COMMENTS OF [redacted]

OSC File No. DI-25-002034

I appreciate the efforts of the Office of Special Counsel (OSC) and the Department of Veterans Affairs investigators in reviewing my disclosure. I agree with several important findings in the report, including the determination that Oklahoma City primary care providers failed to consistently comply with opioid-monitoring requirements required by Oklahoma law and VA guidance and failed to consistently document reasonable efforts to decrease opioid use or pursue alternative treatment modalities.

However, the report does not include an evaluation of one of the most important concerns I raised before and during the investigation: whether chronic opioid patients were being assessed for opioid use disorder (OUD), a serious and potentially life-threatening medical condition, as required by Oklahoma law.

This issue is not separate from the allegations referred for investigation. Allegation 2 specifically concerned whether providers made and documented reasonable efforts to reduce the potential for the development of OUD among chronic opioid patients. **Evaluating whether patients were being assessed for OUD was integral to the evaluation of that allegation.** The development of OUD cannot be meaningfully evaluated without assessing whether patients have developed the condition.

I repeatedly raised concerns regarding the absence of documented assessment for OUD among patients receiving chronic opioid therapy. These concerns were raised with facility leadership, discussed with national VA representatives, and communicated during the investigative process.

Oklahoma law requires practitioners who continuously prescribe opioids for chronic pain for three months or more to assess patients for problems associated with opioid use disorder, as defined by the American Psychiatric Association (APA), at specified intervals and to document the results of those assessments. In addition, Oklahoma opioid prescribing guidance published by the Oklahoma State Department of Health and disseminated through the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDD) states: “Screen all patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated.”

Because Oklahoma law specifically requires assessment for OUD and documentation of that assessment, compliance with that requirement was measurable and readily capable of evaluation during the investigation. Yet the report does not evaluate whether chronic opioid patients were assessed for OUD, report compliance rates for such assessments, or determine whether patients with OUD were identified.

Instead, the report focuses primarily on measures intended to reduce the risk of opioid-related harm. While those measures are important, they are not substitutes for assessing whether a patient currently suffers from OUD.

Among the report's principal conclusions was a determination that no patient harm was identified related to primary care opioid prescribing practices.

The APA has reported that approximately 3% to 12% of patients treated with opioids for chronic pain may develop opioid addiction or OUD.

The report notes that Oklahoma City had approximately 2,222 veterans receiving long-term opioid therapy during the period reviewed. Applying the APA's reported range to a population of this size would suggest that approximately 67 to 267 veterans could be expected to suffer from OUD. **OUD is a serious medical condition associated with substantial morbidity and mortality, including overdose and death.** The possibility that affected patients may not have been consistently identified is therefore directly relevant to any assessment of patient harm.

If compliance with Oklahoma's OUD assessment requirements was not evaluated, there is no reliable basis for determining whether veterans with OUD were being consistently identified.

For that reason, the conclusion that no patient harm was identified should be interpreted in the context of the report's limited evaluation of OUD assessment practices.

I do not suggest that any specific number of Oklahoma City veterans had OUD. Rather, my concern is that the report does not evaluate compliance with Oklahoma's statutory requirement to assess patients for OUD or with Oklahoma opioid prescribing guidance published by the Oklahoma State Department of Health and disseminated through OBNDD stating, "Screen all patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated."

More importantly, if providers are not consistently performing and documenting the assessments required by Oklahoma law, the healthcare system is necessarily deficient in its ability to identify the cohort of patients experiencing OUD. The primary purpose of these assessments is to identify patients who have developed OUD and ensure they receive appropriate treatment.

The report also appears to understate the scope of the deficiencies that were identified. The report characterizes the deficiencies as episodic and presents noncompliance rates by individual compliance category. However, it does not state what percentage of reviewed patients had one or more opioid-management deficiencies.

Based on the report's figures, at least 31% of reviewed patients had a deficiency in one compliance category. Even under this most conservative interpretation of the data, **a reasonable question exists as to whether deficiencies affecting nearly one-third of reviewed patients should be characterized as episodic.** The actual percentage of affected patients may have been substantially higher.

Because the report does not provide patient-level analysis showing the degree of overlap between deficiency categories, it is not possible to determine from the report what percentage of patients had one or more deficiencies. **Depending on that overlap, the proportion of affected patients could theoretically range from approximately 31% to nearly all reviewed patients.**

The report does not provide sufficient information to determine where within that range the true value lies.

This limitation is important because the scope of patient impact is directly relevant to whether the identified deficiencies should be characterized as episodic or systemic. As the percentage of affected patients increases, the characterization of the deficiencies as systemic becomes progressively more compelling.

My purpose in raising these concerns has never been to assign blame. Rather, it has been to improve patient care and ensure compliance with Oklahoma law and evidence-based opioid prescribing practices. I appreciate that the investigation substantiated important deficiencies and recommended corrective actions. These comments are offered in the hope that remaining gaps, particularly those involving assessment for OUD, can be addressed so that veterans receive the safest and highest-quality care possible.

Selected statutory and clinical references supporting the concerns discussed above are attached as Appendix A and accompanying attachments.

Respectfully submitted,

Date: 6/5/2026

APPENDIX A
AUTHORITIES AND REFERENCES

1. Oklahoma Statute – 63 O.S. § 2-309I(F)(2)

"When an opioid drug is continuously prescribed for three (3) months or more for chronic pain, the practitioner shall … assess the patient … to determine whether the patient is experiencing problems associated with opioid use disorder as defined by the American Psychiatric Association and document the results of that assessment."

(See Attachment 1.)

2. Oklahoma Opioid Prescribing Guidance

"Screen all patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated."

(See Attachment 2.)

3. American Psychiatric Association (APA)

The APA reports that approximately 3% to 12% of patients treated with opioids for chronic pain develop opioid addiction or opioid use disorder.

(See Attachment 3.)

4. National Institutes of Health / National Center for Biotechnology Information (NCBI)

NIH-supported medical literature describes OUD as a condition associated with substantial morbidity and mortality, including overdose and death.

(See Attachment 4.)

ATTACHMENT 1

OKLAHOMA STATUTE 63 O.S. § 2-309I(F)(2)

Purpose of Attachment

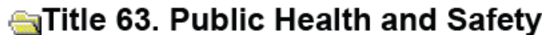
This attachment is submitted in support of the comments provided in OSC File No. DI-25-002034 regarding assessment of opioid use disorder (OUD) among patients receiving chronic opioid therapy.

The attached statute requires practitioners who continuously prescribe opioids for chronic pain to assess patients for problems associated with OUD at specified intervals and to document the results of those assessments.

This authority is relevant because the accompanying comments note that compliance with this statutory requirement does not appear to have been evaluated during the investigation despite its direct relevance to Allegation 2.

Relevant statutory language highlighted.

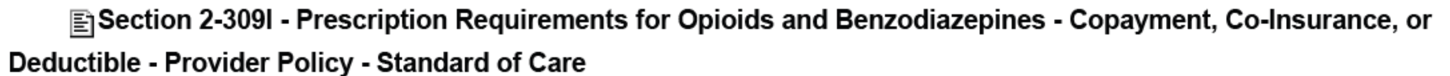
Oklahoma Statutes Citationized



Title 63. Public Health and Safety

Chapter 2 - Uniform Controlled Dangerous Substances Act

Article Article 3 - Regulation of Manufacture, Distribution, Dispensing, Prescribing, Administering, and Using for Scientific Purposes of Controlled Dangerous Substances



Section 2-309I - Prescription Requirements for Opioids and Benzodiazepines - Copayment, Co-Insurance, or Deductible - Provider Policy - Standard of Care

Cite as 63 O S § 2 309I (OSCN 2026)

A. A practitioner shall not issue an initial prescription for an opioid drug in a quantity exceeding a seven-day supply for treatment of acute pain. Any opioid prescription for acute pain shall be for the lowest effective dose of an immediate-release drug.

B. Prior to issuing an initial prescription for an opioid drug in a course of treatment for acute or chronic pain, a practitioner shall:

1. Take and document the results of a thorough medical history, including the experience of the patient with nonopioid medication and nonpharmacological pain-management approaches and substance abuse history;

2. Conduct, as appropriate, and document the results of a physical examination;

3. Develop a treatment plan with particular attention focused on determining the cause of pain of the patient;

4. Access relevant prescription monitoring information from the central repository pursuant to Section 2-309D of this title;

5. Limit the supply of any opioid drug prescribed for acute pain to a duration of no more than seven (7) days as determined by the directed dosage and frequency of dosage; provided, however, upon issuing an initial prescription for acute pain pursuant to this section, the practitioner may issue one (1) subsequent prescription for an opioid drug in a quantity not to exceed seven (7) days if:

a. the subsequent prescription is due to a major surgical procedure or "confined to home" status as defined in 42 U.S.C., Section 1395n(a),

b. the practitioner provides the subsequent prescription on the same day as the initial prescription,

c. the practitioner provides written instructions on the subsequent prescription indicating the earliest date on which the prescription may be filled, otherwise known as a "do not fill until" date, and

d. the subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription;

6. In the case of a patient under the age of eighteen (18) years, enter into a patient-provider agreement with a parent or guardian of the patient; and

7. In the case of a patient who is a pregnant woman, enter into a patient-provider agreement with the patient.

C. No less than seven (7) days after issuing the initial prescription pursuant to subsection A of this section, the practitioner, after consultation with the patient, may issue a subsequent prescription for the drug to the patient in a quantity not to exceed seven (7) days, provided that:

1. The subsequent prescription would not be deemed an initial prescription under this section;

2. The practitioner determines the prescription is necessary and appropriate to the treatment needs of the patient and documents the rationale for the issuance of the subsequent prescription; and

3. The practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction or diversion and documents that determination.

D. Prior to issuing the initial prescription of an opioid drug in a course of treatment for acute or chronic pain and again prior to issuing the third prescription of the course of treatment, a practitioner shall discuss with the patient or the parent or guardian of the patient if the patient is under eighteen (18) years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to:

1. The risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;

2. The reasons why the prescription is necessary;

3. Alternative treatments that may be available; and

4. Risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed or mixing sedatives, benzodiazepines or alcohol with opioids can result in fatal respiratory depression.

The practitioner shall include a note in the medical record of the patient that the patient or the parent or guardian of the patient, as applicable, has discussed with the practitioner the risks of developing a physical or psychological dependence on the controlled dangerous substance and alternative treatments that may be available. The applicable state licensing board of the practitioner shall develop and make available to practitioners guidelines for the discussion required pursuant to this subsection.

E. At the time of the issuance of the third prescription for an opioid drug, the practitioner shall enter into a patient-provider agreement with the patient.

F. When an opioid drug is continuously prescribed for three (3) months or more for chronic pain, the practitioner shall:

1. Review, at a minimum of every three (3) months, the course of treatment, any new information about the etiology of the pain, and the progress of the patient toward treatment objectives and document the results of that review;

2. In the first year of the patient-provider agreement, assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with an opioid use disorder as defined by the American Psychiatric Association and document the results of that assessment. Following one (1) year of compliance with the patient-provider agreement, the practitioner shall assess the patient at a minimum of every six (6) months;

3. Periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of an opioid use disorder as defined by the American Psychiatric Association and document with specificity the efforts undertaken;

4. Review the central repository information in accordance with Section 2-309D of this title; and

5. Monitor compliance with the patient-provider agreement and any recommendations that the patient seek a referral.

G. 1. Any prescription for acute pain pursuant to this section shall have the words "acute pain" notated on the face of the prescription by the practitioner.

ATTACHMENT 2

OKLAHOMA OPIOID PRESCRIBING GUIDELINES

Oklahoma State Department of Health

Issued September 2024

Purpose of Attachment

This attachment is submitted in support of the comments provided in OSC File No. DI-25-002034 regarding assessment of opioid use disorder (OUD) among patients receiving chronic opioid therapy.

The Oklahoma Opioid Prescribing Guidelines, published by the Oklahoma State Department of Health and disseminated through the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDD), state:

“Screen all patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated.”

This guidance is relevant because it reflects Oklahoma’s expectation that patients receiving opioid therapy be screened for OUD and referred for treatment when appropriate.

Relevant excerpt highlighted.

OKLAHOMA OPIOID PRESCRIBING GUIDELINES

2024

Note: These guidelines do not replace clinical judgment in the appropriate care of patients. They are not intended as standards of care or as templates for legislation and do not apply to pain related to sickle cell disease or cancer, patients receiving palliative or end-of-life care, or residents of long-term care facilities. The recommendations are an educational tool for clinicians providing pain care to patients 18 years and older based on the expert opinions of numerous physicians and other health care providers, medical/nursing boards, mental and public health officials, and law enforcement personnel in Oklahoma and throughout the United States[1,2,3,4]. For details on Oklahoma's opioid prescribing laws, visit okmedicalboard.org/download/884/Opioid_Best_Practices.pdf.

Opioid Treatment for Acute and Subacute Pain

1. Consider non-pharmacological therapies and/or non-opioid pain medications. Opioids should only be used for the treatment of acute and subacute pain when the severity of the pain warrants that choice. *By Oklahoma law, prior to the initial prescription, health care providers must discuss and document risks associated with opioid use.*
2. *By Oklahoma law, it is mandatory that health care providers check the Oklahoma Prescription Monitoring Program (PMP) prior to prescribing and every 180 days prior to authorizing refills for opioids, synthetic opioids, semi-synthetic opioids, benzodiazepines, or carisoprodol. More frequent checks of the PMP are recommended.*
3. When opioids are started, consider the lowest possible effective dose. Prescribe no more than a short course; most patients require immediate-release opioids for no more than three days. By Oklahoma law, the quantity shall not exceed a seven-day supply.
4. Avoid prescribing opioids to patients currently taking benzodiazepines and/or other opioids.
5. Patients should be counseled to store medications securely, never to share them with others, and to dispose of medications when the pain has resolved.
6. Long-acting or extended-release opioids should not be prescribed for acute or subacute pain.
7. Consider screening patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated.
8. Continued opioid use should be evaluated carefully, including assessing the potential for misuse, if pain persists beyond the anticipated period of acute or subacute pain. By Oklahoma law, at the time of the third opioid prescription, the health care provider shall enter into a patient-provider agreement with the patient.
9. In general, health care providers should not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Opioid Treatment for Chronic Pain

1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment for chronic pain.
2. *By Oklahoma law, it is mandatory that health care providers check the Oklahoma Prescription Monitoring Program (PMP) prior to prescribing and every 180 days prior to authorizing refills for opioids, synthetic opioids, semi-synthetic opiods, benzodiazepines, or carisoprodol. More frequent checks of the PMP are recommended.*
3. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.
4. Screen all patients (using a validated screening tool) for opioid use disorder and provide brief intervention and referral to treatment, if indicated.
5. Patients should be counseled to store medications securely, never to share them with others, and to dispose of medications when pain has resolved.
6. Long-acting or extended-release opioids are associated with an increased risk of overdose death and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.
7. A written treatment plan should be established that includes measurable goals for the reduction of pain and improvement of function. *By Oklahoma law, at the time of the third opioid prescription, the health care provider shall enter into a patient-provider agreement with the patient.*

8. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement. Consider co-prescribing naloxone for patients with increased risk of opioid overdose. *By Oklahoma law, prior to the initial prescription, health care providers must discuss and document risks associated with opioid use.*

9. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. The trial should begin with a short-acting opioid medication.

10. During the titration period, regular visits for evaluation of progress toward goals should be scheduled and the PMP should be checked more frequently.

11. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, tapering whenever possible. A second opinion or consultation may be useful in making that decision. *By Oklahoma law, if opioid treatment is continued for three or more months, the health care provider must: (1) review every three months the course of treatment, any new information regarding etiology of pain and progress toward treatment objectives; (2) assess patient prior to every renewal to determine if patient is experiencing dependency and document assessment; (3) periodically make reasonable efforts, unless clinically contraindicated to stop, decrease dosage, or try other treatment modalities; (4) review PMP; (5) monitor compliance with patient/provider agreement, and state "chronic pain" on the face of the prescription. After one year of compliance with the patient/provider agreement, physician may review treatment plan and assess patient at six-month intervals.*

12. Opioid treatment should be tapered or gradually discontinued if adverse effects outweigh benefits or if aberrant, dangerous, or illegal behaviors are demonstrated. Care should be taken when tapering opioid treatment, particularly in patients on higher dosages, the elderly, and patients who are pregnant. Abrupt discontinuation of opioids should be avoided. *By Oklahoma law, the health care provider must periodically make reasonable efforts, unless clinically contradicted, to stop, decrease dosage, or try other treatment modalities.*

13. Consider consultation for patients with complex pain conditions, serious comorbidities, mental illness, or a history or evidence of substance use disorder or misuse.

14. In general, health care providers should not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

15. Health care providers should offer or refer to evidence-based treatment (usually medication for opioid use disorder in combination with behavioral therapies) for patients with opioid use disorder. Detoxification on its own, without medication for opioid use disorder, is not recommended for opioid use disorder because of increased risk of resuming drug use, overdose, and overdose death.

OKLAHOMA BOARD OF NURSING

Resources

1. **Centers for Disease Control and Prevention. (2022).** *CDC Clinical Practice Guideline for Prescribing Opioids for Pain.* Retrieved from cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm. Accessed June 19, 2024.

2. **Oklahoma State Department of Health. (2017).** *Oklahoma Opioid Prescribing Guidelines.* Retrieved from oklahoma.gov/content/dam/ok/en/health/health2/documents/oklahoma-opioid-prescribing-guidelines-2017.pdf. Accessed June 19, 2024.

3. **Oklahoma State Department of Health. (2013).** *Oklahoma Emergency Department (ED) and Urgent Care Clinic (UCC) Opioid Prescribing Guidelines.* Retrieved from oklahoma.gov/content/dam/ok/en/health/health2/aem-documents/prevention-and-preparedness/injury-prevention/drug-overdose/Oklahoma_ED_Guidelines_FINAL%20with%20logos%20v4.pdf. Accessed June 19, 2024.

4. **Oklahoma State Department of Health. (2014).** *Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office-Based Setting.* Retrieved from oklahoma.gov/content/dam/ok/en/health/health2/aem-documents/prevention-and-preparedness/injury-prevention/drug-overdose/Oklahoma_Office%20Based_Guidelines_FINAL.pdf. Accessed June 19, 2024.

Learn more: oklahoma.gov/health/overdose

This publication was supported by the Cooperative Agreement Number 6NU17CE010188-01 funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services. This publication was issued by the Oklahoma State Department of Health (OSDH), an equal opportunity employer and provider. A digital file has been deposited with the Publications Clearinghouse of the Oklahoma Department of Libraries in compliance with section 3-114 of Title 65 of the Oklahoma Statutes and is available for download at documents.ok.gov. | Issued September 2024

ATTACHMENT 3

AMERICAN PSYCHIATRIC ASSOCIATION (APA)

Opioid Use Disorder Reference

Purpose of Attachment

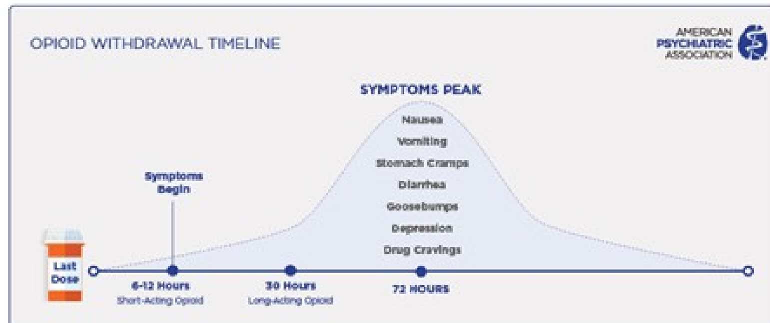
This attachment is submitted in support of the comments provided in OSC File No. DI-25-002034 regarding the prevalence of opioid use disorder (OUD) among patients receiving chronic opioid therapy.

The attached APA reference reports that approximately 3% to 12% of patients treated with opioids for chronic pain may develop opioid addiction or OUD.

This information is relevant to the accompanying comments because the report identified approximately 2,222 veterans receiving long-term opioid therapy, making assessment and identification of OUD clinically significant when evaluating opioid-prescribing practices and patient safety.

Relevant excerpt highlighted.

suddenly stopping opioid use leads to opioid 'withdrawal'. Symptoms of opioid withdrawal include whole-body pain, chills, cramps, diarrhea, dilated pupils, restlessness, anxiety, nausea, vomiting, insomnia, and very intense opioid cravings. Unlike withdrawal from alcohol or benzodiazepines, opioid withdrawal is not life-threatening on its own. However, the intensity of opioid withdrawal symptoms are so severe that patients will continue to use opioids in order to avoid them.



Expand Image

As with other substance use disorders, both genetic (such as mutations in the opioid receptor gene (10)) and environmental factors (such as exposure to trauma), contribute to the risk of developing opioid use disorder.(11) Ready access to prescription opioid, heroin, and fentanyl have all contributed to the current opioid epidemic.

An estimated 3-12% of people treated with opioids fo chronic pain will develop an addiction or abuse with negative consequences.(12) Approximately 8.6 million Americans reported misusing prescription opioids in 2023.(13) People who develop tolerance or dependence to prescription opioids may transition to illegally produced opioids, such as a fentanyl.

Treatment

The treatments for opioid use disorder are highly effective and reduce the use of illicit opioids by up to 90%.(14) Unfortunately, only a minority of patients with opioid use disorder receive treatment.(15) Medications for opioid use disorder, also called 'MOUD', are evidence-based, effective, and safe.(16) Counseling and behavioral therapies may be an important part of treatment alongside medications; however, they are effective by themselves.(17) MOUD relieve cravings, prevent withdrawal symptoms, and block the euphoric effects of illicit opioids. Similar to the majority of chronic diseases (for instance, diabetes), there is no cure for opioid use disorder, or

Opioid Use Disorder Symptoms

Opioids produce feelings of euphoria that make it more likely that people will continue to use opioids, despite any negative consequences that may go along with opioid use. Opioid use disorder ('OUD' – opioid addiction) is a chronic, medical disease, with serious potential consequences including disability, relapse, and death. The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision (DSM 5-TR) describes OUD as a pattern of opioid use leading to problems or distress, where at least two of the following occurring within a 12-month period:

1. Taking larger amounts or taking drugs over a longer period than intended.
2. Persistent desire or unsuccessful efforts to cut down or control opioid use.
3. Spending a great deal of time obtaining or using the opioid or recovering from its effects.
4. Craving, or a strong desire or urge to use opioids
5. Problems fulfilling obligations at work, school or home.
6. Continued opioid use despite having recurring social or interpersonal problems.
7. Giving up or reducing activities because of opioid use.
8. Using opioids in physically hazardous situations such as driving while under the influence of opiates.
9. Continued opioid use despite ongoing physical or psychological problem likely to have been caused or worsened by opioids.
10. Tolerance (i.e., need for increased amounts or diminished effect with continued use of the same amount)*
11. Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.*

*Patients who are taking opioids as prescribed by a healthcare provider may experience tolerance and withdrawal, but in that case, do not have opioid use disorder.

Opioid Withdrawal Symptoms

Regularly taking opioids for a short period of time (weeks),(7) can lead the brain and body to become used to the opioids. This causes physical (body) and psychological (brain) 'dependence' – an adaptation that makes it difficult to function without opioids. With opioid dependence,

ATTACHMENT 4

NATIONAL INSTITUTES OF HEALTH (NIH) NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (NCBI)

Opioid Use Disorder Reference

Purpose of Attachment

This attachment is submitted in support of the comments provided in OSC File No. DI-25-002034 regarding the clinical significance of opioid use disorder (OUD).

The attached NIH/NCBI reference describes OUD as a condition associated with substantial morbidity and mortality, including overdose and death.

This information is relevant to the accompanying comments because the report concluded that no patient harm was identified. The seriousness of OUD is directly relevant to evaluating whether failure to identify patients with OUD may have implications for patient safety and patient harm.

Relevant excerpt highlighted.

NCBI Bookshelf. A service of the National Library of Medicine, National Institutes of Health.

StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-.

Opioid Use Disorder: Evaluation and Management

Alexander M. Dydyk; Nitesh K. Jain; Mohit Gupta.

Author Information and Affiliations

Last Update: January 17, 2024.

Continuing Education Activity

This activity focuses on the critical evaluation and management of opioid use disorder (OUD), a pervasive condition significantly diminishing patients' quality of life and contributing to a widespread epidemic in the United States. With over 16 million affected globally and 2.1 million in the United States, the course emphasizes the urgency of identifying and promptly treating persistent opioid use and misuse. Participants will review evidence-based treatment options, including methadone and buprenorphine, and examine their roles in both the acute phase for detoxification and long-term management. The program also discusses the Mainstreaming Addiction Treatment (MAT) Act, which empowers healthcare providers to prescribe buprenorphine without the previous X-Waiver limitations. Furthermore, the course explores the multidimensional approach to treatment, including behavioral therapy, peer support, and the integration of nonpharmacologic interventions, reinforcing the need for an interprofessional team in optimizing patient care. Overall, this activity will equip healthcare professionals with the knowledge and skills necessary to navigate the intricate landscape of OUD, emphasizing a patient-centered, evidence-based, and interdisciplinary approach to improve outcomes and address the ongoing opioid epidemic.

Objectives:

- Identify the symptoms of opioid use disorder and opioid-related medical emergencies.
- Implement appropriate evaluation and diagnosis strategies for opioid use disorder.
- Differentiate the various treatment options for opioid use disorder, including pharmacologic and nonpharmacologic strategies.
- Collaborate effectively with other healthcare professionals to diagnose, treat, and comprehensively manage opioid use disorder.

Access free multiple choice questions on this topic.

Introduction

Opioid use disorder (OUD) is defined as the chronic use of opioids that causes clinically significant distress or impairment. Symptoms of this disease include an overpowering desire to use opioids, increased opioid tolerance, and withdrawal syndrome when opioids are discontinued. Thus, OUD can range from dependence on opioids to addiction.[1] OUD affects over 16 million people worldwide and over 2.1 million in the United States. Strikingly, there are as many patients using opioids regularly as there are patients diagnosed with obsessive-compulsive disorder, psoriatic arthritis, and epilepsy in the United States. More than 120,000

deaths worldwide every year are attributed to opioids.[2] Examples of opioids include heroin (diacetylmorphine), morphine, codeine, fentanyl, and oxycodone.

A rise in the prevalence of OUD and opioid deaths lends to the importance of clinicians' appreciation for the complexity of OUD. OUD typically involves periods of exacerbation and remission, but the vulnerability to relapse occurs throughout a patient's lifetime. Stressful events, loss of economic stability, and relationship issues can increase the risk of relapse. Opioid addiction is similar to other chronic relapsing conditions; signs and symptoms can be severe, and treatment adherence is often problematic.

Mainstreaming Addiction Treatment (MAT) Act

The Mainstreaming Addiction Treatment (MAT) Act provision updates federal guidelines to expand the availability of evidence-based treatment to address the opioid epidemic. The MAT Act empowers all health care providers with a controlled substance certificate to prescribe buprenorphine for OUD, just as they prescribe other essential medications. The MAT Act is intended to help destigmatize a standard of care for OUD and strives to integrate substance use disorder treatment across healthcare settings.

As of December 2022, the MAT Act eliminated the DATA-Waiver (X-Waiver) program that was previously required to prescribe medications for the treatment of OUD. All DEA-registered practitioners with Schedule III prescribing authority may now prescribe buprenorphine for OUD in their practice if permitted by applicable state law. Prescribers previously registered with a DATA Waiver will receive a new DEA registration certificate reflecting this change without further action. Additionally, there are no longer limits on the number of patients with OUD that a practitioner may treat with buprenorphine or tracking of patients treated with buprenorphine required. Pharmacists can now dispense buprenorphine prescriptions using the prescribing authority's DEA number. Of note, prescribers are still required to comply with any applicable state limits regarding the treatment of patients with OUD. Information on State Opioid Treatment Authorities (SOTA) can be found at SAMHSA.gov.

Etiology

Opioid dependence and addiction are products of many biological, environmental, genetic, and psychosocial factors.[3] Most opioids in use are prescribed, but many are also obtained illegally. After a relatively brief period, many patients taking opioids demonstrate opioid dependence. Opioid dependence can manifest as physical dependence, psychological dependence, or both. Opioid-dependent patients will experience withdrawal if opioids are stopped abruptly. Thus, many opioid-dependent patients will seek continued access to opioids, by legal or illegal means, to prevent withdrawal. Ongoing opioid dependence may lead to addiction and uncontrolled opioid use.

OUD occurs in individuals from all educational and socioeconomic backgrounds. Patients at particular risk for OUD include those deficient in neurotransmitters such as dopamine or with first-degree relatives who have a substance abuse disorder.[4] Patients who have been exposed to an environment that includes opioid use may also be more likely to develop OUD. Environmental risks for OUD include peer use of opioids or exposure to opioid analgesics due to a previous injury. Patients with a history of untreated depression, post-traumatic stress disorder, anxiety, or childhood trauma are also at risk for OUD.[5]

Epidemiology