California Dental Certifications
1059 First Avenue, San Diego CA 92101
CE Provider Id #:

## Course Title: Responsibilities and Requirements of Prescribing Schedule II Opioid Drugs

#### **Course Description:**

Beginning January 1, 2023, dentists licensed in California are required to complete an approved Dental Board of California (DBC) two-unit continuing education course every two years on the responsibilities and requirements of prescribing and dispensing Schedule II opioids as a condition of license renewal. The new mandatory course is in addition to the courses in basic life support, California Infection Control and the California Dental Practice Act that are already **required for license renewal.** The course includes "the requirements of prescribing Schedule II opioid drugs, the practices for pain management in dentistry, regulatory requirements for prescribers and dispensers, and dental office procedures for managing vulnerable or substance use disorder patients". (Ref. Dental Board 16 CCR 1016, 1016.2, 1017)

Schedule II opioids are defined as drugs with a high potential for abuse that can lead to both psychological and/or physical dependence. This course will assist dentists to reduce the incidence of opioid addiction and overdose by increasing awareness and education among prescribers and patients regarding acute pain management in dentistry including vulnerable patients. Education is a key component in understanding the very addictive nature of Schedule II controlled substances which can be very addictive and cause drug overdoses if not used carefully. The primary goal of the course is to assist practitioners to provide patients with customized pain management plans that fit their needs and reduce their need for opioids.

#### **Learning Objectives:**

Upon completion of this course, students will be able to:

- 1. Understand best practices for: Pain Management in Dentistry.
- 2. Understand the: Regulatory Requirements for Prescribers and Dispensers.
- 3. Know the expected levels of: Post-operative Pain for Common Dental Procedures.
- 4. Understand dental office procedures for: <u>Managing Vulnerable or Substance Use Disorder</u>
  Patients.
- 5. Be familiar with the: <u>Schedule of Prescription drugs including examples in each category and the associated risk levels of each schedule.</u>
- 6. Understand the definitions of: <u>Drug misuse</u>, <u>drug abuse and drug addiction and their differences</u>.
- 7. Identify: <u>Drug seeking behaviors in patients.</u>
- 8. Understand the practitioner's responsibilities of: <u>Following safe and appropriate management of prescriptions and opioids.</u>

#### **Contact Hours:** 2 Hours

This course will satisfy the new California mandate for all narcotic prescribers to complete a 2-hour continuing education course on the responsibilities and regulations of prescribing Schedule II opioids.

#### **Course Outline:**

- History of Opioids in the United States
  - 5th Vital Sign
- Pharmacology of Opioids and Their Risks
  - Natural or Synthetic
  - o Effects
  - What is MME
  - Schedule II Opioid Medications
  - o Risks
- Opioid Misuse and Concerns in Dentistry
  - o Diversion
  - Controlled Substances Act (1970)
- Regulatory Agencies and Requirements for Prescribers and Dispensers
  - DEA Registration
  - o U.S. FDA Responsibilities
  - California Department of Justice
  - E-prescriptions
  - Controlled Substance Utilization Review and Evaluation System (CURES 2.0)
- Prescribing Controlled Substances
  - Record Keeping
  - o Prescriptions for Minors Informed Consent for Opioids
  - Refills
  - Emergency Situations
- Dispensing Controlled Substances
  - Quantities Allowed
  - Storage and Recordkeeping
  - Inventory
  - o Container Requirements
  - Prescription Alternatives
  - Prescription Labels
  - o CURES 2.0 Reporting
- Prohibited Actions Regarding Prescriptions
- CDC Recommendations
- Dentist's Responsibility as a Prescriber
- Medications for Dental Related Pain
  - o NSAIDs
  - Acetaminophen
  - Local Anesthetics
  - Opioid Analgesics
- Practices for Pain Management I Dentistry
  - Health History (Medical/Dental)
  - Informed Consent

- o Discussing Post-Treatment Expectations
- o Pain Management Before, During and After Treatment
- o Medication Abuse Awareness CURES 2.0
- Dental Office Procedures for Managing Vulnerable or Substance Abuse Disorder Patients
  - o Prescribing to Minors
  - o Opioid Use Disorder (OUD) Substance Use Disorder (SUD)
  - o Underlying Health Conditions
- Conclusion
  - o Dentist's Responsibility

## Responsibilities and Requirements of Prescribing

#### **Schedule II Opioid Drugs**

#### Introduction:

Effective January 1, 2023, in order to renew their license in California, dentists are required to complete a two-unit Board approved continuing education course on the responsibilities and requirements of prescribing Schedule II opioids every two years. (CCR, tit. 16, § 1016, subs. (b)(1)(D).) At minimum, the course shall include the practices for pain management in dentistry, regulatory requirements for



prescribers and dispensers, and dental office procedures for managing vulnerable or substance use disorder patients. This course will address prescribing and dispensing of Schedule II opioids which are defined as drugs with a high potential for abuse and can potentially lead to severe psychological or physical dependence. Awareness through education of alternative medications for healthcare professionals will benefit the larger public health efforts in addressing the opioid addiction epidemic.

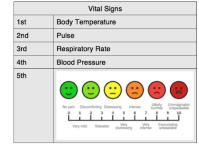
#### <u>History of Opioids in the United States</u>

In the 1990s, the intensified marketing of newly reformulated prescription opioid medications (e.g., OxyContin) and an influential pain advocacy campaign that encouraged greater pain management led to a rise in opioid use in the United States. Research from the Centers for Disease Control and Prevention (CDC) shows that prescription opioid sales in the United States quadrupled from 1999 to 2010. At the same time, opioid misuse and opioid-involved overdose deaths increased. Between 1999 and 2010, the rate of opioid involved overdose deaths in the United States doubled from 2.9 to 6.8 deaths per 100,000 people. This initial rise in opioid-related deaths is often referred to as the first wave of the recent opioid crisis.

#### The 5<sup>th</sup> Vital Sign

In 1995, James Campbell, President of the American Pain Society, referred to pain as the fifth vital sign to encourage health professionals to assess a patient's pain.

Medical experts reclassified and recommended the use of this "5th Vital Sign". It included the evaluation of pain and became a requirement for proper patient care that was as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and heart rate. Ultimately, the inclusion of this 5th vital sign led to more opioid prescriptions while simultaneously, pharmaceutical companies



were concentrating on the marketing of opioids to healthcare providers. They even went so far as to offer health professionals incentives and gifts for meeting prescription goals.

While measuring pain at every clinical encounter is important, calling it a vital sign fails to recognize the fundamental differences between acute and chronic pain. While it may be appropriate to consider the

rating of acute pain (that which is destined to naturally abate) as a vital sign, chronic pain should be viewed in a different light. Chronic pain is not a vital sign, but classified as persistent or intermittent pain that lasts for more than 3 months. Furthermore, unlike a vital sign, pain is subjective.

In 2016, The Joint Commission and the American Medical Association recommended that pain assessment no longer be considered the 5<sup>th</sup> vital sign.

#### Pharmacology of Opioids and the Risks of Their Use

#### Natural vs. Synthetic

Opiates and opioids are narcotics. Narcotics are a class of drugs that are chemicals, natural or synthetic, that interact with nerve cells and have the potential to reduce pain. Opiates occur in nature, though they can still be very dangerous in their purified and concentrated forms. Opioids are almost always made by using chemistry.

#### **Effects**

Opioids affect the brain and body by attaching specific proteins called opioid receptors that are found in the brain, spinal cord, gastrointestinal tract, and other organs. When attached to the receptors, these drugs reduce the feelings of pain.

#### MME's

"Morphine Milligram Equivalent" (MME), refers to the number of milligrams of morphine an opioid dose is equal to when prescribed. This formula is frequently used by prescribers and is used to calculate differences in opioid drug type and strength.

#### Schedule 2 (II) Controlled Substances Commonly Used in Dentistry:

- Fentanyl: Used for pain management during dental procedures. (e.g., Duragesic)
- Hydrocodone: Used for pain management after dental procedures. (e.g. Vicodin, Norco)
- Morphine: Used for pain management after dental procedures. (e.g., Kadian)
- Oxycodone: Used for pain management after dental procedures. (e.g., Oxycontin, Percocet)
- Methadone: Used for pain management after dental procedures. (e.g., Dolophine)

#### Risks of using opioids include:

- Addiction and overuse.
- Severe drowsiness, decreased awareness, breathing problems, coma, or death when taken with certain medications.
- Disease when the opioid drug is injected.
- Irregular heartbeat, increased risk of heart attack, depression, constipation, severe abdominal pain, hormonal problems, and weak bones.



Overdose, especially if the user has a history of overdose or a substance use disorder, sleep apnea
or other sleep-disordered breathing, takes higher dosages of opioids, takes benzodiazepines with
opioids, has kidney or liver failure, or is 65 years and older.

Hydrocodone and Oxycodone drugs are the most commonly prescribed (and most often abused) opioids. They are used for many painful conditions including dental treatment and injury related pain but have a

high potential for misuse that can lead to <u>'Opioid Use Disorder'</u> (OUD), brain damage, unintentional overdose, and death. The CDC states that the misuse of prescription opioids is defined as the use in *any way* not directed by the doctor. This includes taking larger doses of one's own medication, taking the medication more often or longer than prescribed. Additional side effects can occur even when medication is taken as directed. This can include physical dependence, drug tolerance, increased sensitivity to pain, respiratory problems, constipation, nausea, vomiting, xerostomia, sleepiness, confusion, dizziness, itching and sweating. Drug addiction to opioids causing OUD can destroy a person's self-control and ability to make reasonable decisions. It causes one to have an intense desire to take drugs. The condition is treatable but takes discipline, motivation, and proper therapy as do most <u>'Substance Abuse Disorders'</u> (SUD's).

#### **Opioid Misuse and Concerns in Dentistry**

<u>Diversion</u> of opioids refers to the <u>unauthorized distribution</u> of prescription drugs, including opioids, to individuals for whom they were not prescribed. Opioid diversion is a serious problem in the United States, and dentists are not immune to it. According to the National Institute of Dental and Craniofacial Research (NIDCR),



prescription opioids continue to contribute to the opioid overdose epidemic in the United States. In fact, more than 40 percent of all U.S. opioid overdose deaths in 2016 involved a prescription opioid. Prescription drugs are the third leading cause of death after heart disease and cancer in the United States and Europe. Diversion can lead to a range of negative outcomes, including addiction, overdose, and death.

There are several factors that contribute to the diversion of opioids. These include inadequate prescribing practices, insufficient monitoring of patients, and poor security measures in healthcare facilities. A common example of prescription opioid misuse is the diverting of an original prescription to help a friend or family member that is experiencing pain.

Dentists can help reduce the risk of misuse and diversion by adhering to evidence-based guidelines recommending nonsteroidal anti-inflammatory drugs and acetaminophen as first-line analgesics, which are more effective than opioids. The American Dental Association (ADA) recommends that dentists reduce the need for "just-in-case" prescriptions for dental pain. Over half of opioids prescribed after dental treatments are not used by the patient.

Prescribers in California must register with and use their state's Prescription Drug Monitoring Program (PDMP) to promote the appropriate use of opioids and deter misuse and abuse. When opioid prescribing is indicated, the risk of misuse and diversion may be mitigated by consistent PDMP use and patient education.

To prevent opioid diversion, it is important to implement effective risk assessment tools and monitoring programs. These can help identify patients who are at high risk of diverting their medication and provide them with appropriate interventions. Additionally, healthcare providers should be trained in how to identify, and report suspected cases of diversion.

50K

Almost 50,000 people die every year from opioid overdose.

10M

Over 10 million people misuse opioids in a year.

72%

Opioids are a factor in at least 7 out of every 10 overdose deaths

Opioid <u>Crisis Statistics</u> [2023]: Prescription <u>Opioid Abuse - NCDAS</u>

The Controlled Substances Act (CSA) is the statute establishing federal U.S. drug policy under which the manufacture, importation, possession, use, and distribution of certain substances is regulated. CSA places all substances which were in some manner regulated under existing federal law into one of five schedules based on the substance's potential for misuse. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. Controlled substances include opioids (neurotics), stimulants, depressants, hallucinogens, and anabolic steroids. Schedule I substances have no accepted medical use for treatment in the United States and are not available through prescription (i.e., heroin). Schedule II - V substances do have an accepted medical purpose and

Classification	Examples	Description
Schedule I	- Marijuana - LSD - Ecstasy (MDMA) - Heroin	Schedule I drugs as classified as substances that have a high potential for abuse and no accepted medical use and are not safe to use under medical supervision
Schedule II	- Cocaine - Opium - High Grade Morphine - Oxycodone - Methamphetamines (i.e. Adderall)	Schedule II drugs are classified as substances that have a high potential for abuse, despite having an accepted medicinal use in the U.S.
Schedule III	- Low-Grade Morphine - Anabolic Steroids - Ketamine - Certain Codeine Mixtures	Schedule III drugs are classified as substances that have less potential for abuse than Schedule I or II but abuse can lead to moderate physical dependence or high psychological dependence.
Schedule IV	- Ambien - Soma - Valium - Darvon - Xanax - Darvocet - Rohypnol - Ativan - Zolpidem - Talwin	Schedule IV drugs are classified as substances that have less potential for abuse than Schedule III and has accepted medical use in the U.S. but abuse of the drug may lead to limited physical or psychological dependence compared to those of Schedule III
Schedule V	- Cough Syrup (less than 200 mg) - Lomotil - Motofen - Lyrica - Parepectolin	Schedule V drugs are classified as substances with limited quantities of certain narcotics that have less potential for abuse than Schedule IV and have accepted medical use in the U.S. with limited risk of physical/

varying potential for OUD and dependency. The <u>Drug Enforcement Administration (DEA)</u> is responsible for enforcing the controlled substances laws and regulations. Drugs classified as Schedule II may be dangerous when misused. Schedule II drugs are considered high-risk for drug misuse, physical dependence, and can be addictive.

#### **Regulatory Agencies and Requirements**

#### **Drug Enforcement Agency (DEA)**

A dentist who prescribes administers or dispenses controlled substances must register with the U.S. Drug Enforcement Agency. The DEA registration is address-specific therefore a new dentist should not start their application until a practice location is confirmed. The DEA relies on

# Regulatory Agencies Occupational Safety and Health Administration (OSHA) Drug Enforcement Agency (DEA) Food and Drug Administration (FDA) Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Pharmacy Boards

state licensing boards to determine a practitioner's eligibility to dispense, prescribe, or administer controlled substances and which schedules they may dispense, prescribe, or administer. Registrants must comply with their state's requirements for drug security and record keeping. DEA registration must be renewed every three years.

#### U.S. Food and Drug Administration (FDA)

The FDA is a federal agency of the United States Department of Health and Human Services. The main purpose of the FDA is to protect public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. The FDA has a process for approving drugs for over the counter (OTC) use. They review each drug closely using an independent team of clinicians and scientists who evaluate safety, efficacy, and labeling of the drug product. After approval, FDA follow-up continues to make sure new drugs continue to be safe and effective. The FDA also considers whether the drug can be used safely without a healthcare provider's supervision. An example of a recent change is the drug Naloxone, brand name Narcan. This non-addictive and lifesaving medication is used to reverse the side effects of overdose of opioids. This non-addictive and lifesaving medication is used to reverse the side effects of overdose of opioids.

#### Department Of Justice - California

The California Department of Justice is responsible for administering and enforcing California laws that pertain to controlled substances. The California Health and Safety Code §11153. (a) states: "A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice."

This code is a California statute that makes it a crime for a medical professional to engage in prescription fraud. Prescription fraud is the act of knowingly writing a prescription that is not for a legitimate medical purpose or is outside the usual course of treatment. This crime can only be committed by someone with the authority to prescribe drugs, such as a doctor or nurse practitioner. A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The laws surrounding controlled substances in California have been updated for 2023. In California, possessing a controlled substance without the proper prescription is a crime. Perpetrators face misdemeanor charges with up to a year in prison.

#### **E-Prescriptions**

Licensees of the Dental Board with prescribing authority are subject to the e-prescribing requirements established by Assembly Bill (AB) 2789 (Wood, 2018). Beginning January 1, 2022, prescriptions for both controlled and non-controlled substances (with a few exceptions) issued by a licensed healthcare practitioner to a California pharmacy must be submitted electronically. Electronic prescribing for Controlled Substances (EPCS) is the process of electronically transmitting prescriptions for Schedule II-V controlled substances from the point-of-care to the pharmacy. This process can improve patient safety, workflow efficiencies, fraud deterrence, adherence management, and reduce burden. EPCS also enables more efficient pain management and minimizes medication errors. EPCS is an important element in combating the opioid epidemic by reducing prescription forgery, diversion, and theft. EPCS requires a software application that meets DEA requirements and integrates with prescription drug monitoring programs (PDMPs), which are electronic databases that track controlled substance prescriptions.

If there is an exception, a prescriber who does not transmit a prescription electronically for a controlled substance, must document the reason for electronic data transmission failure in the patient's record within 72 hours. The paper prescription must be written on tamper resistant security prescription forms from a private printer that is approved by the California Attorney General's Bureau of Investigation. Dentists and other health care practitioners in California who issue 100 or fewer prescriptions in a

calendar year could receive an exemption from the state's existing law requiring practitioners to electronically prescribe all medications. The exemption is available to prescribers who register with the California State Board of Pharmacy and state that they meet one or more of the following:

- They issue 100 or fewer prescriptions per calendar year.
- Their practice is in the area of an emergency disaster declared by a federal, state, or local government.
- They are unable to issue electronic data transmission prescriptions due to circumstances beyond their control.

#### CURES 2.0

California CURES 2.0 (Controlled Substance Utilization Review and Evaluation System) is an online system that tracks prescriptions of controlled substances in the state. It is used by prescribers and pharmacists to review patient prescriptions and prevent drug abuse and diversion. Since October 2018, it is mandatory for prescribers to consult CURES 2.0 before prescribing, ordering, administering, or furnishing a Schedule II-IV controlled substance to a patient for the first time or at least once every four months thereafter. California law requires all licensed dentists in California authorized to prescribe controlled substances to register for access to CURES 2.0 at <a href="mailto:oag.ca.gov/cures">oag.ca.gov/cures</a> upon issuance of DEA registration. All DEA-registered healthcare providers, with a few exceptions, are required to check CURES 2.0 before the first time prescribing of Schedule II-IV medications and every six months after when a medication will remain part of the patient's treatment.

#### **Prescribing Controlled Substances**

Record keeping is a vital part of managing controlled substances. Complete and accurate records help maintain inventories to avoid diversions and losses. Logbooks and records should be separated from

CONTROLLED

SUBSTANCES

other records and kept near the controlled substance work area. Anyone who prescribes a Schedule II controlled substance is required to keep a record of the patient's name and address, the date, the name, strength and the quantity, the pathology and purpose for which the controlled substance was prescribed or administered.

#### <u>Prescriptions for Minors - Informed Consent for Opioids</u>

In California, healthcare providers are required to discuss the risks of opioid use and contraindications with the minor, the minor's parent, or guardian, or other adult authorized to consent to the minor's medical treatment prior to directly dispensing or issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid .

<u>Refills</u> are **NOT** allowed for Schedule II controlled substances. A new prescription must be provided by the practitioner.

In the case of <u>"Emergency Situations"</u>, written, call-in, or faxed prescriptions are allowed. The medication's quantity must be limited only to an amount that is adequate to treat the patient during the emergency situation.

#### **Dispensing Controlled Substances**

A dentist who dispenses or administers controlled substances must comply with federal and state laws for their storage and must maintain required documentation. There are limits on drug dispensing, and their containers must be childproof and labeled with specific information.

The <u>quantity</u> of Schedule II drugs can only be dispensed in an amount not to exceed three days (72 hours). A prescribing practitioner may prescribe up to a 7-day supply if the prescriber:

- 1. determines it is medically necessary
- 2. indicates "acute pain exception" on the prescription; AND
- 3. documents the justification for deviating from the 3-day supply limit in the patient's medical record.

#### Storage and Record Keeping

A dentist must store controlled substances in a locked cabinet or drawer with limited access. It is recommended to document who has had access to the key or combination. If a theft or significant loss occurs, the DEA registrant must immediately contact the DEA.

Accurate <u>record keeping</u> is required. A log of drugs dispensed in the office must be kept and maintained for three years. This log must include:

- o The full name of the patient, their address and telephone number
- o The patient's gender and date of birth
- The prescriber's category of licensure, license number, DEA registration number and NPI (National Provider Identifier)
- National Drug Code (NDC) of controlled substance
- o ICD-9 (diagnosis code), if available
- Number of refills ordered
- o Information on whether the drug was a first-time prescription request or a refill
- o Date of origin of the prescription

<u>An inventory</u> of controlled substances must be taken at least once every two years. The inventory record may be handwritten, typewritten or on a printed form. It should be maintained at the practice for at least two years from the date that the inventory was conducted. Controlled substance samples provided by pharmaceutical companies must be included in the inventory record. Each inventory record must contain the following information:

- o Date of inventory and whether the inventory was taken at the beginning or close of business.
- Names of controlled substances.
- o Each finished form of the substances (e.g., 100 mg tablet).
- The number of dosage units of each finished form in the commercial container (e.g., 100-tablet bottle).
- o The number of commercial containers of each finished form (e.g., four 100-tablet bottles).
- Disposition of controlled substances.

#### **Container Requirements**

FDA regulations require that all medication labels include:

- o Name of Product
- Table of Drug Facts
- Active Ingredients
- o Proper Use and Purpose
- Warnings
- Directions
- o Allergic Reactions/Harmful Side Effects
- Inactive Ingredients

#### **Prescription Alternatives**

The biggest benefit of the dentist dispensing prescriptions to the patient comes in the form of improved primary medication adherence. Approximately 20-30% of prescriptions *are never filled*. The dispenser is required to provide patients with a written disclosure informing them they have a choice between obtaining the medication from the dispensing prescriber or having their prescription filled by a pharmacy of the patient's choice.

<u>Prescription labels</u> must be available to the patient in languages other than English if requested by the patient. Translated prescription labels play a critical role in the patient's ability to understand and adhere to medication directions for use.

#### Reporting to CURES 2.0

Dispensers of Schedule II – IV drugs are required to submit prescription record information weekly to CURES 2.0. There are a few exceptions, the dispensing of Schedule IV drugs in a quantity to treat a patient for 48 hours or less does not need to be reported, and dispensing Schedule II or III in a quantity to treat a patient for only 48 hours or less is reported only monthly.

Beginning August 1, 2024, dispensers will be required to report dispensations to the <u>Controlled Substance Utilization Review and Evaluation</u> System (CURES) using version 4.2B of the <u>American Society for Automation in Pharmacy</u> (ASAP) format. Presently, California dispensation data is reported using the ASAP version 4.1 format. This format change will improve data quality by offering more data fields and clarifying certain other data fields.

#### **Prohibited Actions Regarding Prescriptions**

- Prescribing any controlled medication for yourself is prohibited.
- > Prescribing, administering, or furnishing a controlled substance is allowed only as allowed by law.
- > Prescriptions may not be pre or postdated.
- False statements on any prescription are not allowed on the order, report, or record.
- False labeling on a package or receptacle containing a controlled substance.
- No person shall, when prescribing, furnishing, administering, or dispensing a controlled substance, give a false name or false address.

#### **CDC Recommendations**

The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain is a clinical tool to help clinicians and patients work together to make informed, patient-centered decisions about pain care. It includes recommendations for clinicians providing pain care for outpatients aged 18 years or older with acute pain (duration less than 1 month), subacute pain (duration of 1-3 months), or chronic pain (duration of more than 3 months).

The Centers for Disease Control and Prevention (CDC) provides evidence-based recommendations for dentists and other oral health practitioners to effectively manage acute pain conditions including mild postoperative pain resulting from a simple dental extraction.

Here are some of the key recommendations:

- Nonopioid therapies are at least as effective as opioids for many common types of acute pain, including dental pain and pain related to a simple dental extraction. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient.
- NSAIDs have been found to be more effective than opioids for surgical dental pain. The American
  Dental Association recommends NSAIDs as first-line treatment for acute dental pain management.
- When diagnosis and severity of acute pain warrant the use of opioids, clinicians should prescribe immediate-release opioids, at the lowest effective dose, and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional long-term opioid use.
- Clinicians should discuss the realistic benefits and known common risks of opioid therapy and nonopioid therapies with patients before prescribing opioids.

Guideline recommendations and guiding principles are grouped into four areas of consideration.



Determining whether or not to initiate opioids for pain



Deciding duration of initial opioid prescription and conducting follow-up



Selecting opioids and determining opioid dosages



Assessing risk and addressing potential harms of opioid use

#### **Dentist's Responsibility and Role as a Prescriber**

The management of pain in dentistry encompasses a number of procedural issues, including the delivery of anesthetic and the management of postprocedural pain, as well as pain diagnosis, management strategies for orofacial conditions that cause pain in the face and head, and the management of pain in special populations. Effective pain management is a priority in treating dental patients. There is, however, a high risk for the misuse of prescription drugs especially when they are not used as prescribed.

The clinical considerations when determining pain therapy to be used in patient treatment include, but are not limited to, the following: how severe is the pain, the patient's sensitivity, medical history, dental

pathology and treatment, and the degree of trauma. Morphine milligram equivalents (MME) or morphine equivalent doses (MED) are values that represent the potency of an opioid dose relative to morphine. MME is intended to help clinicians make safe, appropriate decisions concerning changes to opioid regimens.

To ease discomfort that can result from some dental procedures, such as tooth extraction, gum and other dental surgery, or placement of dental implants, dentists may prescribe medications for pain relief, including opioids. Dentists that have the authority to prescribe opioids are responsible for:

- ✓ Making sound judgment when diagnosing and treating pain may involve prescribing opioids only as a last resort.
- ✓ Minimize the potential for adverse effects of pain management which includes the potential for abuse and addiction.
- ✓ Maintain and continue updated education regarding the knowledge and skills that meet current standards of patient care and pain management. Education must include the appropriate use of opioids, recognizing addictive behaviors and disease, various methods to minimize addiction and/or diversion.

#### **Medications for Dental Related Pain**

Non-opioid pain medications include non-steroidal anti-inflammatory drugs (NSAIDs). Acetaminophen is generally considered safer than other pain relievers. It doesn't cause side effects such as stomach pain and bleeding.



Generally, acetaminophens are considered equal to or better than opioids when it comes to pain management and produce a lower occurrence of side effects, including the potential for misuse. (Taking more than the recommended dose or taking acetaminophen with alcohol increases the risk of kidney damage and liver failure over time.)

NSAIDs (nonsteroidal anti-inflammatory drugs) can reduce pain, fever, and other types of inflammation. Common over the counter NSAIDs include aspirin, ibuprofen, and naproxen sodium. Healthcare providers can also prescribe stronger NSAIDs when appropriate. NSAIDs taken after dental treatment procedures are as effective, or better than, opioids for reducing the frequency and intensity of acute dental pain and are recommended as the first line of treatment.

<u>Acetaminophen</u> - Acetaminophen is generally a safe option to try first for many types of pain, including chronic pain. If NSAIDs use is indicated, they should be initiated prior to the dental procedure and alternate NSAID and acetaminophen dosing on a scheduled basis after treatment. Patient education and instruction is imperative. Acetaminophen (Tylenol) can be dangerous when taken with other medications that contain acetaminophen. Too much acetaminophen can make it more likely to have liver damage. It can also put you at risk of acetaminophen overdose. Taking acetaminophen and drinking alcohol in large amounts can be risky. Large amounts of either of these substances can cause liver damage.

Acetaminophen can also interact with warfarin, some seizure medications, and isoniazid (TB medication).

<u>Local Anesthesia</u> - Local anesthetics have an impressive history of efficacy and safety in medical and dental practice. To assist in pain management, clinicians should consider using long-acting local anesthetics whenever possible. This can help reduce the need for additional pain management

medications such as opioids. NSAID therapy that is started before the local anesthetic wears off is recommended.

<u>Opioid Analgesics</u> - Opioid analgesics can be used to treat moderate to severe acute pain and include drugs such as oxycodone, hydrocodone, and codeine. Opioids can cause serious side effects such as respiratory depression, increased risk of persistent opioid use, addiction, and overdose. Nonsteroidal anti-inflammatory drugs (NSAIDs) have been shown to be more effective at reducing pain than opioid analgesics. If opioids are prescribed to the patient, they should only be for a short period of time and at the lowest potency and quantity needed to relieve pain. Potential drug interactions, and complications should always be assessed.

#### **Patient Management, Screening and Counseling**

The most common dental complaint is pain. It accounts for more than 80% of all dental visits. Pain diminishes the quality of life for many people, although it also may be a vital teacher or a warning message to be heeded. How humans process pain is a complicated, individualized process affected by genetics, personality, life experiences and straight forward physiological process. Due to the complexity of pain, it is recommended that dentists do a thorough patient assessment and evaluation. To provide the best patient centered outcome the evaluation should include a risk assessment if opioid use is indicated. Pain management plans will identify risk factors taken from the patient's personal and family history, screening, and diagnostic tools such as prescription drug monitoring programs.

<u>Health History (Medical and Dental)</u> - An accurate medical/dental health history is vital since it may provide valuable information for the dentist prior to beginning treatment as certain medications can influence treatment decisions or may impact post-operative care instructions. The medical/dental health history should include:

- o the patient's health conditions and illnesses
- Contact information for the patient's primary health care provider and/or any specialists coordinating specific medical treatment
- Current medications that the patient is taking
- Questions regarding substance abuse, abstinence-based therapy, or medication-assisted therapy for opioid misuse

If the dentist feels opioids may be prescribed, the initial evaluation should document the patient's mental status and SUD history.

<u>Informed Consent</u> - Informed consent gives the patient the opportunity to be an informed participant in health care decisions and provides a way to document full disclosure of the benefits and risks of opioid therapy. The dentist will discuss with the patient and/or parents of a minor, the risks and benefits of pain treatment options. This will include the use of NSAIDs and encouraging their use first. For opioid pain medications, counsel the patient regarding their legal and ethical obligations, the importance of not mixing drugs and alcohol or other sedative medications. Patients should be advised they are not to share prescription drugs and to properly dispose of any unused medications.

<u>Post Treatment</u> – Expectations regarding the patient's expected recovery and pain management goals should be discussed. Patients should be made aware of opioid alternatives for postoperative pain control. (ice packs, heating pads, rest, diet)

#### Pain Management: Before, During and After Treatment

Pain management is an important consideration before, during, and after dental treatment. Administering a single dose of an oral NSAID 30-60 minutes *before* dental treatment can delay the onset and reduce the intensity of post-procedural pain. (except in cases where significant bleeding to tissue trauma is anticipated). Distracting the patient during treatment can also help reduce pain, along with using relaxation techniques such as deep breathing and progressive muscle relaxation to manage pain during dental treatment. The use of antiseptic mouth rinse can promote healing, prevent post-procedural infection, and reduce pain.

NSAIDs and acetaminophen should be considered initially as first-line pain therapy. Both have been shown to be very effective for treating dental pain. Post-procedural pain includes inflammatory components making NSAIDs necessary and better than the use of opioids. The use of longer lasting local anesthesia when possible is a feasible way to reduce the need for opioids when NSAIDs are started before the anesthetic wears off.

Opioids that may be prescribed for acute pain following dental treatment, the dose and duration should be for only a short period of time, and only for conditions that typically are expected to cause more severe pain. Again, it is important to prescribe the lowest effective dose and quantity needed, and for no more than three days. When prescribing opioids, always assess other medications the patient may be taking and any contraindications or possible adverse interactions that could occur. Specific instructions provided to the patient for pain relief should be carefully documented.

#### Medication Abuse Awareness (Prescriber's Additional Responsibilities)

Medication dispensing and prescription safeguards are critical to ensure patient safety. It is important to follow recommended CDC guidelines, and:

- Utilize CURES 2.0 to aid in the identification of any patient who may be misusing their opioid prescriptions
- Ensure all prescription pads, electronic prescription programs, and any opioid medications in the office are secure with limited accessibility to staff and patients.
- Utilize and update all office policies and provide staff with training on how to prevent prescription opioid abuse.
- Establish a connection and referral system that includes other healthcare providers and community services. This provides additional information about patients that may exhibit worrisome behaviors indicating possible SUD. Patients should be encouraged to seek help for possible treatment through a primary care provider or local SUD treatment programs.
- The practitioner should be aware of all current, or new, peer reviewed recommendations for pain.

When prescribing opioids to patients, it is important to be aware of certain <u>Red Flags</u> that may indicate the patient is at risk for abuse or addiction. Common red flags to watch out for :

 New patients who may report prolonged or unexpected pain, especially those who do not have any ongoing pathology

- Refusal to sign or comply with an opioid pain care agreement governing the use of opioid analgesics
- A patient claiming to be allergic or intolerant to alternative nonopioid pain medications
- Refusal to try nonpharmacologic therapies
- o Illicit behavior: Attempts to alter, forge, or rewrite prescriptions
- The patient has multiple prescriptions for pain medications from several different prescribers that are filled at different pharmacies
- o The patient misrepresents their condition or medical history to get a prescription
- A patient with multiple prescriptions for different medications, when taken together, creates a much stronger drug

#### Additional behaviors that may also be indicative of opioid abuse or addiction:

- Never prescribe opioids to a patient if the office is closed. In general, it is not acceptable to prescribe opioids without actually seeing the patient.
- Patients who claim to have had medications dropped in the sink, lost, or stolen
- Patients who doctor shop and travel long distances to receive their medication from a pharmacy.
- o Patients who pay cash rather than using insurance.
- o Patients who seek multiple prescriptions from different prescribers.
- Patients who use slang to describe medication.

It is important to note that these behaviors do not necessarily indicate that a patient is abusing opioids. They should, however, be taken seriously and investigated further if they are observed.

#### **Dental Procedures for Managing Vulnerable or Substance Use Disorder Patients**

Minors – According to the California Dental Association, dentists write approximately 31% of opioid prescriptions for patients between 10 to 19 years, and an estimated 56 million tablets of 5 mg hydrocodone is prescribed after third molar extractions each year in the United States. According to the National Institute on Drug Abuse, research shows that the earlier people begin to use drugs, the more likely they are to develop serious problems. This may be due to the harmful effect that drugs can have on the developing brain. Adolescence is a developmental period during which the presence of risk factors, such as peers who use drugs, may lead to substance use. The National Council on Alcoholism and Drug Dependence states that drug abuse often begins in adolescence, with the average age of first use being 13 years old. Taking the time to carefully plan out pain management in children and adolescents is key to prevention strategies.

<u>OUD/SUD</u> - The confusion surrounding the definitions of addiction and dependence is not new. Development of opioid tolerance, dependence, and addiction are all manifestations of chemical changes occurring to the brain. It is important to remember that not every person treated with an opioid will develop OUD, just as an SUD condition is not solely the result of drug exposure.

The American Dental Association recommends that nonsteroidal anti-inflammatory medications (NSAIDs) be used as the first-line therapy for acute dental pain management. Interdisciplinary care for chronic orofacial pain is indicated, and opioids should only be prescribed for acute dental pain for a maximum of 3 days after risk assessment.

The Centers for Disease Control and Prevention (CDC) has issued a 2022 Clinical Practice Guideline for Prescribing Opioids for Pain. The guideline provides voluntary guidance for clinicians that was created to help informed decision making. The guideline emphasizes individualized patient care, safe and effective pain management options, improving communication between clinicians and patients so they can make decisions together about the best care for the patient, and reducing risks associated with opioid pain therapy, including opioid use disorder, overdose, and death.

<u>Underlying Health Conditions</u> – It is important to note that patients with underlying health conditions may require special considerations when it comes to pain management. For example, patients with liver or kidney disease may need lower doses of certain medications. Patients with heart disease may need to avoid certain medications that can increase the risk of heart attack or stroke. Patients with a history of substance abuse may need to avoid opioids altogether. Dentists should consult with the patient's physician when treating a patient with health conditions that may require special care.

#### **Conclusion**

Dentists have a responsibility to follow safe and appropriate management of prescriptions and opioids. Implementing effective office policies and management when prescribing opioids is effective in preventing the diversion of opioids. This includes tailoring prescription practices to provide pain control while still limiting the possibilities of abuse and diversion. Always consider nonsteroidal anti-inflammatory drugs (NSAIDs) as the first-line therapy for acute dental pain management. Consider using multimodal opioid-sparing strategies such as pre-treatment with NSAIDs and long-acting local anesthesia. If you consider prescribing an opioid for acute pain, follow the CDC guidelines. Remember that three days or less will often be sufficient, and more than seven days will rarely be needed.

### Responsibilities and Requirements of Prescribing Schedule II Opioid Drugs Course Examination

Se	elect the best possible answer from the choices provided.
1.	Prescriptions for Schedule II drugs may include how many refills?  a. 0  b. 1  c. 2  d. 3
2.	The analgesic used most as first line treatment options for patients with dental pain is:  a. Hydrocodone  b. Acetaminophen  c. NSAIDs  d. Codeine
3.	The unauthorized distribution of prescription drugs is referred to as:  a. Addiction b. Diversion c. OUD d. SUD
4.	and drugs are the most commonly prescribed (and most often abused) Opioids.  a. Hydrocodone b. Oxycodone c. Acetaminophen d. Both a and b are correct
5.	Interdisciplinary care for chronic orofacial pain is indicated, and opioids should only be prescribed for acute dental pain for a maximum of days.  a. 2 days  b. 3 days  c. 4 days  d. 5 days
7.	Records of Schedule II-IV controlled substances must be maintained for at least years.  a. 3 b. 5 c. 7 d. 10

<ul> <li>8. Pain is:</li> <li>a. The most common dental complaint</li> <li>b. Unavoidable in some cases</li> <li>c. A fact of life</li> <li>d. Only minor in most cases</li> </ul>
<ul> <li>9 is the agency that is responsible for administering and enforcing California laws that pertain to controlled substances.</li> <li>a. Cal/OSHA</li> <li>b. Department of Public Health</li> <li>c. Department of Justice</li> <li>d. California Dental Board</li> </ul>
<ul> <li>10. NSAIDs are used to help manage pain, and reduce inflammation after dental Treatment because: <ul> <li>a. It is non-addictive</li> <li>b. It has a low incidence of side effects</li> <li>c. It generally is equivalent to or better than using opioids</li> <li>d. All are correct</li> </ul> </li> </ul>