

# THE OPIOIDS CRISIS

## *Trump Administration Response*

---

### *Preventing Drug Use Initiation and Reducing Demand and Risks*

- To ensure that covered Medicare Part D drugs, including opioids, are used optimally and safely, in April, the Centers for Medicare & Medicaid Services' (CMS) calendar year 2018 Medication Therapy Management (MTM) program guidance encouraged sponsors to offer MTM services to additional beneficiaries to help patients, pharmacists, and providers improve outcomes and reduce risk.
- In May, the Food and Drug Administration (FDA) released draft revisions to its [“blueprint”](#) for prescriber education. These revisions will expand the educational content by adding the principles of pain management—including non-pharmacologic treatments and non-opioid analgesic medications as well as how to assess, treat, and monitor patients when opioids are appropriate. Once finalized, this blueprint will provide guidelines for accredited continuing medical education companies to develop prescriber education courses that can be funded through unrestricted educational grants by pharmaceutical companies under the current Extended-Release and Long-Acting Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS).
- In July, the FDA announced its intention to expand REMS requirements that already applied to Extended-Release and Long-Acting Opioid Analgesics to also include immediate-release opioid analgesics. This will require manufactures to provide additional education and training to providers for immediate-release opioid analgesics. The expansion of the Opioid Analgesic REMS represents a significant step forward, given that approximately 90% of all opioid analgesic prescriptions are for immediate release products. In September, [FDA issued a letter to 74 manufacturers](#) that they will now be subject to a more stringent set of requirements.
- In July, the Centers for Disease Control and Prevention (CDC) awarded more than \$12 million to 23 States and the District of Columbia to support their responses to the opioid overdose epidemic. The funds are being used to strengthen prevention efforts and better track opioid-related overdoses.
- In August, CDC released new guidance for first responders, emergency medical services (EMS), and other stakeholders on how to prevent and respond to occupational exposures to fentanyl. This critical guidance will equip those first responders so that they can rescue people faster, more safely, and with confidence.
- In September, CDC [launched the Rx Awareness Campaign](#), a large, multimedia campaign aimed at spreading awareness of opioid risks. The campaign features real-life stories of people recovering from opioid addiction, as well as people who have lost loved ones to prescription opioid overdose.
- In September, CDC awarded more than \$28.6 million in additional funding to 44 States and the District of Columbia to support their responses to the opioid overdose epidemic, including increasing the use of prescription drug monitoring programs and better tracking and prevention of opioid-involved overdoses.

## **THE OPIOIDS CRISIS**

### ***Trump Administration Response***

---

- Health care providers have long expressed concern that scores related to pain management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, tied to hospital reimbursement, could be leading to inappropriate prescribing of opioids. As of [October 1, 2017](#), CMS no longer links the HCAHPS pain management scores to hospital payment under the Hospital Value-Based Purchasing program. Furthermore, CMS replaced pain management questions in the Hospital IQR Program with new ones focused on communication about pain between providers and their patients.
- CMS published in November a proposed regulation that, in part, establishes the framework under which Medicare Part D sponsors may voluntarily create and manage drug management programs for beneficiaries who are at risk of abusing frequently abused drugs such as opioids. This new authority was provided to CMS under the Comprehensive Addiction and Recovery Act of 2016. Through these drug management programs, sponsors would be able to limit at-risk beneficiaries' access to coverage of prescription opioids to a selected prescriber(s) and/or pharmacy(ies). This new program will help support providers, pharmacists, and patients in ensuring appropriate access to and use of drugs subject to abuse.
- In November, the Administration expanded on the CDC guidance and [released a one-page document on fentanyl handling for first responders](#). This science-based set of action steps was developed by a Federal interagency working group of law enforcement officials, public health professionals, occupational safety experts, fire and rescue personnel, scientists, and EMS responders. It is a tool for first responders to use in the field to safely conduct their daily activities.

### **Expanding Access to Evidence-based, World-class Care and Treatment**

- In April, the Department of Health and Human Services (HHS) [laid out a comprehensive five-point strategy](#) to combat the opioid abuse crisis:
  - (1) Improving access to prevention, treatment, and recovery support services, including the full range of medication-assisted treatments.
  - (2) Targeting availability and distribution of overdose-reversing drugs.
  - (3) Strengthening our understanding of the crisis through better public health data and reporting.
  - (4) Supporting cutting-edge research on pain and addiction.
  - (5) Advancing better practices for pain management.
- In April, [HHS distributed \\$485 million](#) under the newly created *State Targeted Response to the Opioid Crisis* grant program to support a comprehensive array of prevention, treatment, and recovery services. States and territories were awarded funds based on rates of overdose deaths and unmet need for opioid addiction treatment. The second round of funding will be provided in FY 2018.
- In September, [SAMHSA awarded \\$144 million](#) in grants to support opioid and other substance abuse efforts:
  - \$44.7 million for the First Responders—a program to provide training and medication for emergency treatment of opioid overdose;
  - \$35 million for the Medication Assisted Treatment (MAT) Prescription Drug and Opioid Addiction Targeted Capacity Expansion grants;

## **THE OPIOIDS CRISIS**

### *Trump Administration Response*

---

- \$49 million for Residential Treatment of Pregnant and Postpartum Women;
  - \$9.8 million for State Pilot Grants for the Treatment of Pregnant and Postpartum Women;
  - \$4.6 million for Building Communities of Recovery to increase the availability of long-term recovery support services; and
  - \$1 million for Improving Access to Overdose Treatment to expand access to FDA-approved products to reverse opioid overdoses.
- 
- In September, the Health Resources and Services Administration (HRSA) [awarded approximately \\$200 million](#) to 1,178 health centers to expand mental health and substance abuse services.
  - In September, HRSA awarded nearly \$3.3 million to 13 rural health organizations, in every State in the United States. These grants will increase access to treatment and recovery services for opioid abuse under the Rural Health Opioid Program and the Substance Abuse Treatment Telehealth Network Grant Program. They will advance evidence-based, opioid abuse interventions to overcome challenges in rural communities, such as longer emergency response times and lack of access to substance abuse treatment providers.
  - In September, HRSA provided approximately \$4 million in supplemental funding to 59 grantees for MAT training under its Primary Care Training and Enhancement program. These grants support enhanced training for primary care physicians and physician assistants in more than 25 States in treating opioid abuse, thereby increasing the number of healthcare providers who can respond to patients needing this care at the local level. The grants also provide support for developing and integrating new MAT curricula into educational programs provided to primary care practitioners.
  - In September, the Bureau of Justice Assistance [awarded more than \\$12 million](#) to the 50 States, the District of Columbia, and 5 territories to promote broader adoption of evidence-based MAT in State correctional institution Residential Substance Treatment programs for inmates addicted to alcohol, prescription opioids, heroin, or other drugs.
  - In October, the Office of Civil Rights at HHS [published a guidance document](#) to clarify circumstances to ensure that healthcare providers understand their broad ability to share information with patients' family members during crisis situations without violating Health Insurance Portability and Accountability Act (HIPAA). HIPAA allows health professionals to share information with loved ones in emergency or dangerous situations—but misunderstandings to the contrary persist and create obstacles to family support that is crucial to the proper care and treatment of people experiencing a crisis situation, such as an opioid overdose.
  - In November, CMS [announced a bold new policy](#) that increases the flexibility for States to apply for new expenditure authority to address one of the biggest barriers to treatment: the decades-old statute that prohibits Medicaid—the healthcare safety net program for the poor—from paying for inpatient or residential addiction treatment at facilities with more than 16 treatment slots. Under CMS' new policy, States can more quickly gain approval for new expenditure authority to help patients in certain inpatient or residential addiction treatment facilities while the state is building their broader treatment capacity. Two States have already received approvals under the new policy (New Jersey and Utah) and several more applications have come in for review.

# THE OPIOIDS CRISIS

## *Trump Administration Response*

---

### **Kickstarting Innovation to Deliver Tomorrow's Solutions**

- The National Institutes of Health (NIH) [began developing a partnership](#) between innovator companies and NIH to help facilitate the development of new treatments for pain, addiction, overdose-reversal, and non-addictive therapies for pain. Three meetings have been convened and have laid the foundation for a public-private initiative to advance research to address the opioid abuse crisis. NIH is also funding research to develop technology to more accurately and objectively measure the presence and level of pain.
- Announced in 2017, [a new study](#) called the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome will evaluate treatment options and improve clinical care of infants with neonatal abstinence syndrome/neonatal opioid withdrawal syndrome.
- In September, HHS through NIH, the Department of Defense, and Department of Veterans Affairs [announced a joint research partnership of \\$81 million](#) over six years to support military and veteran pain management research.

### **Cracking Down on Bad Actors Fueling the Crisis**

- In July, the Department of Justice (DOJ) and HHS conducted the [largest ever healthcare fraud enforcement action](#) by the Medicare Fraud Strike Force. More than 120 people, including doctors, were charged for prescribing and distributing opioids and other dangerous narcotics as part of a healthcare fraud scheme. The fraud scheme was responsible for \$1.3 billion in false billings to Medicare, Medicaid, TRICARE, and other Federal and private insurance programs.
- In July, a multi-agency and international effort led by the DOJ resulted in the [seizure of the largest criminal marketplace](#) on the internet, AlphaBay, greatly disrupting the sale of fentanyl and other dangerous drugs on the internet. AlphaBay, which operated for more than two years on the dark web, was a major source of fentanyl and heroin, linked to overdose deaths, and was used by hundreds of thousands of people to buy and sell illegal goods and services anonymously on the internet.
- In August, the DOJ established an [Opioid Fraud and Abuse Detection Unit](#) to serve as a specialized enforcement action team targeting the reduction of fraudulent prescribing, over prescribing, and the availability of prescription opioids used for non-medical reasons.
- In September, the FDA took action, in partnership with international regulatory and law enforcement agencies, against online pharmacies that illegally sell potentially dangerous, unapproved versions of prescription medicines, including opioids. In this action, the [FDA sent 13 warning letters to companies and subsidiaries comprising 401 website operators](#). The FDA also seized nearly 100 website domain names such as buyhydrocodoneonline.com, and detained nearly 500 packages that appeared to be in violation of United States law.
- In October, [DOJ announced the first ever indictments](#) against two Chinese manufacturers of deadly illicit fentanyl and other opiate substances. The Chinese nationals operated at least six chemical plants and labs in China to produce and sell illicit fentanyl to customers in the United States.

## **THE OPIOIDS CRISIS**

### ***Trump Administration Response***

---

- In fiscal year (FY) 2016, the United States Postal Inspection Service (USPIS) seized approximately 24 international mailings and 15 domestic mailings containing synthetic opioids. In FY 2017, there was a significant increase in the amount of mailings seized by USPIS containing synthetic opioids, resulting in the seizure of approximately 142 international and 147 domestic mailings.
- The Department of State expanded its assistance to the International Narcotics Control Board to work with the chemical and shipping industry internationally, as well as postal carriers, to improve efforts to identify suspected fentanyl shipments and prevent the diversion of fentanyl precursor chemicals.
- The Department of State's Bureau of International Narcotics and Law Enforcement Affairs (INL) led a diplomatic campaign that resulted in a March 2017 decision by the United Nations to create binding international controls over the chemicals used most commonly to produce illicit fentanyl.
  - These new international controls went into effect on October 18, and will make it harder for criminals to access the chemicals needed to produce fentanyl and fentanyl analogues.
  - State/INL is taking similar action to establish international controls on carfentanil.