OPIOID RAPID RESPONSE PROGRAM

Background and Description

The **Opioid Rapid Response Program (ORRP)** is an interagency, coordinated federal effort to mitigate drug overdose risk among patients impacted by law enforcement actions that disrupt access to prescription opioids or medication assisted treatment/medication for opioid use disorder (MAT/MOUD). Overseen by United States Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) and coordinated by US Centers for Disease Control and Prevention (CDC) and the Office of the Inspector General within HHS (HHS OIG), ORRP supports care continuity and risk reduction for patients by coordinating federal law enforcement actions and public health overdose risk mitigation.

This document presents the context and basis for ORRP. It begins by describing the roles of different federal law enforcement programs in identifying, investigating and prosecuting prescribers and the downstream impact these types of actions can have on people with opioid use disorder or physical dependency. It then describes CDC's public health role in addressing the opioid overdose epidemic, including CDC's support for state and local overdose prevention efforts. Finally, the ORRP's origin and its specific strategic components, goals, and activities are presented.

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National Center for Injury Prevention and Control

Law Enforcement Actions Against Prescribers and The Impact on Patients

Similar to state medical licensing boards, state attorneys general and state **Medicaid Fraud Control Units (MFCUs)**, the **Drug Enforcement Administration (DEA)**, and **HHS OIG** investigate illegal prescribing and prescription drug diversion. These law enforcement agencies coordinate with one another often, and prescribers can be the subject of multiple concurrent investigations.

HHS OIG Fraud Prevention Programs

HHS OIG is the largest Inspector General's office in the federal government, with approximately 1,600 personnel dedicated to combating fraud, waste and abuse and improving the efficiency of HHS programs. OIG's oversight and law enforcement activities extend to all HHS agencies and programs, including the Centers for Medicare & Medicaid Services (CMS), the National Institutes of Health (NIH), Administration for Children and Families (ACF), CDC, Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Food and Drug Administration (FDA).

HHS OIG identifies and holds accountable those engaged in fraud and enforces the law. A key component of HHS OIG's mission is to detect and root out fraud in federal healthcare programs, including Medicare and Medicaid. Fraud diverts scarce resources meant to pay for the care of patients and other beneficiaries. Not only does fraud increase costs for vital health and human services, but it can also potentially harm beneficiaries, including Medicare and Medicaid patients.

Most of HHS OIG's resources are spent on the oversight of Medicare and Medicaid funded programs because these programs account for the largest portion of the HHS budget and they support many of the country's most vulnerable citizens.

Although many HHS OIG investigations focus on Medicare and Medicaid, the impact and scope of their investigations can reach patients and providers from any payor population (i.e., Medicare, Medicaid, private insurance, and self-pay) receiving prescriptions from the target of the investigation.

DEA's Diversion Control Division

The DEA's Diversion Control Division's mission is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

Under federal law, all health professionals must be registered with the DEA to dispense, administer, or prescribe federally controlled substances. Likewise, all pharmacies that fill prescriptions for federally controlled substances must be registered with the DEA. Registrants must comply with regulatory requirements relating to drug security and recordkeeping.

Diversion investigations often target physicians who provide prescriptions to individuals for purposes other than a legitimate medical treatment or outside the scope of legitimate medical practice. Investigations also often involve pharmacies that fill prescriptions despite "red flag" indicators of diversion; pharmacists who falsify records and subsequently sell the drugs; employees who steal from inventory and falsify orders to cover illicit sales; prescription forgers; and individuals who steal from pharmacies, drug distributors, or other DEA registrants.

Law enforcement actions that may disrupt prescription supply and impact patients include:

- Search warrant on a facility where opioid prescribing occurs or MAT/MOUD is provided
- Provider arrest
- DEA registration suspension
- DEA registration surrender by a prescriber
- Medical license suspension

Impact of Supply Disruption on Patients

Disruptions that involve prescribers of opioids are particularly dangerous for several reasons related to the overdose crisis.

High Risk Prescribing and Patients with Opioid Dependency

Subjects of investigations tend to be prescribers who do not routinely follow clinical prescribing guidelines or are not compliant with federal and state laws designed to prevent misuse of prescription drugs or diversion to illicit drugs. Therefore, investigated providers' pain management patients may have opioid dependency and may be taking high doses of opioids or dangerous contraindicated prescriptions, such as benzodiazepines (a schedule four narcotic used to treat anxiety) or sleep aids, in addition to opioids. When law enforcement officials execute actions, such as a search warrant on a clinic or a provider arrest, patients may lose access to their prescriber.

Risks of Sudden Discontinuation of Opioids and Opioid Withdrawal

For patients using opioids for a prolonged duration, any abrupt change in the patient's regimen may put the patient at risk of harm. Although opioid withdrawal may not be deadly, the reactive behaviors of a person suffering acute opioid withdrawal symptoms can be. The extreme pain and discomfort of opioid withdrawal can lead a person to take measures that may risk their health in search of relief.

In 2019, HHS released HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, a guide for clinicians who are considering tapering patients' opioid prescriptions. In addition to highlighting the benefits of safe reductions in dosages, the guide lists the risks of rapid tapering or sudden discontinuation and advises against abrupt opioid dose reduction or discontinuation unless there are indications of a life-threatening issue.

Risks of sudden discontinuation of opioid use in physically dependent patients include

- acute withdrawal symptoms,
- exacerbation of pain,
- serious psychological distress, and
- thoughts of suicide.[1]

Often, individuals will seek alternative sources of opioids if their typical supply is not available. They may obtain or purchase opioids illegally. The prevalence of counterfeit pills and illicitly manufactured fentanyl in the illicit drug supply creates a deadly threat to patients seeking drugs on the black market.

Patient Abandonment

Finally, physicians may be reluctant to accept new patients with a history of opioid use disorder or who are on high doses of opioids. Reasons for this reluctance include liability concerns, the potential for patient complexity or volatility, and stigma.

This phenomenon of patient abandonment can increase the risk of harm and death to patients. A patient whose prescriber abruptly becomes unavailable may require the following:

1. Care continuity in the form of an immediate **referral to a legitimate prescriber** who can maintain the patient's prescription access
2. **A skilled healthcare provider** able to evaluate the patient's overall health and develop a patient-centered plan for pain management therapy, which may include appropriate and tailored tapering protocols for opioids or benzodiazepines
3. **Patient education** about opioid use disorder and overdose risk
4. Access to **naloxone**, an overdose reversing drug
5. Harm reduction services

Additional behavioral health support such as treatment and recovery services may also be needed, particularly for patients impacted by a law enforcement action against an MAT/MOUD provider. In some cases, crisis response teams that include mental healthcare professionals may be advisable as well.

CDC's Role in Addressing the Opioid Overdose Epidemic

The opioid overdose epidemic remains a national public health crisis. Despite marked declines in opioid prescribing since 2012, overdoses involving opioids, including prescription opioids, heroin, and synthetic opioids (like fentanyl) have increased almost six times since 1999.[2] Overdoses involving opioids killed nearly 50,000 people in 2019, and over 28% of those deaths involved prescription opioids.[3]

As the nation's premier public health agency, CDC leads efforts to reduce fatal and non-fatal overdose deaths by serving five critical roles:

- Using data to monitor emerging trends and direct prevention activities
- Strengthening state, local, and tribal capacity to respond to the epidemic
- Working with providers, health systems, and payors to reduce unsafe exposure to opioids and treat addiction
- Coordinating with public safety and community-based partners to rapidly identify overdose threats, reverse overdoses, link people to effective treatment, and reduce harms associated with illicit opioids
- Increasing public awareness about the risks of opioids

CDC'S Overdose Data to Action

Overdose Data to Action (OD2A) is a four-year cooperative agreement that began in September 2019. It focuses on the complex and changing nature of the drug overdose epidemic and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. Funds awarded as part of this agreement support state, territorial, county, and city health departments in obtaining high quality, more comprehensive, and timelier data on overdose morbidity and mortality and using those data to inform prevention and response efforts. Efforts funded by OD2A fall into two main categories:

- **Epidemiology and Surveillance** – OD2A funding is used by recipients to conduct surveillance activities to monitor and gather data about the scope and nature of the overdose problem.
- **Prevention** – The prevention component of OD2A includes:
  - strengthening prescription drug monitoring programs (PDMP)
  - improving state-local integration
  - establishing linkages to care
  - improving provider and health system support
  - improving partnerships with public safety and first responders
  - empowering individuals to make safer choices

History and Role of ORRP

ORRP grew out of the **Appalachian Region Prescription Opioid Strike Force (ARPO)**, which began in 2018 to combat the opioid overdose epidemic by identifying, investigating, and effectively and efficiently prosecuting medical professionals involved in the illegal prescription and distribution of opioids in six states: Ohio, West Virginia, Virginia, Kentucky, Tennessee, and Alabama. ORRP (then known as Opioid Rapid Response Teams) was founded to help state and local authorities ensure that patients dependent on pain medications and left without medical care by ARPO efforts were directed to reputable professionals and addiction treatment providers. The initiative was an unprecedented federal effort requiring coordination between public health and law enforcement agencies, including HHS OASH, CDC, HHS OIG, DEA, and the U.S. Public Health Service Commissioned Corps (USPHS).

Trained rapid response teams were composed of public health experts ready to deploy on short notice to support state and local agencies experiencing a spike in opioid-related overdoses or closure of a clinic where patients were prescribed opioid therapy. CDC worked closely with federal law enforcement to establish trusted contacts within state health agencies, allowing for early notification of law enforcement actions that could disrupt patients' access to medication.

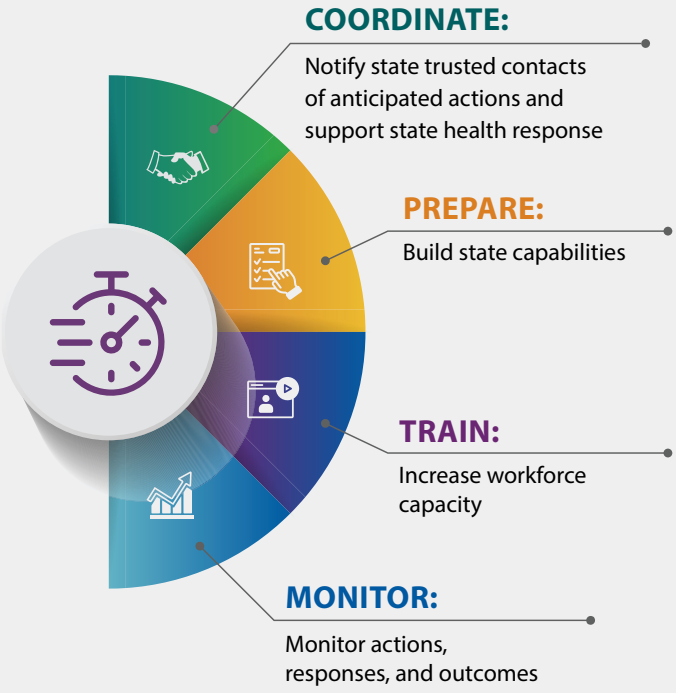
Some of the barriers identified throughout the initiative's roll-out included:

1. Lack of state and local protocols to respond to such events
2. Challenges assessing patient risk and/or contacting patients due to limited or variable state-by-state or case-by-case information, such as PDMP data use restrictions and incomplete or inaccessible patient records
3. Difficulty identifying physicians who were willing and able to accept patients taking high doses of opioids

In 2020, CDC transitioned ORRP's management and activity to its Division of Overdose Prevention's Public Health and Public Safety Team to better leverage existing federal and state partnerships with both law enforcement and public health officials working on overdose prevention. Concurrently, with continued support from OASH, a USPHS officer was positioned directly within HHS OIG to accelerate coordination between the agency and CDC.

Today, ORRP supports all 50 US states and the District of Columbia when federal law enforcement actions may result in a provider's abruptly losing the ability to prescribe or dispense controlled substances, including opioids or MAT/MOUD. The program leverages relationships across federal, state, and local agencies to facilitate timely communication, care coordination, risk reduction, and other overdose prevention interventions. ORRP coordinators work closely with law enforcement agents involved in each action to ensure that sensitive information remains confidential and the integrity of an investigation is not compromised.

ORRP Strategic Components



ORRP STRATEGIC COMPONENT 1:
Federal Law Enforcement Coordination with State Public Health and Behavioral Health

GOAL 1. Enhance Federal law enforcement coordination with state public health and behavioral health officials through ORRP on or before the date of action.

To enhance federal law enforcement coordination with state public health and behavioral health officials, ORRP 1) establishes and engages trusted contacts from public health and behavioral health and 2) engages law enforcement agents in ORRP and educates them about the potential impact of supply disruptions on patients.

Trusted Contacts

ORRP establishes and maintains trusted contacts within each state with whom information about impending actions can be shared without compromising operational security. Trusted contacts typically include one individual from the state health department, and another from the state behavioral health or substance abuse services agency. These individuals are entrusted with confidential law enforcement information prior to an action being taken against a prescriber of opioids or MAT/MOUD. In many cases, trusted contacts are the principal investigators for CDC's OD2A Cooperative Agreement and directors of the state agency funded by SAMHSA.

CDC's ORRP team contacts trusted contacts prior to a law enforcement action and provides them with information that can help them assess patient risk and identify appropriate mitigation measures for patients and others in the community (in cases of diversion). Sensitive information related to the action is shared with trusted contacts only at the request of law enforcement agents. Trusted contacts may take immediate steps to further assess patient risk and prepare to put mitigation measures in place. The actions a state chooses to take depend on circumstances, context, and available resources. Examples of actions a state may decide to take include the following:

- Querying the PDMP database to determine the scope and types of risk (e.g., by identifying numbers of patients' living in surrounding counties and their medications and dosing)
- Arranging to have on-site support for patients while an action (e.g., an arrest) is taking place (only at the request of law enforcement)
- Identifying available providers to whom patients can be referred
- Developing notices with contact numbers for patient referrals
- Preparing health alert notices for local hospitals/emergency departments, first responders and harm reduction organizations
- Increasing naloxone distribution in the area
- Accessing care coordinators to help patients navigate options, including offering treatment
- Contacting local law enforcement to assess current illicit supply risks (e.g., counterfeit pills) and incorporate information into patient or public education
- Issuing a press release or providing risk reduction information to include in a law enforcement press release
- Monitoring outcomes through Medicare and Medicaid claims data

ORRP STRATEGIC COMPONENT 2:
State and Local Preparedness

GOAL 2. Improve state and local preparedness.

As part of overdose prevention efforts, states should develop and exercise protocols to mitigate risks of overdose when a disruption in prescription supply occurs. Every law enforcement action unfolds somewhat uniquely; therefore, it is important to have protocols that account for a variety of scenarios. For example, agents may not be able to determine whether a physician will surrender their DEA registration during an action or if a clinic will be closed for only a few hours or permanently. Some cases may involve patients who are diverting their prescription drugs (selling them or trading them to other people). In these cases, the disruption in supply can impact people outside the identified patient population. Patient information and access to PDMP data can also influence the response efforts taken by a state. Because of the variables involved in each law enforcement action, state and local health departments should be prepared to coordinate any number of prevention interventions among their partner organizations to effectively mitigate risk.

Having readily accessible plans and protocols to decrease the burden on state and local health departments is a critical component. ORRP assists states with preparedness efforts by developing tools, templates, and guidance materials; coordinating tabletop exercises; and facilitating learning communities among states.

ORRP STRATEGIC COMPONENT 3:
Workforce Training and Development

GOAL 3. Increase the knowledge and capacity of the workforce.

ORRP conducts a variety of trainings to increase the knowledge and capacity of clinicians and non-clinicians through the ORRP Training Plan. The plan provides a comprehensive overview of the current opioid overdose epidemic in the United States for ORRP partners and others who may be involved in the epidemic's response. Topics include clinical aspects of opioids, harm reduction strategies, and federal agency roles.

In addition, ORRP relies heavily on the continued dissemination of clinical opioid prescribing and tapering guidelines for physicians, including academic detailing programs to train healthcare providers. The hope is that by equipping and empowering more providers to care for patients on long-term opioid therapy, fewer patients will be abandoned by the healthcare system and forced to turn to an illicit drug supply.

To enhance the capacity of the USPHS to treat opioid dependency, CDC partners with the University of New Mexico to deliver a 16-week Project Echo curriculum focused on pain management, opioid prescribing, and treatment of opioid use disorders. Project Echo is a medical training model that combines short, didactic curricula with real-world examples to help practitioners engage in case-based learning and problem solving. Through this partnership with Project Echo, USPHS medical officers with prescribing abilities are also offered a four-hour training to count toward "DATA waiver" training requirements. The DATA waiver (also known as an "X waiver") requirement stems from the Drug Addiction Treatment Act (DATA) of 2000, which allows physicians who meet certain qualifications to treat opioid use disorder with buprenorphine in clinic offices.

ORRP STRATEGIC COMPONENT 4:
Outcome Monitoring

GOAL 4. Monitor patient outcomes related to care continuity and risk mitigation.

ORRP plans to utilize available healthcare data sets to assess patient outcomes following discontinued access to a prescriber of opioids or MAT/MOUD.

References

[1]FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. Available at https://www.fda.gov/Drugs/DrugSafety/ ucm635038.htm (accessed April 13, 2019)

[2]Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2020. Available at http://wonder.cdc.gov.

[3]National Center for Health Statistics, National Vital Statistics System, Mortality

ORRP Contact Information

For more information, visit CDC's Opioid Rapid Response Program (https://www.cdc.gov/opioids/opioid-rapid-response-program.html) or email ORRP@cdc.gov.