

Dr. Agrawal’s Hearing
“Medicare Part D: Measures Needed to Strengthen Program Integrity”
Before
E&C O&I Subcommittee

July 14, 2015

Attachment 1—Additional Questions for the Record

The Honorable Susan W. Brooks

- 1. The total number of beneficiaries receiving commonly abused opioids (Schedule II and Schedule III drugs) grew by 92 percent, compared to 68 percent for all drugs. Similarly, the average number of prescriptions for commonly abused opioids per beneficiary grew by 20 percent, compared to 3 percent for all drugs.**
 - a. What do you attribute this large increase to?**
 - b. Why was there such a dramatic increase for commonly abused opioids compared to all other drugs?**

Answer to 1a & b: The Part D program has not been immune from the nationwide epidemic caused by the expanded availability of prescription opioid medicines and their non-medical use. We have seen the increasing use of opioid medications throughout the healthcare system, including both the public sector and the private sector. The causes for this dramatic increase are multi-faceted and will require a comprehensive approach, including educating beneficiaries/patients, prescribers, pharmacies, and plan sponsors. In March, Secretary Burwell announced a targeted initiative aimed at reducing prescription opioid and heroin related overdose, death and dependence.

The Secretary’s efforts focus on three priority areas that tackle the opioid crisis, significantly impacting those struggling with substance use disorders and helping save lives:

1. Providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions and address the overprescribing of opioids.
2. Increasing use of naloxone, as well as continuing to support the development and distribution of the lifesaving drug, to help reduce the number of deaths associated with prescription opioid and heroin overdose.
3. Expanding the use of Medication Assisted Treatment (MAT), a comprehensive way to address the needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

Addressing the opioid crisis is a top priority for the department and the Secretary is committed to bipartisan solutions and evidence informed interventions to turn the tide against opioid drug related overdose and misuse.

c. Is CMS concerned by this trend? What is it doing to combat commonly abused opioids from stopping this trend?

Answer: CMS shares the deep concerns raised by this Committee and numerous other stakeholders about the increasing overutilization of opioids. 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 potential opioid or acetaminophen overutilization identified through analyses of prescription drug event (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 26 percent, or 7,500 beneficiaries.¹ 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.²

2. What is CMS doing to prevent diversion of Part D drugs?

Answer: 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.³

Additionally, CMS has begun to implement critical safeguards to make sure that only legitimate prescribers are prescribing covered 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 finalized regulations to use this authority to require most prescribers of drugs paid for by

¹ 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.

² 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.

³ 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.

Part D to enroll in Medicare.⁴⁵ CMS will enforce this requirement starting on June 1, 2016. To allow enough time to enroll all prescribers, CMS is recommending that prescribers of Part D drugs enroll by January 1, 2016. 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.

CMS has also established its authority to remove prescribers from Medicare when they demonstrate abusive prescribing patterns.⁶ 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.

3. Just last year you spoke before the committee on CMS's efforts to tighten up enrollment. My concern is speaking on the issue of provider ID abuse – this illegal distribution of Medicare beneficiary or provider ID numbers is yet another way individuals can abuse the system and the trust of our seniors, costing us millions. Above all else, this is a crime.

a. Can you update us on what specific efforts your office has taken to enforce the law and avert this trend?

Answer: CMS takes seriously its responsibility to protect the identities of both Medicare providers and beneficiaries. When CMS receives a complaint that a beneficiary's identity may have been compromised, a beneficiary's ID number may be added to the Compromised Number Checklist (CNC) database. The CNC is a web-based system that allows direct entry and retrieval of compromised Medicare provider and beneficiary numbers by CMS and CMS contractors. A number may be considered "compromised" if it is stolen or misused. CMS uses the compromised numbers in the CNC database to inform sophisticated analytics through the Fraud Prevention System (FPS). The FPS screens all Medicare Part A and Part B claims prior to payment, running each claim against multiple models that create alerts as they identify claims and other data that suggest aberrant billing. The FPS uses compromised provider numbers as one of the data elements within FPS models. Based on the results, CMS focuses its investigative and administrative resources on those in the highest risk tier for fraud. Following investigations, CMS may take appropriate administrative action against a provider or supplier, including revoking a provider's or supplier's billing privileges, implementing a payment suspension,

⁴ 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.

⁵ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Part-D-Prescriber-Enrollment-About.html>

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

implementing prepayment edits, requesting an overpayment, and/or referring the provider to law enforcement. CMS also provides education to beneficiaries urging them to protect their identities. This education conveys the need for beneficiaries to guard their Medicare number and not share their card, to review their Medicare Summary Notice to ensure that they and Medicare are only being charged for actual services, and to beware of sham marketing activities.

CMS is also taking additional measures to protect beneficiary ID numbers. To protect against identity theft and strengthen the security of millions of beneficiaries' personal information, the President's FY 2016 Budget proposes a \$50 million investment in FY 2016 for a multi-year process of removing social security numbers (SSNs) from beneficiaries' Medicare cards. As you are aware, the Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10) provides resources for the Secretary of Health and Human Services, in consultation with the Commissioner of Social Security, to establish "cost-effective" procedures to remove the SSN from Medicare cards, which will enable CMS to implement a significant GAO recommendation. By April 2019, CMS, other Federal Agencies and private-sector partners will eliminate the use of an individual's SSN as the primary identifier on Medicare cards to improve and better protect private health care and financial information and the payments associated with their Federal health care benefits and services. The President's FY 2016 Budget also includes a proposal to increase penalties for knowingly distributing Medicare, Medicaid, or CHIP beneficiary identification, or billing privileges. This proposal strengthens penalties for individuals other than beneficiaries who illegally distribute Medicare, Medicaid, and CHIP identification numbers, such as providers.

The Honorable Markwayne Mullin

- 1. In 2014, 43 percent of Oklahomans enrolled in Medicare Part D received a commonly abused opioid. According to the supplemental data for a recent OIG report, Medicare Part D alone spent \$24 million on methadone in 2014. Now, this is behind drugs like OxyContin and Percocet, but why do we continue to spend millions of dollars on a medication that by CMS's own recommendation should not be used for the first line of defense for pain? Does CMS have any plans to rein in spending on this drug in particular?**

Answer: CMS shares your concern about prescription opioid misuse and the harm that opioid use disorders can cause. Addressing the opioid crisis is a top priority, and we are committed to evidence-informed interventions to turn the tide against opioid drug-related overdose and misuse. The Secretary's larger three-part initiative to address opioid-drug related overdoses and drug dependence includes providing further training and education resources to assist health professionals in making informed prescribing decisions.

CMS is committed to reducing overutilization while protecting beneficiary access to needed medications. Methadone is not covered for substance abuse treatment under Part D. Methadone may be an appropriate, clinically-indicated medication for some beneficiaries with severe chronic pain. While there are precautions and limitations associated with its use, methadone use for patients with cancer is addressed in the National Comprehensive Cancer Network's Adult Cancer Pain Guidelines, and the Centers for Disease Control and Prevention (CDC) addressed methadone use for chronic pain in the Common Elements in Guidelines for Prescribing Opioid for Chronic Pain. For the current plan year, a methadone product is included on nearly 98 percent of Part D formularies. Quantity-limit restrictions have been imposed on approximately two thirds of all formulary methadone products.

- 2. Several members of the subcommittee brought up the OIG's recommendation to restrict certain beneficiaries who are at risk of abusing opioids to a limited number of pharmacies or prescribers. Are there potential risks when implementing a "lock-in" policy? In my district, we have recently been experiencing flooding and other natural disasters. In this type of situation, do you think such a policy could put patients at risk if they can't fill their prescriptions?**

Answer: We share your concern about protecting beneficiary access to needed medications. The FY 2016 President's Budget proposes to give the Secretary authority to establish a program in Medicare Part D that would require that at-risk beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to the programs many states have implemented in Medicaid. Beneficiaries would still be able to obtain prescriptions for non-controlled substances (e.g., antibiotics) from other pharmacies. Further, the Administration's proposal would require that CMS ensure that beneficiaries retain reasonable access to Medicare services of adequate quality and that any restricted period for a given beneficiary could only last for a reasonable period of time. We look forward to working with you and other stakeholders to improve Part D program integrity while ensuring that beneficiaries maintain access to needed medications.

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Tim Murphy

1. What steps is CMS taking to discover providers who are prescribing children psychotropic medications in cases where it isn't medically necessary?

Answer: CMS has been working over the past two years with its many partners, including the Medicaid Medical Directors Network (MMDN), as well as the Administration for Children and Families (ACF) and the Substance Abuse and Mental Health Services Administration (SAMHSA), to strengthen oversight and monitoring of psychotropic medications use among children. Examples of these efforts include:

- Issuing guidance in a 2013 State Medicaid Director letter⁷ concerning the safe, appropriate and effective use of these medications among children;
- Organizing a two day state summit in August 2012, “*Because Minds Matter: Collaborating to Strengthen Psychotropic Medication Management for Children and Youth in Foster Care,*” that brought together child welfare, mental health and Medicaid leaders from across the country to address the issue;
- Releasing a CMS Informational Bulletin in August 2012 that encouraged states to use “drug utilization review” to address the use of psychotropic medications in vulnerable populations and provided states with additional tools to promote the appropriate use and enhanced oversight of psychotropic medications for children in foster care;⁸
- Promoting patient safety and sharing best practices by surveying states annually and publishing specifics of their programs to manage/monitor the appropriate use of psychotropic drugs in children in addition to their innovative practices on www.medicaid.gov;⁹
- Posting on Medicaid.gov the FY 2013 Medicaid Drug Utilization Review State Comparison/Summary Annual Report, which describes state practice in monitoring use of psychotropic medications among children. The summary shows that: 41 states have programs in place to monitor the use of psychotropic medications in children; 37 states monitor all children (not just those children in foster care); and 41 states have restrictions or special programs in place to monitor/control the use of stimulants.¹⁰

⁷ <http://medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-07-11.pdf>

⁸ <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-08-24-12.pdf>

⁹ <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html>

¹⁰ <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/dur-survey-comparison-report-2013.pdf>

The President's FY 2016 Budget also includes a five-year demonstration, a collaboration between Medicaid and the Administration for Children and Families, beginning in FY 2016 to encourage states to implement evidence-based psychosocial interventions targeting children and youth in the foster care system. This transformational approach will include the development and scaling up of screening, assessment, and evidence-based treatment of trauma and mental health disorders among children and youth in foster care in order to reduce the reliance on psychotropic medications and improve child and family well-being. CMS would invest \$500 million in incentive payments to states that demonstrate measured improvement in outcomes.

2. Does CMS have a report, or is CMS aware of a report, that studies price increases in Medicare Part D and any corresponding decreases in hospitalizations or doctor visits?

Answer: CMS has not produced a report that directly examines the correlation between drug prices and utilization of health care services. However, studies show that increases in patient costs for medication are significantly associated with decreases in treatment adherence,¹¹ and other studies indicate that poor adherence leads to increased use of other health care services, such as hospitalizations.¹²

¹¹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>

¹² http://avalere.com/research/docs/20130612_NACDS_Medication_Adherence.pdf

The Honorable Michael C. Burgess

1. Has the \$18 million paid to Dr. Tariq Mahood for fraudulent EHR system development been recovered?

Answer: As you know, Dr. Mahmood was convicted for health care fraud and sent to prison, and his CFO has been convicted for making a false statement about Medicare Electronic Health Records (EHR) payments and sent to prison.¹³

As part of our oversight of the Electronic Health Record (EHR) Incentive Programs established under the HITECH Act, CMS conducts audits of professionals and hospitals that demonstrate meaningful use of certified EHR technology under Medicare. CMS conducted Medicare EHR Meaningful Use audits for six hospitals associated with Dr. Mahmood, in 2013. Based on the audits, it was determined that all six hospitals did not meet the Meaningful Use criteria. CMS issued demand letters for approximately \$12.1 million. CMS collected \$700,000. Consistent with CMS policy, approximately \$11.4 million of the identified debt was referred to Treasury for collection. An additional approximately \$700,000 has been collected by Treasury through this process. With accrued interest, the current balance at Treasury is about \$12.2 million.

The same six hospitals also received approximately \$5.6 million in incentive payments through the Medicaid EHR Incentive Program. Each state administers its own Medicaid EHR Incentive Program, which includes disbursing and recouping payments as appropriate. According to the state of Texas, they did not recover any EHR funds from these hospitals.

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<http://www.justice.gov/usao-edtx/pr/texas-doctor-sentenced-prison-health-care-fraud-scheme>
<https://www.fbi.gov/dallas/press-releases/2015/former-shelby-county-hospital-cfo-sentenced-in-ehr-incentive-case>

The Honorable Yvette Clarke

1. How does CMS evaluate the effectiveness of sponsor's compliance programs?

- a. Have these efforts changed recently?**
- b. What is CMS doing to follow up with audited plans to ensure that identified deficiencies are being remedied?**

Answer: CMS conducts annual audits of Medicare Part D plan sponsors' compliance programs, as well as other core program functions relating to access to care and medications. The compliance program effectiveness audits evaluate the plan sponsor's infrastructure around monitoring, identifying, and correcting their own operations to ensure compliance with CMS requirements. CMS validates correction of deficiencies identified during an audit before closing the audit. In the event that a Part D Sponsor performs poorly during an audit, CMS can take a variety of compliance and enforcement actions. These range from notices of non-compliance to terminating a Sponsor's Part D contract, with civil money penalties being the most common outcome of poor audit results.

In 2014, based on two recommendations from the OIG, CMS piloted audits of Part D sponsor's programs to address fraud and abuse. These program integrity activities are recorded in the sponsor's 'Compliance Plans'. As a result of those pilots, in 2015 CMS incorporated a review of program integrity activities into the audits of Sponsor Compliance Plans that CMS conducts annually. Now, every CMS Part D sponsor audit includes an analysis of whether their efforts to address fraud and abuse are working effectively. We specifically review cases of reported fraud and look at the sponsors' follow up actions; the results of these reviews provide an indication of the plan sponsor's overall performance and allow us to target guidance and education.

The Honorable David McKinley

- 1. Please provide the year-to-year Medicare Part D error rate for all years for which CMS has error rate data.**

Answer: It is important to note that an error rate is not a “fraud rate” but simply a measurement of payments made that did not meet statutory, regulatory or administrative requirements. CMS began reporting a payment error measure for the Part D Program in 2011. For the Part D program, CMS reports a composite improper payment error rate estimate based on final Part D payments made two years prior (e.g. FY 2011 represents final Part D payments made for 2009 claims). CMS expects to release its FY2015 (based on CY 2013 payments) later this year.

Year	Improper Payment Rate
FY 2011 (Based on Calendar Year 2009 payments final Part D payments)	3.2%
FY 2012 (Based on CY 2010 final Part D payments)	3.1%
FY 2013 (Based on CY 2011 final Part D payments)	3.7%
FY 2014 (Based on CY 2012 final Part D payments)	3.3%