STATEMENT OF

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ON

"COMBATTING THE OPIOID EPIDEMIC:

A REVIEW OF ANTI-ABUSE EFFORTS BY FEDERAL AUTHORITIES AND PRIVATE INSURERS"

BEFORE THE

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Statement of Shantanu Agrawal, M.D.
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Chairman Portman, Ranking Member McCaskill, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS') work to ensure that all Medicare beneficiaries are receiving the medicines they need while also reducing and preventing non-medical prescription drug use. CMS is engaging in a variety of efforts to impact the national opioid misuse epidemic by combatting non-medical prescription opioid use, dependence, and overdose through safe and appropriate opiate utilization while promoting evidence-based practices for acute and chronic pain management.

As you know, non-medical opioid use is deeply affecting communities, families, and individuals across the nation. Deaths from drug overdose have risen steadily over the past two decades and have become a leading cause of injury and death in the United States. Prescription drugs, especially opioids—a class of prescription drugs used to treat both acute and chronic pain that includes hydrocodone, oxycodone, and morphine—have been increasingly implicated in drug overdose deaths over the last decade. From 2000 to 2014, the rate of overdose deaths involving prescription opioids increased by 160 percent.[1] The monetary costs and associated collateral impact to society due to substance use disorder (SUD), including opioid use disorder, are substantial.

Combating non-medical prescription opioid use, opioid use disorders, and overdose continues to be a priority for Department of Health and Human Services (HHS) and the Administration as a whole. As part of that commitment, HHS launched an evidence-based opioid initiative that focuses on three targeted areas: improving opioid prescribing practices, increasing the use of naloxone (a drug that reverses the deadly respiratory effects of opioid drug overdose), and expanding access to medication-assisted treatment to treat opioid use disorder. In July of this year, HHS announced several actions under the initiative that were aimed at combatting the

[1] Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, (Jan. 1, 2016) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm

national opioid epidemic. The actions include expanding access to buprenorphine, a medication to treat opioid use disorder, by allowing practitioners who have had a waiver to prescribe buprenorphine for up to 100 patients for a year or more, to now obtain a waiver to treat up to 275 patients, a proposal to eliminate any potential financial incentive for doctors to prescribe opioids based on patient experience survey questions, and a requirement for Indian Health Service prescribers and pharmacists to check state Prescription Drug Monitoring Program (PDMP) databases before prescribing or dispensing opioids for pain. In addition, the department is launching more than a dozen new scientific studies on opioid misuse and pain treatment and soliciting feedback to improve and expand prescriber education and training programs.

As a part of the HHS opioid initiative, CMS has launched its own multi-pronged initiative that includes improving CMS data systems to better identify the misuse of opioid prescriptions, increasing beneficiaries' access to medication-assisted treatment, and improving provider education. CMS' actions under HHS' opioid initiative reflect our responsibility to protect the health of Medicare and Medicaid beneficiaries by putting in place appropriate safeguards to help prevent non-medical use of opioids while ensuring that beneficiaries can access needed medications and appropriate treatments for SUD.

Preventing Overprescribing and Misuse of Opioids in Medicare Part D

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 more beneficiary satisfaction with their Medicare coverage.[2]

While most beneficiaries and prescribers utilize opioids in ways that are medically appropriate, Part D is not immune from opioid overutilization. Based on input from the HHS Office of Inspector General (OIG), the Government Accountability Office, and stakeholders, over the past several years, CMS has broadened its focus from strengthening beneficiary access to prescribed drugs to include prescription drug misuse, overuse, and fraud. CMS is committed to working

[2] In 2013, more than one million distinct health care providers collectively prescribed $103 billion in prescription drugs under the Part D program. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html

with Medicare Advantage (MA) and Prescription Drug Plan (PDP) sponsors to assure they are in compliance with requirements that protect beneficiaries and can help prevent and address opioid overutilization.

CMS has taken several steps to protect beneficiaries from the harm associated with prescription drug overuse, to prevent and detect fraud related to prescription drugs, and to reduce inappropriate use through better coordinated care.

Initiatives to Strengthen Medicare Part D and Reduce Prescription Opioid Overutilization

CMS has adopted an opioid overutilization policy to reduce inappropriate use. Under this policy, Medicare Part D plan sponsors are expected to use various drug utilization management tools to review prescriptions for opioids and to deter overutilization while maintaining coverage for appropriate drug therapies that are deemed medically necessary and meet safety and efficacy standards. These tools include: improved formulary-level controls at the point of sale (such as safety edits and quantity limits), a retrospective review of beneficiaries' claims history and clinical activity to identify high-risk beneficiaries, case management outreach to high-risk beneficiaries' prescribers and pharmacies, and beneficiary-level point of sale claim edits (such as restricting the prescription opioids and quantities that a sponsor will cover for a specific beneficiary).

To strengthen CMS' monitoring of Part D plan sponsors' compliance with the prescription opioid overutilization policy, CMS implemented the Medicare Part D Overutilization Monitoring System (OMS) in 2013. We believe this Part D overutilization policy has played a key role in reducing prescription opioid overutilization in the program. From 2011 through 2015, the number of potential prescription opioid over-utilizers identified within the OMS decreased by approximately 47 percent, or 13,753 beneficiaries.[3]

Through this system, CMS provides quarterly reports to sponsors on high-risk beneficiaries with potential prescription opioid overutilization identified through analyses of Prescription Drug Event data and on beneficiaries referred by the CMS Center for Program Integrity. Sponsors

[3] There were 29,404 potential opioid overutilizers, (or 0.29 percent of all Part D opioid users) in 2011 and there were 15,651 potential opioid overutilizers, (0.13 percent of all Part D opioid users) in 2015.

then provide CMS with the outcome of their review of each case. If a particular beneficiary's sponsor has concluded that a beneficiary-level point-of-sale edit is appropriate to reduce prescription opioid overutilization, and the beneficiary later changes plans, that sponsor is expected to use CMS' systems to share such a finding with the new sponsor.

Although the overutilization of opioids has decreased in Part D as discussed above, CMS believes Part D sponsors should implement formulary-level cumulative opioid edits at point-of-sale to prospectively prevent opioid overutilization. For Calendar Year 2017, we expect sponsors to implement either a soft edit or a hard edit, or they may use both soft and hard edits, and work towards a hard edit at a minimum in 2018 using reasonable controls to limit false positives. Additionally, the recently-enacted Comprehensive Addiction and Recovery Act gives Part D sponsors the authority to implement programs requiring high-risk Medicare beneficiaries to use only certain prescribers and/or pharmacies to obtain controlled-substance prescriptions.

CMS also has a new tool to take action against problematic prescribers. CMS is requiring nearly all prescribers of Part D drugs to enroll in Medicare in order for the prescriptions to be payable or have a valid opt-out affidavit on file and has established a new revocation authority for abusive prescribing patterns.[4] In 2015, CMS enrolled approximately 75,000 prescribers of Part D drugs. Requiring prescribers to enroll in Medicare helps CMS make sure that Part D drugs are prescribed by qualified individuals and prevents prescriptions ordered by excluded or 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 its outreach strategy to target these provider types. During the enrollment process, these prescribers are subject to the same risk-based screening requirements that have already contributed to the removal of more than 700,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Upon enforcement of the Part D prescriber enrollment requirement, CMS will require Part D plans to use point of sale edits to deny payment for prescriptions from prescribers who do not meet applicable enrollment/opt-out requirements after the affected beneficiaries receive a three-month provisional supply and written notice from their plans. Also, in response to an HHS OIG audit,

[4] https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf and https://www.gpo.gov/fdsys/pkg/FR-2015-05-06/pdf/2015-10545.pdf

CMS implemented edits that reject prescriptions written by providers excluded from the Medicare program.

Additionally, CMS established its authority to revoke a physician's or eligible professional's Medicare billing privileges when he or she demonstrates improper prescribing practices related to Part D drugs.[5] A revocation for improper prescribing practices is based on criteria that demonstrate a pattern or practice of prescribing that is abusive or represents a threat to beneficiary health and safety, or both. There is also authority to revoke if the pattern or practice of prescribing does not comply with Medicare requirements. CMS may also revoke a physician's or eligible professional's Medicare billing privileges if his or her Drug Enforcement Administration Certificate of Registration to prescribe controlled substances is suspended or revoked, or if the applicable licensing or administrative body for any State in which a physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs. These newly-implemented steps enhance CMS' ability to remove problematic prescribers from the Medicare program, which prevents them from treating Medicare beneficiaries and protects both the beneficiaries and the Medicare Trust Funds.

Using Data Analysis to Identify and Combat Fraud, Waste, and Abuse

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

CMS has released an interactive online mapping tool that shows geographic comparisons at the state, county, and ZIP code levels of de-identified Medicare Part D opioid prescription claims within the United States.[6] This new tool allows the user to see both the number and percentage of prescription opioid claims at the local level and better understand how this critical issue

[5] https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf
[6] CMS, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html

impacts communities nationwide.[7] The data set, which is privacy-protected, contains information from over one million distinct providers who collectively prescribed approximately $103 billion in prescription drugs and supplies paid under the Part D program in 2013. The data characterize the individual prescribing patterns of health providers that participate in Medicare Part D for over 3,000 distinct drug products. Of the 1.4 billion total Part D claims in 2013, there were approximately 80.7 million prescription opioid claims for 116 distinct prescription opioid products, contributing to $3.7 billion of the total Part D prescription drug costs.[8] By openly sharing data in a secure, broad, and interactive way, CMS is supporting a better understanding of regional provider prescribing behavior variability and is adding insight to local health care delivery. We believe that this level of transparency will inform community awareness among providers and local public health officials.

CMS also has developed a "Pill Mill Doctor Project" to identify prescribers with high risks of fraud, waste, and abuse in prescribing Schedule II-IV controlled substances. These high-risk prescribers may be engaged in what is commonly referred to as a Pill Mill scheme, which involves prescribing medications without a legitimate medical purpose. As a result of the Pill Mill project, Medicare Part D plan sponsors have taken actions which include provider terminations, desk audits and interviews, as well as referrals to law enforcement.

Improving Transparency in Prescriber Level Data

In August 2016, CMS released an updated public use dataset on the prescription drugs that individual physicians and other health care providers prescribed in 2014 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 $121 billion in prescription drugs under the Part D program in 2014. This dataset 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

[7] The data used in this mapping tool are from 2013 Medicare Part D prescription drug claims and do not contain beneficiary information.
[8] CMS, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-11-03.html
[9] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html

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.

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

CMS also contracts with the National Benefit Integrity (NBI) Medicare Drug Integrity Contractor (MEDIC), which is charged with identifying and investigating potential fraud, waste, and abuse in the Part C and Part D programs on a national level, and developing cases for referral to law enforcement agencies. In September 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in Part D, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacy assessments.[10]

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 include data analysis, impact calculations, clinical review of claims and medical records, and prescription drug invoice reconciliation reviews. As a result of its work, the NBI MEDIC also makes administrative action recommendations to both CMS and the OIG, including revocations from the Medicare program and exclusions from Federally-funded health care programs, respectively. The NBI MEDIC also uses PLATO, a voluntary, web-based system that allows CMS and plan sponsors to more easily share information and help combat fraud, waste, and abuse in the Medicare Advantage and Part D programs. PLATO can also help plan sponsors

[10] CMS uses multiple indicators in the high risk pharmacy assessment, including factors such as average number of prescriptions per beneficiary, average number of prescriptions per prescriber ID, percentage of prescriptions that were for Schedule II drugs, and average amount paid per prescriber ID.

identify suspicious pharmacies and providers and assist in tracking investigations from start to finish.

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

CMS is leading the Government and health care industry in systematically applying advanced predictive analytics to claims on a nationwide scale. Since 2011, CMS has been using its Fraud Prevention System (FPS) to apply predictive analytics to all Medicare fee-for-service (FFS) claims on a streaming, national basis by using predictive algorithms and other sophisticated analytics to identify provider networks, billing patterns, and beneficiary utilization patterns, and detect patterns that represent a high risk of fraudulent activity. The system also incorporates other data sources, including information on compromised Medicare identification and complaints made through 1-800-MEDICARE. CMS is developing ways to leverage data from the Part D program to broaden the scope of FPS models that identify potentially fraudulent, wasteful, or abusive Medicare FFS providers. The information from Part D will not change the focus on the provider, but will be used to develop new risk factors. CMS will develop one or more FPS models that identify providers who are prescribing at rates far above the normal rate or who are prescribing in ways contrary to established medical practice. By incorporating these types of analyses into the FPS, CMS will be better able to investigate and take swift action on bad actors in a coordinated way.

Communicating and Collaborating with Partners

Federal, state, and local law enforcement health care fraud, waste, and abuse activities are being coordinated to a greater extent than ever before. As evidence of this coordination, CMS is 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, waste, and abuse.

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 partners. The HFPP is a voluntary public-private partnership between the federal government, state agencies, law enforcement, private health insurance plans, and healthcare anti-fraud associations. The HFPP aims to foster a proactive approach to detect and prevent healthcare

fraud through data and information sharing. 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. Data collected and shared across payers can assist payers in evaluating trends, recognizing patterns consistent with potential fraud, and potentially uncover schemes or bad actors they could not otherwise identify using only their own information. 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 and studies that assist users in conducting investigations and other compliance program activities.

Most recently, on June 22, 2016, HHS Secretary Sylvia M. Burwell and Attorney General Loretta E. Lynch announced a nationwide sweep led by the Medicare Fraud Strike Force in 36 districts, resulting in charges against 301 individuals, including 61 doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately $900 million in false billings.[11] Since the start of the Medicare Strike Force, it has shut down health care fraud schemes around the country, arrested more than a thousand criminals, and recovered millions of taxpayer dollars.

Preventing Inappropriate Prescribing of Opioids through Provider Education

CMS is actively working to stem the overprescribing of opioids in a number of ways, including providing prescribers with access to the tools and education they need to make informed decisions.

In February 2016, CMS distributed a Drug Diversion Toolkit for prescribers and pharmacists participating in Medicare and Medicaid. The toolkit identifies oral and transdermal opioids, discusses the mechanism of action of opioids, and highlights common reasons for misuse, side effects associated with use, and signs or symptoms that may indicate misuse. It also provides guidance regarding opioid regulatory requirements, including the Controlled Substances Act scheduling, verification of Drug Enforcement Administration registration numbers, the value of

[11] See https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-301-individuals-approximately-900.

participating in State-managed prescription drug monitoring programs, and risk evaluation and mitigation strategies. The booklet also addresses recent extended-release and long-acting opioid labeling revisions and provides guidance regarding prescriber tactics that may reduce the likelihood that prescription opioids may be diverted for a nonmedical use. Just this August, the U.S. Surgeon General Dr. Vivek H. Murthy sent a letter to 2.3 million American health professionals, asking them to lead a national movement to turn the tide on the national opioid epidemic. The letter also contained a pocket card[12] outlining the Center for Disease Control and Prevention's (CDC's) opioid prescribing guidelines.

Due to concern expressed by many clinicians, as a part of the Calendar Year 2017 Hospital Outpatient Prospective Payment System proposed rule, CMS proposed to eliminate the link between pain-management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and payments under the Hospital Value-Based Purchasing program, thereby removing the perception that there are financial incentives to prescribe opioids. Under the proposal, CMS would continue to survey patients about their in-hospital pain management using the HCAHPS survey pain questions, but the answers to these questions would not be used to determine the level of payment a hospital receives.

Ensuring Adequate Access to Treatment in Medicare Part D

Despite efforts such as those outlined above, opioid use disorders continue to be a significant public health concern. In October 2015, the President issued a memorandum directing Federal Departments and Agencies to identify barriers to medication-assisted treatment (MAT) for opioid use disorders and develop action plans to address these barriers. In response, CMS is using available vehicles, such as the Contract Year 2017 MA Capitation Rates and MA and Part D Payment Policies and Final Call Letter, to inform physicians, MA organizations, and Part D sponsors about MAT coverage, including clarifying that MA plans have the same obligation to cover SUD treatment as is available under Original Medicare and that Part D plans must ensure access to MAT that is covered under Medicare Part D.

[12] http://turnthetiderx.org/treatment/#

It is critical that Medicare beneficiaries who are in need of MAT have appropriate access to the required medications in Part D.[13] CMS has informed Part D sponsors that Part D formulary and plan benefit designs that hinder access to MAT, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.

Preventing Overprescribing and Misuse of Opioids in Medicaid While Ensuring Access to Needed Treatments

An estimated six percent of adolescent and 12 percent of adult Medicaid beneficiaries have SUD.[14] Research shows the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients and are at three-to-six times the risk of overdose by prescription opioids.[15,16] Given the high impact on the program, Medicaid plays an important role in curbing the epidemic of deaths and injuries from opioid medications. CMS is committed to helping states effectively serve these individuals and introduce benefit, practice, and payment reforms through program support technical assistance and coverage initiatives.

Initiatives to Ensure State Medicaid Programs Ensure Appropriate Opioid Utilization

Earlier this year, CMS released an Informational Bulletin highlighting emerging Medicaid strategies for preventing opioid–related harms.[17] The effective approaches outlined in the bulletin promote expanded coverage and access to opioid use disorder treatment and effective pharmacy benefit management strategies to prevent and combat prescription drug misuse involving opioid pain medications. CMS hosted several webinars discussing how states can review their preferred drug lists and other pharmacy benefit management techniques to ensure appropriate utilization of opioid pain medications, especially methadone prescribed for pain

[13] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf
[14] Substance Abuse and Mental Health Services Administration. Behavioral Health Treatment Needs Assessment Toolkit for States [online]. 2013. Retrieved from: http://store.samhsa.gov/shin/content/SMA13-4757/SMA13-4757.pdf, p.10.
[15] Sharp MJ, Melnik TA. Poisoning deaths involving opioid analgesics-New York State, 2003-2012. Morb Mortal Wkly Rep 2015; 64:377-380.
[16] Coolen P, Lima A, Savel J, et al. Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004-2007. Morb Mortal Wkly Rep. 2009; 58:1171-1175.
[17] https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf

relief, given the disproportionate share of overdose deaths associated with methadone when used as a pain reliever nationally and in the Medicaid population.[18]

Medicaid programs can encourage the use of safer, effective alternatives to opioid pain medications—in particular, alternatives to methadone prescribed for pain relief—by working collaboratively with other state agencies to educate Medicaid providers about proper opioid prescribing and dispensing practices. Medicaid programs can consider pharmacy benefit management strategies such as reassessing preferred drug list (PDL) placement, introducing clinical criteria, prior authorization, step therapy, quantity limits, and implementing drug utilization review processes. These strategies should be revisited continually as the nature of the opioid epidemic evolves and new information emerges. States can also work to increase access to (and use of) PDMPs to monitor opioid prescribing. Importantly, as part of a comprehensive strategy to address opioid use disorder and reduce opioid-related overdose deaths, states can consider strategies to increase the provision of naloxone and medically necessary SUD treatment services.

CMS supports states' important efforts to improve care for individuals with SUD, including individuals with opioid use disorder. Over the past several years, CMS has provided states with information and program support to enhance coverage for behavioral health conditions. In July 2014, CMS partnered with CDC, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration (SAMHSA) to release a joint Informational Bulletin describing best practices, state-based initiatives, and useful resources to help ensure proper delivery of MAT for SUD.[19] In January 2015, CMS and SAMHSA jointly released an Informational Bulletin promoting behavioral health coverage opportunities for youths with SUD.[20]

In 2014, CMS launched the Innovation Accelerator Program (IAP) with the goal of improving health and health care for Medicaid beneficiaries by supporting states' ongoing payment and service delivery reform efforts. CMS created the IAP in response to the National Governors

[18] https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/iap-downloads/201512tlo9_combatopioidcrisis.pdf; https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/iap-downloads/06102016-iap-sud-tlo14.pdf.
[19] http://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf
[20] http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf

Association Health Care Sustainability Task Force, which focused on system transformation and state innovations that rely on the redesign of health care delivery and payment systems. Through the IAP, states can receive targeted program support designed around their ongoing delivery and payment system innovations efforts. Based on our work with states and stakeholders, CMS identified SUD as the first area of focus.[21]

The IAP provides states with expert resources, coaching opportunities, and hands-on technical support to accelerate policy, program and payment reforms appropriate for a robust SUD system. CMS has been working intensively with six states to make meaningful changes to their Medicaid program for beneficiaries with SUD and have committed staff and program support resources to assist these and other states design and implement changes over the next three years.

In July 2015, CMS issued a State Medicaid Director letter that describes a new section 1115 demonstration opportunity designed to support states to provide more effective care to individuals with SUD.[22] This initiative identifies a number of important benefit, practice, and system reforms that foster improved care and health outcomes for individuals with SUD, including targeted strategies to address illicit opioid and prescription drug misuse. One important reform is the ability through demonstration or managed-care authority to provide coverage for short-term inpatient and residential SUD services not otherwise covered by Medicaid. This new opportunity is geared to support states engaged in broad and deep SUD system transformation efforts, enabling them to provide a full continuum of care by introducing service, payment, and delivery-system reforms to improve care for individuals with SUD.

In August 2015, CMS approved a research and demonstration project for California under section 1115 of the Social Security Act that reflects the expectations that we set forth in the guidance regarding this opportunity, including: (1) an evidence-based benefit design covering the full continuum of care; (2) a requirement for providers to meet industry standards of care; (3) a strategy to coordinate and integrate across systems of care; (4) a requirement for reporting specific quality measures; and (5) a requirement to implement the necessary program integrity

[21] https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/reducing-substance-use-disorders/reducing-substance-use-disorders.html
[22] https://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf

safeguards as well as a benefit-management strategy. CMS is providing ongoing strategic-design support to a number of states to assist with their section-1115 SUD proposals.

In September 2015, CMS hosted a national Medicaid webinar to discuss issues concerning methadone utilization and encourage states to utilize their resources, such as Drug Utilization Review Boards and Pharmacy and Therapeutics Committees, to review their preferred drug lists to ensure appropriate utilization of methadone used for pain management.

CMS also has collaborated with the American Drug Utilization Review Society to host a teleconference where up to four states' Medicaid drug utilization review managers present their recent strategic efforts to combat the opioid epidemic to the remaining 46 states and Washington, D.C., to be completed by October 2016.

Conclusion

CMS is dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically-appropriate care. CMS is committed to working with MA and PDP sponsors to assure they are in compliance with requirements that protect beneficiaries and can prevent and address opioid overutilization. CMS also will continue to educate prescribers and state Medicaid agencies on proper prescribing practices and other effective practices to identify and treat mental health and SUD. As part of these efforts, CMS has broadened its focus from ensuring beneficiaries have access to prescribed drugs to also ensuring that plan sponsors implement effective safeguards and provide coverage for medically necessary drug therapies that meet standards for safety and efficacy. Although there is still work that needs to be done, CMS is confident that our efforts will maintain beneficiary access to appropriate medications for pain control while decreasing inappropriate opioid prescribing patterns and reducing the rate of opioid use disorders and overdoses. We look forward to working with this Committee and the Congress on these efforts.