

# FOR A HEALTHIER AMERICA:

## PhRMA's Public Policy Strategy to Combat the Opioid Crisis

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its members are committed to working with other stakeholders to collectively address this growing public health crisis. We support public policies that

- ensure patients with legitimate medical needs have access to appropriate pain treatment options;
- ensure patients with abuse addiction and those who may have other mental health issues receive appropriate treatment;
- reduce the potential risks of abuse and addiction; and
- provide law enforcement with the necessary tools and capacity to combat diversion, fraud and abuse.

As part of its expanded proactive approach, PhRMA supports the following policies:



### IMPLEMENTING NEW PRESCRIBER REQUIREMENTS TO CURB OVERPRESCRIBING

Physicians and other prescribers are often on the frontlines of the fight against prescription drug abuse. PhRMA recommends a number of policies to support appropriate prescribing of opioid pain medications:

- **Implementation of 7-day script limits for opioids for acute pain treatment, with appropriate exceptions, including:**
  - Certain conditions or patients, such as chronic pain, pain associated with a cancer diagnosis or treatment, palliative care, hospice or end-of-life care, residents of long-term care or nursing facilities and individuals receiving medication assisted treatments for addiction.
  - Exemptions to limits when the medical professional determines that the condition causing the acute pain requires more than initial limited supply, accompanied by a notation by the prescriber in the patient's health record.
- **Policies supporting a 30-day supply limit for opioid medications for chronic pain treatment, with additional measures to encourage appropriate use, including:**
  - Requirement that prescribers check the relevant prescription drug monitoring programs (PDMPs) when first prescribing an opioid medication and then periodically (e.g., every 90 days) in conjunction with regular reassessment of the patient's treatment plan.
  - Development of guidelines to inform appropriate treatment of pain, such as the Centers for Disease Control (CDC) guidelines for primary care providers and the development of best practices in pain management by the Health and Human Services (HHS) Task Force.
  - Use of patient treatment agreements, to ensure better communication between patients and providers before initial opioid treatment and use of other measures to monitor and assess patients on opioid therapy.
- **Prohibition on dispensing Schedule II medications in an office setting.**

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### IMPLEMENT MANDATORY, ONGOING PRESCRIBER TRAINING TO IMPROVE EDUCATION

Physicians and other prescribers need the appropriate training and tools to ensure they can meet their patients' legitimate medical needs while reducing the potential for abuse. Ongoing training should be a requirement for prescribers seeking either a Drug Enforcement Administration (DEA) license or license renewal to prescribe controlled substances or a state license from an entity such as a Board of Pharmacy. PhRMA supports mandatory training in the areas outlined below:

- **Pain management**, such as best practices in pain management, the CDC guidelines for primary care prescribers for chronic pain treatment, and evidence-based clinical guidelines to help inform appropriate treatment, including appropriate medication selection, dosage and duration.
- **Risks and benefits of prescription opioids**, information on immediate-release, extended-release and long-acting opioid formulations.
- **Screening for mental health** and substance abuse issues.
- **New pain treatment alternatives**, including opioid overdose reversal agents, addiction treatment and recovery options including medication-assisted treatments, abuse-deterrent formulations and non-opioid analgesics.
- **Prescription drug monitoring programs (PDMPs)** and other tools for identifying potential doctor shoppers.



### EXPAND COVERAGE AND ACCESS TO RANGE OF OPTIONS TO TREAT ADDICTION

The opioid crisis is a complex problem with no single solution. Patients need to be able to access a range of treatment options. Yet despite existing parity laws, patients who want to reduce the risk of drug abuse or to find support for addiction recovery often run into hurdles preventing them from accessing the care they need. PhRMA supports a comprehensive approach to improving coverage and access to treatment that includes the following:

- **Improved coverage and access** to the full range of treatment and recovery services, from in-patient and out-patient treatment options to medication-assisted treatments (MAT).
- **Elimination of barriers to treatment** based on federal Institutes of Mental Diseases exclusion within Medicaid.
- **Enforcement of mental health parity** and expanded prescriber screening of patients for potential mental health and substance abuse issues, followed by referral to appropriate treatment and recovery services.
- **Expanded training for and access to opioid overdose reversal agents**, enacted through use of standing orders and adoption of "good Samaritan laws."

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### USE PRESCRIPTION DRUG MONITORING PROGRAMS TO PREVENT DOCTOR SHOPPING

Consistent use of prescription drug monitoring programs (PDMPs) is one of the most promising tools we have to prevent and detect potential doctor shoppers, while still allowing for legitimate medical use of needed medicines. These state-run databases collect, analyze and share dispensing information on controlled substances, providing critical information to providers to inform their prescribing. PhRMA supports public policies to:

- **Mandate PDMP registration, use and training** by prescribers.
- **Address the lack of cross-state interoperability**, which is a significant shortcoming of state PDMPs.
- **Ensure federal health care system providers share data** with PDMPs and consult state PDMPs, including agencies like the Department of Veterans Affairs.
- **Identify and disseminate PDMP best practices** to identify potential doctor shopping and assess patient risk for opioid use disorder and overdose.



### DEVELOP AND USE NEW MEDICATIONS TO REDUCE THE RISK OF ABUSE, PREVENT ADDICTION AND TREAT ADDICTION AND OVERDOSE

To truly solve the opioid crisis, we must break the current cycle of addiction and take steps to prevent abuse before it starts. PhRMA supports public policies to advance the development of new technologies and treatments:

- **Advance a public-private partnership** between innovative biopharmaceutical companies and the National Institutes of Health and National Institute on Drug Abuse to
  - ① develop new formulations and combinations of medications to treat opioid use disorders, prevent and reverse overdose;
  - ② accelerate development of new non-addictive pain therapies.
- **Expedite the review and encourage the development** of non-opioid pain medications and abuse-deterrent formulation (ADF) products, as well as products that treat opioid use disorder, addiction and overdose, which can be accomplished through the Food and Drug Administration's existing authority.
- **Review and address potential coverage and access barriers** by insurers and pharmacy benefit managers to ensure they are not contributing to the opioid crisis by impeding access to ADF medicines that have demonstrated potential to deter and prevent abuse, non-opioid pain medications, as well as medications to treat addiction and overdose.

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## STRENGTHEN LAW ENFORCEMENT'S TOOLS AND CAPACITY TO GO AFTER ILLEGAL ACTIVITY

The impact of drug diversion goes beyond the toll it brings to the person abusing prescription or illicit drugs. It costs our health care system, our communities and our workforce dearly, not to mention the emotional toll placed on families and friends. It also puts a disproportionate burden on law enforcement officials and first responders, who face the devastating consequences of addiction and overdose every day. PhRMA supports policies to:

- **Expand law enforcement's ability and capacity to shut down key sources of diversion**, fraud and abuse, including illegal pill mills, rogue online pharmacies and multi-national criminal organizations manufacturing and distributing counterfeit fentanyl.
- **Enhance DEA's emergency scheduling authority** to address synthetic drugs and other emerging threats.
- **Independently assess the DEA's role and authorities** related to enforcing the Controlled Substances Act, including the roles and responsibilities of the more than 1.5 million DEA registrants.