CDA AND DENTISTRY WORKING TO REDUCE OPIOID MISUSE AND ABUSE

A message from CDA President Natasha Lee, DDS

As you read the September CDA Update, you will see that this issue is different from any other our organization has ever produced. The focus is entirely on the opioid crisis gripping America and dentistry's leadership on this issue.

While there is much work ahead of us, CDA and the profession are already actively addressing the epidemic at the state and national levels. This issue is dedicated to providing you with a full view of these efforts, including a look at dentistry's biggest opportunity: to reduce opioid misuse and abuse subsequent to “first exposure” of the drug. We also detail CDA’s work with the state Legislature to address the epidemic through regulations as well as prescribers’ responsibility to utilize the state’s controlled-substance database. Additionally, educational opportunities through CDA Presents will provide updated best practices for dental pain management.

Also, be on the lookout for the February 2019 issue of the Journal of the California Dental Association, dedicated to this topic and guest edited by national expert Michael O’Neil, PharmD, who for many years has served as a consultant on prescription drug abuse, substance abuse and drug diversion.

The next time someone asks you what dentistry is doing to reduce the misuse and abuse of opioids, you can tell them: “a lot!”

Opioids in California: What is CDA doing?

By Kerry K. Carney, DDS, CDE

I spoke the other day with a colleague who has a personal connection to the tragedy that is the national opioid crisis. Out of this experience, my colleague made a commitment to his bereaved friend: He promised he would do whatever he could to help reduce the number of deaths attributed to prescription opioids. He then asked me, “Where is CDA in this crisis?” I shared with him all of CDA’s activities that I was aware of but it occurred to me that some dentists may not fully understand dentistry’s role and how CDA is answering this tremendous social challenge.

CDA began addressing opioid abuse more than three years ago, but the data and countless personal stories tell us that now is a good time to pull together all our resources and efforts and provide our membership with a 360-degree look at the issue in California and CDA’s leadership on it.

First, what is the problem?

Record numbers of people are using, abusing and dying from opioid medications. According to the Centers for Medicare and Medicaid Services, more than 115 people died every day in 2016 from opioids and 40 percent of those overdose deaths involved a prescription opioid. The Substance Abuse and Mental Health Services Administration estimates that 2.1 million Americans suffer an opioid use disorder.

Federal and state agencies have gone on high alert and significant attention and resources are focused on the problem, but it did not occur overnight and there is every reason to think it will take multiple strategies and changing behaviors in numerous participants to effect needed change.

What are we doing about it in California?

CDA noted the rising problem early on and over the last several years has responded to reverse the trend in this state. Here is a summary of CDA’s actions:

In one dedicated place on CDA’s website, members can easily access updated, comprehensive information on opioids and CURES. On the cda.org homepage, a large “button” on the right directs readers to a webpage with links to resources and news from CDA, the dental board, ADA and others.

Since spring 2014, CDA Presents The Art and Science of Dentistry has offered a course on the pharmacologic and regulatory
Rethinking pain management in our dental practices

At least 130 bills to combat the nation’s opioid epidemic have been introduced in the U.S. Congress since January, as the ADA reported in March when it unveiled its national policy on opioid prescribing. California is simultaneously mounting its own legislative efforts to curb opioid abuse. Over 30 bills have been introduced in the current session that can be classified into five main categories: prescribing/practicing, continuing education, CURES 2.0 — California’s prescription drug monitoring program, insurance and resolutions. Summarized here are the bills that may be signed by Gov. Jerry Brown and how they may impact the way dentists practice and prescribe.

Opioid bills affecting dentistry expected to reach governor’s desk

Managing postoperative pain

There are various approaches to managing acute pain from dental treatment. I have tried several approaches myself over the years and have my own algorithm for these types of decisions. However, as the number of people experiencing substance use disorders has skyrocketed and there is intense focus on contributing factors, it is more important than ever to look to experts in the field and follow best practices. Gone are the days where I could decide these things without considering the bigger picture. With that as background, here is the stepwise recommendation for acute pain management published in the 2015 ADA Practice Guide to Substance Use Disorders and Safe Prescribing (p 45):

- Mild pain: Ibuprofen 200-400 mg every four to six hours as needed for pain (p. 18).
- Mild-to-moderate pain: Ibuprofen 400-600 mg every six hours: fixed interval for 24 hrs., then ibuprofen 400 mg q 4-6 hrs. p.r.n. pain.
- Moderate-to-severe pain: Ibuprofen 400-600 mg plus APAP 500 mg every six hours: fixed interval for 24 hrs., then ibuprofen 400-600 mg plus APAP 500 mg q 6 hrs. p.r.n. pain.

Severe pain: Ibuprofen 400-600 mg plus APAP 650 mg hydrocodone 10 mg q six hours: fixed interval for 24-48 hrs., then ibuprofen 400-600 mg plus APAP 500 mg q six hrs. p.r.n. pain.

Additional considerations include:
- Patients should be cautioned to avoid APAP in other medications. Maximum dose for APAP is 3,000 mg/day. To avoid potential APAP toxicity, dentists should consider prescribing a rescue medication containing ibuprofen (Vicoprofen) if patients experience breakthrough pain. Maximum dose of ibuprofen is 2,400 mg/day. Higher maximal daily doses have been reported for osteoarthritis when prescribed under the direction of a physician.
- Future revisions of the guidelines may take into account a finding that was reported in a recent overview of systemic reviews. In “Benefits and Harms Associated with Analgesics Used in the Management of Acute Dental Pain,” published in the April 2018 Journal of the American Dental Association, the authors concluded:
  - When comparing the efficacy of non-steroidal anti-inflammatory medications with opioids in relation to the magnitude of pain relief, the combination of 400 mg of ibuprofen plus 1,000 mg of acetaminophen was found to be superior to any opioid-containing medication combination studied. In addition, the opioid-containing medications or medication combinations studied were all found to have higher risk of inducing acute adverse events than 400 mg of ibuprofen plus 1,000 mg of acetaminophen. Thus, in general, when considering either benefits or harms, management of acute pain with nonsteroidal medications, with or without acetaminophen, appears to have a therapeutic advantage to opioid-containing medications.
  - Although there are situations in which clinical judgment indicates an opioid-containing medication may be warranted, the data make a compelling case favoring use of nonsteroidal medications, with or without acetaminophen.

E-prescribing mandates

AB 2789 by Assemblymember Jim Wood (D-Healdsburg), DDS, requires dentists and other health care practitioners authorized to issue prescriptions to have the capability to transmit electronic prescriptions (for controlled and noncontrolled substances) and would require pharmacies to have the capability to receive those prescriptions by Jan. 1, 2022. This legislation mirrors other initiatives mandated in states such as New York and is aimed to reduce prescription fraud and handwriting errors. CDA has worked with Dr. Wood’s office and the Legislature to achieve a delayed implementation date of 2022 to give dentists and other health care practitioners ample time to obtain adequate e-prescribing systems, train staff and update office workflow protocols.

Controlled Substances Regulation in California

To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing and dispensing of controlled substances, the state of California’s Department of Justice established the Controlled Substance Utilization Review and Evaluation System, CURES, if used consistently by controlled substance prescribers and dispensers, is an excellent tool for regulatory and law enforcement agencies to reduce the diversion and resultant abuse of Schedule II, Schedule III and Schedule IV controlled substances and for statistical analysis, education and research.

This system makes it possible for controlled-substance prescribers, those who possess an active DEA license and a California health care provider license, to review the database prior to prescribing medications with the potential for abuse. Under California law, all California-licensed prescribers authorized to prescribe controlled substances were required to register to access CURES 2.0 by July 1, 2016. The law requires mandatory use beginning Oct. 1, 2018. Once a provider is registered in the system, the program requires passwords to be changed every 90 days. The system is very easy to use — and fast. It can be utilized in about two minutes. CURES 2.0 is committed to the reduction of prescription drug abuse and diversion without affecting legitimate health care practice or patient care. Hopefully, this state-mandated program will help prescribers see the true drug history of their patients and alert dispensers before dispensing controlled substances.

Continuing education and minor informed consent requirements

SB 1189 by Sen. Patricia Bates (R-Laguna Niguel) would provide for additional education about opioid addiction in the continuing education courses for prescribers, establish warning labels on opioid prescriptions and increase the level of awareness regarding the use and abuse of opioids among California’s minors, student athletes and the parents or guardians of minors and student athletes.

Most notably, this bill would allow the dental board to consider and adopt mandatory continuing education regulations on course curriculum pertaining to the risks of addiction associated with the use of Schedule II controlled substances. Additionally, this bill would require a prescriber to discuss the risks associated with Schedule II controlled substances with a minor patient and adult authorized to consent to the minor’s medical treatment.
treatment prior to prescribing such medications.

Opioid prescribing policy
AB 1998 by Assemblymember Freddie Rodriguez (D-Pomona) would require dentists and other health care practitioners who prescribe, administer or furnish opioids to adopt a safe opioid prescribing policy by July 1, 2019.

The policy must include, as applicable to the prescribing dentist’s practice, a general prescribing policy for the dose and duration of prescriptions for adult and pediatric patients experiencing acute pain, alternatives to opioid treatment, recommendations for assessing patients’ continued use of opioids for pain management, and recommendations for counseling patients on overdose and addiction. When a dentist deviates from this general policy, a note explaining why should be placed in the patient’s record.

Dentists may create their own policy or adopt guidelines that have been published by professionally recognized organizations. (This bill died shortly before Update printing.)

CURES 2.0 and interstate prescription data sharing
AB 1751 by Assemblymember Evan Low (D-San Jose) authorizes the California Department of Justice to participate in an interstate data share hub for the purpose of sharing information in prescription drug monitoring programs across state lines.

The bill would link CURES 2.0, California’s prescription drug monitoring program, with drug monitoring databases in other states while ensuring that patient privacy remains adequately protected. The bill requires that any interstate access meets data security standards and complies with California law. The bill’s author hopes that enhancing CURES to allow California’s prescribers, dispensers, regulators and law enforcement to share information across state lines will help curb the overprescribing of controlled substances and prevent “doctor shopping.”

All prescribing dentists were required to register to use CURES 2.0 by July 2016. Beginning Oct. 1, 2018, prescribers must check a patient’s prescription history in the database before prescribing a Schedule II-V substance, with some notable exceptions outlined elsewhere in this special-edition Update.

But CURES 2.0 only contains records of controlled-substance prescriptions dispensed within California; prescriptions dispensed in Nevada and Oregon, for example, are not accessible to prescribers in California, nor are California prescriptions visible to out-of-state prescribers.

CURES 2.0 data reporting and access
Also authored by Low, AB 1752 proposes two significant changes: It adds Schedule V controlled substances to the CURES 2.0 database, noting an increase in theft and abuse of these drugs, and requires a dispensing pharmacy, clinic or other dispenser to report dispensed prescriptions no later than one working day after the controlled substance is dispensed.

Changing the reporting timeline from the current seven days after a prescription is dispensed to the next business day allows for “more real-time access to data used to prevent drug abuse” and provides dentists and other prescribers “with an even more powerful tool for saving lives from drugs like opioids,” Low’s office states in the bill’s fact sheet. (This bill died shortly before Update printing.)

Another CURES-related bill, AB 2086 (Gallagher, R-Yuba City), would allow a prescriber of controlled substances to request from the Department of Justice a list of patients for whom he or she is named as a prescriber.

While dentists and other controlled-substance prescribers can monitor the prescription history of their individual patients in the CURES database to help reduce prescription “shopping” and abuse, prescribers do not have the ability to see a list of all patients who have identified them, correctly or falsely, as having written a prescription for them. AB 2086 can help prevent fraudulent prescriptions by allowing providers to access their own prescribing history in order to verify accuracy.

Resolution recognizes impact of opioids
In connection with Opioid Overdose Death Awareness Week, SCR 115 (McGuire, D-Healdsburg) creates a resolution to recognize the impact that opioid-related deaths have had on California communities and encourages the state to increase funding for support and other programs in rural areas facing the epidemic. SCR 115 supports groups and organizations working in California to combat the opioid epidemic. The resolution designates the first week of March as Opioid Overdose Death Awareness Week.

The governor has until Sept. 30 to sign or veto bills passed by the Legislature. CDA will report on the status of these opioid bills in the October CDA Update and on cda.org.
Sometimes you read a research article and it hits you between the eyes like a sledgehammer. So it was when I read “Prescription Opioids in Adolescence and Future Opioid Misuse” published in the journal Pediatrics in 2015. It made me really reconsider the impact dentists can have on ameliorating the opioid crisis.

The devastation of prescription opioid misuse and its associated overdose deaths can hardly be overstated. Opioid overdose emergency department visits rose 30 percent in all parts of the U.S. from July 2016 through September 2017, according to an article in the March 2018 CDC monthly report VitalSigns. “Opioid Overdoses Treated in Emergency Departments: Identity Opportunities for Action” reports that midwestern states were particularly hard hit with a 70 percent increase in opioid overdoses. Opioid overdoses increased for both women (24 percent) and men (30 percent) as well as in all age groups, and people who have had an opioid overdose are more likely to have another overdose. Opioid overdoses in large cities increased by 54 percent in 16 states, according to the report.

When I first wrote about the United States opioid crisis in the November 2015 issue of the CDA Journal, the death rate from prescription opioids was about the same as the number of fatalities that could be expected if two jumbo jets crashed every month. Now the figures are even worse. It is more like three jumbo jets full of victims every month. Some regions are more hard-hit than others. The drug overdose death rates in those high-incidence areas are even more harrowing. Whereas the national death rate is just over 19 per 100,000, Pennsylvania has a rate of 37, Ohio and New Hampshire have rates of 39 and West Virginia has a rate of 52. These top four states accounted for more than 10,000 deaths in 2016. These statistics should spur everyone to try to do something to stem this tide of tragedy.

Opioid use is known to be associated with opioid misuse among adults, according to the aforementioned Pediatrics journal study. The use of prescription opioids to relieve chronic back pain carries such a substantial risk of future opioid misuse that it has been suggested that the risk outweighs the analgesic benefits. Though this risk pattern has been shown in adult populations, the study investigated the size of the risk in an adolescent population.

“An association between legitimate opioid use before high school completion and an increased risk of subsequent misuse after high school could change the risk/benefit considerations for clinicians who treat pediatric patients with painful conditions,” the study’s authors state.

What they found was striking. According to the study:

- Legitimate opioid use by 12th grade significantly predicts future opioid misuse after high school. However, this association is concentrated among adolescents who are least expected to misuse opioids: 12th-grade students who have little to no history of drug use and strong disapproval of marijuana use.
- In the overall sample, individuals who have an opioid prescription by the 12th grade are, on average, 33 percent more likely to misuse prescription opioids after high school by age 23 than those with no history of an opioid prescription.

Specifically, among respondents with low predicted risk for future opioid misuse in 12th grade, an opioid prescription increases risk for opioid misuse after high school threefold.

To reiterate, “among 12th-grade students who have little experience with illegal drug use and strongly disapprove of marijuana use, a legitimate opioid prescription predicts opioid misuse after high school,” the authors state.

The authors also postulate that the novelty of drug-use effects may help explain why an opioid prescription predicts future opioid misuse most strongly among individuals with little to no experience with use of illegal drugs. For these drug-naive individuals, an opioid prescription is likely to be their initial experience with an addictive substance. Most likely the initial experience of pain relief is pleasurable, and a safe initial experience with opioids may reduce perceived risk. A pleasurable and safe initial experience with a psychotropic drug is a central factor in theories of who goes on to misuse drugs.” It is important to emphasize that sometimes you read a research article and it hits you between the eyes like a sledgehammer.

“For clinical practice, the results suggest an unrecognized risk of opioid prescribing. This risk should be incorporated into prescribing decisions and patient counseling,” the authors state. But they do emphasize the importance of their findings for clinical practice:

- “Among 12th-grade students who have little experience with illegal drug use and strongly disapprove of marijuana use, a legitimate opioid prescription predicts opioid misuse after high school.”
- “results do not support legitimate opioid prescription use, by itself, as a major contributor to chronic opioid misuse, at least not by age 23,” the authors state.
- But they do emphasize the importance of their findings for clinical practice:

Opioid prescription use does not support legitimate opioid prescription use, by itself, as a major contributor to chronic opioid misuse, at least not by age 23,” the authors state. But they do emphasize the importance of their findings for clinical practice:

- “Among 12th-grade students who have little experience with illegal drug use and strongly disapprove of marijuana use, a legitimate opioid prescription predicts opioid misuse after high school.”
Offered here are synopses of findings in three studies cited in “End first exposure: Dentistry’s biggest opportunity in the opioid crisis” by Kerry K. Carney, DDS, CDE.

Early exposure in adolescents can lead to opioid misuse

A study published in the November 2015 Pediatrics journal, “Prescription Opioids in Adolescence and Future Opioid Misuse,” found that early exposure to prescription opioids can lead to future opioid misuse among adolescents who have little drug experience and disapprove of illegal drug use. Eliminating first exposure within this vulnerable group may have a substantial potential to reduce future opioid misuse among these individuals, according to the study.

Data for the research came from the annual Monitoring the Future study, which uses classroom questionnaires to survey nationally representative samples of U.S. 12th-graders annually. The survey selects 130 public and private schools containing 12th-graders and those students are randomly assigned to one of six questionnaire forms that contain both core and form-specific questions. Then 2,450 high school seniors are randomly selected from the baseline sample to participate in follow-up mail surveys that include questions on opioid misuse.

In the overall research sample, the study found that individuals who have an opioid prescription by 12th grade are, on average, 33 percent more likely to misuse prescription opioids by age 23 than those with no history of an opioid prescription. This association is concentrated among adolescents who are least expected to misuse opioids: 12th-grade students who have little to no history of drug use and strongly disapprove of marijuana use, according to the study.

The novelty of drug-use effects may help explain why an opioid prescription predicts future opioid misuse most strongly among adolescents with little to no experience with illegal drugs. For these drug-naïve individuals, an opioid prescription may be their initial experience with an addictive substance and that experience may be pleasurable.

Common pain relievers beat opioids for dental pain relief

Over-the-counter pain pills are safer and more effective than prescription opioids for controlling the pain following dental procedures, a review of the evidence has found. The study, “Benefits and harms associated with analgesic medications used in the management of acute dental pain,” was published in the April 2018 issue of the Journal of the American Dental Association.

Researchers analyzed five reviews of studies of medication and medication combinations for pain relief. They included only reviews of high or moderate methodological quality. The data included many randomized trials on the use of oral medication for the most severe pain.

Dentists play crucial role in fighting opioid epidemic

In 2009, a nationwide study of prescribing patterns found that dentists were responsible for 8 percent of all opioid prescriptions in the U.S., were the major prescribers of opioids among the 10- to-19-year-old age group and frequent prescribers of immediate-release opioids, which tend to be more frequently abused than extended-release opioids. With these statistics in mind, dentists can play a major role in helping to combat the prescription opioid epidemic, according to the study “Combating an Epidemic of Prescription Opioid Abuse” by Doreen Foro, PharmD, BCOP, BCPS, et al. The American Dental Association.

Researchers analyzed five reviews of studies of medication and medication combinations for pain relief. They included only reviews of high or moderate methodological quality. The data included many randomized trials on the use of oral medication for the most severe pain.

Help is one call away.

CDA’s Well-Being Program

If someone you know or love may have an alcohol or chemical dependency problem, contact a support person near you for 24-hour confidential assistance.

Northern California
530.310.2395 (cell)
San Francisco/Bay Area
209.601.4410 (cell)
Central California
916.947.5676 (cell)
Southern California
661.312.4135 (cell)
San Diego
562.832.2489 (cell)
Lecture examines clinical and legal considerations of prescribing controlled substances

On Friday, Sept. 7, at CDA Presents The Art and Science of Dentistry in San Francisco, CDA Public Affairs will host “Clinical and Legal Considerations for Prescribing Controlled Substances.” Led by Michael J. Bundy, PharmD, DMD, MD, and Tony J. Park, PharmD, JD, the course will help attendees:

- Recognize the problem of prescription drug abuse
- Develop acute pain control plans that reduce reliance on narcotic pain medication
- Understand California’s prescribing requirements relating to the CURES database

“Non-steroidal anti-inflammatory drugs, or NSAIDs, such as ibuprofen, should be first-line therapy for acute pain control in dentistry,” says Bundy, who works in the maxillofacial surgery department at Kaiser Permanente Los Angeles. He says the effectiveness of NSAIDs is “often underestimated.” As part of the course, he will teach dentists how to optimize their use in pain control.

Bundy and Park have co-presented this lecture at CDA’s biannual education convention since fall of 2015, but they continually update the course material to reflect recent statistics as well as the latest legal and regulatory developments, particularly with respect to CURES 2.0, California’s prescription drug monitoring program.

Those who attend the lecture will receive step-by-step instructions for accessing CURES 2.0 along with a review of legitimate medical purposes for prescribing and many examples of what to watch out for — so-called red flags for drug-seeking behaviors.

“If the patient asks to be seen immediately, claims to live out of town or describes or exaggerates dental symptoms that are not corroborated by a physical exam … these are a few red-flag behaviors,” says Park. He adds that these red flags merely serve as “notice” to the prescribing dentist or health care provider of the possibility of abuse, addiction or diversion.

During the course, attendees will see a sample “patient/client activity” page from the CURES database. When accessing a patient’s or client’s record in CURES 2.0, prescribers can look for additional red flags such as duplicate prescriptions, prescriptions in high strength or quantity and the use of multiple pharmacies.

The Department of Justice announced in April that CURES 2.0 was ready for statewide use. Beginning Oct. 2, as required by Assembly Bill 482 signed into law in 2016, providers must check a patient’s prescription history in CURES 2.0 before prescribing a Schedule II-IV substance except in exempt circumstances. (Notable dentistry-specific exemptions are explained elsewhere in this issue, on cda.org and on the CURES website at www.oag.ca.gov/cures.)

Still, even if a prescriber is exempt from the mandatory CURES consultation requirement, Park stresses that dentists with DEA numbers must still be registered to use it and will benefit from checking the database before prescribing a controlled substance in their practice. “You want to

know everything about your patient that you can before prescribing a controlled and highly addictive substance,” he says. “Clinical and Legal Considerations for Prescribing Controlled Substances” is open to the entire dental team and offers 2.5 core C.E. units. Register to attend or learn more about the lecture at cdapresents.com/sf2018.
How to start prescribing controlled substances electronically

Electronic data prescribing can reduce opportunities for diversion of controlled substances by eliminating the use of paper forms that can be stolen, lost or left behind and used illegally. E-prescribing also aids in providing timely patient care by, for example, relieving a patient from making a trip to the dental practice to pick up a written prescription for a Schedule II drug.

Use of e-prescribing for controlled substances is growing nationally due to state mandates and prescribers’ increasing comfort with technology. In California, less than 25 percent of prescribers are utilizing EPCS while more than 93 percent of pharmacies are enabled to accept it, according to e-prescription network Surescripts in its 2017 National Progress Report. For the purpose of this article, e-prescribing and EPCS refer only to electronic data prescriptions.

What do I need to know to get started with EPCS?
The U.S. Drug Enforcement Administration in June 2010 adopted the rule establishing the EPCS procedures. These procedures include:

1. Identity proofing
2. Two-factor authentication
3. Third-party certification that prescription software applications meet DEA requirements
4. Identify proofing of prescribers
5. Two-factor authentication when signing prescriptions
6. Access controls established by software users
7. Prescription software is sold with or without EPCS. Software with EPCS costs more because of the additional costs of regulatory compliance.
8. Dentrix, Eaglesoft, OpenDental, Curve, Carestream and MacPractice allow you to add e-prescribing with or without EPCS. A list of prescribing software applications is available on the Surescripts website (https://surescripts.com/network-connections/prescriber-software), but many are proprietary products associated with a specific practice management software or electronic health record or an entity such as Access Dental. If you have practice management software, check with that company. If you do not have practice management software, refer to the names of some stand-alone prescribing software applications with EPCS at the end of this article.

What factors should I consider when purchasing prescribing software?

- Stand-alone versus practice management software. The benefit of using a PMS-associated application is that patient demographic information can be flowed with a few keystrokes from PMS to prescription and the prescription entered as part of the treatment record. Stand-alone software requires the prescriber to enter all of the patient’s demographic information for the first prescription but not thereafter. The prescription also must be entered separately in the patient’s treatment record.
- Practice type. If you are an associate or locum tenens working at more than one practice, it may be easier to use stand-alone software because it can be used anywhere in the U.S. and is not tied to a specific PMS. If your practice has multiple locations and you want to use the PMS-associated application, a separate user license for each location may be required. A practice with multiple prescribers on site will need each prescriber to have their own subscription, identity proofing and hard token, sometimes called an authentication token. If you work at an institution, such as a dental school or hospital, and prescribe using the institution’s DEA registration, you will need to complete steps with the appropriate entity within the institution.
- Basic versus enhanced: Software is offered as a basic version with optional enhanced information or it is offered with everything included in the annual subscription. Enhanced versions include such things as the ability to check for patient drug allergy, drug interactions, drug history and drug formulary.
- Mobility: Some software may be used on mobile platforms such as Android and iOS.
- Cost: The cost range for EPCS is $170 to $450 per user per year. A fee for setup, including identity proofing and provision of a hard token, can vary and may or may not be included in the software subscription rate. Promotions may be available from the stand-alone companies; check with each company.

What are the next steps after I select the software?
The basic steps are the same although each vendor or institution may differ in the details.
1. Identity proofing
2. Two-factor authentication
3. Setting access controls

Follow the software vendor’s instructions to complete identity proofing. You will need to submit your dental license, DEA registration and NPI Type 1 numbers and answer a series of questions. Once a prescriber’s identity is proved, he or she can receive credentials necessary to sign an EPCS. If a prescriber works at multiple locations with different prescribing software, each location’s software
Rules for storing and disposing of controlled substances

A dentist who stores controlled substances must follow both state and federal rules for storage, inventory and disposal of those drugs. DEA registration is required for each address where a dentist stores controlled substances.

Store controlled substances in a securely locked, substantially constructed cabinet. The DEA uses a list of factors to determine the adequacy of security:

1. Location of the premises and the relationship such location bears on security needs
2. Type of building and office construction
3. Type and quantity of controlled substances stored on the premises
4. Type of storage medium (safe, vault or steel cabinet)
5. Control of public access to the facility
6. Adequacy of registrant’s monitoring system (alarms and detection systems)
7. Availability of local police protection

Maintain a log of drugs stored and retain information on the log for no less than three years.

Take inventory of controlled substances at least once every two years and include controlled substance samples provided by pharmaceutical companies in the record. The inventory record must be in a handwritten, typewritten or printed form and be maintained at the practice for at least two years from the date that the inventory was conducted. Each inventory record must contain the following information:

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

Clinics, but not private dental practices, that are licensed under Business & Professions Code section 4180 or 4190 are required to follow new state inventory regulations that became effective in April 2018. Those regulations are found in Title 16 California Code of Regulations section 1715.65.

Prescribers should encourage patients to properly dispose of their unused or expired controlled substances through their local pharmacy or take-back event sponsored by local law enforcement.

The DEA amended regulations in September 2014 to allow retail pharmacies, hospitals and clinics with pharmacies to collect the drugs from the ultimate users and to place collection containers at long-term care facilities.

Clinics, but not private dental practices, that are licensed under Business & Professions Code section 4180 or 4190 are required to follow new state inventory regulations that became effective in April 2018. Those regulations are found in Title 16 California Code of Regulations section 1715.65.

The theft or loss of controlled substances from a prescriber’s premises must be reported to local law enforcement and to the DEA. Report the theft or loss to the DEA using Form 106, available at www.deadiversion.usdoj.gov/21cfr_reports/theft.

Dispose of out-of-date, damaged or otherwise unusable or unwanted controlled substances, including samples, by transferring them to an entity that is authorized to receive such materials. These entities are referred to as “reverse distributors.” Contact your local DEA field office (www.deadiversion.usdoj.gov/inside.html#contact_us) for a list of authorized reverse distributors. Mail-back programs are also available. Schedule II controlled substances should be transferred using DEA Form 222, while Schedule III, IV and V compounds may be transferred via invoice. Maintain copies of the records documenting the transfer and disposal of controlled substances for two years.
study was published in the November 2015 CDA Journal.

The rate of illicit drug use is highest among young adults ages 18 to 25 (19.6 percent) compared to any other age group. Pain and prescribing accordingly, prescribing the minimum quantity of opioid to manage acute pain, educating patients to dispose of and never share leftover prescription opioids and using prescription drug monitoring programs, such as California’s Controlled Substance Utilization Review and Evaluation System - CURES, to verify drug-use histories and prevent “doctor shopping.”

Co-author Anita Aminoshariae, an associate professor at Case Western Reserve University, said there may be some people who can get relief only with opioids. But for most patients, she said, opioids are not only less effective, they also have unpleasant side effects, including nausea, constipation and dizziness. They also carry a high risk of addiction.

“You have to start with an NSAID,” she said, meaning a nonsteroidal anti-inflammatory drug. “If that doesn’t work, add Tylenol. No one should go home in pain, but opioids should not be the first choice.”

Read more of this study at https://jada.ada.org/issue.

This “Impression” was previously published in the July 2018 issue of the CDA Journal.

Opportunity

From PAGE 4

probably the most common events that require pain management in this age group.

We may be crucial to this young population. When we write a script for a completely appropriate opioid for short-term, postsurgical pain management, we need to realize that we may be responsible for that child’s first exposure to opioids. This young population appears to be more at risk than the adult population for later opioid misuse when their first exposure is for a legitimate need from a trusted oral health care provider.

If we tie these research findings to what is well-proven and well-known about the susceptibility of the developing brain in the adolescent to the introduction of pleasurable experiences and subsequent risk behaviors to reproduce this emotional state, we should be thunderstruck. We should have a heightened concern as individuals and as a profession about our prescribing and dispensing of opioids to this significantly more vulnerable population.

It is fortunate that we have alternatives to help manage dental pain. Recent evidence indicates that 400 mg of ibuprofen in combination with 1,000 mg of acetaminophen has proven to be more effective than opioids in controlling pain and reducing inflammation, according to the study “Benefits and harms associated with analgesic medications used in the management of acute dental pain” published in the Journal of the American Dental Association in April 2018. We may not have to be responsible for a child’s first exposure to opioids if we first try simple, easily accessible, over-the-counter medications.

We need to understand fully our crucial role. We do not have to be the provider of the first opioid exposure to a pediatric population at risk for later opioid misuse. We need to be able to translate the risk/benefit balance of that first opioid exposure during the informed consent discussion with the pediatric patient’s parent or guardian. In the context of the current opioid crisis, our most important contribution to the future health and welfare of our adolescent patients may be the pain management recommendations we make.

A version of this editorial originally appeared in the July 2018 issue of the Journal of the California Dental Association and is reprinted here with permission.
The November 2015 issue of the *Journal of the California Dental Association* is dedicated to pain control and prevention. Offered here are synopses of research cited in four articles that appeared in the journal. Read more of these studies at cda.org/journal.

### Medications other than opioids to use for orofacial pain

Dentists can choose medications other than opioids to treat chronic orofacial pain, according to the CDA Journal article “Evidence-Based Pharmacologic Approaches for Chronic Orofacial Pain” by Glenn Clark, DDS, MS, a professor and the director of the Orofacial Pain and Oral Medicine Center at the Herman Ostrow School of Dentistry of USC.

For patients who have moderate to very frequent daily headaches, clinicians have at least three types of systemic oral medications (beta-blockers, TCAs and anti-epileptic drugs) to use as well as an NMDA (N-methyl-D-aspartate) blocking agent. For the patient who does not want to take prescription medications, the evidence reviewed suggests that Petasites (butterbur) would be a first-line therapy along with 500 milligrams of naproxen sodium. Opioids are used (almost 20 percent of the time, according to this 2015 study) in the emergency room when patients with severe headache pain seek emergency help. But in general, most experts believe opioids are not a logical treatment choice for either episodic or continuous headaches.

Three types of systemic medications, gabapentinoids, tricyclic antidepressants and serotonin norepinephrine reuptake inhibitors, can be used as well as topical anesthetics to help patients manage their chronic continuous neuropathic pain. Those who do not want to take systemic pain suppressive medications may get adequate relief with topical anesthetics applied directly to the neuropathic pain site.

The available data on NSAIDs show they, along with corticosteroid injections, are reasonably efficacious for osteoarthritis. Acetaminophen was also cited as a good choice for relieving arthritis pain for the gastritis-susceptible patient.

However, the data on pregabalin, duloxetine and milnacipran, the three medications approved by the FDA for fibromyalgia, suggest that they work better than placebos but are not robust in their efficacy and are best judged as poor treatments. Fibromyalgia and widespread myofascial pain treatment will continue to involve combining medications with nonpharmacologic treatment methods with the latter being the preferred method of treatment, according to the study.

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**‘Take them back’**

Oct. 27 – help prevent addiction and overdose

The next DEA National Prescription Drug Take Back Day is set for Saturday, Oct. 27, and more than 300 locations in California are prepared to help people dispose of unused prescription drugs safely and anonymously.

The Drug Enforcement Agency cites a national survey showing that most abused prescription drugs in 2015 were obtained from family and friends — often from the medicine cabinet. Take-back days, held twice annually, provide an opportunity “to prevent drug addiction and overdose deaths,” the DEA states. California alone disposed of 69,883 tons of prescription drugs at 318 statewide collection sites on the take-back day in April.

Dentists and other health care providers can encourage their patients and others to dispose of prescription drugs from 10 a.m. to 2 p.m. Oct. 27. Patients should also be made aware that they do not need to wait for a take-back day, but can dispose of unused prescription drugs anytime at designated locations.

Collection sites, including year-round sites, can be found at https://takebackday.dea.gov. Also available are resources such as posters and website buttons that providers can use to promote the event.
Shifting from traditional “take as needed” acetaminophen or aspirin-orally opioid combinations to a preventive strategy for procedures that warrant postoperative analgesia can produce less discomfort for the patient and a more predictable postoperative course, according to the study “Changing Paradigms for Acute Dental Pain: Prevention Is Better Than PRN” by Raymond A. Boone, DDS, MPH, PhD, et al.

Administration of 400-600 milligrams of ibuprofen or a similar NSAID that the patient tolerates prior to the procedure or immediately afterward will result in delayed onset and less intensity of pain due to the suppression of inflammatory mediators released by tissue injury. Use of a long-acting local anesthetic should attenuate the development of hyperalgesia by blocking the afferent nociceptive barrage that results in greater pain that can persist for two to three days. Combining these two preventive strategies results in additive effects that can minimize pain following surgical procedures with minimal adverse effects, according to the study. However, due to the wide individual variability that exists across the patient population, some individuals will still report pain that warrants intervention. In those cases, administration of an opioid-containing prevention NSAID combination such as oxycodone or hydrocodone without lowering the NSAID dose can result in additional relief for the two- to three-day postoperative period when pain is maximal. Only a limited amount of the opioid combination should be prescribed, and parents or a significant other should manage the dosing and frequency of administration.

The study states that all unused opioid-containing drug supplies should be destroyed or returned to the pharmacy as the pain subsides, and any continued requests for opioids should be met with concern and require an exam to confirm the nature of the problem and to rule out complications such as infection that are not appropriately treated with an opioid.

Preventive strategy more effective than traditional opioid use

Pharmacist-dentist collaboration important when prescribing opioids

The importance of cooperation and collaboration between dentists and pharmacists when prescribing controlled substances is reinforced and explained in the article “A New Paradigm for Providers: Dentists and Pharmacists” by Tony Park, PharmD, JD, the principal attorney of an independent law practice devoted solely to pharmacy law.

When pharmacists contact dentists soliciting initial clinical justification for a controlled substance, it is an attempt to resolve the existence of one or more red-flag indicators that may suggest that the controlled substance is sought for a purpose other than a legitimate medical one.

California Health & Safety Code (HSC) § 11153(a) states that 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.” And according to California Code of Regulation (CCR) § 1751(b), “[e]ven after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.”

From the perspective of the pharmacist, every controlled substance prescription written by dentists and other health care providers must be subjected to the test of whether any of 13 red-flag indicators exists. These red-flag indicators include:

- Irregularities on the face of the prescription
- Nervous patient demeanor
- Age or presentation of the patient
- Multiple patients at the same address
- Cash payments
- Early refill requests
- Prescriptions for unusually high quantities
- Prescriptions for duplicate drugs
- The same prescribing patterns for multiple patients
- Initial prescriptions written for high-dose opiates
- Long distances traveled from patient’s home to physician and/or pharmacy
- Inconsistent prescriber qualifications in relation to prescriptions prescribed
- Prescriptions with no logical connection to diagnosis or treatment

If the pharmacist detects a red flag, they must conduct a follow-up inquiry that could require detective-like questioning of both prescriber and patient. If the pharmacist cannot obtain a reasonable explanation for the red flag, then the pharmacist may not, even after confirming with the prescribing dentist that the medication was prescribed for a legitimate pain need, dispense the controlled-substance prescription.

One way dentists in California can minimize red-flag detection by pharmacists is by utilizing the Controlled Substance Utilization Review and Evaluation System — CURES, the state’s prescription drug monitoring database, according to the article. The database allows health care practitioners to look up a patient’s historical controlled substance prescribing and dispensing patterns that might suggest a high likelihood of drug-seeking behavior.
Dietary supplements and alternative herbal therapies are often used for pain management. While some research has found these alternatives to be effective in treating pain, other studies have not supported those findings, according to the article “Dietary Supplements and Alternative Therapies for Pain Management” by Philip J. Gregory, PharmD, MS.

The article reports that a 2012 National Health Interview Survey found that 33.2 percent of respondents reported using some form of complementary and alternative medicines in the previous 12 months, while a survey of adult patients in a U.S. dental school clinic found that 24 percent reported the use of herbal supplements.

One of the supplements used for pain and inflammation is cayenne pepper, which includes capsaicin, a counter-irritant that makes the pepper hot. Topical capsaicin is thought to work by stimulating peripheral nociceptors in the skin, desensitizing the nervous tissue over time and resulting in pain relief, according to the article.

Another supplement is Bromelain, a proteolytic enzyme isolated from the fruit and stems of the pineapple plant. Bromelain is thought to have anti-inflammatory effects through a variety of potential mechanisms, such as decreasing proinflammatory prostaglandin synthesis and inhibiting leukocyte migration and activation.

Cat’s claw, a woody vine native to tropical areas of South and Central America, is thought to reduce inflammation by inhibiting production of inflammatory prostaglandins and decreasing levels of tumor necrosis factor-alpha. In clinical trials, a 100-milligram daily freeze-dried extract of cat’s claw reduced knee pain following physical activity in patients with osteoarthritis and modestly reduced the number of painful joints compared to placebo in patients with rheumatoid arthritis.

Several clinical trials have evaluated devil’s claw, a native to the Kalahari and Savannah desert regions of Africa, for treating pain related to osteoarthritids. When used alone or in combination with anti-inflammatory drugs, devil’s claw appears to decrease osteoarthritids pain and reduce the need for conventional drugs.

The curcumin constituent of turmeric, a spice commonly used in Asian food, also seems to have anti-inflammatory effects through inhibition of COX-2, leukotrienes and other proinflammatory pathways. Willow bark extract has also been found to reduce inflammation that causes lower-back pain.

Other herbal supplements that have been found to reduce pain and inflammation are glucosamine and arnica. The article also describes alternative treatments for pain, including acupuncture, hypnosis and aromatherapy.

Exposure
From PAGE 5

And if they have a “safe” experience with the opioid, their perception of any risks involved may be reduced. Many theories cite a pleasurable and safe initial experience with a psychotropic drug as the central factor in who goes on to misuse drugs, according to the study.

When informed of these risks for children, parents may opt for nonopioids as the initial treatment of minor painful conditions, according to the authors.

Read more of this study in the November 2015 issue of Pediatrics journal at http://pediatrics.aappublications.org/content/136/5.

How to terminate a DEA registration

Prescribers who wish to discontinue prescribing, dispensing and administering controlled substances must submit by mail written notification to terminate registration. The notification should be sent to the nearest Drug Enforcement Administration field office, attention “Registration Unit,” and must be accompanied by the DEA Certificate of Registration and any unused official order forms (DEA Form 222).

Locate the nearest DEA field office by city or ZIP code on the U.S. Department of Justice website at https://apps.deadiversion.usdoj.gov/contactDea.

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The DEA requires two-factor authentication for signing EPCS. The factors must be two of the following:
- Something you know (a password, for example)
- Something you are (a measurement of a human characteristic, such as a fingerprint)
- Something you have (a hard token, such as a fob or cell phone, to receive a short-term code)
- Something “you are” (a measurement of a human characteristic, such as a fingerprint)

The prescriber may not give any of the factors to another individual, doing so may lead to revocation or suspension of the prescriber’s DEA registration. A staff member may enter information into the software but only the prescriber may “sign,” that is submit, the two factors to the prescribing system.

Setting access controls requires at least two factors. One or both individuals, one of whom must be a DEA registrant with active EPCS privilege. One or both individuals can be set up as administrators in the system, depending on the prescriber for ensuring the DEA registrant’s credentials are current. The administrator is responsible for regularly reviewing internal audit reports and reporting security incidents as soon as possible to the software vendor and to the DEA.

Additional information on EPCS is available from the DEA (www.deadiversion.usdoj.gov/ecomm/e_rx/digipractitioner.html) and from individual EPCS vendors.

## States where EPCS is mandated

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Reference: Sanscripts.com, as of June 2018

### Management

Management From PAGE 2

Substances to patients who are seeking them for illegitimate purposes.

**Substance use disorders and first exposure**

Substance use disorders are not well understood and are often viewed as a moral problem or just a lack of self-control. However, as brain research into these disorders advances, we continue to learn more about the SUD continuum and the contributing biological, physiological and psychological factors. The SUD we know as “addiction” is a concern with the prescription of opiates and opioids and likely the cause of various drug-seeking behaviors we see in the dental office, including exaggeration of pain severity, running out of medication early or frequent dental visits that are apparently unnecessary.

According to the ADA guide, “Addiction is a primary chronic disease of brain reward, motivation, memory, judgment and related circuitry... characterized by the inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems related to their behavioral pattern, and primary, subservient drug-seeking behavior.”

Of particular concern to me, as an oral surgeon is research showing an association between exposure to drugs and alcohol early in life with an SUD in later life. Sometimes even a small amount of a substance results in subsequent drug-seeking activity.

Given the current evidence, I prefer a non-narcotic prescription for postsurgical pain in children and young adults. I spend a bit more time on my post-op discussion reassuring parents and patients that their pain will be effectively controlled without narcotics. Most parents welcome the approach and understand that I have their child’s best interests at heart at all stages of treatment, during surgery and afterward.

I encourage other dentists to contemplate their routine prescribing practices, read the available evidence and try a different approach if they tend to prescribe a narcotic to most patients. As each patient is different and requires tailored medical and dental treatment, the same cannot be said of postoperative pain management.
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Concerns of opioid prescribing. Michael Bundy, MD, DDS, PharmD, and Tony Park, PharmD, JD, discuss pain management options and best practices, red flags for substance use disorders, professionals’ and dentists’ responsibilities when prescribing and dispensing controlled substances, and the use of CURES, California’s prescription drug monitoring program. “Clinical and Legal Considerations for Prescribing Controlled Substances” will be presented again at the San Francisco convention on Friday, Sept. 7, at 3:30 p.m. [Read more about the lecture on page 6.]

In November 2015, CDA collaborated with the California Pharmacy Association to publish an issue of the Journal of the California Dental Association devoted to the science and practice of pain management in dentistry. That issue captured best practices for managing acute, inflammatory pain, recognizing that opioids are actually not the best or most effective choice in most instances. Highlights of that issue are covered in another section of this special-edition update.

In June 2016, as the deadline for mandatory CURES registration approached, CDA hosted a webinar presented by the Department of Justice to assist members with and answer their questions about the CURES 2.0 registration process.

Since 2015, CDA has published many articles with information about CURES registration and dentistry’s role in fighting the opioid epidemic in the Update and member newsletter. Those articles can be accessed on the “CURES and Opioid Pain Management” webpage on cda.org.

CDA members can submit questions to the Practice Support experts online at cda.org/practicesupport or search the Q&A archive for previously answered questions. Member questions are lightly edited for clarity.

**Question:**
I have not renewed my DEA license for the past five years in hopes of trying to combat the abuse of opioids from drug seekers. I do not do RCT or oral surgery procedures and have found that really do not need to spend the fees [they are outrageous now!] to have an active DEA license. But I work as an associate now, and wonder, should one of the doctors have an active DEA in case we need to prescribe? What do the law say? Are we out of compliance?

**Answer:**
CDA registration is not required to prescribe noncontrolled medications. However, my colleagues who specialize in dental benefits tell me that DEA registration may be necessary for credentialed purposes. Check with the professional relationships representative at the dental plans with which you are contracted.

(Answered Jan. 24, 2018.)

**Question:**
A DEA registration is not required to practice dentistry in California. A DEA registration is required if the dentist plans to prescribe, dispense or administer controlled substances. It is not required to prescribe antibiotics or other noncontrolled substances. A dentist practicing without a DEA registration is not uncommon in California.

(Answered Aug. 16, 2016.)

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(Answered Aug. 16, 2016.)

**Question:**
SB 482 (Lara), passed in 2016, requires all licensees authorized to prescribe, order, administer, furnish or dispense controlled substances to check CURES under specified circumstances. Acknowledging that CURES 2.0 is a new system, the law included a requirement that implementation begin after the certification by the Department of Justice that CURES is fully operational. Certification happened April 2, 2018, and implementation will occur on Oct. 2, 2018.

Once implemented, prescribers in California will be required, with some exceptions, to check CURES when writing a prescription for Schedule II-IV medications. One exemption relevant to dental treatment allows prescribing a one-time nonrefillable five-day supply of a controlled substance if prescribed as part of a treatment for a surgical procedure the provider performed—an exemption CDA was instrumental in securing.

The current legislative session includes bills that, if successful, will place further limits on the prescriber or dispenser of opioids, change the operation, reporting and data retrieval within CURES and require continuing education for controlled substance prescribers. Read about these bills on page 2.

These early actions have had a positive impact; dentists are writing fewer opioid prescriptions and for fewer numbers of pills, as are other health care providers. This is great news, but it is not the end of the story.

Research into the epidemic of addiction is revealing that dentists have a unique position in this crisis. Dentists are frequently the first source of exposure to an opioid for patients ages 11 to 18. See more on that subject on page 4.

This special edition on opioids would not be complete without acknowledging that California and CDA are not the only sources of information and action in organized dentistry. The American Dental Association provides multiple professional resources, including:

- Interim Board on Opioid Prescribing (March 26, 2018)
- April 2018 Journal of the American Dental Association
- ADA Practical Guide to Substance Use Disorders and Safe Prescribing, available for purchase on the ADA website
- Webinar series on opioids and prescriber tips

Supporting members in their practices and in service to their patients and the public is what CDA does every day, for every member. In my role on the executive committee, I am pleased to see this up close, to know it and contribute to it.

And as you can see, CDA has been busy, working with regulators, legislators and our members to reduce opioid use in California, and you can be sure we will continue that work.

**Resources:**
- CMS Roadmap to address the Opioid Epidemic, June 2018
- Final.pdf
- Journal of the California Dental Association, November 2017
- CDA Regulatory Compliance Manual

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**ASK AN EXPERT**

**Practicing without a DEA license**

In two Q&As from the archive, Teresa Pichay, regulatory compliance analyst with CDA Practice Support, responds to members’ questions related to DEA license requirements.

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**California**

*From PAGE 1*

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