

## Prescribing and Dispensing Q&A

This resource provides information on requirements for prescribing, dispensing and administering both controlled substances (Schedule II-V drugs) and noncontrolled substances such as antibiotics.

### What is required to prescribe medicines in California?

A dentist must have an active dental license to prescribe medicines. No other registration is required.

### What is required to prescribe controlled substances in California?

A dentist must have an active dental license and a DEA registration number to prescribe controlled substances. California does not have a state DEA registration system. A dentist with a DEA registration must **register to access** the state's prescription drug monitoring program, CURES.

### How does a prescriber obtain a DEA registration number?

Information and an application are available on the DEA website, <https://www.deadiversion.usdoj.gov/drugreg/index.html>. A DEA registration is site specific and the address used on the application must match the address registered with the dental board.

If a dentist has a second office where controlled substances are also administered or dispensed, then the dentist must have a separate DEA registration for that location. If the dentist only prescribes from the second location and does not dispense or administer controlled substances, then the dentist need not have a second DEA registration. The second location must be within the same state in which the prescriber maintains their DEA registration.

Prior to submitting a change of address request to the DEA, a dentist must ensure the dental board has registered the new address. If moving to a new location in another state, the prescriber must have the appropriate state license prior to the DEA approving a registration modification.

## ELECTRONIC DATA PRESCRIBING

### Is electronic data prescribing (e-prescribing) mandated?

Starting Jan. 1, 2022, all prescriptions in California, with few exceptions, must be issued as electronic data prescriptions and all pharmacies in the state must be capable of accepting these prescriptions. Until then, controlled substance prescription forms must meet the requirements of **Health & Safety Code §§ 11161.5, 11161.7, 11162.1 and 11162.2** and noncontrolled substance prescription forms must meet the requirements of **Business & Professions Code §4040**. After Jan 1, 2022, these forms may be used should any of the exceptions to the e-prescribing mandate arise.

## What do I need to know about e-prescribing?

E-prescribing provides timely patient care and reduces opportunities for diversion of controlled substances by eliminating the use of paper forms that can be stolen, lost or left behind and used illegally. Prescribing software is available with or without the ability to electronically prescribe controlled substances. EPCS software costs more due to the additional costs of regulatory compliance.

These are factors to consider when purchasing prescribing software:

- *Stand-alone versus EHR:* The benefit of using an application associated with an electronic health record (EHR) is that patient demographic information can be flowed with a few keystrokes to the e-prescription and the prescription is automatically entered into the treatment record. Stand-alone software requires the prescriber to enter all of the patient's demographic information for the first prescription, but not for subsequent prescriptions for that patient. The prescription also must be recorded separately in the patient's treatment record.
- *Practice type:* It may be easier for an associate or locum tenens working at more than one practice to use stand-alone software because it can be used anywhere in the U.S. and is not tied to a specific EHR. If a practice has multiple locations using the same EHR, a separate user license for each location may be required. A practice with multiple controlled substance prescribers on site will need each prescriber to have their own subscription, identity proofing and hard token. A dentist working at an institution, such as a dental school or hospital, and who prescribes using the institution's DEA registration will need to complete steps with the appropriate entity within the institution.
- *Basic versus enhanced.* Prescribing 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, drug formulary and a state's prescription drug monitoring database.
- *Mobility.* Some software may be used on mobile platforms such as Android and iOS.
- *Cost.* Controlled substance prescribers will pay an additional fee for set-up which includes identity proofing and provision of a hard token. Stand-alone companies may offer a promotional price.

## How is EPCS software different from regular prescribing software?

EPCS software must be certified that it complies with the DEA regulation adopted in June 2010. The regulation established procedures that include:

- Third-party certification that prescription software applications meet DEA requirements.
- Identity proofing of prescribers.
- Two-factor authentication when signing prescription.
- Software users establishing access controls.

A prescriber must undergo an identity-proofing process, which includes submission of dental license, DEA registration and NPI Type 1 number. Once a prescriber's identity is proved, the prescriber will receive credentials necessary to sign a controlled substance prescription. If a prescriber works at multiple locations with different prescribing software, each location's software vendor will determine the necessity of the prescriber undergoing identity proofing more than once.

The DEA requires use of two-factor authentication for signing a controlled substance prescription. The factors must be two of the following:

- Something you know (a password, for example).
- Something you have (a hard token, such as a fob or cell phone, to receive a short-term code).
- Something you are (a biometric 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 an e-prescription but only the prescriber may "sign" by submitting the two factors to the prescribing system.

Setting access controls requires at least two 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 software. The non-DEA registrant is responsible for ensuring the DEA registrant's credentials are current. The administrator also 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 is available from the DEA [deadiversion.usdoj.gov/ecommm/e\\_rx/index.html](https://deadiversion.usdoj.gov/ecommm/e_rx/index.html) and from individual EPCS vendors.

### How do I get started with e-prescribing?

A prescriber with an EHR should check with that company. E-prescribing, with or without EPCS, can be added to Dentrax, Eaglesoft, OpenDental, Curve, Carestream or MacPractice. A list of prescribing software applications is available on a [Surescripts website](#); however, many are proprietary products associated with a specific EHR or an entity such as Aspen Dental. Listed here are some stand-alone prescribing software applications with EPCS:

- [NewCrop](#)
- [RxNT](#)
- [Treat](#)
- DrFirst: [Rcopia](#) and [iPrescribe](#) (mobile version)

### What are the exceptions to electronic data prescribing?

- A prescription for a terminally ill patient issued pursuant to Health & Safety Code §11159.2.
- An electronic data transmission prescription is not available due to a temporary technological or electrical failure, meaning a failure of a computer system, application or device, or the loss of electrical power to that system, application or device, or any other service interruption.
- The prescriber is issuing a prescription to be dispensed by a pharmacy located outside California.
- The prescription is issued in a hospital emergency department or urgent care clinic and one or more of the following conditions are present:
  - The patient resides outside California.
  - The patient resides outside the geographic area of the hospital.
  - The patient is homeless or indigent and does not have a preferred pharmacy.
  - The prescription is issued at a time when a patient's regular or preferred pharmacy is likely to be closed.

A prescription under the above conditions shall be issued electronically but does not require electronic transmission and may be provided directly to the patient.

- The prescription is issued by a veterinarian.
- The prescription is for eyeglasses or contact lenses.
- The prescribing health care practitioner and the dispenser are the same entity.
- The prescription is issued under circumstances whereby the prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronic data transmission prescription in a timely manner and the delay would adversely impact the patient's medical condition.
- The prescription includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard.

The electronic data prescription mandate does not apply when providing health care services to an inmate, an individual on parole or a youth under the jurisdiction of the Department of Corrections and Rehabilitation.

A prescriber who issues a prescription for a controlled substance but does not transmit the prescription as an electronic data transmission prescription must document the reason in the patient's record as soon as practicable and within 72 hours of the end of the technological or electrical failure that prevented the electronic data transmission of the prescription.

### **May a prescriber still call in a prescription?**

Yes, but only in situations that qualify as an exception to the mandate for electronic data prescribing.

Only in an emergency situation may a prescriber phone in a prescription for a Schedule II drug, and this action is subject to several limitations. Additionally, a pharmacist is subject to several restrictions and requirements in fulfilling such a prescription. Notable requirements for prescribers phoning in an emergency prescription for a Schedule II drug include:

- Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.
- No appropriate alternative treatment is available, including administration of a non-Schedule II drug.
- The quantity prescribed and dispensed must be limited to an amount adequate to treat the patient during the emergency period.
- It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the dispenser prior to dispensing.
- Additionally, the prescriber must then provide to the pharmacy within seven days of the original order a written prescription that, in addition to conforming to the other requirements, must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order.

### **SCOPE OF PRACTICE**

**May a pharmacist substitute the medicine I prescribed, even though I indicated "Do Not Substitute" on the prescription? Another pharmacist told my patient the prescription I wrote is outside my scope of practice. What can I do?**

A pharmacist may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form and of the same generic drug name of those drug products having the same active chemical ingredients. However, in no case shall a substitution be made if the prescriber checks a box indicating "Do not substitute" or words of similar meaning on the e-prescription.

*Reference: Business & Professions Code §4073.*

A pharmacist's license is at risk whenever they fill a prescription. The pharmacist has a professional responsibility to ensure the prescribed medication is appropriate for the patient and within the prescriber's scope of practice. Many pharmacists expect dentist-generated prescriptions to be for antibiotics or for relief of acute pain. Prescriptions for medicines not typically associated with oral disorders or for controlled substances for an extended time can raise red flags.

Dentists and pharmacists must work together for the patient's benefit. It can help to introduce yourself to local pharmacies and the respective pharmacists in charge. Send a letter of introduction that includes a description of your practice and any education/training you have had that supports the type of prescriptions you write. A practice, for example, that focuses on TMD/TMJ cases may generate prescriptions outside what is typically expected from a general dentist.

If your patient uses a pharmacy that is unfamiliar with you and you have provided an atypical prescription, include a note to the pharmacist that provides your rationale or that asks the pharmacist to contact you to discuss the patient's case. For example, a pharmacy may question your prescription of one antibiotic instead of another, but you can use your patient's history to demonstrate that the patient responds best to the antibiotic you prescribe.

Building a professional relationship with pharmacists helps your patients and your practice.

### **May I write a prescription for a family member?**

Yes, you may write a prescription for a family member if the family member is a patient of record and the prescription is related to treatment you are providing. A prescription for controlled substances for a family member, however, may be filled only in specific circumstances on an interim basis.

Any prescription written by a dentist must be in conjunction with dental treatment provided by the dentist. There are limited exceptions to this rule.

## **PRESCRIBING OR DISPENSING CONTROLLED SUBSTANCES**

### **What is CURES and who must use it?**

CURES (Controlled Substance Utilization Review and Evaluation System) is the state's prescription drug monitoring database. All prescribers and dispensers of controlled substances must register to access it, <https://cures.doj.ca.gov/registration/confirmEmailPnDRegistration.xhtml>. Access credentials must be updated regularly.

Once access to CURES has been granted, a prescriber must make any changes to their account (for example, an address change) within three days of the effective date. CURES users are required to maintain effective controls for access to patient activity reports (PARs). Accessing information for any other reason than caring for one's patients or falsifying an application for access may result in disciplinary action.

The Department of Justice may conduct audits of CURES and its users to ensure appropriate use. Distribution of the PAR to anyone other than the registered user or patient who requests a copy is prohibited. All users of the

information must comply with state and federal health information privacy laws. Disciplinary, civil or criminal actions will be taken by the Department of Justice and the appropriate licensing agency for any misuse or inappropriate access of patient data.

### **What CURES functions may be delegated to staff?**

Staff registered with CURES as a “delegate” to the “parent” prescriber or dispenser user may initiate a search for the PAR. Only the “parent” prescriber or dispenser user can view the actual report containing the patient’s history. Prescribers and dispensers can view, add and remove delegates from their own user profiles.

### **When must a prescriber check a patient’s record on CURES?**

A prescriber is required to check CURES for a patient’s controlled substances prescription history before prescribing a Schedule II–IV drug. The intent of the requirement is to assist prescribers in making better prescribing decisions and to cut down on prescription drug abuse. One exception to this requirement is:

. . . if a health care practitioner prescribes, orders, administers, furnishes or dispenses a controlled substance to a patient as part of the patient’s treatment for a surgical procedure, if the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use . . .

If the controlled substance remains part of the patient’s treatment, a dentist must subsequently check the CURES database prior to writing another prescription and every four months while the substance is part of the patient’s treatment. The CURES PAR must be pulled no earlier than 24 hours prior to prescribing.

### **May the patient get a copy of their PAR?**

You may provide a patient with a copy of the patient’s CURES PAR, but no additional CURES data can be provided. The report is protected health information safeguarded by the state Confidentiality of Medical Information Act and HIPAA. You may retain a copy of the report as part of the patient’s record.

### **How can I get a report of the controlled substance prescriptions I have written?**

The ability to review this information is useful when a dentist has misplaced or had a prescription pad stolen or when a dentist suspects someone is misusing their DEA number. A dentist can obtain a report that contains the patient’s name, address, date of birth and gender. The report will cover the time period of up to one year prior to the date the report is generated. Follow these steps to generate a report:

1. Log in to CURES and choose the Patient Activity Report tab.
2. Search Criteria – Choose the button for Patient List by DEA#s. Then select your DEA number. (Note: A dentist with more than one DEA number can choose all DEA numbers.) Then enter the date.
3. Patient List – Once users submit the search, the matching patient lists are displayed.

After a list is created, a dentist can go back into the system and run separate CURES reports for each patient on the list if more information is needed. If a dentist discovers a prescription in the CURES report that they did not prescribe, the dentist should contact the pharmacy as well as the California State Board of Pharmacy.

## What are the rules for dispensing controlled substances?

Prescribers who dispense controlled substances must comply with federal law (summarized in the DEA's resource [A Practitioner's Manual](#)) and with state law. Some of these requirements include:

### Storage and record-keeping

- Store controlled substances in a locked cabinet or drawer.
- Maintain a log, which must be maintained for three years.
- Inventory controlled substances at least once every two years. The inventory record must be in written, 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 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.

Controlled substance samples provided by pharmaceutical companies must be included in the inventory record.

### Dispensing

- Dispense to a patient no more than a 72-hour supply of a Schedule II controlled substance in accordance with normal use when the patient is not expected to require any additional amount of the controlled substance beyond the 72-hour supply.
- Prior to dispensing, offer to give a written prescription to the patient that the patient may elect to have filled by the dentist or by any pharmacy. The patient must be provided with a written disclosure that they have a choice between obtaining the prescription from the dentist or obtaining the prescription at a pharmacy of the patient's choice.
- When dispensing controlled substances to a patient, a prescriber must:
  - Use a childproof container.
  - Label the container as described below.
  - Inform the patient orally or in writing of possible side effects of the drug.
  - Report the dispensing to CURES within one working day.

Schedule II controlled substances may not be dispensed at free or nonprofit clinics.

## What is required when prescribing or dispensing a controlled substance to a minor patient?

A prescriber is required to discuss the following information with the minor, the minor's parent or legal guardian prior to dispensing or issuing to the minor the first prescription in a single course of treatment for a controlled substance containing an opioid:

- The risks of addiction and overdose associated with the use of opioids.



- The increased risk of addiction to an opioid to an individual who is suffering from both mental and substance abuse disorders.
- The danger of taking an opioid with a benzodiazepine, alcohol or another central nervous system depressant.
- Any other information required by law.

The requirement does not apply when the patient is undergoing treatment for drug addiction or chronic pain or emergency surgery or care. If provision of the above information would be detrimental to the minor's health or safety or in violation of the minor's legal rights regarding confidentiality in the prescriber's professional judgement, the prescriber need not provide the information. See "Consent to Prescribe Opioid to a Minor" on [cda.org/practicesupport](https://cda.org/practicesupport).

### **When must a prescription for naloxone be offered to a patient?**

A prescriber must offer to a patient a prescription for naloxone hydrochloride or other FDA-approved drug for the complete or partial reversal of opioid depression when one or more of the following conditions are present:

1. The prescription dosage for the patient is 90 or more morphine milligram equivalents of an opioid medication per day. (See this [CDC document](#) on how to calculate MME.)
2. An opioid medication is prescribed concurrently with a prescription for benzodiazepine.
3. The patient presents with an increased risk for overdose, including a patient with a history of overdose, a patient with a history of substance use disorder or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

Additionally, a prescriber must provide education to a patient, or a patient's guardian if the patient is a minor, receiving a prescription per the above circumstance on overdose prevention and the use of naloxone hydrochloride or other FDA-approved drug for the complete or partial reversal of opioid depression.

### **What is required if I decide to discontinue administering, prescribing and dispensing controlled substances?**

A prescriber who wishes to discontinue administering, prescribing and dispensing controlled substances must submit written notification of registration termination to the nearest DEA field office. The notification must be accompanied by the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222).

### **How should controlled substances be disposed?**

Use an authorized mail-back program or "reverse distributor" to dispose of controlled substances. Contact a [local DEA field office](#) for a list of authorized reverse distributors. Maintain copies of the records documenting the transfer and disposal of controlled substances for two years.

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.



## Examples of Controlled Substances

Schedule II	Schedule III	Schedule IV
Oxycodone combination products (Percodan, Percocet)	Tylenol #3 (with codeine)	Zolpidem (Ambien)
*Hydrocodone combination products (Vicodin, Vicoprofen, Lortab, Lorcet, Norco)	Anabolic steroids	Lorazepam (Ativan)
Meperidine (Demerol)	Ketamine	Triazolam (Halcion)
Hydromorphone (Dilaudid)		Hydroxyzine (Vistaril)

\*Moved into Schedule II effective Oct. 6, 2014.

## DISPENSING MEDICATION

### Must a prescriber offer a patient a written prescription even if they are able to dispense the medication?

Yes. Prior to dispensing medication, a prescriber must offer a written prescription to the patient that the patient may elect to have filled by the dentist or by any pharmacy. The prescriber must also provide the patient with a written disclosure that the patient has a choice between obtaining the prescription from you, the dentist, or obtaining the prescription at a pharmacy of the patient's choice.

### Can a dentist dispense medication to a patient for a condition not related to dental care or treatment?

No. Any medication dispensed by a dentist to a patient must be in conjunction with dental treatment provided by the dentist.

### What are the rules for storing drugs? What are the record-keeping requirements?

Drugs to be dispensed must be stored in a secure area, which means a locked storage area within the dentist's office. The keys to the locked storage area shall be available only to staff authorized by the dentist. A record or log of drug acquisition and disposition must be maintained by the dentist. Records must be preserved for three years.

### Can a dentist give medication samples to patients?

A dentist may furnish to a patient at no charge a limited quantity of drug samples if furnished in the package provided by the manufacturer. This transaction should be recorded in the patient record.

## Are coin envelopes acceptable to contain dispensed medicine?

No. State law requires prescribers who dispense to follow all the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

## How must the containers be labeled?

Label requirements are intended to provide patients with easy-to-read labels. The following elements must be printed in at least 12-point sans serif typeface, listed in the following order and clustered into one area of the label that comprises at least 50 percent of the label:

- Patient's name.
- Drug name and strength.
- Directions for use.
- Purpose or condition for which the drug is prescribed.

This part of the label must be highlighted in bold typeface or color or have blank space to set off the above items.

The remaining required elements of the label must be printed so as not to interfere with the legibility of the four elements listed above. The remaining required elements are:

- Prescriber's name and address.
- Date medication was dispensed.
- Quantity of medication dispensed.
- Expiration date of the effectiveness of the medication dispensed.
- Physical description of the dispensed medication, including its color, shape and identification code that appears on the tablets or capsules.

Upon the request of a patient or patient's representative, a prescriber who dispenses must provide translated directions for use on the prescription container, label or on a supplemental document. (An example of directions for use is "Take one pill at bedtime.") The English-language version of the directions for use must also appear on the container or label (not on a supplemental document). The California State Board of Pharmacy has [translated directions online](#) in Chinese, Korean, Russian, Spanish and Vietnamese. A dispenser may provide their own translated directions for use or can use the translations made available by the Board of Pharmacy. The prescriber dispenser is not obligated to provide translated directions for use beyond the languages that the pharmacy board has made available or beyond the directions that the board has made available in translated form.

When applicable, directions for use must use one of the 16 directions listed in Section 1707.5 of Title 16 of the California Code of Regulations. The one likely to be used by dental practices is:

*"If you have pain, take \_\_ (insert appropriate dosage form — pill, caplet, capsule or tablet) at a time. Wait at least \_\_ hours before taking again. Do not take more than \_\_ (appropriate dosage form) in one day."*

Many of the 16 directions are variations of the following:

*"Take two (insert appropriate dosage form) in the morning and take two (insert appropriate dosage form) at bedtime."*

The regulation, which contains the list of directions, is available on the pharmacy board [website](#). All possible directions for use are not included in the regulation. If a prescription's directions for use is not included in the regulation, the prescriber dispenser is not required to use one listed in the regulation. Also, inform the patient of possible side effects of the drug. This information does not have to be on the label. False or misleading information may not be included on a prescription label.

Samples of patient-centered prescription drug container labels can be found on the pharmacy board [website](#).

### **How should medicines that are not controlled substances be disposed?**

This is categorized as pharmaceutical waste, a type of regulated medical waste. Refer to "Dental Office Waste Management Options" on [cda.org/practicesupport](http://cda.org/practicesupport) for more information.

### **References**

Health & Safety Code § [11000 et seq.](#) -

Business & Professions Code §§ [4040](#), [4070-4078](#), [4080-4081](#), [4105](#), [4170-4175](#), [4184](#)

California Code of Regulations Title 16 §§ [1356.3](#) and [1707.5](#)