedures that CMS will be implementing to better prevent overutilization as well as clinical abuse and misuse. CMS supports the DUR requirements for Part D sponsors and is currently taking action to improve and enforce those requirements.

Moving Forward

CMS is strongly committed to protecting taxpayer dollars and ensuring the sound financial management of the Medicare program. As evidenced by my testimony today, CMS is improving its procedures to address the serious issues raised by the GAO. CMS is making progress in

overseeing the management of Part D, and remains committed to rooting out waste, fraud, and abuse in the Part D program.

CMS appreciates the Subcommittee and GAO's efforts and is seriously considering their recommendations. We are evaluating the GAO's data on questionable overutilization to develop and implement program changes that prevent beneficiary abuse of the Part D program. Those changes will supplement the DUR programs, while ensuring that the policy does not jeopardize a patient's access to care. In addition, CMS is undertaking an additional evaluation of MEDIC data and findings on overutilization and questionable access to certain covered Part D drugs. This evaluation will help us better understand the problem of overutilization of the Part D program and identify solutions tailored to the Part D program's unique design. CMS issued program guidance on new DUR requirements for Part D sponsors' consideration. CMS will consider those sponsors' comments, as well as our evaluations of the MEDIC and GAO's data, to identify best practices that address excessive prescription drug utilization in the Medicare Part D program. CMS will continue to work with Congress and this Subcommittee in protecting taxpayer dollars, beneficiary health, and the integrity of the Medicare program.