

## **Guidelines for Chronic Use of Opioid Analgesics (Model Policy)**

Revises the Federation of State Medical Boards's Model Policy for the prescription of opioid pain relievers, in accordance with recent scientific evidence and expert opinion, to guide medical professionals in the effective and responsible prescription of opioid analgesics.

Updated last **August 10, 2017**  
for the April 2017 Guidelines.

### **WHAT IT DOES**

The 2017 "[Guidelines for the Chronic Use of Opioid Analgesics](#)" (Guidelines) by the [Federation of State Medical Boards](#) (FSMB) serve as a resource for state medical and osteopathic boards in evaluating a clinician's prescription of opioid pain-relieving drugs to patients with chronic, non-cancer pain. These Guidelines revise and replace the FSMB's 2013 "[Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain](#)" to align with recent scientific research and input from medical and policy experts. The FSMB encourages state boards to endorse and adopt the Guidelines but does not mandate that they do so; the Guidelines function merely as recommendations. Furthermore, the FSMB recognizes that treatment necessities vary circumstantially between patients and does not claim to create a standard of care, to recommend opioid based treatment over other treatments, or to recommend opioid treatment in cases of acute pain.

The Guidelines recommend that state medical boards adopt certain criteria to assess how physicians manage their patients' pain through opioid analgesic prescriptions:

1. **Patient Evaluation and Risk Stratification:** Clinicians should first evaluate the type, cause, and severity of a patient's pain and ensure that prescribing an opioid analgesic could provide pain relief. Clinicians should also evaluate and document the patient's full medical history, making sure to note co-existing diseases and risk factors for substance use disorder such as history of drug abuse, history of physical or sexual abuse, or mental health disorders. Consultation with the state prescription drug monitoring program (PDMP) should occur. A clinician should also determine if the patient is taking opioids prescribed by another clinician, and should give special consideration to elderly patients and female patients of childbearing age.
2. **Development of a Treatment Plan and Goals:** Clinicians should develop treatment plans that aim to decrease suffering and pain-related conditions and increase patient functionality. Clinicians should establish documentation outlining individualized treatment plans and goals prior to the initiation of treatment and revisit that documentation with patients as treatment progresses.
3. **Informed Consent and Treatment Agreement:** Clinicians should discuss with the patient the potential and actual advantages and disadvantages of the treatment plan and opioid analgesics involved, including the risk of substance use disorder, potential drug interactions, potential physical and mental effects, safe storage practices, and prescription frequency expectations. Especially when prescribing the chronic use of opioid analgesics, clinicians should utilize a written informed consent and treatment agreement that establishes responsibilities of the medical professional and patient.
4. **Initiating an Opioid Trial:** Clinicians should consider non-opioid treatment before initiating opioid treatment. Before approving chronic opioid treatment, clinicians should initiate opioid treatment through a therapeutic trial lasting no more than 30 days with predetermined evaluation checkpoints and constant monitoring. Clinicians ought to prescribe the lowest dosage possible of a short acting opioid before approving higher dosages or recommending long acting / extended release opioids; they should also consider the co-prescription of naloxone in case of overdose.
5. **Ongoing Monitoring and Adapting the Treatment Plan:** Clinicians should routinely review patient progress, including relevant medical information, treatment response, and overall health. Follow-up visits should be scheduled frequently during treatment plan initiation or the adjustment of the treatment plan. Clinicians should evaluate patient progress and actual risks through the treatment and continue, alter, or discontinue treatment accordingly.
6. **Periodic and Unannounced Drug Testing:** Clinicians should periodically and without warning perform drug tests to verify patient self-reports and ensure compliance with the treatment plan. Such drug tests should be documented in the patient's medical

- record and discussed with the patient if the clinician discovers opioid drug misuse.
7. **Adapting Treatment:** Clinicians should determine whether to revise or augment the treatment plan if a patient's progress is unsatisfactory, paying particular attention to misuse of prescribed opioids, use of drugs not prescribed by a clinician, and potentially threatening behaviors.
  8. **Consultation and Referral:** Clinicians should make themselves aware of pain management treatments independent of opioid analgesics and consider referring patients to appropriate forms of non-medicinal therapeutic treatment, including but not limited to interventional pain management, acupuncture, physical therapy, and occupational therapy. In instances where the clinician does not feel comfortable prescribing an appropriate level of opioids to handle the patient's pain, the clinician should advise a specialty consultation. Clinicians should also make themselves aware of opioid use disorder treatment options.
  9. **Discontinuing Opioid Therapy:** Clinicians should consider tapering or discontinuing opioid therapy if the painful condition is resolved, harmful side effects emerge, or the treatment has not improved the quality of life of the patient. When opioid therapy is discontinued, clinicians should gradually wean patients off opioid dependence through tapered prescription amounts. Clinicians should also manage withdrawal and physical dependence.
  10. **Medical Records:** Clinicians should maintain updated medical records that include medical history, prescription orders, prescription instructions, informed consent and treatment agreements, results of all forms of patient assessment prior to and throughout treatment, results of the PDMP report, and authorization for release of the aforementioned information to other medical professionals.
  11. **Compliance with Controlled Substance Laws and Regulations:** Clinicians ought to comply with the [Physicians' Manual of the U.S. Drug Enforcement Administration](#), all state and federal regulations, and the Drug Enforcement Agency.

#### RELEVANT SCIENCE

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[Opioids](#) are substances that attach to opioid receptor sites found on [neurons](#), cells that transmit information between the brain and the rest of the body. This transmission of information is known as [neurotransmission](#). During neurotransmission, neurotransmitters, or chemical messengers, spread information between neurons by either activating or inhibiting those neurons from producing their own chemical messages. Neurotransmission is naturally regulated by a series of inhibitory and activation signals that control neuronal activation; some neurotransmitters cause neurons to activate while some neurotransmitters prevent neurons from activating. The signals received by neurons from neurotransmitters regulate pathways of neuron signaling.

[According to the National Institutes of Health](#) (NIH), opioids function as neurotransmitters capable of activating certain pathways of neuron signaling by binding to their specific opioid receptor sites. The body naturally produces [endogenous opioids](#) that bind to and activate opioid receptor sites on neurons to release "feel-good" chemicals such as [endorphins](#), [serotonin](#), [oxytocin](#), and [dopamine](#) that control our reaction to painful stimuli.

However, [the NIH states](#) that externally-administered, opioid drugs not produced by the body can disrupt the natural regulation of neurotransmission. These opioid drugs mimic the molecular structure of the brain's natural opioids to bind to natural opioid receptor sites, activate neurons, and cause neurons to overproduce the "feel-good" neurotransmitters. In this way, these opioid drugs "fool" the nervous system into a state of overstimulation that ultimately results in the excess release of neurotransmitters that produce feelings of relaxation and pleasure. For this reason, clinicians can prescribe opioid analgesics as a form of pain-managing medical treatment because of the drugs' ability to induce the release the chemicals that alleviate painful feelings.

[According to the National Institute on Drug Abuse](#) (NIDA), one risk of using prescription opioids is addiction: opioid usage particularly activates the production of [dopamine](#), the neurotransmitter that cause the desire to repeat behavior. Dopamine signaling activates the brain's reward system and causes the desire to repeat pleasurable experiences. As a result, a small percentage of patients develop an unwanted addiction to opioids that begins with the usage of prescription opioids. The usage of heroin, an illegal opioid drug, is [nineteen times higher](#) for individuals who began using opioids as prescription medication than those who had no prior prescription access to opioids.

Despite the link between prescription opioid usage and illicit opioid usage, the prescription rate for opioids has [significantly grown](#) over the past few years, perhaps [over three times higher](#) than it was three decades ago.

Opioids and opioid medications can be classified into three [main categories](#), distinguished by their synthetic properties:

- Natural opioid: opioids derived from the [opium poppy](#) (e.g., [morphine](#), [codeine](#), thebaine);
- Semi-synthetic opioids: opioids created from natural opiates (e.g., [hydromorphone](#), [hydrocodone](#), [oxycodone](#), [heroin](#)); and
- Fully synthetic opioids: opioids created entirely synthetically (e.g., [fentanyl](#), [pethidine](#), [levorphanol](#)).

#### WHY IT MATTERS

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[Studies](#) have shown that many medical professionals legally qualified to prescribe opioid analgesics are uncomfortable with their knowledge of the extent to which opioid analgesics relieve pain, of the risks associated with opioid analgesics, and of the standards for opioid prescription. [Other studies](#) reinforce this notion, demonstrating that there is little consistency among physicians in frequency of opioid prescriptions and duration of opioid prescription treatment.

The FSMB Guidelines for opioid prescription thus attempt to educate and guide medical professionals in the prescription of opioid analgesics. Such guidelines have the potential to increase medical professionals' comfort with writing prescriptions by providing advice and recommendations that do not necessarily deter the usage of opioid analgesics. Moreover, if state medical boards decide to adopt the FSMB Guidelines, those boards have the assurance that they are presenting recommendations backed by recent scientific research and expert opinion.

#### RELEVANT EXPERTS

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[Li-Tzy Wu, D.Sc.](#), is a Professor in Psychiatry and Behavioral Sciences at Duke University. Her research focuses on substance use disorder and treatment for drug use and alcohol use disorder.

Relevant publications:

- Wu, Li-Tzy, He Zhu, and Marvin S. Schwartz. 2016. "Treatment Utilization Among Persons with Opioid Use Disorder in the United States." *Drug and Alcohol Dependence* 169: 117-127. doi:[10.1016/j.drugalcdep.2016.10.015](#)
- Ling, Walter, Larissa Mooney, and Li-Tzy Wu. 2012. "Advances in Opioid Antagonist Treatment for Opioid Addiction." *Psychiatric Clinics of North America* 35(2): 297-308. doi:[10.1016/j.psc.2012.03.002](#)
- Wu, Li-Tzy, G.E. Woody, C. Yang, J.J. Pan, and Daniel Blazer. 2011. "Abuse and Dependence on Prescription Opioids in Adults: A Mixture Categorical and Dimensional Approach to Diagnostic Classification." *Psychological Medicine* 41(3): 653-664. doi:[10.1017/S0033291710000954](#)
- Wu, Li-Tzy, G.E. Woody, C. Yang, and Daniel Blazer. 2010. "Subtypes of Nonmedical Opioid Users: Results from the National Epidemiologic Survey on Alcohol and Related Conditions." *Drug and Alcohol Dependence* 112(1-2): 69-80. doi:[10.1016/j.drugalcdep.2010.05.013](#)

#### BACKGROUND

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In light of increased opioid prescriptions by medical professionals, the Federation of State Medical Boards developed the [Model Guidelines for the Use of Controlled Substances for the Treatment of Pain](#) in 1998 to set guidelines and standards for the prescription of opioid drugs to patients by medical professionals. The Model Guidelines intended to set general principles for the appropriate prescription of opioids rather than recommend specific treatments or strategies of care. These guidelines were distributed to and adopted by state medical boards to universalize standards for opioid treatments and guide medical professionals to prescribe opioid drugs responsibly. Since its initial creation in 1998, the Model Guidelines were updated and expanded to create the [Model Policy for the Use of Controlled Substances for the Treatment of Pain](#) in 2004. To more specifically address the prescription of opioids separately from the prescription of other controlled substances, the [Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain](#) was published in 2013.

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**ENDORSEMENTS & OPPOSITION**

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## Endorsements:

- Macon Jones (former Indiana Assistant State Attorney), [essay](#) (in reference to the 2004 FSMB Model Policy), 2012: “The Board should adopt a guideline based on a widely accepted standard of practice for physicians who prescribe controlled substances for pain treatment, such as the FSMB’s Model Policy of 2004. Such a formally adopted or codified guideline will provide the Board with a foundational source for what has been determined to be proper standards of conduct.”

## Opposition:

- American Medical Association (AMA), [public letter to FSMB](#) (in reference to the 2013 Model Policy), September 24, 2013: “Encouraging state medical boards only to engage with state attorneys general sends the wrong message to policymakers about solutions for this complicated public health issue.... A second area of concern is the final Model Policy's emphasis on what physicians ‘should’ do. The AMA is concerned that multiplicity of these new standards of care may have the unintended effect of creating so many requirements that prompt, effective care is impeded.... The new requirements also do not take into account that some states, for example, lack effective ‘take back’ or safe disposal programs, yet the FSMB mandates that physicians provide guidance to patients on take back and disposal efforts.”
- Physicians for Responsible Opioid Prescribing, [public letter](#) (in reference to the 2013 Model Policy), March 29, 2013: “We believe that if your state were to adopt the proposed policy it might encourage opioid overprescribing, potentially worsening the epidemic of opioid analgesic addiction and overdose deaths. We believe that this document minimizes opioid risks and encourages the highly controversial practice of treating chronic non-cancer pain (CNCP) with opioids. Furthermore, because it fails to suggest practical policies to reduce risky prescribing, we believe an important opportunity to assist your state in addressing this urgent public health crisis may have been lost.”

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**STATUS**

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Adopted as policy by the FSMB in April of 2017 as an update to existing policy on the prescription of opioid analgesics.

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**RELATED POLICIES**

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The following list features recent governmental actions related to opioid analgesic legality, accessibility, and prescription rates from the 114th and 115th Congress.

## 115th Congress:

- Protecting Americans from Dangerous Opioids Act ([S 1079](#)) was introduced in the Senate on May 5, 2017. This bill would require the Food and Drug Administration (FDA) to revoke approval of a currently approved opioid medication for every opioid medication gaining new approval in a one-for-one exchange. This bill seeks to prevent the overall list of approved opioid medication from growing.
- Prescription Drug Monitoring Act of 2017 ([HR 1854](#)) was introduced in the House on April 24, 2017. Another version of the bill ([S 778](#)) was introduced in the Senate on March 30, 2017. This bill would require all states to use PDMPs and encourage states to share drug monitoring information.
- Abuse-Deterrent Opioids Plan for Tomorrow Act of 2017 ([HR 2025](#)) was introduced in the House on April 7, 2017. This bill would amend the Federal Food, Drug, and Cosmetic Act to prevent certain opioids from being ineligible for approval because they were labelled without description of their abuse-deterrent properties.

## 114th Congress:

- 21st Century Cures Act ([HR 34](#)) ([SciPol brief available](#)) was enacted into law on December 13, 2016. This bill would provide regulations for opioid abuse research regarding protections for research subjects, grant/funding framework for research, sharing of research data, and the drug approval process.
- Dangerous Synthetic Drug Control Act of 2016 ([HR 3537](#)) was passed in the House on September 26, 2016. This bill would amend the Controlled Substances Act to add specific synthetic opioids, hallucinogens, and cannabinoids to Schedule I (i.e., most restrictive) drugs under the Controlled Substances Act.
- Comprehensive Addiction and Recovery Act of 2016 ([S 524](#)) was enacted into law on July 22, 2016. The act authorizes the Department of Justice and Department of Health and Human Services to award grants for education efforts and treatment programs and creates new regulations on the FDA approval of opioid drugs.
- Opioid Review Modernization Act of 2016 ([HR 4976](#)) passed in the House on May 11, 2016. This bill would require the Commissioner of Food and Drugs to assess recommendations from the FDA advisory committee before approving new opioids without abuse-deterrent properties.

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**ORGANIZATIONS**

The Federation of State Medical Boards is a non-profit organization that represents the 70 state medical and osteopathic boards in the United States. The FSMB supports state medical boards by providing research, evaluations, and model regulations that allow state medical boards to promote the best public safety and health practices.

The Workgroup on FSMB *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* was appointed in April 2015 by the former FSMB Chair [J. Daniel Gifford, MD, FACP](#). The workgroup met three times over the course of a year to conduct an analysis and revision of existing FSMB policy. The workgroup produced the Guidelines for Chronic Use of Opioid Analgesics and is expected to continue revising and updating this Model Policy.

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