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## **PREAMBLE**

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. Within that function, the Board recognizes that principles of high-quality medical practice and California law dictates that the people of California have access to appropriate, safe, and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

The Guidelines for Prescribing Controlled Substances for Pain issued by the Board in 2014 were developed in response to concerns that prescription drug abuse was declared a nationwide epidemic and that drug overdoses had become a leading cause of accidental deaths. The intent was to provide guidance to physicians to improve outcomes in patient care and to prevent overdose deaths due to opioid use. The guidelines addressed the use of opioids with a focus on the long-term treatment of chronic pain.

In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines which included recommendations for opioid prescribing by primary care clinicians for the treatment of chronic pain in outpatient settings. The goal of the CDC guidelines was to ensure that clinicians considered safer and more effective pain treatment in order to improve patient outcomes (i.e., reduced pain and improved function), as well as reduce the number of patients who developed opioid use disorder, overdose, or experienced other prescription opioid-related adverse events.

While the number of overall opioid prescriptions in the United States had been declining, the release of the 2016 CDC Guideline furthered these declines but inadvertently contributed to patient harm. Several states designed and implemented new laws, regulations, and policies based on the guideline recommendations. In addition, many states' Medicaid programs, insurers, pharmacy benefit managers, and pharmacies used the CDC guidelines to create some opioid prescribing limits. CDC acknowledged that misinterpretation of their guidelines led to the unintended consequence of untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose through use of illegal drugs, and suicidal ideation.

The Board recognizes the need to ensure patient access to safe and effective pain management treatment and, at the same time, the Board also recognizes the need to support physicians providing treatment to this patient population. Consequently, the guidelines were updated to provide a framework for clinician use when developing a pain management treatment plan involving the use of opioids. The guidelines do not replace a physician's clinical judgment and individualized, patient-centered decision-making.

Since opioids are only one of many options to mitigate pain, the guidelines reinforce that opioid medication may not be the appropriate first line of treatment for a patient with chronic pain. Instead, a treatment plan is customized for each patient based on individual needs and vulnerabilities. The guidelines recommend a collaborative approach with the

patient to develop treatment goals and objectives that are reasonable and attainable. Collaboration is also required in the decision to alter or discontinue opioid therapy if the risks outweigh the benefits to the patient. A common thread running through these Guidelines is the need for individualized care based on the unique characteristics of each patient and the challenges they face. In this care environment, there will be a compelling need for physicians to clearly document the treatment and the rationale for it. Accordingly, proper record keeping will be paramount in this area of treatment and all physicians must take this into account in practice.

Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal.

## **UNDERSTANDING PAIN TERMINOLOGY**

The diagnosis and treatment of pain is integral to the practice of medicine. To prescribe opioids safely and effectively, physicians must carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Traditionally, pain has been classified by its duration. In this perspective, “acute” pain is relatively short duration, arises from obvious injury, and usually fades with healing. “Chronic” pain, in contrast, has been defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as three or six months.

For the purposes of these Guidelines, the following terms are defined as shown:

**Acute pain** is defined as pain lasting for less than one month.

**Subacute pain** is defined as pain lasting from one-three months.

**Chronic pain** is defined as pain lasting greater than three months

**End-of-life care** is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.

**High Impact Chronic pain** is defined as persistent pain with substantial restriction of life activities lasting 6 months or more.

**Intractable pain** is a state in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

**Long-term opioid therapy** is defined as use of opioids on most days for greater than three months.

**Physical dependence** occurs because of physiological adaptations to exposure to a drug and is not the same as addiction. Someone who is physically dependent on medication

will experience withdrawal symptoms when the use of the medicine is suddenly reduced or stopped or when an antagonist to the drug is administered. These symptoms can be minor or severe and can usually be managed medically or avoided by using a slow drug taper.

**Tolerance** is present when the same dose of a drug when given repeatedly produces a reduced biological response. Stated another way, it takes a higher dose of the drug to achieve the same level of response achieved initially.

**Addiction** is a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

**Opioid Use Disorder** is defined in the DSM-5 as a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two [DSM-5 criteria](#) occurring within a 12-month period. It is important to note that opioid use disorder exists on a continuum of severity and the severity distinction has treatment implications. A scale for assigning severity exists and is based upon the number of criteria that have been met (mild, moderate, severe).

## **RECOMMENDED PRACTICES FOR THE MANAGEMENT OF PATIENTS WITH PAIN**

The following practices should be incorporated into the care and management of a patient being treated for pain with opioid analgesics.

### **PATIENT EVALUATION AND RISK STRATIFICATION**

When considering long-term use of opioids for chronic, non-cancer pain, careful and thorough patient assessment is critical. Assessment of the patient's pain and risk stratification is a key element to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning. In the sections below, patient reported outcome (PRO) tools are provided as examples. Recognizing that improvements in PROs as science advances, the recommendations are not meant to be prescriptive. Other PROs may be used to assess and longitudinally assess and track the patients progress over time. A thorough patient assessment includes but is not limited to:

- **Completing a medical history and physical exam**

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use. A comprehensive history can also include the "4 A's" (analgesia, adverse effects, activity, and aberrancies) as part of the documentation of opioid response. Screening tools for pain and/or function include but are not limited to:

- [Pain Intensity and interference \(pain scale\)](#)
- [Brief Pain Inventory - Short Form \(BPI-SF\)](#)
- [PROMIS Pain Interference](#)
- [PROMIS Function](#) tests are available through HealthMeasures in both pdf and digital formats

Patients can also be screened for depression and other mental health disorders, as part of the risk evaluation. Psychological distress frequently interferes with improvement of pain and function in patients with chronic pain.

- **Assessment for opioid misuse behavior**

Assessment of the patient's personal and family history of alcohol or drug use and relative risk for medication misuse also should be part of the initial evaluation. Ideally this should be completed prior to a decision to prescribe opioid analgesics. This can be done through a careful clinical interview, which also can inquire into any history of physical, emotional,

or sexual abuse, as these have been correlated with substance misuse. Refer to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) for [criteria for diagnosing Opioid Use Disorder](#).

Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of medication assisted therapy such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat opioid use disorder using office-based buprenorphine treatment. Referral to a pain medicine specialist or addiction medicine specialist prior to initiation of opioid therapy in high-risk patients may be considered as part of a risk mitigation strategy.

Common Risk Mitigation tools that can be considered for use include:

- [TAPS](#)
- [SOAPP-R](#)
- [CRAFT for adolescents](#)

Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians should be aware that some patients may anticipate how to respond in order to attain a “reduced” risk level.

- **Establishing a diagnosis and medical necessity**

A diagnosis should be reached through a review of past medical records, laboratory studies, imaging studies, etc. and ordering new ones, if previous studies are outdated. Information provided by the patient is a necessary but an incomplete part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Some patients are not reliable historians, so it is best to request records directly from the other providers.

- **Exploring non-opioid therapeutic options.**

Opioid medications should not be the first line of treatment for a patient with chronic non-cancer pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy, pain psychology, nerve block, joint injections), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Determining if potential benefits of opioid analgesics outweigh the potential risks is key. Resources that can be consulted include:

- [Non-Opioid Treatments for Chronic Pain - Health and Human Services](#)
- [Non-Opioid Treatments - American Society of Anesthesiologists](#)

With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own risk-benefit analysis coupled with their comfort level in prescribing such medications and the resources for patient support that are available in the community. The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation, assessment, use of mitigation tools, and a discussion of risk/benefits and alternatives with patients.

## **TREATMENT PLAN AND OBJECTIVES**

After conducting a thorough Patient Evaluation/Risk Stratification assessment and determining that the use of opioid analgesics is indicated, the physician and the patient should develop treatment goals and objectives together when starting an opioid trial. The goal of pain treatment should include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important but is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. *Effective pain relief improves functioning.* Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient. An "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment.

The plan should also document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. Because pain management in patients with a history of substance use disorder can be complex, consider consulting with a specialist in addiction medicine. If the patient has a current history of substance use disorder, communicate with the patient's substance use disorder treatment provider.

After an appropriate opioid trial, treatment efficacy should be reassessed, and opioids should only be continued if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. If the opioid trial fails, meaning it does not achieve the desired pain control or functional outcome, the opioid should be discontinued as other modalities are explored. That discontinuation may involve a compassionate, slow taper depending on the patient and circumstances

## **Patient Consent**

When considering long-term use of opioids and periodically during opioid therapy, the physician should discuss the risks and benefits of the treatment plan with the patient and persons designated by the patient, if applicable. A sample [Informed Consent form](#) is available through the National Institute on Drug Abuse. For convenience, patient consent and a pain management agreement can be combined into one document

If the patient is a minor, the law requires that the risks be explained to both the minor patient and the patient's parent/guardian before dispensing or issuing the first prescription. The patient/parent must be advised of: 1) the risks of addiction and overdose associated with the use of opioids, 2) the increased risk of addiction to an opioid if the patient is suffering from both mental and substance abuse disorders and, 3) the increased risk of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

The patient (and family members, if appropriate) should also be counseled on [safe ways to store and dispose of medications](#).

## **Pain Management Agreements**

Use of a pain management agreement is recommended for patients when the opioid therapy is expected to require more than three months of opioids or when initiating an opioid trial for a chronic pain patient. Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:

- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (e.g., by using more medication than prescribed or using the opioid in combination with alcohol or other substances; not storing medications in a secure location; and safe disposal of any unused medication to prevent misuse by other household members).
- The patient's responsibility for following instructions given for safe opioid medication use by their clinician.
- The patient's responsibility to obtain their prescribed opioids from only one physician or practice. Patient's agreement to obtain their medication from one pharmacy provided that the pharmacy is able to dispense the prescribed monthly supply.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Examples of pain management agreements include:

- [Sample Patient Agreement](#)
- [Patient Pain Medication Agreement and Consent](#)
- [Treatment Plan Using Prescription Opioids](#)



## INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Non-opioid therapies are preferred for chronic pain (including nonpharmacologic therapy). If opioids are prescribed, they should be used in combination with non-opioid therapy such as pain psychology, exercise therapy, physical therapy and/or non-opioid pharmacologic therapy.

California law requires that physicians review a Patient Activity Report (PAR) generated from CURES (California's prescription monitoring program) on each patient within 24 hours before prescribing or ordering a controlled substance for the first time, with some limited exceptions.

Evaluate the benefit and harm within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward, if needed, to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as older persons or those with co-morbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to "start low and go slow."

### **Morphine Equivalent Dose (MED)**

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, being offered a prescription for naloxone, or other measures to reduce risk of overdose. While some clinicians have questioned the conceptual validity of MED because of its use as a tool in prescribing guideline development and the lack of a universally accepted opioid-conversion method, this concept remains in common use. CDC has developed a fact sheet titled [Calculating Total Daily Dose of Opioids](#). After calculating the total daily dosage, CDC recommends physicians use extra precautions when increasing to  $\geq 50$  MME per day such as monitor and assess pain and function more frequently; discuss reducing the dose or tapering and discontinuing opioids if benefits do not outweigh harms and consider offering naloxone. Doses  $\geq 90$  MMEs should either be avoided or carefully justified. California law also requires that a prescription for naloxone be offered each time the patient is seen when the dosage is  $\geq 90$  MMEs per day.

## COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE

It is important to educate patients and family/caregivers about the danger signs of respiratory depression or overdose while on opioids and how to respond to the potential medical emergency. Family/caregivers should know to summon medical help immediately if a person demonstrates any of the following signs:

- Unconsciousness or inability to awaken.
- Slow or shallow breathing or breathing difficulty such as choking sounds or a gurgling/snoring noise from a person who cannot be awakened.
- Fingernails or lips turning blue/purple.

Family/caregivers should also be educated on the use of naloxone and how to administer it, if necessary. Prescribers are required to offer a prescription for naloxone, or another drug approved by the FDA to reverse the effects of opioids, to a patient who is receiving 90 MME or higher per day, receiving concurrent benzodiazepines, or at risk of overdose. Pharmacists are also authorized to prescribe and dispense naloxone to patients or family/caregivers at risk of experiencing or witnessing an opioid overdose.

[SAMHSA's Opioid Overdose Toolkit](#) and [Prescribe to Prevent](#) contains educational materials relating to overdose prevention and management as well as patient education material and videos on the use of naloxone. A brochure titled [Opioid Safety and How to Use Naloxone](#) also provides helpful information for family/caregivers.

## ONGOING PATIENT ASSESSMENT

When a trial of an opioid medication is started, regular review and monitoring should be undertaken for the duration of treatment. Within one-four weeks after starting opioid therapy, and at least every three months, evaluate benefits and harms with the patient.

- Assess the patient's pain and function regularly.
- Discuss patient-centered goals and improvements in function (such as returning to work and recreational activities) and assess pain using validated instruments such as the three-item [PEG Assessment Scale](#), the [Pain Assessment Documentation Tool](#), or [PROMIS Pain Interference](#).
- Evaluate for factors that could increase the patient's risk for harm from opioid therapy such as: personal or family history of substance use disorder, mental health conditions (e.g., anxiety or depression), pregnancy, age 65 or older, chronic obstructive pulmonary disease or other underlying respiratory conditions or renal or hepatic insufficiency.
- Conduct regular urine drug testing and review CURES reports as described elsewhere in this document.
- Observe patient for signs of over-sedation or overdose risk and consider tapering dose to a lower dose if identified.

- Assess patient for signs of [opioid use disorder](#) using Diagnostic and Statistical Manual of Mental Disorders (5<sup>th</sup> Edition) criteria. It is important to note that opioid use disorder exists on a continuum of severity and the severity distinction has treatment implications. A scale for assigning severity exists and is based upon the number of criteria that have been met (mild, moderate, severe). If the criteria for opioid use disorder are met, arrange for patient to be evaluated by a provider experienced in treating OUD.
- Ask the patient about their concerns and determine any harm they may be experiencing such as: nausea or constipation, feeling sedated or confused, breathing interruptions during sleep, taking or craving more opioids than prescribed or difficulty controlling use.

If the patient does not have an improvement in pain and function, consider reducing dose or tapering and discontinuing opioids. The decision to continue opioids must be based on a careful assessment between the physician and patient when improvements in both pain and function outweigh the harms.

## COMPLIANCE MONITORING

The physician must decide whether to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory. If it is suspected that a patient may be misusing or diverting prescribed medications, or using illicit drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of misuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, an untreated or under treated underlying substance use disorder, a language barrier, or economic concerns. A physician should arrange for an in-person meeting to have a non-judgmental conversation to clarify their concerns. If misuse is confirmed, consultation with an addiction medicine specialist or mental health specialist trained in substance use disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives. Refer to the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) for [criteria for diagnosing Opioid Use Disorder](#).

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient relationship. In situations where the patient has engaged in prescription forgery, prescription theft or assaultive behaviors directed towards the physician or staff, the physician is strongly encouraged to contact the police/Drug Enforcement Agency (DEA).

For other criminal behaviors, the physician is encouraged to contact legal counsel to determine whether it is appropriate to report to law enforcement. Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrest and incarceration, or even death.

The following strategies should be used to monitor compliance with the pain management agreement or to identify potential issues with the treatment plan. Remember, aberrancies in any of the strategies described below does not necessarily equate to a substance use disorder and needs to be analyzed along with the entire patient presentation.

## **CURES Reports**

CURES is a database that tracks all controlled substance prescriptions dispensed in California. All licensed physicians must register for access to CURES and generate a Patient Activity Report (PAR) on each patient within 24 hours before prescribing or ordering a controlled substance for the first time, with some limited exceptions. It is recommended that a PAR be generated and reviewed at least every 3-6 months as part of the physician's ongoing patient assessment if controlled substances remain a part of the patient's treatment plan. California law requires that a PAR be generated on each patient at least every 6 months.

CURES also alerts prescribers to patients with multiple prescribers, high-dose opioid prescriptions, concomitant opioids and benzodiazepines, and daily opioids over 90 days.

Patients should not be dismissed from care based solely on information from the CURES database. Instead, use the opportunity to discuss any areas of concern with the patient and emphasize concerns about patient safety. Attempt to confirm that the information in the PAR is correct. Check for potential data entry errors, use of a nickname or maiden name, or possible identity theft to obtain prescriptions.

## **Urine Drug Testing**

All patients on long-term opioid therapy should have periodic urine drug tests (UDT). Physicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually using the risk assessment to guide UDT screening frequency. Consider more frequent testing for higher risk individuals or at the time of aberrant behavior. Properly performed urine drug testing involves two steps: an initial screening test followed by confirmatory testing for substances with positive screening results. Confirmatory testing is also needed in situations with an unexpected negative result as a means of distinguishing a false negative from a true negative.

If unexpected results occur after ordering a UDT, remember that the focus is to improve patient safety. Have a plan in place for communicating results and do not dismiss patients from care based solely on UDT results. CDC developed a fact sheet on [urine drug testing](#) with tips for discussing the use of UDTs with patients as well as the types and limitations of UDTs. Additional information and recommendations are also available from the

American Family Physician in an article entitled [Urine Drug Tests: Ordering and Interpretation](#).

## **Pill Counting**

Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing, or giving away medications). The CURES report only gives total dispensing numbers but day to day or week to week usage can be monitored with pill counts when needed.

## **DISCONTINUING OPIOID THERAPY**

Discontinuing or tapering of opioid therapy may be required for many reasons and ideally, an “exit strategy” should be included in the treatment plan for all patients receiving opioids at the outset of treatment. Reasons for discontinuing opioids may include:

- Resolution or healing of the painful condition
- Patient experiences side effects that diminish quality of life or impair function
- Failure to achieve anticipated pain relief or functional improvement (after ensuring that this failure is not the result of inadequate treatment)
- Patient has been treated with opioids for a prolonged period (e.g., years) and current benefit-risk balance is unclear
- Patient experiences an overdose or other serious event (e.g., leading to hospitalization or injury)
- Evidence of non-medical or opioid misuse
- Failure to comply with pain management agreement and/or urine drug screen monitoring
- Exhibition of drug-seeking behaviors (after ensuring this behavior is not the result of inadequate treatment) or diversion

The rate of tapering should be individualized based on the clinical situation of the patient. It should be noted that abruptly stopping opioid therapy has been shown to increase illicit opioid use, emergency medical care utilization, mental health crises, and death from overdose and suicide. Tapers can be completed over several months to years depending on the opioid dosage and should be individualized based on patient goals and concerns. Longer durations of previous opioid therapy might require longer tapers.

A slower taper will produce fewer unpleasant symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection). The symptoms of withdrawal can be more difficult for those diagnosed with an opioid use disorder. The severity of withdrawal symptoms can be assessed and measured using the [Clinical Opioid Withdrawal Scale](#) (COWS). Medications can be used to manage opiate withdrawal symptoms of nausea,

vomiting, diarrhea, anxiety, and vasomotor complaints. Commonly used medications include clonidine, hydroxyzine, loperamide, and others.

Tapers of approximately 10% per month or slower are likely to be better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., a year or longer). ***Tapers might have to be paused and restarted again but may be considered successful as long as the patient is making progress.*** Health and Human Services (HHS) has produced a guide with tapering strategies titled the [Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics](#).

Patients with unanticipated challenges to tapering, such as inability to make progress in tapering despite opioid-related harm, might have undiagnosed opioid use disorder. Patients experiencing such challenges should be assessed for [opioid use disorder](#) using Diagnostic and Statistical Manual of Mental Disorders (5<sup>th</sup> Edition) criteria. If the criteria for opioid use disorder are met, consider whether the use of buprenorphine would be appropriate. Buprenorphine has been shown to be a safe treatment for pain management and OUD and is FDA-approved for both conditions. Buprenorphine reduces craving, withdrawal, and overdose risk, has low potential for misuse and diversion, and increases retention in care. Physicians can prescribe buprenorphine for opioid use disorder for up to 30 patients in an office-based setting after requesting a [waiver from SAMHSA with no training required](#).

Physicians unable to provide treatment themselves should arrange for the patient to receive treatment from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider or an opioid treatment program certified by [SAMHSA](#).

Physicians should not dismiss patients from their practice **solely** because of opioid use disorder as this can adversely affect patient safety and could potentially represent patient abandonment.

The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If the decision is made to either terminate opioid therapy or completely terminate care, it is recommended that the patient be notified in writing **at least 30 days** in advance. Physicians can be held accountable for patient abandonment if medical care is discontinued without allowing adequate provision for subsequent care. The written notification to the patient should include tapering instructions and a bridging prescription (if appropriate) and options to locate alternative sources of medical care. Patients can be referred to other physicians by name, to the patient's insurance company for a list of providers, the medical society's referral service or provided with information about local treatment facilities, methadone maintenance programs or local buprenorphine treatment providers. Examples of patient termination letters are provided in Appendix 1. A copy of the termination letter should be retained in the patient's chart.



Physicians may want to also review their health plan contracts for guidance on terminating and/or reassigning patients to another provider.

If a patient is known to be abusing a medication, initiating an opioid wean may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Conversely, if a patient has been found to be diverting the medication, there is no requirement to provide additional prescriptions, tapering instructions or advance notice of termination beyond the standard 15 days.

## **MEDICAL RECORDS**

The decision to prescribe controlled substances for pain is a clinical decision made by the physician based on the unique needs of the individual patient. The rationale for each prescribing decision must be documented in the patient's medical record. If a complaint is filed with the Medical Board regarding a physician's care and treatment, peer expert review will be sought by the Board. The expert reviewer will consider the totality of circumstances surrounding the physician's prescribing practice through a review of the documentation contained in the patient's medical record. The expert reviewer will attempt to identify whether the physician reached a *clear medical diagnosis* and documented a medical indication for any controlled substances prescribed. A *clear medical diagnosis* is determined by obtaining objective evidence that includes documenting a complete medical history, including information regarding the beginning of the condition, location, specific symptoms and duration of the condition, exacerbating or palliative triggers and the efficacy of prior treatments; obtaining and reviewing prior medical records and imaging studies; performing and documenting a robust physical examination, particularly of the affected part of the patient's body and the patient's history of substance abuse.

California law requires that physicians maintain adequate and accurate medical records. An adequate medical record includes, but is not limited to, the documentation of the:

- patient's medical and pain history;
- notes on relevant history from other providers and evaluations or consultations with specialists;
- results of the current pain and risk assessment, including any screening instrument(s) used;
- results of the physical examination and any laboratory tests or imaging studies ordered by the physician;
- results of CURES and urine drug screens;
- treatments provided, including medications prescribed or administered with the date, type, dose and quantity indicated;
- results of ongoing monitoring of the patient's progress (or lack of progress) in terms of pain management and functional improvement;
- instructions given to the patient, including discussions of risks and benefits with the patient and any significant others;

- patient consent and the pain management agreement;
- information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors.

Appendix 2 reflects an example of a medical record documenting a clinician's initial assessment and treatment of a patient being seen for chronic pain. This example can also be accessed through the Center for Innovation in Academic Detailing on Opioids (CIAO) in a document titled [Opioids for Chronic Pain Documentation Suggestions](#).

## **SUPERVISING ALLIED HEALTH PROFESSIONALS**

Physicians may work in an integrated practice with allied health professionals and be called upon to provide supervision. Below are the regulatory requirements for each along with the parameters for prescribing controlled substances.

**Physician Assistants** (PA's) provide services pursuant to a practice agreement under physician supervision. The supervising physician must be available either in person or by telephone or other electronic communication when the PA is caring for patients. PAs are authorized to order controlled substances (Schedules II-V) that have been agreed upon in the practice agreement and are consistent with the PA's education or for which clinical competency has been established and maintained. Orders for Schedule II or III controlled substances must be in defined in the practice agreement or in a patient-specific order approved by the treating or supervising physician.

**Nurse Practitioners** (NPs) who have *completed a transition to practice*, and meet other requirements, are authorized to practice independently, and prescribe, order, or administer controlled substances, pursuant to Business and Professions Code section 2837.103. NPs who do not complete the transition to practice continue to work under standardized procedures with an overseeing physician. Orders for Schedule II or III controlled substances must be in accordance with patient-specific protocols approved by the treating/supervising physician. Protocols for Schedule II substances must address the diagnosis of illness, injury, or condition for which the substance is to be furnished.



## **SPECIAL PATIENT POPULATIONS**

Below are treatment considerations for differing patient populations or scenarios and are intended to provide additional guidance in prescribing opioids when appropriate.

### **Acute Pain**

It is important to emphasize that numerous recommendations in these guidelines may not be relevant for the physician treating a patient for acute pain. For example, a primary care physician treating a patient who presents with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a complete psychological assessment, utilize a pain management agreement, etc. Physicians should, however, consider any underlying or co-occurring disorders or conditions while assessing risks of opioid therapy. When implementing an acute pain management plan, a standardized approach that starts with non-pharmacological and non-opioid medications and proceeds with stepwise escalation based on pain trajectory and response to treatment is recommended. Non-opioid options such as peripheral nerve blocks and neuraxial analgesia are a reasonable and effective option for surgical pain control. The CURES database should be consulted to ensure a new opioid prescription will not contribute to cumulative opioid dosages or medication combinations that put the patient at risk for overdose. Naloxone should be offered if the patient has risk factors for opioid overdose. As more clinical guidance is required (especially in complex patients such as substance use disorder, opioid tolerance), a consultation with a pain specialist may be indicated.

Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief from acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see [Pain Control in Patients on Buprenorphine, Methadone or Naltrexone](#)

### **Cancer Pain/End-of-Life Pain**

In the 1990's, the Pain Patient's Bill of Rights and the Intractable Pain Treatment Act were created to ensure patients received adequate pain medication and to protect physicians from being disciplined solely because of the amounts of controlled substances prescribed or administered. It was recognized that inadequate treatment of pain originating from cancer or noncancerous conditions was a significant health problem and patients suffering from severe chronic intractable pain should have access to proper treatment for their pain.

The Pain Patient's Bill of Rights indicates that patients suffering from severe chronic intractable pain have the option to request or reject the use of any or all modalities to relieve pain and choose opiate medications without first having to submit to an invasive

medical procedure if the physician acts in conformance with the Intractable Pain Treatment Act. A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain if that prescribing conforms with the Business and Professions Code. Finally, a physician may refuse to prescribe opiate medications to a patient with severe chronic intractable pain but must inform the patient that there are physicians who will treat pain using opiates.

California law also eliminated the need for security prescription pads or e-prescriptions when prescribing pain relief for the terminally ill. "Terminally ill" was defined as the patient is suffering from an incurable and irreversible illness that will bring about death within one year if the illness takes its normal course and the treatment is for pain control and/or symptom management rather than to cure the illness. Under these circumstances, a prescription must only contain the patient's name, the name, quantity of drug and directions for use and the prescriber's signature, date, and the phrase "11159.2 exemption".

**The Guidelines for Prescribing Controlled Substances for Pain are not meant to be used in the treatment of patients with "end of life" or intractable pain and are not intended to limit treatment where improved function is not anticipated and pain relief is the primary goal.** However, given the advancements in diagnosis and treatment of cancer, more patients are surviving cancer but are left with chronic pain resulting from their exposure to cancer treatments. The guidelines **are** applicable to cancer survivors being treated for chronic pain.

### **Emergency Departments/Urgent Care Clinics**

Treating patients for acute pain in an emergency department (ED) or urgent care setting presents challenges in that often there is limited ability to procure adequate patient history from a primary care physician. All physicians have access to CURES and must generate a Patient Activity Report (PAR) before prescribing a controlled substance to a patient for the first time. While there is an exception for physicians in an ED of an acute care hospital when the prescription does not exceed a non-refillable 7-day supply, a PAR will provide some patient history information that is otherwise not available. Physicians practicing in an urgent care setting are not exempt from the requirement to consult CURES before prescribing a controlled substance.

The [American College of Emergency Physicians](#) notes that opioid prescribing in the ED, even when limited to short-acting, low-potency medications for a few days of therapy, is not risk free. Therefore, opioid prescribing from the ED for an acute painful condition should be reserved for patients for whom there is a need for pain relief and alternative therapies are expected to be ineffective or are contraindicated. In those cases, anticipated risks and benefits along with alternatives should be discussed with the patient. If deemed appropriate, only low-dose, short-acting opioids with a short duration of therapy should be prescribed.

A coalition of stakeholders from Los Angeles County developed a toolkit titled [Safe Pain Medicine Prescribing in Emergency Departments and Urgent Care Centers](#)” with the goal of establishing safe norms surrounding the use of pain medications. Patient materials, handouts and clinical practice guidelines are contained in this toolkit.

## **Inherited/Legacy Patients**

Patients started on long-term opioid therapy can find themselves suddenly without a physician either due to physician retirement, state or federal action, or some other cause. Given the national shortage in pain management clinicians, it is anticipated that patients taking long-term opioids for their chronic pain may have difficulty finding a new clinician and primary care physicians may inherit these patients. Abrupt cessation of opioids can increase the risk of OUD and/or subsequent death. Consider the following as best practices:

- *Continue Opioid Therapy for Patients in Transition.* Physicians are encouraged to consider providing opioids to patients during transition to avoid dangerous disruptions in care. While the clinician may not have chosen to start opioids for a given chronic pain condition, stopping opioid therapy is different due to the physiological changes brought on by long-term opioid therapy. Stopping opioid therapy has been shown to increase illicit opioid use, emergency medical care utilization, mental health crises and death from overdose and suicide. It may be necessary and medically appropriate to continue opioid therapy, particularly if the patient has been doing well on long-term opioids or the patient will have a prolonged wait to see a pain management specialist. Whenever possible, discuss the patient’s history with their former clinician, complete baseline assessments of pain and review expectations for opioid prescribing. Assess presence of opioid use disorder and discuss treatment if appropriate. If unable to treat the patient, provide a direct provider to provider hand-off to another clinician to avoid the experience or perception of abandonment.
- *Develop a Patient-Centered, Individualized Care Plan.* Develop an individualized plan in collaboration with the patient for continuing opioid therapy, tapering down or off opioid therapy, or transitioning to buprenorphine. Engage the patient and include discussions around social issues and support, mental health services, alternative pain management strategies, and overdose risk. Consider the patient’s perceived risks and benefits of opioid therapy. Document the rationale for continuing or modifying a patient’s opioid therapy.
- *Use Caution when Tapering Opioid Therapy.* Clinicians should not abruptly discontinue or rapidly taper opioids in patients. All patients, including legacy patients, deserve a slow, balanced, empathetic, good faith taper trial. Those that fail tapering can be considered for buprenorphine therapy or evaluated for [opioid use disorder](#). Additional information on tapering strategies is discussed in the section titled “Discontinuing Opioid Therapy”.

- *Consider the use of Buprenorphine when Appropriate.* Buprenorphine has been shown to be a safe treatment for pain management and OUD and is FDA-approved for both conditions. Buprenorphine reduces craving, withdrawal, and overdose risk, has low potential for misuse and diversion, and increases retention in care.

## **Legal Cannabis Use and Opioids**

Cannabis was legalized for nonmedical use by adults (over 21) in 2016. As part of the initial patient evaluation/assessment, the patient's personal history of alcohol and drug use is explored. Although some studies have shown that the combination of cannabis and opioids can be therapeutic to some chronic pain patients, carefully consider the use of opioid medications in individuals with a history of illicit drug or cannabinoids use. The risk of overdose and development of an opioid use disorder (OUD) is higher in these cases, and therefore the provider should carefully evaluate the use of opioids to justify that the benefits outweigh the risks. Specific counseling on increased risks for overdose should be provided when opioids are combined with concurrent use of substances with depressant effects.

Cannabis use might also come to the attention of the physician through urine drug testing. This is a legal substance so a positive result should not directly result in dismissal of a patient from care unless the use conflicts with the terms of the pain management agreement. Instead, it may be necessary to consider whether to revise or adjust the treatment plan if the patient's progress is unsatisfactory. Physicians may also wish to consider whether consultation with a specialist in addiction medicine is indicated.

Research on the clinical limitations and benefits of cannabis is ongoing by the [Center for Medicinal Cannabis](#) among others. It may be helpful to monitor the progress of their research to assess the benefits and risks associated with cannabis use.

## **Older Adults**

Pain in older adults is common and management is often more complex because of polypharmacy, changes in pharmacodynamics and cognitive and functional declines. As with all patients with mild to moderate pain, acetaminophen should be considered a first-line treatment. NSAIDs can also be helpful but older adults can be more prone to side effects (gastrointestinal and renal toxicity, bleeding). Opioid medications have a role in the management of severe pain but have higher rates of side effects in older patients including constipation, increased risk of falls and higher rates of respiratory depression. Therefore, physicians should start with lower initial doses, longer dosing intervals and have closer follow up, especially in opioid-naïve patients. Physicians should anticipate side effects and attempt to prevent them (i.e., universal treatment of constipation, physical therapy or risk assessment for fall prevention, monitoring for cognitive impairment). Because of higher rates of respiratory depression, consider offering a prescription for naloxone if the patient presents an increased risk of overdose or the dosage is 90

MMEs/day. If the patient has a caregiver, evaluate their ability to properly dispense opioid medications and be aware of the possibility of diversion. Because of the complexity of prescribing opioids in older adults, referral and/or consultation with geriatric specialists or pain specialists can be considered.

## **Pediatric Patients**

Children of all ages deserve compassionate and effective pain treatment. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that a trial of opioids for short term use has a place in the range of treatment options when non-opioid alternatives, including referral to a pain medicine specialist, has failed or is unlikely to be effective for pain. Given the potential risks of opioid analgesics, a careful and thorough patient assessment and risk stratification should be performed. If opioid therapy is initiated, the law requires that the risks be explained to both the minor patient and the patient's parent or guardian before dispensing or issuing the first prescription. The patient/parent must be advised of, 1) the risks of addiction and overdose associated with the use of opioids, 2) the increased risk of addiction to an opioid if the patient is suffering from both mental and substance abuse disorders, 3) the danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant. Note: The risk discussion is not required if the minor patient's treatment is for chronic intractable pain, relative to emergency services or surgery or is considered by the physician to be detrimental to the patient's health and safety or violates the minor's rights regarding confidentiality.

Since 2018, the FDA has required safety labeling for prescription cough and cold medicines containing codeine or hydrocodone to indicate that these products should only be used in adults over 18 years. FDA concluded that the risks of slowed or difficult breathing, misuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

It is noted that children/adolescents are at a greater risk than adults of becoming addicted when exposed to drugs. The American Academy of Pediatrics recommends universal screening for adolescent substance use as a routine part of health care. The National Institute on Drug Abuse has launched two online screening tools that providers can use to [assess for substance use disorder](#) (SUD) risk among adolescents 12-17 years old.

## **Pregnant Women**

Opioid use in pregnancy has escalated dramatically in recent years, paralleling the epidemic observed in the general population. Obstetric care providers need to be

knowledgeable about the medical, social, and legal consequences that can accompany opioid use by pregnant women. A joint committee opinion issued by American Congress of Obstetricians and Gynecologists (ACOG) and the American Society of Addiction Medicine (ASAM) makes the following recommendations:

- **Universal** screening for substance use should be part of comprehensive obstetric care and should be done at the first prenatal visit, routine screening should rely on [validated screening tools](#), such as questionnaires including 4Ps, NIDA Quick Screen, and CRAFFT (for women 26 years or younger).
- Pregnancy provides an important opportunity to identify and treat women with substance use disorders. Identify patients with substance use disorders using validated screening tools, offer brief interventions (i.e., engage the patient in a short conversation when the patient is showing risky substance use behaviors, provide feedback and advice), and provide a referral to brief therapy or treatment as needed
- For pregnant patients with an opioid use disorder, opioid agonist pharmacotherapy is the recommended therapy and is preferable to medically supervised withdrawal because withdrawal is associated with high relapse rates, leading to worse outcomes.
- Infants born to women who used opioids during pregnancy should be monitored by a pediatric care provider for neonatal abstinence syndrome, a drug withdrawal syndrome that opioid-exposed neonates may experience shortly after birth.

An interactive online toolkit, the [Mother & Baby Substance Exposure Initiative](#), shares best practices to improve outcomes for substance exposed mothers and newborns.

### **Patients Covered by Workers Compensation**

This population of patients presents its own unique circumstances as medical treatment decisions must be reviewed and approved for medical necessity through utilization review. Utilization review programs use medical treatment guidelines developed by the American College of Occupational and Environmental Medicine (ACOEM) and adopted in regulation by California to determine what is reasonable and necessary medical care for an injured worker. These treatment guidelines also address the use of opioids and treatment for chronic pain. The [Medical Treatment Utilization Schedule \(MTUS\)](#) is available online to healthcare providers treating, evaluating, or performing utilization review in the California workers' system.

### **Patients with History of Substance Use Disorder**

Use of opioids for patients with a history of substance use disorder is challenging because such patients are likely to experience greater risks for opioid use disorder and



overdose than persons without these conditions. Physicians should ask patients about their drug and alcohol use using validated screening tools such as the [Alcohol Use Disorders Identification Test \(AUDIT\)](#) or [TAPS](#). In addition to these tools, include other assessments such as discussions with patients, family and caregivers, clinical records, CURES data and toxicology screening.

If the patient's medical history, self-report or scores on screening assessment tools suggest an above-average risk of substance use disorder, physicians should consider the following steps in proceeding with a pain management strategy:

- Carefully consider whether benefits of opioids outweigh increased risks
- Discuss increased risks for opioid use disorder and overdose with patient
- Provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol
- Prescribe naloxone and provide education to one or more persons designated by the patient in its use
- Increase frequency of monitoring using CURES data and drug testing as appropriate to assess for concurrent substance use placing a patient at higher risk for opioid use disorder and overdose
- If misuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, and present options for referral, opioid taper/discontinuation or switching to non-opioid treatments. Avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

Because pain management in patients with a history of substance use disorder can be complex, physicians should consider consulting a specialist in addiction medicine. If the patient has a current history of substance use disorder, communicate with patient's substance use disorder treatment provider if opioids are prescribed.

### **Patients with Psychiatric Conditions**

Psychological distress frequently interferes with improvement of pain and function in patients with chronic pain. Use validated instruments to support assessment for anxiety, post-traumatic stress disorder, and/or depression might help improve overall pain treatment outcomes. Examples include the [Generalized Anxiety Disorder \(GAD\)-7](#), the [Patient Health Questionnaire \(PHQ\)-9](#) and [PROMIS Depression and Anxiety](#) assessment measures among others. In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose. Consult with behavioral health specialists when needed.

## Patients Prescribed Benzodiazepines

Physicians should use caution when prescribing opioids and benzodiazepines concurrently. There may be circumstances when it might be appropriate to prescribe opioids to a patient who is also prescribed benzodiazepines (e.g., severe acute pain in a patient taking long-term stable low-dose benzodiazepine therapy), however, physicians should use caution when prescribing these drugs concurrently. Physicians should also consider whether the benefits outweigh risks of concurrent use of opioids with other central nervous system depressants (e.g., muscle relaxants, non-benzodiazepine sedative hypnotics, potentially sedating anticonvulsant medications such as gabapentin and pregabalin).

Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression and overdose. Naloxone is an opioid antagonist and can be safely administered by laypersons with virtually no side effects and no effect in the absence of opioids. CDC recommends that a prescription for naloxone be provided when opioid use  $\geq 50$  MMEs/day. California law requires that the physician offer a prescription for naloxone to the patient when one or more of the following conditions are present: 1) the dosage of the opioid medication is 90 MMEs/day; 2) an opioid is prescribed concurrently with benzodiazepine (within a year from the date the benzodiazepine was dispensed); or 3) the patient presents with an increased risk for opioid overdose. Education on opioid overdose prevention and the use of naloxone must also be provided to the patient and individual(s) designated by patient. For additional information, see [Prescribe to Prevent](#) for prescribing and dispensing naloxone (Narcan) rescue kits.

If the risks are determined to outweigh the benefits of continuing the opioid and benzodiazepine therapy and a decision is made to taper one or more medications, develop an individualized tapering strategy based on the clinical situation of the patient. An example of an opioid tapering strategy is available in the [Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics](#). Examples of [benzodiazepine tapers and tips for managing withdrawal](#) symptoms are available through the Department of Veteran's Affairs.

Physicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure and coordinate care.

## Telehealth

Telehealth is seen as a tool in medical practice, not a separate form of medicine. The law states that prescribing without an appropriate prior examination and a medical indication is unprofessional conduct. However, an appropriate exam does not require a synchronous interaction between the patient and physician and can be conducted via telehealth. As always, the physician must comply with the appropriate standard of care.



As discussed previously, a thorough patient assessment is critical when considering long-term use of opioids for chronic pain. While it is preferable to conduct a face-to-face evaluation of the patient's condition as part of this assessment, there may be circumstances that make this challenging. Physicians are expected to use their best clinical judgement and patient-centered decision making to determine how best to ensure that a thorough assessment is performed before prescribing opioids and to adequately monitor patient progress for the duration of treatment.

As of March 31, 2020, an exception was made for clinicians to prescribe buprenorphine to new and existing patients for OUD via telehealth as long as an adequate evaluation can be conducted by telephone. A [DATA 2000 waiver](#) can be obtained from the Substance Abuse and Mental Health Services Administration (SAMHSA) to allow practitioners to forego the training and counseling requirements if treating 30 patients or less with buprenorphine for OUD.

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## COMPLIANCE WITH CONTROLLED SUBSTANCE LAWS

<b>Business and Professions Code</b>	
208	CURES fees
209	CURES Application and approval process
725	Unprofessional Conduct, excessive prescribing
740	Definition of administer, drug order and prescriber
741	Duties of Prescriber
742	Administrative sanction- failing to offer prescription or education
2190.5	Mandatory CME in pain management
2190.6	CME on treatment and management of opiate-dependent patients
2220.05	Allegations of excessive prescribing are one of the Board's priorities
2238	Violation of federal statute/regulation is unprofessional conduct
2239	Excessive/self-use of drugs is unprofessional conduct
2241	Furnishing drugs to addict
2241.5	Physician may prescribe for pain and intractable pain
2242	Furnishing dangerous drugs without exam is unprofessional conduct
2242.1	Prescribing dangerous drugs online
<b>Pharmacy Code</b>	
4021	Controlled substance definition
4052.01	Furnishing Naloxone
4052.10	Dispensing schedule II drug prescription as partial fill
Precedential Decision on <a href="#">Pharmacist's Corresponding Responsibility</a> to confirm prescription written for legitimate medical purpose	
<b>Health and Safety Code</b>	
11000-11651	Uniform Controlled Substance Act
11150-11180	Requirements of Prescriptions
11150	Persons permitted to write prescription
11158.1	Discussion with minor prior to prescribing opioid
11161.5	Security printers
11162.1	Features of printed prescription forms
11164	Requirements for prescriptions
11164.1	Intrastate controlled substance dispensed by CA pharmacy
11164.5	Electronic prescriptions
11165	Established CURES
11165.1	Authorized access to controlled substance history info from CURES
11165.4	Duty to consult CURES
11165.6	Prescriber access to CURES database
11215-11223	Treatment of Addicts for Addiction
124960-129461	Pain patient's bill of rights
<b>Federal Law</b>	
Title 21, Chapter 2 United States Code (USC) <a href="#">Controlled Substances Act</a>	

## Sample Termination Letter

Date:

Dear Patient:

This is to advise you that I will no longer provide treatment for you after (insert date that patient will be terminated) due to the following circumstances:

Because opioids cause physical dependence when taken regularly, you may experience withdrawal symptoms if you decrease or stop taking the medications. If it is safe to do so, I will provide you with medications for a period of            weeks to allow you to taper off these medications. I will also provide non-opioid medications to minimize withdrawal symptoms. Please follow the directions provided to taper off the medications.

Listed below are health care providers and treatment facilities/programs that can be contacted for additional services.

Add general source for additional providers

- To locate [treatment facilities](#) (i.e., detox, inpatient or outpatient care) in our area
- To locate [opioid treatment programs](#) in California
- To locate [Buprenorphine Providers](#) in our area

Copies of your patient records can be obtained by submitting a written request directed to insert office address info. Your medical records can also be transferred to your new health care provider by completing the attached Authorization for Release of Medical Information.

Sincerely,

# Sample Notification of Discontinuation of Opioid Treatment Form

Dear \_\_\_\_\_,

Date: \_\_\_\_\_

Although you are welcome to continue receiving medical treatment in this office, I regret that I will no longer be able to provide opioid treatment for you due to the following circumstances:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

Because opioids cause physical dependence when taken regularly, you may experience withdrawal symptoms if you decrease or stop taking the medications. If it is safe to do so, I will provide you with medications for a period of \_\_\_\_\_ weeks to allow you to taper off these medications. I will also provide non-opioid medications to minimize withdrawal symptoms. Please follow the directions provided to taper off the medications.

To locate addiction treatment services in [Insert State], call [insert phone #].

In [insert region of State], for inpatient detoxification services please call:

[insert service organization and city]

[insert phone #]

[insert service organization and city]

[insert phone #]

For methadone maintenance or buprenorphine treatment, please call:

[insert methadone maintenance or  
buprenorphine treatment facility and city]

[insert phone  
#]

[insert methadone maintenance or  
buprenorphine treatment facility and city]

[insert phone  
#]

Sincerely,

Sample letter from National Institute on Drug Abuse

<https://nida.nih.gov/nidamed-medical-health-professionals/opioid-crisis-pain-management>

<p><b>Suggested components of documentation</b></p>	<p><b>Example:</b> 55 y/o cis-gender male seen for initial provider visit. CC: chronic b/l hand pain.</p>
<p><b>Pain history</b> Complete OLD CARTS for pain complaint. <b>TIPS:</b> Treatment: pain medications, non-pharmacologic therapies, surgeries. Severity: PEG scale includes functional impact of pain. <i>See “Current pain assessment” below.</i></p>	<p><b>Onset:</b> 10 years ago, no specific injury reported <b>Location:</b> distal interphalangeal joints of hands and feet <b>Duration:</b> 10 years, progressively worse every year <b>Characterization:</b> intermittent sharp pains and numbness in hands and feet <b>Aggravating:</b> cold and rainy weather <b>Relieving:</b> oxycodone (x15 minutes), does not take other meds or do physical therapy <b>Treatment history:</b> Oxycodone 30mg 4x/day x10 years. Tapered to 100 tabs last month; does not want opioids anymore, but did not agree to taper &amp; reports more pain. <b>Severity:</b> 5-8/10 PEG scale</p>
<p><b>Other relevant history</b> <b>Imaging:</b> x-ray, MRI, ultrasound. <b>Labs:</b> related to disease processes or substance related. <b>Prior notes:</b> past diagnoses, ROI from other providers. <b>Other medications:</b> non-opioid medications.</p>	<p><b>Imaging:</b> 2012: X-ray bilateral hands: erosions <b>Labs:</b> 2012: rheumatoid factor mildly elevated <b>Prior notes:</b> distal interphalangeal joint swelling consistent with arthritis; missed rheumatology appointment after referral 9 years ago <b>Other medications:</b> previously used gabapentin but stopped: “doesn’t help pain”</p>
<p><b>Current pain assessment</b> The 3-question <a href="#">PEG</a> reflects average pain and impact on enjoyment and function over past week (pg. <a href="#">14</a>)</p>	<p><b>Past week average pain:</b> 5 with medication/ 9 without <b>Pain interference on life enjoyment:</b> 6 with medication/ 9 without <b>Pain impact on general activity:</b> 4 with medication/ 7 without</p>
<p><b>Physical exam</b> Complete focused exam yearly or more frequently.</p>	<p>Full range of motion in hands and feet; mild swelling of distal IP joints; sensation intact with sense of numbness in distal and plantar feet.</p>
<p><b>Risk factor assessment</b> Guides clinical decision-making (pg. <a href="#">15</a>).</p>	<p>Substance use (ETOH &amp; meth) and psychiatric history (schizophrenia controlled with medication) noted.</p>
<p><b>Opioid use disorder screening</b> Use DSM-5 (pg. <a href="#">25</a>).</p>	<p>Patient does not meet the criteria for OUD: 1 criterion noted (unable to stop or cut down).</p>
<p><b>Urine drug screen</b> (pg. <a href="#">17</a>)</p>	<p>UDS as expected XX/XX/XXXX and YY/YY/YYYY. Repeat every 3 months given risk profile.</p>
<p><b>Control substance agreement or consent</b> (pg. <a href="#">18</a>)</p>	<p>Controlled substance agreement reviewed with patient XX/XX/XXXX. Copy given to patient.</p>
<p><b>Prescription drug monitoring program</b> (pg. <a href="#">19</a>)</p>	<p>PDMP reviewed XX/XX/XXXX; no unexpected prescriptions.</p>
<p><b>Naloxone</b> (pg. <a href="#">22</a>)</p>	<p>Prescribed intranasal naloxone XX/XX/XXXX. Signs of when to use naloxone reviewed.</p>
<p><b>Plan</b> Include rationale for plan and future goals. <b>TIPS:</b> continuity of care, obtainable goals, and minimizing patient risks make a strong rationale.</p>	<p>Opioids not indicated for neuropathic pain and patient has some risks. However, for now will continue current dose of oxycodone b/c patient has done well for years, underwent challenging recent taper, has no evidence of OUD, and is new to me. Given risks associated with discontinuation, will work closely with patient to reduce reliance on opioids. Repeat hand X-rays ordered. Follow UDS every 3 months and continue screening for OUD.</p>

• Page numbers refer to **Opioids and Chronic Pain: A Guide for Primary Care Providers**, available at [www.ciaosf.org/materials](http://www.ciaosf.org/materials)