

April 30, 2019



Drug Safety Communication: Risks with Sudden Discontinuation of Opioids

Opioids are a class of prescription medicines that are used to manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. Opioids have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

On April 9, 2019, the U.S. Food and Drug Administration (FDA) issued a warning that it has received reports of serious harm in patients who are physically dependent on opioid pain medicines when these medicines are suddenly discontinued or the dose is rapidly decreased. Examples of serious harm include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. The FDA is requiring expanded guidance within the prescribing information of opioids that are intended for use in the outpatient setting on how to safely decrease the dose in patients who are physically dependent on opioids.

While not every patient taking opioids requires tapering, health care professionals should not abruptly discontinue opioids in a patient who is physically dependent on opioids. In order to minimize risk to patients when tapering the dose of opioids, health care professionals should consider the following actions:

- Work with each patient to agree on an appropriate tapering schedule and follow-up plan so both patient and provider goals and expectations are clear and realistic. Tapering should be voluntary.
- Consider a variety of factors in the development of an opioid tapering schedule, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients.
- Counsel every patient to contact a health care professional if they experience increased pain, withdrawal symptoms, changes in mood, or thoughts of suicide.
- When managing patients taking opioid analgesics, particularly those who have been treated for a long duration and/or with high doses for chronic pain, ensure that a multimodal approach to pain management, including mental health support (if needed), is in place prior to tapering the dose of opioids.
- Reassess the patient regularly to manage pain and withdrawal symptoms that emerge, as frequent follow up with patients is important.
- When opioid analgesics are being discontinued due to a suspected substance use disorder, evaluate and treat the patient, or refer them for evaluation and treatment of the substance use disorder. Treatment should include evidence-based approaches such as medication-assisted treatment. Complex patients with comorbid pain and substance use disorders may benefit from referral to a specialist.

To read the full safety announcement, which includes a summary of withdrawal symptoms, refer to the "FDA Drug Safety Communication: FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering" article found on the [Drug Safety and Availability](#) page of the FDA website. For more information about when and how to taper opioids for chronic pain, providers may refer to the resource, "[Pocket Guide: Tapering Opioids for Chronic Pain](#)," which can be found on the Centers for Disease Control and Prevention (CDC) website.