MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED:
ATTENTION: Members, Medical Board of California
SUBJECT: Update on the Revision to the Guidelines on Prescribing Controlled Substances
STAFF CONTACT: Susan Cady, AGPA (Executive Staff)

REQUESTED ACTION:

After review and consideration, approve the updated Guidelines for Prescribing Controlled Substances for Pain.

BACKGROUND:

In January 2021, the Medical Board of California (Board) concurred with the executive director's recommendation to update the Board's 2014 Guidelines for Prescribing Controlled Substances for Pain. An update was necessary to address statutory changes as well as the changes to the practice of treating patients for pain that had occurred in the intervening years.

President Lawson appointed Dr. Thorp and Mr. Brooks to the Prescribing Guidelines Task Force (Task Force). The Task Force and Board staff worked with subject matter experts to develop draft guidelines, which were disseminated to stakeholders and posted to the Board's website in June 2022. The first Interested Parties Meeting was held on July 14, 2022. As a result of the feedback received, edits were made to the Morphine Milligram Equivalent section to remove references to dosages that could be misinterpreted as prescribing limitations and recommendations for physician assessment and monitoring follow-up timeframes were modified. The draft guidelines were also amended to emphasize the Board's intent to encourage physicians to develop individualized patient-centered, medically appropriate treatment plans.

On November 15, 2022, a second Interested Parties Meeting was held to obtain public input on the revised guidelines. Feedback came primarily from patients/patient advocates reiterating concern that physicians could still be reluctant to treat pain patients for fear of enforcement action from the Department of Justice (DOJ), the Drug Enforcement Administration (DEA) and the Medical Board.

The input/feedback received during the two Interested Parties meetings was valuable and most of the concerns raised during these meetings resulted in amendments to the draft guidelines. However, there were some suggestions that were not integrated into the final document and an explanation of the rationale for each is shown below:

- **Add definitions such as hospice care, palliative care, intractable pain syndrome to the "Understanding Pain Terminology" section**.

The intent of this section is to define terms that would be used in the guidelines. If the term was not referenced later in the guidelines, the definition was not added.

- **Add references to specific diseases or pain conditions**.
  The guidelines were designed to provide a broad overview for the assessment and treatment of pain patients rather than provide treatment recommendations for specific conditions. These recommendations were not integrated into the final document.

- **Some of the recommended practices for patient management were either unnecessary or too cumbersome for patients on long term opioid therapy**.
  The guidelines were developed to provide guidance to physicians treating patients in a variety of clinical pain management settings including acute, subacute, chronic, and long-term pain. The guidelines encourage physicians to develop individualized patient-centered treatment plans in all settings which would allow for adjustments to be made for patients on long term opioid therapy.

- **Patients/patient advocates raised concern about the use of the term "risk" throughout the guidelines which, they felt, exaggerated the prospect of harm caused by medications used to treat pain and could potentially jeopardize their ongoing care.**
  The Board's guidelines are geared toward providing guidance to **physicians** who are trained to assess all medical interventions, procedures and/or medications in terms of risk/benefit to the patient. The concept behind "informed consent" is to give patients information, including possible risks and benefits, about a medical procedure or treatment to help them decide how they want to be treated. While the concerns expressed by patients/patient advocates are understandable, the Task Force determined that the use of the term "risk" would not be misinterpreted by the intended audience.

- **The Board was encouraged to pursue or support legislative efforts to update the Pain Patient Bill of Rights to provide enhanced protection from prosecution for physicians treating patients with chronic pain.**
  This recommendation falls outside the scope of updating the Board's prescribing guidelines and was tabled for further action until legislative action is considered or proposed on the Pain Patient Bill of Rights.

- **Physicians raised concerns about the conversion tool used in CURES to calculate MMEs and specifically, that buprenorphine was being considered equivalent to other opioid analgesics in CURES.**
  The concerns expressed about the conversion tool used in CURES to calculate MMEs are significant in that these MME calculations could be used by the Board or DOJ to identify physicians thought to be "overprescribing" based on the MME calculation. While this concern falls outside the scope of updating the Board's prescribing guidelines, Board staff will follow up on this issue further with DOJ and consider additional training for Board staff.

- **Feedback from both patients and the physician community expressed concern that physicians could still be reluctant to treat pain patients for fear of enforcement action from DOJ, DEA or the Medical Board.**
  The Task Force recognizes the legitimacy of this concern and is developing strategies to address these issues during implementation and roll-out of the updated guidelines.

The Board's primary mission and mandate is to provide protection to the public. Within that function, the Board also recognizes the need to ensure patient access to safe and effective pain management treatment and also recognizes the need to support physicians providing treatment to this patient population. The Task Force believes that the updated guidelines meet the Board's objective of integrating current medical practice recommendations and statutory requirements into the Board's 2023 Guidelines for Prescribing Controlled Substances for Pain. At the same time, the Task Force emphasized that the guidelines do not replace a physician's clinical judgment and stressed the need for individualized care based on the specific characteristics of each patient.

RECOMMENDED ACTION:

After review and consideration, the Task Force recommends that the Board approve the updated Guidelines for Prescribing Controlled Substances for Pain.

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR PAIN

MEDICAL BOARD OF CALIFORNIA

MAY 2023

Gavin Newsom, Governor
Kristina D. Lawson, J.D., President, Medical Board of California
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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 and other controlled substances with a focus on the long-term treatment of chronic noncancer pain.

In 2016, the Centers for Disease Control and Prevention (CDC) released guidelines for primary care providers which included recommendations for opioid prescribing 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 prior to starting chronic opioid therapy in order to improve patient outcomes (i.e., reduced pain and improved function). Further, once opioids were prescribed, the goal was to encourage best practices to reduce the number of patients who go on to develop opioid use disorder, overdose, or experience other prescription opioid-related adverse events.

While the number of overall opioid prescriptions in the United States had been declining and the release of the 2016 CDC Guideline furthered these declines, the guidelines might have also inadvertently contributed to patient harm due to the undertreatment of pain. Based in part on the CDC recommendations, nearly all states designed and implemented new laws, regulations, and policies due to increasing rates of opioid overdoses. In addition, many states' Medicaid programs, insurers, pharmacy benefit managers, and pharmacies used the CDC guidelines to create opioid prescribing limits. CDC acknowledged that misinterpretation of their guidelines most likely 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 and behavior.

In addition, to address increasing overdose deaths in California, the Board began work on a "death certificate project" in 2015. This project utilized California death record data provided by the Department of Public Health to identify physicians that may be inappropriately prescribing opioids for their patients. Approximately 2,700 death certificates from 2012-2013 were reviewed and 145 investigations were opened.

It is recognized that between the Board's death certificate project and the CDC 2016 Guidelines, a chilling effect was felt and physicians became less willing to treat patients with chronic pain. This situation became significantly worse with the abrupt closure of 29 pain management centers in May 2021. Approximately 20,000 patients were left without referrals or treatment plans resulting in potentially dangerous disruptions in care for patients receiving treatment with opioid therapy.

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As the Board discussed the need to update the 2014 prescribing guidelines, it was emphasized that a change in tone was necessary to provide support and guidance to physicians to prescribe in a way that is effective for their patients and to also have enough flexibility to deal with pain patients that don't fall into the normal guidelines. Aside from giving physicians more autonomy in treating their patients for pain, statutory changes had been enacted that needed to be integrated into the guidelines.

The Board began the process of updating its guidelines by identifying physicians who practice medicine in various specialties including pain management specialists, family practice physicians, members of academia and others, to serve as subject matter experts and help the Board revise the guidelines. The goal was to provide resources and an updated structure for the management of patients being treated for pain.

The Board recognizes the need to ensure patient access to safe and effective pain management treatment and, at the same time, 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 while also encouraging the development of treatment plans customized for their patients. ***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 comorbidities. 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 showing medical necessity 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.

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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 to 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 whether 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 six 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 (or latest DSM version) occurring within a 12-month period. It is important to note that opioid use disorder

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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).

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RECOMMENDED PRACTICES FOR THE MANAGEMENT OF PATIENTS WITH PAIN

The following practices must be incorporated into the care and management of a patient being treated for pain with opioid analgesics. If any of the following steps are not completed, it is recommended that the medical reasoning be documented to explain why they are not being performed.

PATIENT EVALUATION AND RISK ASSESSMENT

When considering the use of opioids for chronic 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 and ensure proper patient monitoring. 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.

Patient reported outcome (PRO) tools may simplify and organize documentation of these goals. Validated examples are provided in the sections below. Recognizing that improvements in PRO tools are expected as science advances, the recommendation of which specific PRO tool or version to use is not meant to be prescriptive. A PROs tool can also be used to longitudinally track and assess 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 requires 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 must be part of the initial evaluation and ideally 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) (or the current DSM version) for criteria for diagnosing Opioid Use Disorder.

Physicians who treat patients with chronic pain are encouraged to also be knowledgeable about the treatment of addiction, including the role of medication assisted therapy such as methadone and buprenorphine. For some if not most physicians, there may be advantages to becoming eligible to treat opioid use disorder using office-based buprenorphine treatment. Referral to or consultation with a specialist with relevant expertise in pain medicine or addiction medicine prior to initiation of opioid therapy in high-risk patients (defined as having multiple comorbidities and/or clear risks of poor outcomes with controlled substances) may be considered as part of a risk mitigation strategy.

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

- TAPS
- SOAPP-R
- CRAFFT for adolescents

Note: Although the above-listed assessment tools are frequently used and clinically validated, be aware that some patients may anticipate how to respond in order to attain a "reduced" risk level. Simply asking the patient to complete these forms without reviewing and using them to assist with clinical decision making does not fulfill this requirement.

- **Establishing a diagnosis and medical necessity**

A diagnosis can be established or confirmed 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 can be validated 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 and review these documents before starting opioids if there is any question about the certainty of the diagnosis. If records are not immediately available and there is a need to start opioids prior to review, medical decision making must be documented. Efforts to obtain records are still called for and need to be used in making decisions about continuing opioid therapy at subsequent visits but obtaining prior medical records may not always possible.

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

Opioid medications should not be the first line of treatment for a patient with chronic pain. Other measures, including non-opioid therapeutic options such as medications, restorative therapies, interventional approaches, behavioral health approaches, and complementary and integrative health approaches should be tried, and the outcomes of those therapies documented first. This does not mean that patients should be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy or be required to use any specific therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, limited

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access or availability to non-opioid options, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. 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 must 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 must 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 and assessment and determining that the use of opioid analgesics is indicated, the physician and the patient together are encouraged to develop treatment goals and objectives when starting an opioid trial. The goal of pain treatment shall 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 additional medications. Pain relief is important but is difficult to measure objectively. Therefore, it should not be the primary indicator to assess the success of the treatment. In other words*: **effective pain relief improves function***. 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," which means listing reasons why and how controlled medications will be stopped, may also be included in the treatment plan for all patients receiving opioids at the outset of treatment.

The plan may 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 with relevant expertise in addiction medicine to consider any additional goals that need to be documented surrounding sobriety. If the patient has a current history of substance use disorder, ensure that the patient's substance use disorder treatment provider knows controlled substances are being used and ask for any additional recommendations or concerns in monitoring the patient.

After an appropriate opioid trial, which may include dose titration beyond the initial dose, treatment efficacy must be reassessed, and opioids 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. The discontinuation of opioids may involve a compassionate, slow taper depending on the patient and circumstances at the time the opioids are stopped.

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Patient Consent

When considering long-term use of opioids and periodically during opioid therapy, the physician must 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 (caregivers and family members, if appropriate) should also be counseled or provided with information on safe ways to store and dispose of medications.

Pain Management Agreements

Use of a pain management agreement is strongly 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; and not storing medications in a secure location).
- The patient's responsibility for following instructions given by their clinician for safe opioid medication use.
- The patient's responsibility to obtain their prescribed opioids from only one physician or practice and notify that physician/practice should another prescriber issue a controlled substance to them.
- The 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).
- Informing the patient that the CURES database will be reviewed based on clinical indications and California statutory requirements.
- 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

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INITIATING OPIOID TRIAL

Safer alternative treatments, including non-opioid therapies and nonpharmacologic therapies, are preferred before initiating opioid therapy for chronic pain. If opioids are prescribed, they can be used in combination with non-opioid therapy such as pain psychology, exercise therapy, physical therapy non-opioid pharmacologic therapy and/or interventional procedures as appropriate for the individual patient.

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.

After starting opioid therapy for chronic pain or following dose escalation, the physician should regularly evaluate the benefit and harm with the patient. 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. Consider starting patients with no, or modest, previous opioid exposure at the lowest appropriate initial dosage of a short-acting opioid and titrate 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 compared to long-acting or controlled release opioids 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 Milligram Equivalent (MME)

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, a reduction or tapering of opioids, being offered a prescription for naloxone, or other measures to reduce risk of overdose. Because there is a lack of consensus regarding a universally accepted opioid-conversion method for patients taking opioids chronically, some clinicians have questioned the conceptual validity of MME. The CDC has developed a fact sheet titled **Calculating Total Daily Dose of Opioids** that provides one method for calculating a daily dose of opioids. The selection of an opioid dosage for a patient is a clinical decision made on a case-by-case basis in order to provide an individualized, patient-centered treatment plan. The risk to a patient increases as dosages increase and the rationale for the decision to prescribe a dosage ≥ 90 MMEs should be documented in the patient's medical record. This recommendation is not intended to be used as a limitation on prescribing or as a rigid standard of care but instead reinforces the requirement to maintain adequate medical recordkeeping as described elsewhere in this document. In addition, California law requires that a prescription for naloxone be offered to a patient when the dosage ≥ 90 MMEs.

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 can be advised to summon medical help immediately if the patient demonstrates any of the following signs:

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

It is also recommended that family/caregivers be educated on the use of naloxone and how to administer it since patients will not be able to administer this medication if they need it. 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 has been completed and a decision is made to continue opioid medication, regular review and monitoring shall be undertaken for the duration of treatment.

- 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 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 DSM-5 (or the current DSM version) 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 for opioid use disorder graded as 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.

If the patient does not have an improvement in pain and function, consider reducing dose or tapering and discontinuing opioids after ensuring that the failure is not the result of inadequate treatment. 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.

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COMPLIANCE MONITORING

A patient's failure to adhere to a pain management agreement is not necessarily proof of misuse or diversion. Instead, 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. It is recommended that the physician arrange for an in-person meeting to have a non-judgmental conversation to clarify these concerns. It may also be necessary to consider revising or augmenting the pain management agreement or treatment plan if the patient's progress is unsatisfactory and more specific or additional language is needed. If misuse is confirmed, consultation with an addiction medicine specialist or a mental health specialist trained in substance use disorders should be considered. Direct referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) may be offered depending on severity of misuse and if opioids are being stopped abruptly. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and be able to distinguish such disorders from physical dependence—which is expected in chronic therapy employing opioids. Refer to the DSM-5 (or current DSM version) for criteria used to diagnose Opioid Use Disorder.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firm, 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 or stop opioid therapy. In situations where the patient has engaged in possible criminal behaviors (e.g., prescription forgery or theft or assaultive behaviors directed towards the physician or staff) the physician is encouraged to consult with legal counsel for advice to determine whether it is appropriate to report to law enforcement or Drug Enforcement Agency (DEA). 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 can 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 do not necessarily equate to a substance use disorder and need 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 three-six 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 six months.

CURES also alerts prescribers to patients with multiple prescribers, high-dose opioid prescriptions, concomitant opioids and benzodiazepines, daily opioids which have been prescribed continuously over 90 days and all scheduled Class II to IV medications.

Like any database, there may be errors, omissions, or inaccuracies in PARs and 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. If new medication is found on the PAR that the patient did not know was a controlled substance, explain why there is a need to report new medications immediately and take appropriate action with medication reconciliation.

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 or when completely taking over for another prescriber and perform urine drug testing at least annually. The annual requirement for UDT can be performed using a qualitative screening test, such as an immunoassay and does not require quantitative testing. Consider more frequent testing for higher risk individuals or at the time of aberrant behavior. These patients may require broader (more drug classes) and more specific quantitative testing based on clinical presentation. Properly performed urine drug testing involves two steps: an initial screening test followed by confirmatory testing for substances with positive screening results. The use of confirmatory testing can add substantial costs and should be based on the need to detect specific opioids, such as those that are being prescribed, and those that cannot be identified on standard immunoassays or in the presence of unexpected toxicology test results. Restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of toxicology testing.

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 titled Urine Drug Tests: Ordering and Interpretation. It is also important to document clinical decision making after abnormal or unexpected results are found.

Additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, may be deemed necessary to monitor and treat patients receiving chronic opioid treatment and is considered part of a medically necessary treatment and monitoring program.

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. Video visits with patients in their homes provides an excellent opportunity to confirm the number of pills that the patient has and avoids the need to have the patient bring prescriptions to a clinic visit.

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TAPERING AND DISCONTINUING OPIOID THERAPY

A taper is any reduction in daily opioid dosage initiated to improve a patient's safety profile or quality of life. Reasons for tapering or discontinuing opioids may include:

- Resolution or healing of the painful condition.
- Implementing the planned exit strategy included in the patient's treatment plan.
- 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 leading to hospitalization or injury.
- Evidence of non-medical or opioid misuse.
- Exhibition of drug-seeking behaviors after ensuring this behavior is not the result of inadequate treatment or diversion.

In most cases, opioids should not be tapered rapidly or discontinued suddenly due to the risks which could include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, thoughts of suicide, opioid overdose, and illicit opioid use.

Health and Human Services has developed a guide on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics which provides advice to clinicians who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain**.**

If a tapering trial is determined to be the appropriate course of action, the rate of tapering should be individualized based on the clinical situation of the patient. A successful taper requires shared decision making and can result in either a lower daily dose, or discontinuation of opioid therapy, dependent on the patient's goals and risk profile. Tapering is more likely to be successful when patients collaborate on a tapering plan and participate in decisions, such as which medication will be decreased first and how quickly tapering will occur.

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). 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, or tachycardia). However, even slow tapers involve risks and patients should be monitored closely. Not all patients may achieve the agreed upon goal at the outset of the taper.

Tapers might have to be paused. For some patients, the taper may be restarted again after a period of dose adaptation. For other patients, increased symptoms may indicate the need to stop a taper. Taper trials are considered successful if treatment decisions are individual and based on the patient's response to the last dose change.

Adjuvant medications can be co-prescribed to ease withdrawal symptoms and ensure a smoother taper. Medications can be used to manage discomfort that can accompany opioid tapering and associated withdrawal symptoms such as nausea, vomiting, diarrhea, anxiety, and vasomotor

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complaints. Commonly used medications include clonidine, hydroxyzine, loperamide, and others. The severity of withdrawal symptoms can be assessed and measured using the Clinical Opioid Withdrawal Scale (COWS). The Subjective Opiate Withdrawal Scale (SOWS) can be used as a patient-reported measure.

Patients with unanticipated challenges to tapering might have undiagnosed opioid use disorder. Consider assessing patients experiencing such challenges for opioid use disorder using DSM-5 (or the current DSM version) criteria. Recognize that the criteria for opioid tolerance and withdrawal symptoms do not apply in patients taking prescription opioids long-term as these physiologic occurrences do not represent addiction or behavioral disturbance. 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 with a current DEA permit that includes Schedule III prescribing authority.

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.

For patients with challenges to tapering that do not meet the criteria for opioid use disorder, consider that difficulty tapering is not diagnostic and can be expected for patients with major medical complexity. There is the fraction of patients who are likely benefiting from opioids and a dosage reduction makes their pain worse, increasing their difficulty in weaning. For these patients, the benefits of opioid therapy may outweigh risks and continued stable opioid therapy may be the best course of action. For these patients, there needs to be heightened monitoring, continued documentation of benefit and frequent reevaluations regarding the risks and benefits of continuing opioids.

TERMINATING CARE

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 alternate sources of medical care. If additional bridging prescriptions are provided, physicians need to document their clinical decision making about how and why they are extending beyond the original bridging period. 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.

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Physicians may also want to 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 also be prudent in these cases. Conversely, if a patient has been found to be diverting the medication, there is no requirement to provide additional prescriptions, tapering instructions or the 30-day advance notice of termination. Instead, the physician will want to offer only the minimum 15-days of emergency treatment before discontinuing care.

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 of pain, 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;
- patient activity reports from 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 and clinical decision making 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

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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 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 ll substances must address the diagnosis of illness, injury, or condition for which the substance is to be furnished.

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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 conditions or comorbidities 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 to opioids only if these alternative medications are not indicated, fail to succeed, or are not tolerated is recommended. Non opioid options such as peripheral nerve blocks and neuraxial analgesia are reasonable and effective options for surgical pain control. Additionally, while there are some exceptions to the requirement to consult CURES before initiating controlled substance prescriptions for acute pain, it is recommended that CURES 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 with other comorbidities, such as substance use disorder, opioid tolerance, etc.), a consultation with a specialist with relevant expertise in pain medicine or addiction medicine 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 along with 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 that is the result of their cancer or treatment of their cancer. In a patient with chronic pain, who has a remote history of cancer, and whose pain is clearly unrelated to the diagnosis of cancer or its treatment, the Guidelines for Prescribing Controlled Substances for Pain would still apply.

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 the ED of an acute care hospital when the prescription does not exceed a non-refillable seven-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 abruptly 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 the presence of opioid use disorder and discuss treatment options, 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 tapering 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 unless clearly indicated. All patients, including legacy patients, deserve a slow, balanced, empathetic, good faith taper trial. Those who 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 California 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 may want to 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 with relevant expertise 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 is typically 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, it is recommended that physicians 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, risk assessment for fall prevention, monitoring for cognitive impairment). Because of higher rates of respiratory depression, and as required by California law, 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 a specialist with relevant expertise in geriatrics or pain medicine 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 have failed or are unlikely to be effective for pain. Given the potential risks of opioid analgesics, a careful and thorough patient evaluation and risk assessment must be performed. If an 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; and, 3) the danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant. Note: The risk

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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. The 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 is recommended to be part of comprehensive obstetric care and 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

The standard of care for prescribing opioids and managing patients being treated for chronic pain remains the same for all patients, regardless of whether their treatment is being provided as a result of a work-related injury. This population of patients presents its own unique circumstances as

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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. This treatment process is managed in accordance with the regulations of the California Labor Code. The treatment guidelines address the use of opioids and treatment for chronic pain but are not necessarily mandatory. The Medical Treatment Utilization Schedule (MTUS) is available online to healthcare providers treating, evaluating, or performing utilization review in the California workers' compensation system. Physicians providing care to California injured workers are recommended to be familiar with these guidelines and those of the MTUS as well as ACOEM when treating these patients.

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 the patient, family or 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 when 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.
- Offer a prescription for 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.
- Attempt to identify caregivers, family members, and/or sponsors who can help assess for aberrant behaviors and assist with dispensing of the medication.
- Set specific dates and reasons for tapering and/or stopping controlled medications if opioids are not planned to be used long term. (e.g., if patient has surgery, define a cutoff date for discontinuing post-op medications).
- Consult with any other healthcare providers who are treating the patient for SUD disorders including mental health care providers or addictionologist.

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Patients with Psychiatric Conditions

Psychological distress frequently interferes with improvement of pain and function in patients with chronic pain. Use of 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. While 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), exercise 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. 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.

If benzodiazepine was prescribed for mental health reasons, it is recommended that physicians communicate with their patient's mental health professional 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

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between the patient and physician and can be conducted via telehealth pursuant to California law. Federal law, however, may limit the use of telehealth when prescribing controlled substances. As always, the physician must comply with federal and state laws, as well as 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.

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COMPLIANCE WITH CONTROLLED SUBSTANCE LAWS

Business and Professions Code	
208	CURES fees
209	CURES Application and approval process
725	Unprofessional Conduct, excessive prescribing
740	Opioid Medication-Definition of administer, drug order and prescriber
741	Opioid Medication – Offering prescription for naloxone
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
Pharmacy Code	
4021	Controlled substance definition
4052.01	Furnishing Naloxone
4052.10	Dispensing schedule II drug prescription as partial fill
Precedential Decision on Pharmacist's Corresponding Responsibility to confirm prescription written for legitimate medical purpose	
Health and Safety Code	
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
Federal Law	
Title 21, Chapter 2 United States Code (USC) Controlled Substances Act	

Appendix 1

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,

DRAFT

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

DRAFT

Appendix 2

Opioids for Chronic Pain Documentation Suggestions

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

- Page numbers refer to **Opioids and Chronic Pain: A Guide for Primary Care Providers**, available at www.ciaosf.org/materials 1