

## Prescriber Requirements to Help Combat the Opioid Crisis

According to the Centers for Disease Control and Prevention (CDC), “[t]he amount of opioids prescribed in the U.S. is still too high, with too many opioid prescriptions...[h]ealthcare providers have an important role in offering safer and more effective pain management while reducing risks of opioid addiction and overdose.”<sup>i</sup> While we have seen decreases in the amount of opioids prescribed since 2010, the Pharmaceutical Research and Manufacturers of America (PhRMA) believes additional measures are needed to support appropriate prescribing. As 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 including:

- Public policies to implement 7-day script limits for opioids for the treatment of acute pain with appropriate exceptions.
- Policies supporting a 30-day supply limit for opioid medications for chronic pain treatment, and the development and use of additional tools to inform appropriate prescribing (e.g., CDC guidelines and other tools for the treatment of chronic pain).
- Prescriber training requirements in a number of areas to facilitate appropriate prescribing of controlled substances, appropriate treatment of pain, and use of tools to help identify potential doctor shoppers and identify and appropriate referral to treatment of those with a substance use disorder.

Each of these areas is described in more detail below:

**Public policies to establish 7-day script limits for opioids for the treatment of acute pain.** Too often patients are prescribed a 30-day supply of opioid medications for the treatment of acute pain (i.e., pain resulting from acute illness, trauma, surgery, or another cause, that is reasonably expected to last only a short period of time), when a smaller amount would suffice. While PhRMA and its members have always sought to preserve the physician-patient relationship, given the scope of the crisis, we believe script limit policies are necessary to help reduce the risk for addiction associated with inadvertent overprescribing of opioids for the treatment of acute pain. Numerous studies have found that a large percentage of adults who fill an opioid prescription have leftover medication that they plan to hold on to. We believe script limit policies may reduce this potential source of diversion and abuse. Script limit policies should:

- Include exclusions for certain conditions or patients, e.g., chronic pain, pain associated with a cancer diagnosis or treatment, palliative care, hospice care, residents of long-term care or nursing facilities, and individuals receiving treatment for substance use disorders.
- Ensure that prescribers re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust the patient’s treatment plan accordingly. Prescribers should not prescribe additional opioids to patients “just in case” pain may continue longer than expected.

- Consider additional requirements related to prescribing an opioid to a minor, such as:
  - Assessment of the minor’s mental health and substance abuse history.
  - Discussion with the minor and parent(s) or guardian(s) about the risks of addiction/overdose.
  - Written consent for the prescription from the minor’s parent(s) or guardian(s).
  - Consideration of whether a more limited supply is appropriate, e.g., in some states with 7-day script limits for adults, 5-day script limits have been implemented for minors.
  
- Provide an exemption to limits when the prescriber determines that the condition causing the acute pain requires more than the initial limited supply due to projected longer duration of pain. In such cases, the prescriber should use his or her best clinical judgment and document in the patient’s medical record the rationale and affirm that that he or she checked the Prescription Drug Monitoring Program (PDMP) (where operational), screened for potential risk of abuse, and discussed the appropriate use of the medication with the patient.

In addition, we support public policies that would prohibit direct dispensing of any Schedule II drug in an office setting.

**Policies supporting a 30-day supply limit for opioid medications for chronic pain treatment and additional tools and measures to inform appropriate prescribing.** PhRMA supports efforts to ensure patients with legitimate medical needs have access to appropriate pain treatments and maintain an ongoing dialogue with providers on the management of pain. Prescribers need tools to inform appropriate prescribing while also reducing the risk of addiction and opioid-related harms. In addition to supporting a 30-day supply limit for opioid medications, PhRMA supports additional tools and measures:

1. The development and use of guidelines to inform the appropriate treatment of pain, such as:
  - The Centers for Disease Control (CDC) guidelines for primary care providers given they are on the front lines of addressing the crisis.
  - The development of condition-specific evidence-based clinical guidelines to further inform appropriate prescribing and dosages for the treatment of acute and chronic pain by various specialties.
  - The creation of the Pain Management Best Practices Inter-Agency Task Force by the U.S. Department of Health and Human Services, which was authorized by the Comprehensive Addiction and Recovery Act of 2016. This task force is charged with identifying potential gaps or inconsistencies in pain management best practices among federal agencies and making recommendations to address the gaps, which will be open for public comment, and finally with developing a strategy for disseminating those best practices. Bringing together the top experts in pain from across the public and private sectors is an important

step in developing guidance on how to most appropriately address pain while reducing the potential for abuse.

2. Best practice prescribing measures:

- Requirement that prescribers check the relevant Prescription Drug Monitoring Program (PDMP) when first prescribing an opioid medication and then periodically (e.g. every 90 days).
- Reevaluation of the patient's treatment plan periodically to ensure appropriate assessment of benefits and potential harms of the treatment plan.
- Evaluation of the potential risk factors for opioid-related harms, which may inform whether the prescriber also prescribes an opioid reversal agent.
- Offering treatment for opioid use disorder (e.g., medication-assisted treatment in combination with behavioral therapies) for patients with opioid use disorder.
- Use of patient treatment agreements to support communication between patients and providers before initial opioid treatment and use of other measures to monitor and assess patients on opioid therapy.

**Public policies mandating prescriber training.** The reality is that prescribers often are subject to only a handful of hours of training in medical school on pain management and even fewer hours on addiction and how to assess the potential risks for addiction. As voluntary education and training measures have been insufficient, we support mandatory prescriber education focused on:

- Appropriate management of pain and the latest treatment options, including abuse deterrent formulations and non-opioid analgesics.
- Available addiction treatment options, including inpatient and outpatient treatment options, as well as the use of overdose reversal agents (e.g., naloxone) and medications to treat addiction. Currently, too few prescribers have received training regarding opioid reversal agents and medication-assisted treatment.
- Screening for potential substance abuse and other mental health issues.
- Use of PDMPs, which research has demonstrated help promote appropriate prescribing and detect potential doctor shopping.

While there is no consensus on how frequently additional training should be required, we support proposals that would link mandated training to either state or federal laws related to licensure for those prescribing controlled substances, e.g., linkage to DEA licensure and renewal.

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<sup>i</sup> CDC Press Release, Opioid Prescribing is still high and varies widely throughout the US, July 6, 2017: <https://www.cdc.gov/media/releases/2017/p0706-opioid.html>