CENTERS FOR
MEDICARE & MEDICAID SERVICES (CMS)
OPIOID MISUSE STRATEGY 2016

EXECUTIVE SUMMARY

Many Medicare and Medicaid beneficiaries and their families have experienced opioid use disorder, commonly referred to as addiction. Given the growing body of evidence on the risks of misuse, highlighted by the recently published guidance from the Centers for Disease Control (CDC), and the Administration's commitment to combatting the opioid epidemic, CMS is outlining our agency's strategy and the array of actions underway to address the national opioid misuse epidemic. Strategies outlined in this paper do not include CMS's vision for the treatment of cancer and hospice patients. Treatment of patients in these situations requires careful medical supervision based on therapeutic goals, ethical considerations, and the balance of risks and benefits of opioid therapy.

Opioid drugs can treat both acute and chronic pain. While these types of drugs, including fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, and oxymorphone, can have benefits for many patients with serious pain-related conditions, these drugs cause serious and substantial harm when used improperly. Even when used as directed, they contribute to overdose or lead to development of substance use disorder in some individuals. The high potential for misuse of opioids have led to alarming trends across the United States, including record numbers of people developing opioid use disorders, overdosing on opioids, and dying from overdoses. Opioid misuse places Americans at an elevated risk for heroin use, overdose, and death. Use by injection places them at risk for exposure to blood borne diseases, including HIV and Hepatitis C. In 2009, deaths from drug overdose, including heroin and prescription opioids, surpassed motor vehicle crashes as the leading cause of injury death in the U.S., and numbers have continued to rise. In 2015, opioids, including prescription opioids and illicit opioids such as heroin, killed more than 33,000 people – the highest number in recorded history.[1] Additionally, 2015 statistics for methadone related deaths shows an increase in the 65 year old population.[2]

The U.S. Surgeon General recently alerted 2.3 million health care practitioners to the scope of the problem and urged them to visit TurnTheTideRx.org to join the movement to address the opioid epidemic. The message to providers pointed out that the number of opioid prescriptions written each year has quadrupled

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[1] The White House. (2016). *Continued Rise in Opioid Overdose Deaths in 2015 Shows Urgent Need for Treatment* [Press release]. Retreived from https://www.whitehouse.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment

[2] https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm?s_cid=mm655051e1_w

in less than two decades, yet pain reported by Americans has not changed during that time period. Now, after two decades of increasing prescriptions, nearly two million people suffer from prescription opioid use disorder. The Medicare population has among the highest and fastest-growing rates of diagnosed opioid use disorder, currently at more than 6 of every 1,000 beneficiaries.[3] For Medicaid beneficiaries, the prevalence of diagnosed opioid use disorder is even higher, at 8.7 per 1,000, a figure estimated to be over 10 times higher than in populations who receive coverage under private insurance companies.[4] Because there is no systematic policy of screening for opioid use disorder and patients are unlikely to volunteer that they are misusing their medication or are using opioids like heroin because of discrimination and stigma, these rates are likely underestimates.

CMS has made attacking this devastating epidemic a top priority and is providing help and resources to clinicians, beneficiaries, and families. This is an ongoing CMS strategy, as part of the HHS Opioid Initiative launched in March 2015,[5] to combat misuse and promote programs that support treatment and recovery support services. The CMS effort includes four priority areas:

1. *Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion;*

2. *Expand naloxone use, distribution, and access, when clinically appropriate;*

3. *Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and*

4. *Increase the use of evidence-based practices for acute and chronic pain management.*

The success of this strategy depends upon CMS effectively communicating to everyone who interacts with Medicare and Medicaid. We are working with people with Medicare and Medicaid benefits, their physicians, health insurance plans, and states to improve how opioids are prescribed by physicians and used by patients, how opioid use disorder is identified, how patients are connected to treatment, and how alternative approaches to pain management could be promoted.

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[3] Lembke A, Chen J. Use of Opioid Agonist Therapy for Medicare Patients in 2013. JAMA Psychiatry. 2016; 73(9): 990-992.

[4] Ghate SR, Haroutiunian S, Winslow R, McAdam-Marx C. Cost and comorbidities associated with opioid abuse in managed care and Medicaid patients in the United States: a comparison of two recently published studies. Journal of Pain & Palliative Care Pharmacotherapy. 2010 Sep; 24(3): 251-8.

[5] HHS.gov News. (2016). *HHS takes strong steps to address opioid-drug related overdose, death and dependence*, Retrieved from, http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html.

INTRODUCTION

CMS Mission

The mission of CMS's Opioid Misuse Strategy is to impact the national opioid misuse epidemic by combating non-medical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.

Background

When people with opioid use disorder share their experiences, their stories often have an innocuous beginning: some needed a routine surgical procedure; others experienced a fall or were injured in a car crash. In order to manage pain during the healing process, their doctors prescribed a course of opioid medication, a practice that has become common over the past two decades. Providers were trained to think of pain as the "fifth vital sign" and were encouraged to use aggressive treatments to limit patients' pain. As stated by Surgeon General Vivek Murthy, "Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain," he writes. "The results have been devastating."[6] In his letter to health care practitioners, the Surgeon General summarizes, "We arrived at this place on a path paved with good intentions."[7]   Health care providers wanted to control their patients' pain, and opioids seemed to be a low-risk and highly effective means to do so.

Prescription Opioid Medications Commonly Linked to Substance Use Disorder:

- *Fentanyl*
- *Hydrocodone*
- *Oxycodone*
- *Oxymorphone*
- *Hydromorphone*
- *Meperidine*

The generic names for these medications are displayed. Each is also known by trade names unique to the pharmaceutical companies that manufacture them.

Source: https://www.drugabuse.gov/drugs-abuse/prescription-drugs-cold-medicines

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[6] https://www.naemt.org/advocacy/news/2016/08/27/surgeon-general-pens-open-letter-on-opioid-crisis
[7] Turn The Ride Rx: The Surgeon General's Call to End the Opioid Crisis, http://turnthetiderx.org/

While they have benefits, opioid medications, including fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, and oxymorphone, are addictive and can be harmful. Opioids are potent pain relievers that can cause potentially fatal central nervous system and respiratory depression, and their high potential for misuse[8] has led to alarming trends of opioid misuse, use disorder, and overdose across the United States. Those who engage in non-medical opioid use are at an elevated risk for future heroin use,[9] exposure to diseases like HIV and Hepatitis C through injection drug use,[10] unintentional overdose, and death.[11] These patterns are observed across all socioeconomic groups and geographic areas.

Note: Strategies outlined in this paper do not include CMS's vision for the treatment of cancer and hospice patients. Treatment of patients in these situations requires medical supervision based on therapeutic goals, ethical considerations, and the balance of risks and benefits of opioid therapy.

From 2000 to 2014, nearly half a million people died in the United States from drug overdoses, with the rate of prescription opioid overdoses quadrupling since 1999.[12] In 2009, deaths from drug overdose – including those related to heroin – surpassed motor vehicle crashes as the leading cause of injury death in the United States. In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes.[13] The monetary costs and associated collateral impact to society due to substance use disorder (SUD), including opioid use disorder, are substantial. [14,15] When other adverse health consequences are considered, the impact of the opioid epidemic is even more far-reaching. According to the U.S. Department of Health & Human Services (HHS),[16] rates of emergency department (ED) utilization due to opioid use or misuse increased 114 percent between 2004 and 2011. Between 24 and 27 percent of drug-related ED visits become hospital admissions, which further increases the cost of care.[17] Opioid misuse is also associated with an increased risk of infectious disease transmission (most notably HIV and Hepatitis C), falls, and bone fractures. In addition to the devastating impact on patient health, there is also a powerful impact on

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[8] Opioid Medications. Retrieved from: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm

[9] Prescription opioid use is a risk factor for heroin use. Retrieved from: https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use

[10] HIV, AIDS, and Viral Hepatitis. SAMHSA. Retrieved from: https://www.samhsa.gov/hiv-aids-viral-hepatitis

[11] Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D. M.P.H., and Grant T. Baldwin, Ph.D., M.P.H. N Engl J Med 2016; 374:154-163. Retrieved from: http://www.nejm.org/doi/full/10.1056/NEJMra1508490#t=article.

[12] https://www.cdc.gov/media/releases/2015/p1218-drug-overdose.html

[13] CDC Morbidity and Mortality Weekly Report, January 1, 2016, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[14] https://www.medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf

[15] Substance Abuse and Mental Health Services Administration. National Expenditures for Mental Health Services and Substance Abuse Treatment, 1986–2009. HHS Publication No. SMA-13-4740. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[16] ASPE Issue Brief, March 26, 2015, https://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths.

[17] SAMHSA DAWN Report, February 22, 2013, http://www.samhsa.gov/data/sites/default/files/DAWN127/DAWN127/sr127-DAWN-highlights.htm.

the social and emotional well-being of individuals with an opioid use disorder, their caregivers, and family members.

CMS PRIORITY AREAS AND VISION FOR THE FUTURE

HHS has articulated two key goals of its efforts to combat opioid misuse: (1) decreasing opioid overdoses and overall overdose mortality, and (2) decreasing the prevalence of opioid use disorder. To align with and achieve these goals, CMS convened a cross-agency working group to develop CMS's opioid strategy. CMS sought representatives from every component of the agency to ensure a broad range of expertise and perspectives. This diverse group assessed the benefits, limitations, and improvement opportunities within CMS's current policies and programs. The group then defined desired outcomes from the perspective of CMS's unique role as a leading payer of health care and identified key actions to achieve those outcomes.

HHS Priority Areas
Address opioid prescribing practices to reduce opioid use disorders and overdose
Expand use and distribution of naloxone
Expand use of medication-assisted treatment (MAT) to reduce opioid disorders and overdose

Aligning with the Secretary's initiative, the working group defined four priority areas to drive CMS's strategic and operational planning:

1. **Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.**

   Limitations in guidelines, training, and tools for appropriate opioid prescribing were contributing factors to the epidemic and must be addressed in order to reduce the risk and incidence of opioid use disorders and overdoses. Data that can help identify drug seeking behaviors, inappropriate prescribing, and drug diversion must also be utilized to minimize risk.

2. **Expand naloxone use, distribution, and access, when clinically appropriate.**

   Naloxone is an emergency rescue drug used to reverse opioid overdoses. If it is more widely available, it can be used in critical moments to save the lives of overdose victims in the short term, affording opportunity for long term treatment and recovery.

3. **Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment (MAT).**

MAT is the most effective known intervention for long term recovery from opioid use disorder, yet it is not the most widely used treatment. Increased screening and diagnosis of opioid use disorder and improved access to and use of MAT are critical to making a positive impact on the opioid epidemic.

4. Increase the use of evidence-based practices for acute and chronic pain management.

Evidence-based practice is an integral part of all of CMS's priority areas, but expanding the evidence base of effective and alternative treatments for acute and chronic pain is especially vital. CMS stated this priority area specifically to emphasize the need to address the limitations of research that is currently available.

For each priority area, the working group identified specific objectives along with current projects and additional priority actions needed to achieve the desired outcomes. The results of this cross-agency collaborative effort are detailed below. Additional information regarding CMS's current projects is provided in the Appendix.

PRIORITY AREA 1

Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.

Opioids are the most commonly prescribed class of medications in the United States.[18] Although about two-thirds of opioid prescriptions are for treatment lasting less than a month, the remainder are for longer term therapy.[19,20] The frequent and long term use of these medications constitute a major part of the opioid epidemic in two major ways: First, providers often lack training in the appropriate prescription of opioid medications.[21] In fact, rates of accidental prescription opioid overdose nearly quadrupled from 2000 to 2010.[22] Second, prescription opioids often are diverted, which contributes to the problem of opioid misuse.[23] This process is abetted by individuals who engage in provider and pharmacy shopping for the purpose of obtaining large quantities of opioids for resale on the black market and, in some cases, providers who knowingly write opioid prescriptions for such patients without adequate medical justification or oversight.

Current CMS activities and future priority actions are intended to address root causes of each of these

OBJECTIVES

1-1: *Promote use of evidence-based opioid prescribing guidelines to the health care community*

1-2: *Develop additional tools for states, beneficiaries, providers, and other stakeholders to use opioids appropriately*

1-3: *Provide stakeholders with accurate timely, and actionable information on how to use clinical and pharmaceutical data to decrease overdoses*

1-4: *Provide stakeholders with accurate and timely information and tools to decrease the occurrence of drug diversion*

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[18] Centers for Disease Control and Prevention. FastStats. Therapeutic drug use. 2014, http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm.

[19] Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SR. Characteristics of opioid prescriptions in 2009. JAMA 2011; 305: 1299-301.

[20] Boudreau D, Von Korff M, Rutter CM, et al. Trends in long-term opioid therapy for chronic non-cancer pain. Pharmacoepidemiol Drug Saf 2009; 18: 1166-75.

[21] Keller CE, Ashrafioun L, Neumann AM, Van Klein J, Fox CH, Blondell RD. Practices, perceptions, and concerns of primary care physicians about opioid dependence associated with the treatment of chronic pain. Subst Abus 2012; 33: 103-13.

[22] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality: Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings (NSDUH Series H-46, HHS Publication No (SMA) 13-4795). Rockville, Md, 2013

[23] Volkow, ND, McLellan, AT. Opioid abuse in chronic pain – Misconceptions and mitigation strategies. NEJM 374:13 1253 – 1263.

problem areas. Generally, these include: 1) educating and providing feedback to physicians and patients concerning effective pain management and appropriate opioid prescribing; 2) modifying formulary policies and drug plan management to reinforce prescribing guidelines and to minimize use of opioid medications associated with increased overdose risk; and 3) improving and coordinating monitoring and program integrity actions across Medicaid and Medicare to identify and appropriately sanction overprescribers and provide help to overutilizers.

Desired Outcomes

CMS will explore incentivizing prescribing behavior that is consistent with evidence-based guidelines and which actively addresses drug diversion. In partnership with other Federal agencies, such as the CDC and the Agency for Healthcare Research and Quality (AHRQ), CMS will continue to promote evidence-based educational information and tools to prescribers and beneficiaries. The information and tools will be sensitive to the needs of multiple populations, such as racial and ethnic minorities, women, or vulnerable patients at social risk.

Appropriate prescribing and drug diversion will also be addressed by providing appropriate access to current data on beneficiaries and clinicians (inclusive of Medicaid, Medicare Parts C & D, and Marketplace). Clinicians would have access to their own prescribing information and practice patterns compared to their specialty and geographic peers to assess their performance relative to other clinicians. Information on co-prescribing practices, such as the potentially dangerous concurrent prescribing of benzodiazepines and opioids, would be included. Clinicians would also use prescription drug monitoring programs (PDMPs), where available, as a tool to review each patient's prescription history, allowing them to incorporate key information into each patient's individualized pain management plan. Using the same PDMP data, pharmacies would be able to identify prescribers with potentially illicit prescribing practices or beneficiaries who may be overusing opioids. This information can be referred to health plans to investigate provider and beneficiary behaviors that may be indicative of fraud or abuse.

Current CMS Projects

Objective 1-1:
Promote use of evidence-based opioid prescribing guidelines to the health care community

CMS provides information to the health care community that promotes evidence-based guidelines in order to increase the number of providers using them. Quality Improvement Organizations' (QIOs) Learning and Action Networks, for example, promote and circulate to recruited providers and practitioners evidence-based best practices for the management of high-risk medications such as opioids. The QIO Program also began a national campaign focused on gathering and spreading best practices from the perspective of beneficiaries, patients, advocates, and caregivers. Through the CMS Transforming Clinical Practice

Initiative (TCPI)[24], CMS also provides outreach and promotes evidence-based practices (such as the 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain*[25]) to participating clinicians. Where sufficient evidence was not available, the CDC guidelines are based on expert opinion, as noted by the CDC.

> ### Objective 1-2:
> *Develop additional tools for states, beneficiaries, providers, and other stakeholders to use opioids appropriately*

CMS plays a key role in developing and disseminating educational materials and guidance for stakeholders. For beneficiaries, the agency provides informational inserts with Explanations of Benefits (EOBs) for Part C & D beneficiaries that address misuse and abuse and proper disposal of prescription drugs.

The agency has also led educational efforts for state Medicaid agencies: CMS released an informational bulletin to state Medicaid agencies on pharmacy benefit management strategies to prevent opioid-related harms. CMS also conducts stakeholder engagement activities on additional pharmacy drug utilization strategies and actions Medicaid programs can take to address opioid prescription misuse and abuse.[26]
For prescribers and pharmacists, CMS developed publications to provide essential guidance: *Prescription Opioids: An Overview for Prescribers and Pharmacists*,[27] *Buprenorphine: A Primer for Prescribers and Pharmacists*,[28] and *What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?*[29]

The White House Social and Behavioral Sciences Team (SBST) also facilitated collaborative research with CMS to study the effects of an informative letter to providers on reducing inappropriate prescribing of drugs with a high likelihood of abuse to beneficiaries enrolled in Medicare Part D. Initial feedback on the current study suggests that the letter, focused on an atypical antipsychotic, was effective in decreasing inappropriate prescribing practices. Language that is identified as effective in the current letter may be adapted to future messaging campaigns about opioids.[30]

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[24] Transforming Clinical Practice Initiative (2016). Retrieved from: https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/

[25] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

[26] January 28, 2016 Bulletin: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction, http://medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.

[27] Prescription Opioids: An Overview for Prescribers and Pharmacists (2016). Retrieved from: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/drugdiversion-opioids-booklet.pdf

[28] Buprenorphine: A Primer for Prescribers and Pharmacists (2015). Retrieved from: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/drugdiversion-buprenorphine-booklet.pdf

[29] What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs (2014). Retrieved from: https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/provider-education-toolkits/downloads/prescriber-role-drugdiversion.pdf

[30] Sacarny, A., Le, J., Tetkoski, F., Yokum, D., Agrawal, S. (2016). Effect of Review Notification Letters on the Volume and Guideline-Conformity of Quetiapine Prescribing: A Randomized Clinical Trial. Unpublished study.

> ### Objective 1-3:
> *Provide stakeholders with accurate, timely, and actionable information on how to use clinical and pharmaceutical data to decrease overdoses*

CMS is also committed to providing information and tools to identify and address inappropriate provider prescribing and beneficiary utilization of opioids. By January 1, 2019, CMS will enforce requirements that the vast majority of prescribers who write prescriptions for Medicare Part D beneficiaries must be enrolled in Medicare or be validly opted out in order for the beneficiaries' drugs to be covered. This enrollment requirement will allow Medicare to have better oversight of prescriber behaviors and revoke enrollment of providers proven to demonstrate inappropriate behaviors.

The Medicare Part D Opioid Prescriber Summary File, which will build on this Medicare prescriber enrollment requirement, presents information on the individual opioid prescribing rates (for new prescriptions as well as refills) of prescribers of Part D drugs. This public data set will provide information on the number and percentage of prescription claims for opioid drugs, as well as each provider's name, specialty, state, and zip code. The file can be used to explore the impact of prescribing practices of controlled substances on vulnerable populations.

The work of CMS's National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) is another tool for identifying inappropriate activities involving controlled substances, including opioids. Among other responsibilities, the NBI MEDIC performs proactive data analyses focused on identifying trends, anomalies, and questionable physician and pharmacy practices. Examples of these proactive data analysis projects include: (1) the Quarterly Pharmacy Risk Assessment, which categorizes pharmacies as high, medium, or low risk; (2) the Prescriber Risk Assessment, which provides a peer comparison of Schedule II controlled substance prescribing practices; (3) the "Trio Prescriber" initiative, which identifies providers who prescribe beneficiaries the dangerous combination of an opioid, benzodiazepine, and the muscle relaxant carisoprodol; and (4) identification of improper payments for drugs inappropriately covered under the Part D program without a prior authorization; for example, Transmucosal Immediate Release Fentanyl (TIRF). The results of these projects are provided to plan sponsors so that additional actions can be taken, including initiating new investigations, conducting audits, or terminating physicians and pharmacies from their network.

CMS's collaborative research with the White House SBST, introduced in the previous Objective, also aims to address inappropriate prescribing practices.

Finally, through CMS's Overutilization Monitoring System (OMS), Part D sponsors are provided quarterly reports on high risk beneficiaries and provide CMS with the outcome of their review of each case. Since 2011, the OMS helped sponsors reduce the number of potential opioid overutilizers by 47 percent among Medicare Part D beneficiaries. CMS also facilitates the sharing of de-identified data among health plans in an effort to identify fraud schemes and potential inappropriate prescribers. Part D plans can use CMS's

information sharing platform to identify leads for their own internal investigations and can report actions they have taken. For example, if one plan sponsor suspects a provider of inappropriate prescribing behavior, it can alert other plans to that possibility so that those plans can conduct their own evaluations and take coordinated action if warranted.

> ### Objective 1-4:
> *Provide stakeholders with accurate and timely information and tools to decrease the occurrence of drug diversion*

The analytic work of the NBI MEDIC also contributes to CMS's objective of decreasing the rates of drug diversion by identifying outliers and making referrals for investigation. In addition to the Quarterly Pharmacy Risk Assessment, Prescriber Risk Assessment, and identification of improper payments for drugs inappropriately covered without a prior authorization, the NBI MEDIC's Pill Mill Doctor Project identifies prescribers with a high risk of fraud, waste, and abuse in prescribing Schedules II-IV controlled substances, allowing CMS to educate plan sponsors and make referrals to law enforcement when appropriate.

Additionally, state Medicaid fee-for-service agencies and Managed Care Organizations are required to report annually to CMS their drug utilization review (DUR) program activities and processes to ensure appropriate drug utilization, including appropriate opioid utilization, which could include placing quantity limits on opioids, monitoring the concurrent use of opioids and benzodiazepines, employing PDMP requirements, and using tools that measure morphine milligram equivalents (MME) per day. CMS also inquires about the use of patient review and restriction programs (e.g., so-called lock-in programs[31]) to address potential prescription opioid misuse or abuse. CMS compiles this collected information within the CMS Medicaid Drug Utilization Review State Comparison/Summary Report, which is posted annually on the Medicaid.gov website.[32]

Priority Actions

CMS will promote additional educational tools for patients so that expectations for pain treatment are consistent with evidence-based guidelines. CMS will also continue to promote educational tools for clinicians so that opioids are prescribed and managed appropriately and only when necessary.

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[31] Authorized by Congress under the Comprehensive Addiction and Recovery Act (CARA) of 2016 limiting a beneficiary's access to coverage for frequently abused drugs under specific circumstances. Exceptions to certain state plan requirements, 42 CFR §431.54 (2016). Retrieved from http://www.ecfr.gov/cgi-bin/text-idx?SID=2037fe99916e45c1c8c8324784bb32a2&mc=true&node=se42.4.431_154&rgn=div8

[32] Medicaid - Drug Utilization Review (DUR) Program, https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/index.html.

CMS will continue to promote information sharing and data transparency efforts aimed at curbing inappropriate prescribing behavior, such as increasing the use and functionality of PDMP records. States can use the data to compare each clinician's prescribing behavior to those of peers at the county, state, or specialty level, and the agency supports sharing such information publicly or directly with the individual prescriber or entity, as appropriate based on data specificity. For example, in some states, prescribers have been sent "report cards" with this comparative information. CMS will continue to promote improvements to state PDMPs through informational bulletins to support efforts to develop seamless interfaces with clinician EHR systems; data integration into regional health information system resources; and interoperability between states.

Additionally, CMS is addressing the issue of drug diversion by identifying consistent thresholds across programs to flag providers as "high prescribers" and patients as "high utilizers" who may require additional scrutiny. The NBI MEDIC assists law enforcement and Part D plans in addressing drug diversion through data analysis and the Pill Mill Doctor Project results. For example, in response to requests for information from law enforcement, the NBI MEDIC conducts invoice reconciliations, impact calculations, and reviews of medical records.

Leveraging new authority in the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA), CMS will continue its efforts to link fee-for-service payments to quality and value, and encourage improved prescribing practices. For example, CMS will promote methods to encourage prescribers to consult a PDMP prior to issuing a Schedule II prescription for a course lasting longer than three days, with states tailoring these methods to their existing policies. CMS also plans further development of a new measure in the Hospital Outpatient Prospective Payment System, which will report the rates and sources of concurrent prescriptions for opioids and benzodiazepines, a drug combination that places patients at high risk for respiratory depression.

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 1*, metrics are currently under consideration in the following areas:

For prescribers enrolled in Medicare who prescribe Part D drugs:
- Percentage of opioid prescriptions:
  - Exceeding CDC guideline of 90 morphine milligram equivalents (MME) per day
  - Exceeding 7 days of treatment
  - Written for extended release/long-acting opioids
- Percentage with beneficiaries receiving an opioid prescription without other supportive therapies/treatments

PRIORITY AREA 2

Expand naloxone use, distribution, and access, when clinically appropriate.

Respiratory depression is a dangerous side effect of all opioids and is the cause of the majority of deaths due to opioid overdose. When victims of an overdose are discovered in an unresponsive state, family and friends are powerless to reverse the effects of the opioid without medical intervention. Naloxone is a life-saving overdose reversal drug that can be used to reverse the respiratory depression of an opioid overdose victim, but its availability during the critical moments of an overdose is limited.

Desired Outcomes

Naloxone would be widely available to the general public. The rescue drug would also be distributed to high risk groups, such as long-term and high-dose prescription opioid users, intravenous opioid drug users, and sex workers. Naloxone would be in the hands of all first responders, including police officers, fire fighters, and other municipal staff. Members of the general public would be aware of the signs and appearance of a person who is experiencing an overdose and would be educated in the immediate administration of naloxone and the need to summon emergency medical services even after revival.

OBJECTIVES

2-1: *Increase the use and distribution of naloxone for Medicare beneficiaries*

2-2: *Increase the use and distribution of naloxone for Medicaid beneficiaries*

2-3: *Promote naloxone access and coverage among private payers*

Current CMS Projects

Objective 2-1:
Increase the use and distribution of naloxone for Medicare beneficiaries

CMS is promoting improved access to naloxone by requiring that the antidote appear on all Medicare Part D formularies. CMS is also helping to expand community-based naloxone distribution programs and ensure use of naloxone through trainings in overdose prevention and response.

Objective 2-2:
Increase the use and distribution of naloxone for Medicaid beneficiaries

CMS is also assisting states to develop Medicaid strategies that will further expand and improve access to naloxone. A recent CMS informational bulletin encouraged states to add naloxone to their preferred drug lists, which identify medications selected for their clinical efficacy and significance, cost effectiveness, and safety for Medicaid beneficiaries.[33] The agency is also working with states to expand community-based naloxone distribution programs and trainings in overdose prevention and response.

> ### Objective 2-3:
> *Promote naloxone access and coverage among private payers*

CMS's efforts to increase naloxone access extend to individuals covered under private insurance policies. Non-grandfathered individual and small group market plans that are required to comply with the essential health benefits (EHB) must comply with the EHB prescription drug count standard at 45 CFR 156.122(a)(1). The EHB prescription drug count standard establishes that generally, a health plan does not provide EHB unless it covers at least the greater of: 1) one drug in every United States Pharmacopeia (USP) category and class; or 2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. As of the 2017 benefit year, the EHB prescription drug count standard is based upon the USP Medicare Model Guidelines (MMG) Version 6.0 drug classification system, which includes an Anti-Addiction/ Substance Abuse Treatment Agents (Opioid Reversal Agent) class. Naloxone is currently the only active ingredient in the Opioid Reversal Agent class, and as a result, starting with the 2017 benefit year, qualified health plans, which are required to provide EHB, are required to cover at least one form of naloxone in order to comply with the EHB prescription drug count standard.

The agency is also working with private payers to identify ways to further promote and improve access to naloxone, or other rescue drugs when they are FDA approved.

Priority Actions

Today, when patients are prescribed opioids for long term therapy, the majority are prescribed stool softener medications to help manage a common anticipated side effect: constipation. Respiratory depression, another known side effect with the potential for far more devastating consequences, should be addressed with similarly routine practices. As a first step toward this goal, CMS will need to identify standards to guide automatic co-prescribing of naloxone for patients whose opioid prescription reaches certain thresholds of dose, frequency, and/or duration. In an effort to encourage co-prescribing, the agency can also provide outreach and disseminate evidence-based practices through the CMS Transforming Clinical Practice Initiative (TCPI).

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[33] January 28, 2016 Bulletin: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction, http://medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.

Access to the life-saving medication should not be determined by coverage or economic circumstances. Thus, another of CMS's priority actions includes continuous evaluation of CMS programs and state and Medicare Part D formularies. CMS will support adjustments to achieve expanded and consistent coverage of naloxone across Medicare, Medicaid, and Marketplace plans.

In addition to improving availability of naloxone, CMS also aims to increase use of the medication, when indicated, by promoting education. CMS plans to continue available coverage of training for patients who are prescribed opioids and their families. Such training could include recognition of the signs and symptoms of an overdose, how to administer naloxone, and emergency response steps.

While making adjustments to policies, CMS will evaluate any changes within the context of regulatory limitations across states. CMS will also consider the influence of demand on the price of naloxone should the large scale use of the rescue drug occur as envisioned.

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 2*, metrics are currently under consideration in the following areas:
- Percentage of naloxone prescriptions issued for beneficiaries receiving opioid prescriptions:
  - Over a certain period of time (e.g. over 90 days)
  - Over a certain dose (e.g., exceeding CDC recommended guideline), etc.
  - As a co-prescription with medication assisted treatment for opioid use disorder because these people may be vulnerable to overdose if they relapse.
- For incidences in which naloxone is administered to beneficiaries, what percentage of those beneficiaries were receiving:
  - Opioid prescriptions exceeding the CDC guideline
  - Extended release/long-acting opioids
  - A concurrent benzodiazepine prescription
- Rate of naloxone administration to beneficiaries
- Institute reporting requirement for opioid-related adverse drug events (ADEs); compare data year-to-year

PRIORITY AREA 3

Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment (MAT).

Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders, including opioid use disorders, and to reduce opioid use for chronic pain patients. MAT is a valuable intervention that has been proven to be the most effective treatment for opioid use disorder, particularly because it sustains long term recovery. In one study, patients who continued to receive MAT at the 18-month interview were more than twice as likely to report avoidance of non-medical use of opioids when compared to those who were not receiving MAT (80 percent versus 36.6 percent).[34] Priority Area 3 focuses on addressing barriers to access to MAT services and expanding screening and treatment.

OBJECTIVES

3-1: *Identify and address coverage barriers to expansion of screening that leads to treatment*

3-2: *Identify and address barriers to access to treatment and medication-assisted treatment (MAT) services*

Desired Outcomes

The United States health care workforce would not only have a high level of awareness of the opioid epidemic, but would also make wide and routine use of effective screening tools and laboratory tests designed to identify patients with SUD. CMS and other payers would incentivize use of MAT options by providing incentives to programs that offer this proven approach to treatment. Public health education initiatives explaining the changes to the brain that occur with exposure to opioids would have dramatically reduced the stigma surrounding SUD. All those who need treatment for SUD would have access to screening and MAT, regardless of geographic location, type of health insurance coverage, or socioeconomic background.

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[34] Eric Sarlin, "Long-Term Follow-Up of Medication-Assisted Treatment for Addiction to Pain Relievers Yields 'Cause for Optimism,'" National Institute on Drug Abuse, November 30, 2015, https://www.drugabuse.gov/news-events/nida-notes/2015/11/long-term-follow-up-medication-assisted-treatment-addiction-to-pain-relievers-yields-cause-optimism.

Current CMS Projects

> **Objective 3-1:**
>
> *Identify and address coverage barriers to expansion of screening that leads to treatment*

CMS announced a new opportunity for states to obtain section 1115 demonstration authority for broad and deep SUD system transformation efforts, enabling states to provide a full continuum of care by introducing service, payment, and delivery system reforms to improve access to and quality of care for individuals with SUD.[35] CMS has approved two section 1115 SUD demonstrations in California and Massachusetts, and is providing ongoing strategic design support to a number of states to support their 1115 SUD proposals, including Virginia, Kentucky, Michigan, Maryland, West Virginia, Illinois, and Utah. The comprehensive scope of the section 1115 demonstration authority presents an opportunity to improve screening that leads to treatment for individuals with SUD. [36,37]

> **Objective 3-2:**
>
> *Identify and address barriers to access to treatment and medication-assisted treatment (MAT) services*

CMS requires Part D formularies to include covered Part D drugs used for MAT, and mandates Part C coverage of the behavioral health element of MAT services. As Part D is a reimbursement program for pharmacies, MAT drugs for Part D do not include methadone for opioid use disorder or buprenorphine when given at an opioid treatment program because these are not coverable Part D drugs in this setting.[38] It also does not include injectable naltrexone and buprenorphine implants because they involve office based procedures (Part B drugs).[39] In its Medicaid partnerships, CMS encourages states to increase the availability of MAT to Medicaid beneficiaries.[40] In a recent regulatory change, HHS increased the number of patients that qualified practitioners can treat with buprenorphine, one of the MAT options.

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[35] SMD #15-003 July 27, 2015: New Service Delivery Opportunities for Individuals with a Substance Use Disorder, https://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf.

[36] https://www.hhs.gov/about/agencies/asl/testimony/2016-09/a-review-of-anti-abuse-efforts/index.html

[37] http://www.oregon.gov/oha/OHPR/SUDStakeholderMeetingDocs/Concept%20Paper%20Draft%20with%20column%20for%20notes.pdf

[38] A Part D drug is defined, in part, as "a drug that may be dispensed only upon a prescription." Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (NOTE: Methadone is a Part D drug when indicated for pain). From MLN Matters® Number: SE1604, Medicare Coverage of Substance Abuse Services. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1604.pdf

[39] https://www.healthplus.org/uploadedfiles/pdfs/medicare/pdbmchap6formularyreqrmts_03.09.07.pdf

[40] Informational Bulletin: Medication Assisted Treatment for Substance Use Disorders. Retrieved from: https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf

Compliance with the regulations is assessed by SAMHSA-approved and monitored accrediting organizations.

CMS has been working through various initiatives to support states to provide more effective care to individuals with SUDs, including opioid use disorder. Through its Medicaid Innovation Accelerator Program (IAP) for Reducing SUDs,[41] CMS is providing states with technical support designed to accelerate the development and testing of SUD service delivery innovations. The types of technical support include assistance with developing bundled payment models for MAT; performing data analytics on the distribution and characteristics of MAT utilization (especially buprenorphine); implementing quality measurement reporting for SUD; developing strategies regarding care transitions and treatment engagement following withdrawal management; designing model opioid health home programs; leveraging strategic managed care contract language for SUD purchasing; and administrative claims and managed care organization encounter data standardization. In addition, the IAP is connecting states to content experts and leading practices across the country on a number of topics within SUD delivery system reform, such as improving access to MAT, implementing pharmacy benefit management strategies to address opioid use disorder, encouraging SUD provider participation in Medicaid, and the integration of primary care and SUD services.

The SUD system transformation efforts under section 1115 demonstration authority that are described in the previous section will also play a role in reducing barriers to quality treatment, especially MAT services.

Priority Actions

Because evidence demonstrates that MAT is effective,[42] CMS will promote initiatives to educate providers and patients on this SUD treatment option. CMS will encourage the broader adoption of MAT treatments by encouraging use of treatment services that include a valid MAT element. CMS will also provide incentives including training and certification for more providers to become authorized MAT prescribers in order to support the growing need.

CMS will continue to work with states to implement policies in their Medicaid programs that ensure broad coverage of and access to FDA-approved medications to treat opioid use disorder as well as the other components of evidence-based MAT, including counseling and care management.

CMS will continue to collaborate with other HHS operating divisions to accomplish its goals for the development and implementation of screening tools and laboratory tests. CMS will also support efforts to

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[41] IAP for Reducing Substance Use Disorders, https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/reducing-substance-use-disorders/reducing-substance-use-disorders.html.
[42] http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=2190&pageaction=displayproduct

develop guidance on when to use which screening tools and tests (*e.g.*, based on personal risk history, population, dose or treatment period threshold, identified behaviors, etc…). The agency will also explore the addition of an opioid screening tool to the existing Inpatient Psychiatric Facility Quality Reporting measures in an effort to identify opioid SUD in disadvantaged populations.

CMS will strengthen messaging and accelerate widespread adoption of MAT practice by collaborating with Substance Abuse and Mental Health Services Administration (SAMSHA) and other HHS agencies. CMS will also partner with other HHS agencies to de-stigmatize opioid-related SUD to encourage more affected patients to seek treatment.

CMS will evaluate health plan coverage and financial barriers to SUD treatment in an effort to identify and address those key barriers. For example, CMS will collect and analyze utilization data on MAT medications and will assess MAT insurance coverage and out-of-pocket costs to patients. Based on the results of those findings, CMS will focus efforts to address financial and health plan barriers.

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 3*, metrics are currently under consideration in the following areas:
- Percentage of physicians treating a beneficiary diagnosed with opioid use disorder who prescribed one or more MAT medications.
- Percentage of health plans that include access to MAT in their contracts with providers.
- Comparison of number of Part D prescription drug events (PDEs) for buprenorphine-naloxone across calendar years (looking for an increase in PDEs year-to-year).

PRIORITY AREA 4

Increase the use of evidence-based practices for acute and chronic pain management.

This priority area aims to provide clinicians with relevant information on all treatment options to help inform and improve their prescribing practices. An estimated one out of five patients with non-cancer related pain is prescribed opioids. While there are times that opioids may be a clinically justified option for the treatment of pain, evidence suggests that providers may be underutilizing alternative methods of treating pain. These alternative methods include the use of musculoskeletal exercises, cognitive behavioral therapy, multi-modal anesthesia approaches, and others.

OBJECTIVES

4-1: *Expand the use of best practices for evidence-based pain management*

4-2: *Encourage the use of non-pharmacologic therapies, non-opioid pharmaceuticals, and multi-modal analgesia (MMA) as first options for pain management*

Desired Outcomes

Health care providers would have substantial knowledge of the current best practices for pain management. They would begin a therapy regimen by first establishing treatment goals with all patients, including realistic goals for pain and function. Providers would prescribe non-opioids and non-pharmacologic alternative and adjuvant treatments as first line therapies and conduct regular reviews with patients of the effectiveness of the treatment plans. If opioid therapy is later identified as a need, providers would discuss the known risks and potential benefits of opioid therapy with their patients. The provider and patient would also consider how opioid therapy will be tapered and discontinued if its benefits do not continue to outweigh risks. Providers would begin by prescribing the lowest effective dosage of an immediate-release opioid and would avoid any extended-release formulations. Providers would conduct regular and regimented reviews of the effectiveness of the dose regimen and would monitor for adverse effects.

Research would also increase the focus on identifying methods for migrating the significant number of chronic pain patients with long standing opioid use to other medications along with alternative modalities. Without initiating other medications at the same time as alternative therapies, these patients may vigorously resist reducing or giving up the opioids that for many years have allowed them to manage their pain at tolerable levels and lead functional lives. The benefit of tolerable pain levels and functional lives may outweigh the risk of opioid use for these patients.

Patients would have an awareness of the negative and dangerous side effects of opioid medications that make opioids an inappropriate first-line treatment option in most cases. Patients would anticipate non-opioid medication options and non-pharmacologic alternative treatments as their initial treatments, and would be empowered to communicate regularly with their clinician regarding the effectiveness of their pain treatments and any side effects.

Recognizing its critical role in promoting and reinforcing appropriate treatment approaches, Medicare, Medicaid, and Marketplace plans would cover therapies that are consistent with CMS's evidentiary standards.

Current CMS Projects

Objective 4-1:
Expand the use of best practices for evidence-based pain management

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's Practice Transformation Networks. CMS has distributed publications on evidence-based prescribing practices to providers, often in coordination with other HHS agencies, including the Office of the Surgeon General.

For Medicare beneficiaries, CMS implemented Explanation of Benefits inserts for Part C & D beneficiaries that include information on prescription drug misuse, abuse, and proper disposal to raise awareness of these issues. CMS's Partnership for Patients' Hospital Improvement Innovation Networks also promoted hospital-based interventions such as EHR protocols, trainings, webinars, and education activities that could lead to reduced opioid-related ADEs and improved outcomes overall. One such educational effort was the American Board of Internal Medicine (ABIM) Foundation's *Choosing Wisely®* Program, which facilitated conversations between patients and providers regarding medication options.

Objective 4-2:
Encourage the use of non-pharmacologic therapies, non-opioid pharmaceuticals, and multi-modal analgesia (MMA) as first options for pain management

CMS is also playing a part in expanding the evidence base to identify and support effective non-pharmacologic therapies and additional non-opioid pharmaceuticals. The agency's key role is to identify services that need more evidence to support coverage by Medicare and other health plans. CMS then collaborates with research-focused HHS agencies, such as NIH, who can concentrate research on these need areas.

Priority Actions

The focus of CMS's immediate efforts under this priority area is twofold. First, identify non-covered treatments that already have sufficient evidence in order to quickly expand coverage of those therapies; for example, for certain common pain conditions, such as chronic lower back pain, CMS is exploring ways to streamline coverage of evidence-supported alternative therapies.

Secondly, educate providers and beneficiaries in order to improve provider utilization of evidence-based treatments and adjust patient expectations appropriately. CMS will use various bulletins to communicate these expectations to providers. The bulletins will emphasize the short vs. long term costs associated with opioid treatments vs. alternative therapies, and will provide guidance on how best to apply current available research. CMS will also develop a communications framework to educate patients.

CMS's long term priorities focus on broadening coverage and increasing utilization of therapies that are proven to be effective. This approach will accelerate identification and implementation of effective alternative treatments for pain.

CMS will partner with other HHS agencies to thoroughly address research limitations. We will first evaluate the level and type of evidence needed to support or exclude different treatment modalities from coverage. With its partner agencies, CMS will support development of the necessary evidence to determine the effective treatments for different populations and types of pain. Furthermore, CMS will seek evidence on how best to promote adoption of the most effective treatments for all populations, so that all patients are able to achieve relief from pain consistent with their goals.

Metrics

CMS is in the exploratory phase of identifying metrics to quantify and track progress in each priority area. For *priority area 4*, metrics are currently under consideration in the following areas:
For prescribers enrolled in Medicare who prescribe Part D drugs:
- Percentage of opioid prescriptions issued vs. all opioid and non-opioid pain management medication prescriptions; vs. referrals to other treatment modalities
- Percentage participating in CMS-endorsed training on pain management

HHS Collaboration

CMS has been proactive in engaging with other HHS operating divisions with regard to the opioid epidemic.

CMS is working closely with other HHS agencies to share best practices, coordinate current efforts, and identify new opportunities for collaboration. This cross-agency collaboration will enable effective and efficient management of comparable or duplicative HHS efforts, and will ensure coordinated processing of activities for national release. Representative activities include, but are not limited to:

- Informational Bulletins on MAT for Substance Use Disorders with CDC, SAMHSA and NIH;
- Facilitation of the Surgeon General's letter campaign to 2.3 million clinicians to "Turn the Tide" on the prescription drug epidemic;
- Dissemination of the CDC *Guideline for Prescribing Opioids for Chronic Pain* through CMS QIO-QIN efforts to reduce adverse drug events for opioids;
- Discussions with CDC, FDA, and NIH regarding expansion of the evidence base to inform coverage determinations for alternative therapies.

In addition, CMS is currently involved in interagency collaboration forums including, but not limited to:
- HHS Behavioral Health Coordinating Council on Opioids;
- CMS/CDC/FDA/NIH interagency meetings;
- Office of National Drug Control Policy meetings;
- National Pain Strategy Implementation Steering Committee meetings

Appendix: Summary of Highlighted Current Projects

Across these four priority areas, over 40 CMS projects are currently underway, spanning education, policy, data transparency, quality improvement, and technical assistance. These initiatives target beneficiaries, clinicians, states, and other payers. Representative examples are described below. CMS is committed to building on existing activities and achieving significant progress toward accomplishing our objectives. We are also seeking opportunities for inter-agency collaboration to accelerate our response to the opioid epidemic.

Note: Asterisks in table indicate that the named project is also linked to another Objective, which is listed after the asterisk for quick reference.

Priority Area	Objective	Projects
Implement more effective person-centered and population-based strategies to reduce risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.	**1-1:** Promote use of evidence-based opioid prescribing guidelines to the health care community	Quality Improvement Organizations' (QIOs) Learning and Action Networks promote and disseminate evidence-based best practices for management of high-risk medications such as opioids to recruited providers and practitioners. The QIO Program also began a national campaign focused on gathering and spreading best practices from the perspective of beneficiaries, patients, advocates, and caregivers.
	1-2: Develop additional tools for states, beneficiar-ies, providers, and other stakeholders to use opioids appropriately	Provide informational inserts with Explanations of Benefits (EOBs) for Part C & D beneficiaries that address prescription drug misuse and abuse and proper disposal to raise awareness of these issues.
		Released an informational bulletin to state Medicaid agencies on preventing opioid-related harms
		Conduct stakeholder engagement activities on additional pharmacy drug utilization strategies and actions Medicaid programs can take to address opioid prescription misuse and abuse

Priority Area	Objective	Projects
		White House Social and Behavioral Sciences Team (SBST) facilitated collaborative research with CMS to study the effects of an informative letter to providers on reducing inappropriate prescribing of drugs with a high likelihood of abuse to beneficiaries enrolled in Medicare Part D. Language that is identified as effective in the current letter, focused on an atypical antipsychotic,[43] may be adapted to future messaging campaigns about opioids.*1-3
		For prescribers and pharmacists, CMS developed the following publications: *Prescription Opioids: An Overview for Prescribers and Pharmacists*, *Buprenorphine: A Primer for Prescribers and Pharmacists*, and *What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?*
		Overutilization Monitoring System (OMS) provides Part D plans with quarterly reports on high risk beneficiaries; in turn, sponsors provide CMS with their review of each beneficiary's case to demonstrate that they have established reasonable and appropriate drug utilization management programs.*1-3
	1-3: Provide stakeholders with accurate, timely, and actionable information on how to use clinical and pharmaceutical data to decrease overdoses	Medicare Part D Opioid Prescriber Summary File presents information on the individual opioid prescribing rates (for new prescriptions as well as refills) of prescribers that prescribe Part D drugs. This public data set provides information on (1) the number and percentage of prescription claims for opioid drugs, and (2) each provider's name, specialty, state, and zip code. The file can be used to explore the impact of prescribing practices of controlled substances on vulnerable populations.
		White House Social and Behavioral Sciences Team (SBST) facilitated collaborative research with CMS to study the effects of an informative letter to providers on reducing inappropriate prescribing of drugs with a high likelihood of abuse to beneficiaries enrolled in Medicare Part D. Language identified as effective in the current letter, focused on an atypical antipsychotic,[42] may be adapted to future messaging campaigns about opioids.*1-2

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[43] Sacarny, A., Le, J., Tetkoski, F., Yokum, D., Agrawal, S. (2016). Effect of Review Notification Letters on the Volume and Guideline-Conformity of Quetiapine Prescribing: A Randomized Clinical Trial. Unpublished study.

Priority Area	Objective	Projects
		National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) conducts proactive data analysis to identify potential fraud, waste and abuse involving controlled substances. Data analyses include identifying trends, anomalies, and questionable physician and pharmacy practices involving prescription opioids in order to identify outliers, educate plan sponsors, and recover improper payments, as well as make referrals to law enforcement when appropriate. Examples include: • Quarterly Pharmacy Risk Assessment, which categorizes pharmacies as high, medium, or low risk;*1-4 • Prescriber Risk Assessment, which provides a peer comparison of Schedule II controlled substances;*1-4 • "Trio Prescriber" initiative, which identifies providers who prescribe beneficiaries a combination of an opioid, benzodiazepine, and the muscle relaxant carisoprodol; and • Identified improper payments for drugs inappropriately covered under the Part D program without a prior authorization; for example, Transmucosal Immediate Release Fentanyl (TIRF).*1-4
		Overutilization Monitoring System (OMS) provides Part D health plans with quarterly reports on high risk beneficiaries; in turn, sponsors provide CMS with their review of each beneficiary's case to demonstrate that they have established reasonable and appropriate drug utilization management programs.*1-2
		Facilitate sharing of de-identified data among health plans in an effort to identify fraud schemes and potential inappropriate prescribers. Part D plans can use CMS's information sharing platform to identify leads for their own internal investigations and can report actions they have taken. *1-4

Priority Area	Objective	Projects
	1-4: Provide stakeholders with accurate and timely information and tools to decrease the occurrence of drug diversion	National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) conducts proactive data analysis to identify potential fraud, waste and abuse involving controlled substances. Data analyses include identifying trends, anomalies, and questionable physician and pharmacy practices involving prescription opioids in order to identify outliers, educate plan sponsors, and recover improper payments, as well as make referrals to law enforcement when appropriate. Examples include: • Quarterly Pharmacy Risk Assessment, which categorizes pharmacies as high, medium, or low risk;*1-3 • Prescriber Risk Assessment, which provides a peer comparison of Schedule II controlled substances;*1-3 • Pill Mill Doctor Project, which identifies prescribers with a high risk of fraud, waste and abuse in prescribing Schedules II-IV controlled substances; • Identified improper payments for drugs inappropriately covered under the Part D program without a prior authorization; for example, Transmucosal Immediate Release Fentanyl (TIRF).*1-3

Priority Area	Objective	Projects
		Facilitate sharing of de-identified data among health plans in an effort to identify fraud schemes and potential inappropriate prescribers. Part D plans can use CMS's information sharing platform to identify leads for their own internal investigations and can report actions they have taken. *1-3
		Compile annual Medicaid fee-for-service agency reports on state drug utilization review (DUR) program activities and processes within the CMS Medicaid Drug Utilization Review State Comparison/Summary Report, which is posted annually on the Medicaid.gov website. Examples of activities and processes that Medicaid agencies use to ensure appropriate opioid utilization include: placing quantity limits on opioids, monitoring the concurrent use of opioids and benzodiazepines, employing PDMP requirements, and using tools that measure morphine milligram equivalents (MME) per day. CMS also inquires about the use of patient review and restriction programs (i.e., lock-in programs) to address potential prescription opioid misuse or abuse.
Expand naloxone use, distribution, and access, when clinically appropriate	**2-1:** Increase the use and distribution of naloxone for Medicare beneficiaries.	Increase access to naloxone by requiring that the antidote appear on all Medicare Part D plan formularies.
		Help to expand community-based naloxone distribution programs and trainings in overdose prevention and response.*2-2
	2-2: Increase the use and distribution of naloxone for Medicaid beneficiaries.	Assist states to develop Medicaid strategies that will further expand and improve access to naloxone.
		Released informational bulletin encouraging states to add naloxone to their preferred drug lists.
		Help to expand community-based naloxone distribution programs and trainings in overdose prevention and response.*2-1
	2-3: Promote naloxone access and coverage among private payers	Increase access to naloxone by requiring that the antidote appear on all Marketplace plan formularies.

Priority Area	Objective	Projects
Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment (MAT).	**3-1:** Identify and address coverage barriers to expansion of screening that leads to treatment.	Through its Medicaid Innovation Accelerator Program (IAP) for Reducing SUDs, CMS is providing states with technical support designed to accelerate the development and testing of SUD service delivery innovations.
		CMS has announced a new opportunity for states to obtain section 1115 demonstration authority for 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 access to and quality of care for individuals with SUD.*3-2
		Provide outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's Practice Transformation Networks.
	3-2: Identify and address barriers to access to treatment and MAT services.	CMS requires Part D formularies to include Part D drugs used for MAT, and mandates Part C coverage of the behavioral health element of MAT services.
		CMS encourages states to increase the availability of MAT to Medicaid beneficiaries.
		CMS is also working to expand the pool of providers eligible to deliver these services.
		CMS has announced a new opportunity for states to obtain section 1115 demonstration authority for 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 access to and quality of care for individuals with SUD.*3-1
Increase use of evidence-based practices for acute and	**4-1:** Expand the use of best practices for	Provide outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's Practice Transformation Networks.
		Distribute publications on evidence-based prescribing practices to providers, often in coordination with other HHS agencies, including the Office of the Surgeon General.

Priority Area	Objective	Projects
chronic pain management.	evidence-based pain management	Through Hospital Improvement Innovation Networks, promoting hospital-based interventions (*e.g.*, Electronic Medical Record protocols, trainings, webinars, and education) that could potentially lead to improved outcomes by reducing the incidence of adverse drug events related to opioids. An example of one such educational effort is the ABIM Foundation's *Choosing Wisely*® Program, which facilitates conversations between patients and providers regarding medication choices, especially non-opioid options for treatment.
		Provide informational inserts with Explanations of Benefits (EOBs) for Part C & D beneficiaries that address prescription drug misuse, abuse, and proper disposal to raise awareness of these issues.
	4-2: Encourage the use of non-pharmacologic therapies, non-opioid pharmaceuticals, and multi-modal analgesia (MMA) as first options for pain management	Collaborate with HHS on the opioid research strategy: Identify services that need more evidence to support coverage by Medicare and other health plans (collaborate with research-focused HHS agencies)