STATEMENT OF

SHANTANU AGRAWAL, M.D.

DEPUTY ADMINISTRATOR AND DIRECTOR,

CENTER FOR PROGRAM INTEGRITY

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

STRENGTHENING PROGRAM INTEGRITY IN MEDICARE PART D

BEFORE THE

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Statement of Shantanu Agrawal, M.D., on
Strengthening Program Integrity in Medicare Part D
U.S. House Committee on Energy and Commerce
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Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) work to improve the Medicare Prescription Drug Program, also known as Medicare Part D, to ensure that all Medicare beneficiaries are receiving the medicines they need while also reducing and preventing nonmedical use of prescription drugs. I also would like to thank the Subcommittee for its focus on the consequences of the opioid epidemic and efforts to combat the overutilization of prescription drugs to treat pain.

Approximately 75 percent of all Medicare beneficiaries (or more than 41 million people) are enrolled in the Part D program (including those who are in standalone Part D plans, and those who are in Medicare Advantage plans offering a prescription drug benefit).[1] Since its inception in 2006, the Medicare Part D prescription drug benefit program has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and increased beneficiary satisfaction with their Medicare coverage.

Despite these successes, Part D is not immune from the nationwide epidemic of nonmedical prescription opioid use. The growth of nonmedical prescription-drug use has touched providers, pharmacies, and beneficiaries in the Part D program. CMS recognizes that all Part D plan sponsors face unique challenges in administering the Medicare prescription drug benefit. Plan sponsors operate under a different legal and regulatory framework than the traditional Medicare fee-for-service benefit. However, unlike Medicare Advantage plans offering a prescription drug benefit, stand-alone Part D plan sponsors face additional challenges because they manage only the drug benefit, which leaves plan sponsors without a direct relationship with the prescriber, while CMS manages the medical benefit. The ability of Medicare providers, pharmacies, and

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2015-06.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending

beneficiaries to abuse the Medicare prescription drug benefit is one symptom of the complex health care delivery system that must be addressed through broader reforms that result in better-coordinated care.

CMS has concurrently focused on strengthening beneficiary access to prescribed drugs, while also increasing our efforts to combat prescription drug fraud. Today, CMS requires Part D plan sponsors to have drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution.[2] These requirements have strengthened the Part D program and reflect input from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), Government Accountability Office (GAO), and other stakeholders. The Fiscal Year (FY) 2014 Part D Composite Payment Error Rate (based on Calendar Year (CY) 2012 payments) was 3.3 percent.[3]

To build on this progress and address additional recommendations from OIG, GAO, and others, the President's FY 2016 Budget includes several proposals that would provide CMS with additional tools to prevent inappropriate use of opioids.[4] One proposal would give the Secretary of Health and Human Services (HHS) the authority to establish a program that would require that high-risk Medicare beneficiaries only obtain controlled substance prescriptions from certain prescribers and pharmacies, similar to requirements in many State Medicaid programs. CMS would work to ensure that beneficiaries retain reasonable access to quality services. Currently, CMS requires Part D sponsors to conduct drug utilization reviews to assess the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. However, CMS's current statutory authority to take preventive measures in response to this information is limited.

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[2] The Part D sponsor's concurrent drug utilization review program must include, but is not limited to, the following checks each time a prescription is dispensed: (1) screening for potential drug therapy problems due to therapeutic duplication; (2) age- or gender-related contraindications; (3) over-utilization and under-utilization; (4) drug-drug interactions; (5) incorrect drug dosage or duration of drug therapy; (6) drug-allergy contraindications; and (7) clinical abuse or misuse.

[3] The FY 2014 Part D Composite Payment Error Rate combines four component payment error measures: the Payment Error relating to Low Income Subsidy Status; the Payment Error Related to Incorrect Medicaid Status; the Payment Error Related to Prescription Drug Event Data Validation; and the Payment Error related to Direct and Indirect Remuneration. https://paymentaccuracy.gov/tracked/medicare-prescription-drug-benefit-part-d-2014

[4] FY 2016 Budget in Brief, http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html

The President's FY 2016 Budget also proposes to provide the Secretary with new authorities to: (1) suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential; (2) suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients; and (3) require additional information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. While Part D sponsors have the authority to deny coverage for a prescription drug on the basis of lack of medical necessity, there are currently no objective criteria to inform the medical necessity determination, such as maximum daily dosages, for some controlled substances, especially opioids. This proposal would allow plan sponsors to gather additional information, beyond prescriber attestation, as they determine whether a prescription should be filled. We look forward to working with the Congress on legislation to implement these important proposals.

Establishing Prescriber Enrollment in Medicare and Revocation for Abusive Prescribing

In addition to these items in the President's Budget, CMS is implementing new tools to take action against problematic prescribers. CMS has begun to implement critical safeguards to make sure that only legitimate prescribers are prescribing drugs to Part D beneficiaries. In the past, CMS and plan sponsors were limited in their ability to target individual prescribers; however, the Affordable Care Act granted additional authority related to strengthening Medicare enrollment requirements.

CMS has announced plans to use the authority granted to it in the Affordable Care Act to require most prescribers of drugs paid for by Part D to enroll in Medicare.[5] CMS is actively working to enroll over 400,000 prescribers of Part D drugs by January 2016 and to enforce the requirement that plans deny Part D claims that are written by prescribers who do not meet the necessary requirements by June 2016. These prescribers will be subject to the same risk-based screening

[5] Section 6405 of the Affordable Care Act requires that physicians and eligible professionals who order durable medical equipment, prosthetics, orthotics and supplies or certify home health care for beneficiaries be enrolled in Medicare. The statute also permits the Secretary to extend these Medicare enrollment requirements to physicians and eligible professionals who order or certify all other categories of Medicare items or services, including covered Part D drugs. Accordingly, CMS will require that physicians and eligible professionals who write prescriptions for covered Part D drugs must be enrolled in Medicare, or have a valid record of opting out of Medicare for their prescriptions to be covered under Part D.

requirements that have already contributed to the removal of nearly 575,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Requiring prescribers to enroll in Medicare will help CMS make sure that Part D drugs are prescribed by qualified individuals, and will prevent prescriptions from excluded or already revoked prescribers from being filled. Currently CMS is monitoring Part D claims data to identify provider types with a disproportionate number of unenrolled prescribers, such as dentists, and focusing our outreach strategy to target them. As we approach the implementation date, CMS and Part D sponsors will begin to target individual high volume prescribers that remain unenrolled. Upon enforcement of the enrollment requirement, CMS will require Part D plans to use point of sale edits to stop filling and paying for prescriptions from unenrolled prescribers after the affected beneficiaries have received a three month provisional supply and written notice from their plans.

CMS has established its authority to remove providers from Medicare when they demonstrate abusive prescribing patterns.[6] CMS may revoke a prescriber's Medicare enrollment if his or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked, or the applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs. A revocation for abusive prescribing would be based on criteria that demonstrate a pattern of improper prescribing and would address situations where the prescribing was not in compliance with Medicare requirements or where there were patient safety issues involved. These new revocation authorities provide CMS with the ability to remove problematic prescribers from the Medicare program and prevent them from treating people with Medicare.

Harnessing Data to Strengthen the Part D Program

CMS is doing more to use and share data with Part D plan sponsors to enhance the detection and prevention of fraud and overutilization in Medicare Part D. CMS has increased data sharing between plans and is using currently available data better as we work to strengthen the Part D

[6] See http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf.

program. CMS regularly monitors pharmacy billing patterns and has initiatives in place to address the risks posed by pharmacies with questionable billing practices.

Improving Data Analysis Conducted by the Medicare Drug Integrity Contractor (MEDIC)

CMS contracts with the National Benefit Integrity (NBI) MEDIC to identify and investigate potential fraud and abuse, and develop cases for referral to law enforcement agencies. In September 2013, CMS directed the NBI MEDIC to perform more proactive data analysis, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacies assessments.

These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and ultimately terminate pharmacies from their network. For example, one Part D plan sponsor terminated 51 pharmacies from its network as a result of the March 2015 Pharmacy Risk Assessment. Another Part D plan sponsor opened investigations on 16 pharmacies as a result of the September 2014 Pharmacy Risk Assessment.

The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples of the assistance that the NBI MEDIC provides includes: data, data analysis, impact calculations, clinical review of claims and medical records, and prescription drug invoice reconciliation reviews.

Ensuring Timely Access to Data

Last year, CMS finalized a rule that includes a provision to give CMS, its antifraud contractors, and OIG the ability to request and collect information directly from pharmacy benefit managers, pharmacies and other entities that contract or subcontract with Part D plan sponsors to administer the Medicare prescription drug benefit.[7] The provision streamlines both CMS's and the contractors' investigative processes. Previously, CMS's contractors had to work through the Part D plan sponsor to obtain important documents like invoices and prescriptions, which resulted in delays in getting critical information. This provision provides more timely access to

[7] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, https://www.federalregister.gov/articles/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the.

records, including information for investigations of Part D fraud and abuse, and responds to recommendations from OIG.[8]

Incorporating Part D Data in the Fraud Prevention System (FPS)

CMS is leading the government and healthcare industry in systematically applying advanced analytics to claims on a nationwide scale. Since 2011, CMS has been using its Fraud Prevention System (FPS) to apply advanced analytics on all Medicare fee-for-service (FFS) claims on a streaming, national basis by using predictive algorithms and other sophisticated analytics to analyze every Medicare FFS claim against billing patterns. The system also incorporates other data sources, including information on compromised Medicare cards and complaints made through 1 800-MEDICARE. CMS is developing ways to leverage data from the Part D program to strengthen FPS models that identify Medicare FFS providers with behaviors that require intervention. Since the FPS combines information by FFS provider, the information from Part D will not change the focus on the provider, but will be used to develop new risk factors. For example, CMS will include in the FPS a model that monitors for high-risk prescribers as one of the criteria for elevated risk. By incorporating the analysis of high-risk prescribers into the FPS, CMS will be better able to investigate and take swift action on bad actors in a coordinated way.

Using Data to Identify Outlier Prescribers

CMS used prescription drug event (PDE) data to identify 1,525 prescribers as outliers of Schedule II controlled substances in the 95th percentile for the number of prescriptions and the number of 30-day equivalent prescriptions. Using this information, CMS developed reports that clearly identified the differences in prescribing patterns for the identified outliers. Similar to CMS's comparative billing report initiatives, the goal is to: (1) proactively educate providers about aberrant prescribing practices; (2) act as a deterrent by making providers aware of the Government's monitoring of their prescribing practices; and (3) reduce inappropriate prescribing. CMS then sent these reports to half of the providers, alerting them about their status as outliers. This approach allowed us to measure the effectiveness of the letters in changing provider behavior. CMS also shared the list of outlier prescribers with Part D plan sponsors in an

[8] See http://oig.hhs.gov/oei/reports/oei-03-11-00310.asp.

effort to augment their current utilization management program. We are further developing this and other approaches, using a similar analysis related to prescribing of atypical antipsychotics.

Improving Transparency in Prescriber Level Data

In April 2015, CMS released a new public use dataset on the prescription drugs that individual physicians and other health care providers prescribed in 2013 under Part D[9]. The dataset describes the specific medications prescribed and statistics on their utilization and costs. It provides data on more than one million distinct health care providers who collectively prescribed $103 billion in prescription drugs under the Part D program. This adds to the unprecedented information previously released on services and procedures provided to Medicare beneficiaries, including hospital charge data on common inpatient and outpatient services as well as utilization and payment information for physicians and other healthcare professionals. We believe this increased transparency will give patients, researchers, and providers access to information that will help shape the future of our nation's health for the better.

On June 30, 2015, CMS posted the second set of Open Payments data,[10] which provides information about financial relationships between drug and device makers and doctors and teaching hospitals. These data include 11.4 million financial transactions valued at $6.49 billion that occurred throughout CY 2014.

Communicating and Collaborating with Plan Sponsors and Law Enforcement

Federal, state, and local law enforcement health care fraud activities are being coordinated to a greater extent than ever before. As evidence of this coordination, CMS is also taking steps to better disseminate the results of our data analytics work to Part D plan sponsors and our law enforcement partners. CMS also is engaging with the private sector in new ways to better share information to combat fraud.

For example, the Healthcare Fraud Prevention Partnership (HFPP) has made progress since its inception with the successful sharing of data and building confidence and trust among

[9] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html
[10] Available at http://www.cms.gov/openpayments.

partners. We are continuing to grow strategically by adding new partners and increasing the current reach to realize greater potential in identifying overlapping fraud schemes among partners. On April 16, 2015, CMS launched a web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies. This information sharing tool offers leads for potential high-risk pharmacies and providers identified through data projects that assist users in conducting investigations and other compliance program activities.

Collaboration between CMS program officials and law enforcement is a critical cornerstone for improving health care fraud detection and investigation. In addition to CMS's commitment to collaboration, the sustained success of the Health Enforcement Action Team (HEAT) demonstrates the effectiveness of the Cabinet-level commitment between HHS and the Department of Justice to prevent and prosecute health care fraud. CMS conducts analysis and monitors potentially fraudulent activity in geographic hot spots for fraud and abuse and works with the Medicare fraud strike force to focus law enforcement efforts on those areas.

Most recently, on June 18, 2015, HHS Secretary Sylvia M. Burwell and Attorney General Loretta E. Lynch announced a nationwide sweep led by the Medicare Fraud Strike Force in 17 districts, resulting in charges against 243 individuals, including 46 doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately $712 million in false billings. More than 40 of the defendants arrested are charged with fraud related to the Medicare Part D program.[11]

CMS continues to provide strong support to law enforcement. From January 2010 through the present, CMS's MEDIC made 2,275 referrals to law enforcement. Through our collaboration with OIG, CMS has also sought to prevent bad actors from fraudulently extracting Trust Fund dollars. For example, in December 2013, the NBI MEDIC began referring providers who qualify for permissive or mandatory exclusion from participation in Federal health care program to OIG for exclusion. Since 2013, the MEDIC has made 72 referrals for exclusion, of which 11

[11] See http://www.hhs.gov/news/press/2015pres/06/20150618a.html.

have been added to OIG's List of Excluded Individuals and Entities (LEIE) Exclusions Database.[12]

Oversight of Plan Sponsors

In response to OIG reports[13] recommending that CMS have measures in place to ensure that Medicare Part D Prescription Drug Plans (PDPs) have implemented effective measures to prevent, detect, and correct fraud, waste and abuse, CMS conducted a pilot audit in 2014 to assess the maturity and effectiveness of plans' activities.

CMS identified similar trends across Part D plan sponsors that identified best practices and showed the need for improved strategies to combat fraud, waste, and abuse. CMS also determined that plan sponsors could improve their work in the area of preventative and proactive corrective actions against fraud, waste, and abuse, including fraud referrals to Law Enforcement and/or the NBI MEDIC.

As a result of the trends identified, CMS expanded the 2015 Compliance Audits to include an increased focus on fraud, waste, and abuse. CMS has shared these observations such as trends and best practices with plan sponsors during quarterly trainings with plan sponsors. The trainings provide plan sponsors with information on Part D trends, analysis, and fraud schemes, and plan sponsors also share information regarding their own fraud, waste, and abuse activities. Plan sponsor participation in these trainings has significantly increased in recent years.

Overutilization Monitoring System

To address concerns about prescription drug overutilization raised by the GAO[14], CMS provides information to plan sponsors about Part D enrollees who have potential opioid or acetaminophen overutilization that may present a serious threat to patient safety. Since 2013, CMS has been using the Medicare Part D Overutilization Monitoring System (OMS) to monitor Part D plan sponsors' drug utilization management programs to prevent overutilization of these medications. Using OMS, CMS provides quarterly reports to sponsors on beneficiaries with

[12] See https://oig.hhs.gov/exclusions/exclusions_list.asp.
[13] See http://oig.hhs.gov/oei/reports/oei-03-13-00030.pdf and http://oig.hhs.gov/oei/reports/oei-03-08-00230.pdf.
[14] See http://gao.gov/new.items/d11699.pdf.

potential opioid or acetaminophen overutilization identified through analyses of PDE data. Sponsors are expected to use various drug utilization monitoring tools, including: (1) formulary-level controls (such as safety edits and quantity limits) at point-of-sale; (2) reviews of prior claims and clinical activity to identify at-risk beneficiaries; (3) case management outreach to beneficiaries' prescribers and pharmacies; and (4) beneficiary-level point-of-sale claim edits, if necessary to prevent continued overutilization of opioids. Lastly, Part D plan sponsors that have concluded that such point-of-sale edits are appropriate are expected to share information with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

A comparison of overutilization shows a significant reduction of opioid and acetaminophen overutilization in Part D since the overutilization policy went into effect. From 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS, decreased by approximately by approximately 26 percent, or 7,500 beneficiaries.[15] In addition, from 2011 through 2014, the number of beneficiaries identified as potential acetaminophen overutilizers, based on the CMS definition in the OMS, decreased by more than 91 percent, or 70,000 beneficiaries.[16]

Conclusion

CMS has an important role in the effort to combat prescription drug abuse and overutilization. We have taken steps to reduce the potential harm to Medicare beneficiaries, as well as the significant financial impact to taxpayers, of improper prescribing and potentially fraudulent activity. We are committed to working with OIG to address its recommendations as we strengthen program integrity in Medicare Part D. We look forward to working with this Subcommittee and the Congress on these efforts.

[15] There were 29,404 potential opioid overutilizers, (or 0.29 percent of all Part D opioid users) in 2011 and there were 21,838 potential opioid overutilizers, (0.18 percent of all Part D Opioid users) in 2014.
[16] There were 76,581 potential acetaminophen overutilizers, (or 0.81 percent of all Part D acetaminophen users), in 2011 and in 2014 there were 6,286 (0.06 percent of all Part D acetaminophen users) in 2014.