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FROM THE CALIFORNIA PHYSICIAN'S LEGAL HANDBOOK

Document #3201

Controlled Substances: Prescribing

CMA Legal Counsel, January 2019

Prescribing controlled substances requires more stringent procedures than prescribing other medications. The California Uniform Controlled Substances Act (Health & Safety Code §§11000 *et seq*.) codifies and lists controlled substances and drug schedules. (Health & Safety Code §§11053 *et seq*.) A federal list of controlled substances, including the drug schedule, can be found on the Drug Enforcement Administration's (DEA) website at www.deadiversion.usdoj.gov/schedules. This document summarizes the requirements of the California security prescription law and answers common questions about how physicians prescribe controlled substances.

For more information on pain management, including a discussion of the laws encouraging such prescriptions for the terminally ill, the Medical Board of California's (MBC) enforcement policy and various clinical guidelines, *see* CMA ON-CALL document #3210, "Pain Management." For more information on California's Right to Try law making investigational drugs available to eligible patients, *see* CMA ON-CALL document #3700, "Clinical Trials." For a more detailed discussion of the laws pertaining to the dispensing of controlled substances, *see* CMA ON-CALL document #3200, "Controlled Substances: Dispensing." For information on how to dispose of controlled substances as waste products, *see* CMA ON-CALL document #6309, "Medical Waste."

DEA REGISTRATION REQUIREMENTS

1. What are the requirements for registration?

Every physician who administers, prescribes, or dispenses any controlled substance must be registered with the Drug Enforcement Administration (DEA), Registration Section/DDR, P.O. Box 2639, Springfield, VA 22152-2639. A physician must apply on Form DEA-224, which can be obtained or completed online on the DEA's website at www.deadiversion.usdoj.gov/, from the Registration Unit, (800) 882-9539, or any of the following local DEA field offices:

Fresno Resident Office (Central CA)
2444 Main Street, Suite 240
Fresno, CA 93721
(916) 480-7295

San Diego Division (Southern CA)
4560 View Ridge Avenue
San Diego, CA 92123
(800) 284-1152

Los Angeles Division (South Central CA)
255 E. Temple Street, 17th Floor
Los Angeles, CA 90012
(888) 415-9822

Sacramento Resident Office (Northern CA)
4328 Watt Avenue
Sacramento, CA 95821
(916) 480-7295

San Francisco Division
(Central & Northern Coast CA)
450 Golden Gate Avenue
P.O. Box 36035
San Francisco, CA 94102
(888) 304-3251

The registration must be renewed every three (3) years and the certificate of registration must be maintained at the registered location and kept available for official inspection. Every currently registered physician should receive a renewal application approximately forty-five (45) days before the expiration date. If such form is not received within thirty (30) days before the expiration date of the current registration, the physician should contact the local DEA registration office, or DEA Headquarters at 1-800-882-9539, and request a renewal registration form. The registration renewal application may also be completed online at www.deadiversion.usdoj.gov, or in hard copy and mailed to:

Drug Enforcement Administration
Registration Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

(DEA website at www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm.)

It also should be noted that commencing January 2017, the DEA will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration. The DEA will allow the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required. (DEA website at www.deadiversion.usdoj.gov/drugreg/index.html.)

2. What does a physician need to obtain before he or she can complete an application for a DEA registration?

Issuance of a DEA registration to prescribe controlled substances is predicated on successfully completing all of the requirements imposed by the state in which the practitioner will conduct business and obtaining a state license. If the practitioner fails to obtain the required state license or has the license revoked or rescinded, then the DEA cannot issue the requested registration. If an existing DEA registrant loses his or her state privileges, then the DEA must rescind or revoke the federal authority to prescribe controlled substances. (*Registration Applications: Frequently Asked Questions* (Registration FAQs), DEA website at www.deadiversion.usdoj.gov/drugreg/faq.htm.)

3. Does a physician need a separate registration for each office?

It depends. If a physician has more than one office where controlled substances are administered and/or dispensed, and/or maintained, then each office must be registered. If, however, a physician (whose office is registered at another location in the same state or jurisdiction) prescribes controlled substances but does not administer or dispense controlled substances as a regular part of his or her professional practice at such office, then the physician does not need to register the second office. This assumes that supplies of controlled substances are not maintained in the second office either. (21 C.F.R. §1301.12.)

A physician who moves the practice to a new location must request a modification of registration. A modification of registration can be requested online at www.DEAdiversion.usdoj.gov or in writing to the DEA field office responsible for that state. If the change in address involves a change in state, the proper state issued license and controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). (Registration FAQs.)

CALIFORNIA SECURITY PRESCRIPTION REQUIREMENTS

4. What is the California security prescription law?

The law requires the use of security prescription forms for all controlled substances—Schedules II, III, IV, and V.

The security prescription forms must be supplied by printing companies approved by the California Department of Justice (DOJ) and must include specific security features. The DOJ has exclusive control over the approval of these forms. (Health & Safety Code §11161.5(a).)

Note that federal law is more stringent with respect to tamper-free prescription pads used in Medi-Cal or programs receiving federal matching funds. Since 2008, a tamper-resistant prescription pad must be used when a physician executes a written (non-electronic) prescription for patients enrolled in state programs receiving federal matching funds, including Medi-Cal. (42 U.S.C. §1396b(i).) This requirement applies to all outpatient drugs, including over-the-counter drugs covered by Medi-Cal, not just for prescriptions for Schedule II–V drugs as is required by California law generally. For more information, *see* CMA ON-CALL document #3205, "Drug Prescribing (Not Schedule II–V Drugs)."

SECURITY PRINTERS

5. How do I find an approved security printer?

Physicians can find the Approved List of Security Prescription Printers that have been pre-approved by the California Board of Pharmacy and the State of California Department of Justice (DOJ) on the DOJ's website at https://oag.ca.gov/security-printers/approved-list.

6. Has CMA partnered with any security printer to offer a discounted price for CMA members?

RxSecurity is CMA's sponsored security prescription form printer. RxSecurity has been printing secure tamper proof pads for other jurisdictions since 1989 and has an automated authentication process for Medical Board of California (MBC) and Drug Enforcement Agency (DEA) licensure. CMA members enjoy savings of fifteen (15) percent on all orders of tamper-resistant prescription pads and electronic health records printer paper with RxSecurity.

To place an order with RxSecurity, go to its website at www.rxsecurity.com/cma-order (non-members www.rxsecurity.com) or call 1-800-66-RX-PAD or text 1-902-456-9723. Physicians' initial order must include their DEA registration and state license number. Initial orders may be filled out online or may be faxed to 1-866-667-9723.

7. I have been offered free tamper proof pads from a company that previously gave me free pads? Are they legal for controlled substances?

Not unless the prescription pads come directly from a printer approved by the State. Approved printers are listed on the DOJ website at http://oag.ca.gov/security-printers/approved-list.

CMA understands that some physicians have been approached by various vendors offering them "free" tamper-resistant security prescription forms. It is extremely important that a physician verify that the forms they are using come from an approved security printer. If such an offer is made, physicians must verify the printing source for these documents and verify that the printer has been approved by the authorities, including by asking for verification from the vendor or intermediary that is offering the free pads. If a company a physician wishes to use is not listed on the Attorney General's website (http://oag.ca.gov/security-printers/approved-list), it is not an approved security printer and cannot legally print the new tamper-resistant security prescription forms. Physician use of a non-authorized prescription form is a misdemeanor and repeated usage could be the subject of discipline by the MBC. (Health & Safety Code §11162.6.)

Further, if a physician is repeatedly non-compliant with the laws related to the prescribing of controlled substances, law enforcement may petition a court to require the prescriber to summarily surrender all controlled-substance prescription forms and to prohibit the prescriber from obtaining, ordering or using such forms. (Health & Safety §11161.)

8. How do I dispose of unused forms?

Any remaining unused controlled substance prescription forms should be properly destroyed, via shredding, and a record system kept, accounting for their destruction. These records should be kept for a minimum of three years pursuant to California Business & Professions Code §§4080–4081 and California Health & Safety Code §11191.

CURES/PRESCRIPTION DRUG MONITORING PROGRAM

9. What is CURES?

The Controlled Substance Utilization Review and Evaluation System (CURES) is California's statewide database of Schedule II through IV controlled substances dispensed to patients in the state. (CURES/PDMP website at www.oag.ca.gov/cures.) It serves to assist health care practitioners in making appropriate

prescribing decisions and law enforcement and regulatory agencies in their efforts to control the abuse and diversion of controlled substances. Maintained and administered by the Office of the Attorney General in the California Department of Justice (DOJ), California's PDMP system allows pre-registered users, including licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards, to access timely patient controlled substances prescription history information. (Health & Safety Code §11165.)

For more information on CURES, including registering for CURES and accessing data in CURES, *see* CMA ON-CALL document #3212, "California's Prescription Drug Monitoring Program: The Controlled Substance Utilization Review and Evaluation System (CURES)."

Mandatory Enrollment

10. Are physicians required to apply to register for CURES access?

Yes. The law mandates that all California licensed prescribers authorized to prescribe scheduled drugs, upon receipt of a Drug Enforcement Administration (DEA) Controlled Substance Registration Certificate, submit an application to access the CURES database. Physicians with an active license and a DEA Controlled Substance Registration Certificate should have submitted an application by July 1, 2016. (Health & Safety Code §11165.1.) In addition to physicians, individuals who have a valid California license as a dentist, naturopathic doctor, optometrist, osteopathic physician, physician assistant, podiatrist, advanced practice registered nurse, or veterinarian and possess a DEA Controlled Substance Registration Certificate must apply to register with CURES. Pharmacists must also apply to register for CURES access upon licensure. (*Id.*)

To register for access to CURES and for more information including user guides and training materials, visit the DOJ's CURES/PDMP website at www.oag.ca.gov/cures-pdmp.

Patient Activity Report

The patient history of dispensed medications is known as a "Patient Activity Report" or "PAR." The PAR provides the physician with a list of all Schedule II, III, and IV controlled substances that have been prescribed to a patient within a chosen period of time, up to one year. CURES subscribers can log into CURES through its secure website and enter the patient's first name, last name, and date of birth to access and view an individual's PAR. (CURES 2.0 User Guide at 10–11.)

CURES subscribers may also receive a PAR initiated by the DOJ when a patient's CURES profile indicates the possibility of inappropriate, improper, or illegal use of Schedule II, III, and IV controlled substances. (Health & Safety Code §11165.1(c).)

11. What information is included in the PAR?

The PAR includes the patient's name, date of birth, patient address, prescriber name, prescriber DEA number, pharmacy name, pharmacy license number, date the prescription was dispensed, prescription number, drug name, drug quantity and strength, and number of refills remaining. (CURES/PDMP website.) A PAR may provide useful data as to the patient's drug utilization practices and alert the physician if a patient has altered the quantity of drugs prescribed from the original order or if illegal orders have been made in the practitioner's name.

Patient Safety Alerts

In addition to PAR queries by prescribers or dispensers, CURES 2.0 generates unsolicited messages called "Patient Safety Alerts." These alerts occur when prescription information is analyzed according to preset thresholds and reported to certain entities, such as prescribers, dispensers, licensing boards, and/or law enforcement. Clinicians are alerted via flags on their user profile dashboard when a patient's aggregate prescription level exceeds certain thresholds. These patient safety alerts can serve to inform prescribers and pharmacists that an individual may be abusing or diverting controlled substances, help prescribers make better prescribing decisions to improve patient care, and provide an opportunity to intervene and refer patients for substance use disorder treatment when appropriate.

The CURES 2.0 alerts have been set by the DOJ at the following thresholds:

- Patient is currently prescribed more than one hundred (100) morphine milligram equivalents per day;

- Patient has obtained prescriptions from six (6) or more prescribers or six (6) or more pharmacies during last six (6) months;
- Patient is currently prescribed more than forty (40) morphine milligram equivalents of methadone daily;
- Patient is currently prescribed opioids more than ninety (90) consecutive days; and
- Patient is currently prescribed both benzodiazepines and opioids.

CURES 2.0 also provides messaging capability between an individual's different prescribers within the secure database. (CURES/PDMP website.)

Effective January 1, 2019, prescribers are allowed to access the CURES database for a list of patients for whom that prescriber is listed as a prescriber in the CURES database. (Health & Safety Code §11165.6; A.B. 2086, Stats. 2018, ch. 274.) Prior to the passage of A.B. 2086, physicians could only query specific patients and did not have access to view reports of their own prescribing activities or prescriptions attributed to their DEA number in CURES.

Duty to Consult

12. Does a physician have to check CURES prior to prescribing a controlled substance?

Yes. In 2016, the California Legislature enacted S.B. 482 which will require a health care provider to consult CURES prior to prescribing a Schedule II, III, or IV controlled substance to a patient for the first time and at least once every four months thereafter if that substance remains part of the patient's treatment. The "first time" is defined as the "initial occurrence in which a health care practitioner … intends to prescribe, order, administer, or furnish a … controlled substance to a patient and has not previously prescribed a controlled substance to the patient." The physician must consult CURES no earlier than twenty-four (24) hours or the previous business day, prior to the prescribing, ordering, administering, or furnishing of a controlled substance to the patient. (Health & Safety Code §11165.4; S.B. 482, Stats. 2016, ch. 708.)

On April 2, 2018, DOJ certified the CURES database was ready for statewide use and that the department had adequate staff and user support to handle the related technical and administrative workload. As a result, the mandate took effect on October 2, 2018, six months after certification that the CURES database was ready. (Health & Safety Code §11165.4(e); S.B. 482, Stats. 2016, ch. 708.)

The Medical Board of California has prepared answers to the most frequently asked questions regarding the new state requirements: www.mbc.ca.gov/Licensees/Prescribing/CURES/CURES_FAQ.pdf. For more information on the new duty to consult requirement, *see* CMA ON-CALL document #3212, "California's Prescription Drug Monitoring Program: The Controlled Substance Utilization Review and Evaluation System (CURES)."

13. Are there any exceptions to the duty to consult CURES?

Yes. Health care practitioners are exempted from this "first time" querying process (but still must query on any subsequent prescription and at least every 4 months thereafter) where the health care practitioner prescribes, order, administers, or furnishes a controlled substance to a patient:

- **Previous prescription.** It is not the "first time" the physician has prescribed the controlled substance to the patient. Note, however, physicians must check CURES for any subsequent prescriptions to that patient if the subsequent prescription is for a controlled substance that the physician has not previously prescribed to that patient.
- **Administered on-site.** The controlled substance is being administered to a patient while the patient is admitted to, or during an emergency transfer between, a licensed clinic, an outpatient setting, health facility, or a county medical facility for use on the facility premises.
- **Emergency department.** The controlled substance is prescribed in the emergency department of a general acute care hospital, so long as the quantity of the controlled substance does not exceed a non-refillable seven (7) day supply.
- **Surgical procedures.** The controlled substance is prescribed as part of treatment for a surgical procedure for use in a licensed clinic, outpatient setting, health facility, county medical facility, or dental office, so long as the quantity of the controlled substance does not exceed a nonrefillable five (5) day supply.

- **Hospice.** The controlled substance is prescribed to a patient currently receiving hospice care.
- **Timely access not possible.** When access to CURES is not reasonably possible in a timely manner and another health care practitioner or delegate authorized to access CURES is not reasonably available, so long as the quantity of the controlled substance does not exceed a nonrefillable five (5) day supply. Note that physicians must then document in the patient's medical record the reason why the CURES database was not consulted.
- **CURES non-operational.** When CURES is not operational, as determined by the DOJ, or it cannot be accessed because of a temporary technological or electrical failure. The health care practitioner must, without undue delay, seek to correct any cause of the technological or electrical failure that is reasonably within his or her control.
- **Technological limitations.** Where CURES cannot be accessed because of technological limitations that are not reasonably within the control of the health care practitioner so long as the quantity of the controlled substance does not exceed a non-refillable five (5) day supply.
- **Adverse impact on patient.** Where consulting CURES would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and adversely impact the patient's condition, so long as the quantity of the controlled substance does not exceed a non-refillable five (5) day supply.

(Health & Safety Code §11165.4(c); S.B. 482, Stats. 2016, ch. 708.) The duty to consult the CURES database does not apply to veterinarians or pharmacists. (Health & Safety Code §11165.4(b); S.B. 482, Stats. 2016, ch. 708.)

14. What if a physician fails to consult CURES before prescribing as required by S.B. 482?

Physicians who fail to consult the CURES database pursuant to Health & Safety Code §11165.4 may face disciplinary and administrative sanctions. The law, however, does not create a private right of action against a health practitioner for failure to consult CURES. (Health & Safety Code §11165.4(d); S.B. 482, Stats. 2016, ch. 708.)

NALOXONE CO-PRESCRIBING

Effective January 1, 2019, prescribers must offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid-induced respiratory depression to a patient when one or more of the following conditions are present:

- Prescription dosage is 90 or more morphine milligram equivalents of an opioid medication per day.
- Opioid medication is prescribed concurrently with a benzodiazepine.
- Patient presents with an increased risk of overdose, including history of overdose, substance use disorder, or at otherwise at risk.

Prescribers must also provide education to patients receiving a prescription for naloxone, or a person designated by the patient, on overdose prevention and the use of the naloxone hydrochloride or another similar drug. Prescribers must also provide education on overdoes prevention. (Business & Professions Code §741; A.B. 2760, Stats. 2018, ch. 324.); *See* the MBC's FAQs at www.mbc.ca.gov/Licensees/Prescribing/OverdosePrevention/AB2760FAQs.pdf.

CONTENTS OF CONTROLLED SUBSTANCE PRESCRIPTIONS

15. Do I have to handwrite my prescriptions for all controlled substances?

No. The prescriber is only required to sign and date prescriptions for all controlled substances, Schedules II, III, IV, and V. The balance of the required information need not be in the prescriber's handwriting. (Health & Safety Code §11164(a)(1).)

16. What information is required on a controlled drug prescription?

For physicians who are not designated prescribers from a licensed health care facility, clinic or medical group consisting of more than twenty-five (25) physicians, the following fifteen (15) features must be pre-printed on each controlled substance prescription:

1. Latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if

a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription;

2. Watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
3. Chemical void protection that prevents alteration by chemical washing;
4. Feature printed in thermochromic ink;
5. Area of opaque writing so that the writing disappears if the prescription is lightened;
6. Description of the security features included on each prescription form;
7. Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear: 1–24, 25–49, 50–74, 75–100, 101–150, and 151 and over. In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form;
8. Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted";
9. Preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner;
10. Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered;
11. Date of origin of the prescription;
12. Check box indicating the prescriber's order not to substitute;
13. Identifying number assigned to the approved security printer by the Department of Justice;
14. A check box by the name of each prescriber when a prescription form lists multiple prescribers. Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name;
15. A uniquely serialized number, in a manner prescribed by the Department of Justice.

(Health & Safety Code §11162.1(a).)

Further, each batch of forms must have the lot number printed on the form, and each form within the batch must be numbered sequentially beginning with one. Prescribers in licensed health care facility, clinic or medical group consisting of more than twenty-five (25) physicians may order forms without the prescriber's preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner, for use when treating patients in that facility. (Health & Safety Code §11162.1(c).) Note, however, that forms may have additional requirements to identify the name, address, category of licensure, and license number of the licensed health care facility. (*Id.*)

Other than the signature and date by the prescriber in ink, prescriptions for controlled substances must contain the following, but are not required to be preprinted on the prescription and may be handwritten on the prescription:

- The prescriber's telephone number (and address preprinted on the form);
- The date of origin of the prescription;
- The ultimate user or research subject or contact information as required by federal law;
- Refill information, such as the number of refills ordered and whether the prescription is a first time request or a refill;
- The name, quantity, strength and directions for use of the controlled substance prescribed; and
- The address of the person for whom the controlled substance is prescribed. (If the prescriber does not include the address, the pharmacist may fill the prescription and add this information to the form.)

(Health & Safety Code §11164(a).)

17. The pharmacy has informed me that they will no longer accept my prescription pads from an approved Security Printer. Has there been a change in the law? What do I do?

While there has not been a recent change in the law, periodically, pharmacies will update their policies to ensure compliance with the precise requirements of the law. The most recent change to the law has been effective since January 1, 2012, when it was amended to add the requirement that controlled substance

must include the preprinted address of the prescribing practitioner. (Health & Safety Code §11162.1.) All non-compliant prescription forms are invalid and pharmacies are prohibited from accepting them. In addition, physicians should ensure that the notation on the bottom of the prescription form states "Prescription is void if the number of drugs prescribed is not noted." Many physicians may have outdated prescription pads that use the phrase "Prescription is void if more than one controlled substance is written per blank." (*Id.*)

Beginning in 2017, CMA received numerous calls from physicians whose prescriptions are being turned away by pharmacies for being non-compliant with state law. Specifically, the forms in question do not have checkboxes to indicate refills. California law requires fourteen (14) elements that must appear on California security prescription forms, including "check boxes that shall be printed on the form so that the prescriber may indicate the number of refills ordered." Security forms that lack the check boxes, even if they indicate refills in a different way, are deemed non-compliant. This requirement has been in effect since 2007. (Health & Safety Code §11162.1.) Due to recent enforcement actions by the California Board of Pharmacy and a notice that it will cite and fine pharmacists/pharmacies who dispense controlled drugs with non-compliant forms, some pharmacies updated their policies and began to refuse to fill prescriptions written on non-compliant forms.

According to the Board of Pharmacy, physicians who are using non-compliant forms should educate themselves on the required elements of the security prescription forms, order compliant forms from a DOJ approved security printer and consider using e-prescribing for controlled substances. If a physician does not have compliant forms, Schedule III–V controlled substances may be filled as an oral prescription if the pharmacist verifies verbally with the prescriber the number of any refills ordered and notes it on the security form. For Schedule II medications—where there are no alternatives, such as the availability of compliant forms or e-prescribing—the Board of Pharmacy allows use of a non-compliant form on a temporary basis to allow patients to receive any Schedule II medications in a timely manner. There are further exemptions to the security form requirements for a prescription for controlled substances for use by a patient who has a terminal illness. (California State Board of Pharmacy Subscriber Alert (November 28, 2017).)

In addition, effective January 1, 2019, California law requires all security prescription forms to have a 15th element of a uniquely serialized number. This law required California physicians who prescribe controlled substances to use updated controlled substance prescription forms effective January 1, 2019. The legislation did not include any transition or grandfathering period to allow for continued use of old controlled substance security prescription forms on or after January 1. The California Department of Justice (DOJ) did not issue any implementation guidance to security prescription printers in time for a smooth transition. Although the California Board of Pharmacy issued a statement that it would "not make enforcement a priority" if pharmacists choose to fill prescriptions written on non-compliant prescriptions forms, physicians and patients continued to have difficulty filling necessary medications. As a result, CMA sponsored a legislative fix to address this issue. As of press time, A.B. 149, the legislation to postpone implementation of the new law, establish a transition period, and make any prescription written on otherwise valid form valid until January 1, 2021 is awaiting signature by the Governor.

Physicians in Group Practices

18. Do physicians in a medical group have to have their own individualized tamper-resistant security prescription pads?

No. The security prescription forms may be preprinted with more than one (1) prescriber. These forms should include check boxes or some other means to identify the specific prescriber's name, category of licensure, state license and DEA number. In addition, if the individual group has at least twenty-five (25) physicians, it may choose to use a medical group form. (Health & Safety Code §11162.1.)

Institutional Prescription Forms for Licensed Health Facilities, Clinics, and Medical Groups

19. What if a physician is employed by a large clinic or medical group? Do physicians have to use their own pre-printed prescriber information?

A licensed acute care hospital or acute psychiatric hospital may order controlled substance prescription forms for use by prescribers when treating patients in

that facility without the information of each prescribing physician. Similarly, licensed clinics and medical groups or foundations with at least twenty-five (25) physician members may order form for use by their physicians.

These institutional forms require the pre-printed facility information and the name, category of licensure, license number and federal controlled substance registration number of the designated prescriber. The designated prescriber must maintain a record of the physicians to whom controlled substance prescription forms are issued, including the name, category of licensure, license number, federal controlled substance registration number and the quantity of forms issued to each physician. (Health & Safety Code §11162.1(c).) These records must be maintained in the health facility for three (3) years. (Health & Safety Code §11162.1(c)(4)(A).)

The only exception to this record-keeping requirement is for forms that are printed by a computerized prescription generation system. In those cases, in order to encourage physicians to make use of computerized prescribing systems, the tracking of this information is optional. (Health & Safety Code §11162.1(c)(4)(B).)

Each prescription must include the actual prescriber's name, category of license, license number, date of prescription and DEA number. To the extent a medical group or other eligible organization decides to use these "organizational forms" rather than forms specific to individual physicians, the "designated prescriber" must take full responsibility for ordering the security prescription forms, issuing them to the organization's prescribers and maintaining records. (Health & Safety Code §11162.1(c).) Thus, physicians serving in this role will want to ensure that appropriate controls are implemented to reduce the likelihood of any improper activity, as well as the availability of professional liability insurance covering this activity.

TERMINALLY ILL PATIENTS

Security Form Not Required For Controlled Substances

20. Are security prescription forms required for terminally ill patients?

No. Use of the secure form is not required for prescribing any category of controlled substance for terminally ill patients, except as provided below for certain Medi-Cal patients. To qualify as terminally ill, a physician must certify that the patient is:

- Suffering from an incurable, irreversible, illness;
- Expected to die within one year; and
- Receiving a controlled substance prescription for symptom management and not to cure.

Such prescriptions must contain the following handwritten in ink:

- Patient's name,
- Name and quantity of drug;
- Directions for use; and
- The prescriber's signature and date.

(Health & Safety Code §11159.2.)

In addition to the information ordinarily contained on a prescription pad, the words "11159.2 exemption" must appear. Pharmacists may fill prescriptions if the "11159.2 exemption" language is missing if the pharmacist knows the terminal illness status of the patient and returns the prescription to the prescriber for correction within seventy-two (72) hours. Physicians likely to issue such prescriptions frequently may wish to order a stamp or pre-printed prescription pads including these words.

For more information on this law, including a sample notification, *see* CMA ON-CALL document #3210, "Pain Management."

TAMPER-RESISTANT PRESCRIPTION PADS FOR MEDI-CAL PATIENTS

21. How does state law compare with federal law requirements for tamper-resistant prescription pads?

A tamper-resistant prescription pad must generally be used when a physician executes a written (non-electronic) prescription for patients enrolled in state programs receiving federal matching funds, including Medi-Cal. (42 U.S.C. §1396b(i).) This requirement applies to ALL outpatient drugs, including over-the-counter drugs covered by Medi-Cal, not just for prescriptions for Schedule II–V drugs as is required by California law generally. For a detailed discussion of this requirement, *see* CMA ON-CALL document #3205, "Drug Prescribing (Not Schedule II–V Drugs)."

RE-SCHEDULING OF CONTROLLED SUBSTANCES

The DEA has been active in re-scheduling three classes of controlled substances:

Tramadol

Starting on August 18, 2014, Tramadol, an opioid analgesic, was placed on Schedule IV of the Controlled Substances Act. (21 C.F.R. §1308.14(b)(3).) Physicians must now handle and inventory Tramadol with all the applicable requirements of a Schedule IV controlled substance.

Hydrocodone Combination Products (HCP)

On October 6, 2014, Hydrocodone Combination Products (HCP) were moved from Schedule III to Schedule II. (21 C.F.R. §1308.13(e).)

Thiafentanil

On August 26, 2015, the DEA placed the substance thiafentanil (4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine), including its isomers, esters, ethers, salts and salts of isomers, esters and ethers as possible, into schedule II of the Controlled Substances Act. (21 C.F.R. §1308.12.)

CMA is aware that this re-scheduling places an additional burden on physicians by requiring them to write new prescriptions instead of relying on refills. However, physicians may take advantage of federal regulations that allow physicians to write multiple, sequential prescriptions for a Schedule II drug, up to a 90-day supply. *See* Question 39 for more information.

ORAL, FAX AND ELECTRONIC PRESCRIBING

Schedule II Controlled Substances

22. Does the security prescription law allow me to orally prescribe Schedule II drugs or fax them to the pharmacy?

Generally, prescription orders for drugs classified in Schedule II may not be faxed, emailed or orally prescribed, but must be signed and dated by the physician in the handwriting of the prescriber. (Health & Safety Code §11164.) A Schedule II prescription may be faxed to a pharmacy, but the drug cannot be dispensed unless the original manually signed prescription is presented to the pharmacist (21 C.F.R. §1306.11.) State and federal law differ as to allowed exceptions, but generally the exceptions are as follows:

Emergency. Under state law, in an emergency, a Schedule II substance may be dispensed upon an oral, written or e-mail prescription. Any written order must be signed and dated by the prescriber in ink, and the pharmacy must reduce any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance. However, the prescriber must provide to the pharmacist a prescription that meets the requirements of Health & Safety Code §11162.1, discussed above, by the seventh (7th) day following transmission of the initial order. (A postmark by the seventh day following transmission of the initial order complies with this law.) The pharmacist must report any prescriber who fails to do so to the Department of Justice within 144 hours of the failure to do so. (Health & Safety Code §11167.)

Federal law allows for faxing provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing except as outlined below. The federal regulations (which generally supersede state law), allow oral prescribing in the case of an emergency situation, provided, among other things, the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. (21 C.F.R. §1306.11(d).) Dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescriber. (21 C.F.R. §1306.11.)

Skilled Nursing Facility, Intermediate Care Facility, or Hospice. Under state law, in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care, a Schedule II substance may be dispensed upon an oral, fax or e-mail prescription. (Health & Safety Code §11167.5.) If the prescription is transmitted orally, the pharmacist must, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist and obtain the signature of the person to whom the drugs are delivered. (*Id.*) If the prescription is transmitted electronically, the pharmacist must, prior to filling the prescription, produce, sign and date a hard copy prescription

and obtain the signature of the person to whom the drugs are delivered. (*Id.*)

23. Can a physician use electronic prescribing for Schedule II?

Yes, the DEA permits e-prescribing of Schedule II substances. (21 C.F.R. §1306.08.) Although this is not expressly stated as a requirement for e-prescribing of Schedule II, in the past, CMA heard of California pharmacies that request the original prescription be submitted before the drug is dispensed. This practice, most likely adapted from the requirement for a faxed Schedule II prescription that the original prescription is presented before dispensing, no longer appears to be an issue. (21 C.F.R. §1306.11(a).)

Schedule III, IV, and V Controlled Substances

24. Can a physician fax or orally prescribe Schedule III, IV, or V controlled substances?

Both California and federal law allow Schedule III, IV, or V controlled substances to be prescribed orally or via fax to the pharmacist. (Health & Safety Code §11164(b); 21 C.F.R. 1306.21.) If a prescriber's employee orally transmits the order, the prescription must specify the name of that employee who transmitted the prescription. An oral prescription must be promptly reduced to writing by a pharmacist. (*Id.*)

25. What about electronic prescribing of Schedule III, IV, or V substances?

California law. With regard to electronic transmission of prescriptions for Schedule III, IV, and V drugs, California law clearly allows such prescribing so long as the electronically transmitted prescription is produced in hard copy form and signed and dated by the pharmacist filling the prescription. (Health & Safety Code §11164(b).) However, any person who transmits, maintains, or receives any electronically transmitted prescription must ensure the security, integrity, authority, and confidentiality of the prescription. (*Id.*)

Federal law. The federal DEA adopted regulations, effective June 1, 2010, that allow physicians to issue electronic controlled substance prescriptions only when the electronic prescription or electronic health record application the physician is using complies with a number of federal requirements. (75 Fed.Reg. 16310 (March 31, 2010).) These regulations are voluntary and do not require that physicians use electronic prescriptions for controlled substances. Among other things, the regulations require that all e-prescribing applications be certified as being compliant with the new standards. (21 C.F.R. §1311.120.)

The following matrix summarizes and compares state and federal law for prescribing Schedule II, III, IV, and V drugs:

Comparison of State and Federal Law for Prescribing Methods for Schedule II, III, IV, and V Drugs

	Security Form Required?	**Faxing Allowed?**	**Electronic?**	**Oral Prescribing?**
Schedule II	**Yes**.	**No**, except: 1) In an **emergency**, security form must be sent (postmarked) within seven (7) days (Health & Safety Code §11167); or 2) Fax generally ok if original prescription is presented before dispensing (21 C.F.R. §1306.11(a)). 3) If patient is in a skilled nursing facility, intermediate care facility, home health agency or hospice, the pharmacist must reduce to writing when prescription is transmitted orally, or produce a hard copy when prescription is transmitted electronically (Health & Safety Code §11167.5, 21 C.F.R. §1306.11(f)(g).)	**Yes**, the DEA permits e-prescribing of Schedule II. (21 C.F.R. §1306.08.) State and federal law allows for emergency, long term care (LTC) and hospice. (Health & Safety Code §11167.5, 21 C.F.R. §1306.11(f)(g).)	In an emergency so long as certain conditions are met. (21 C.F.R. §1306.11(d); Health & Safety Code §11167.) California law also allows oral prescribing for LTC and hospice and emergency. (Health & Safety Code §11167.5.)

	Security Form Required?	Faxing Allowed?	Electronic?	Oral Prescribing?
Schedule III–V	**If written: Yes.** If **faxed**: Board of Pharmacy says yes (tamper-proof form can be used with an agreed protocol with pharmacist).	Yes. (Health & Safety Code §11164(c); 21 C.F.R. §1306.21.)	**Yes,** under federal law so long as detailed requirements are met. **Yes,** under California law (Health & Safety Code §11164(b).)	Yes. (Health & Safety Code §11164(b); 21 C.F.R. §1306.21.)

26. How can a physician determine whether his or her application complies with the federal rules?

An application provider must have a third-party audit or certification report available to any physician that uses or is considering the use of the application. (21 C.F.R. §1311.300.)

ELECTRONIC PRESCRIPTION REQUIREMENTS

27. How can a physician determine whether his or her electronic prescribing application complies with the federal rules?

An application provider must make a third-party audit or certification report available to any physician that uses or is considering using the application. (21 C.F.R. §1311.300.)

Data Elements

28. What data must be on the electronic prescription?

The electronic prescription application must present for the practitioner's review and approval all of the following data for each controlled substance prescription:

- Date of issuance;
- Full name of the patient;
- Drug name;
- Dosage strength and form, quantity prescribed, and directions for use;
- Number of refills authorized, if applicable, for prescriptions for Schedule III, IV, and V controlled substances.
- For prescriptions written in accordance with the requirements of 21 C.F.R. §1306.12(b) (governing the refilling and/or issuance of multiple prescriptions), the earliest date on which a pharmacy may fill each prescription.
- The name, address, and DEA registration number of the prescribing practitioner.
- The mandated statement that displays the following or its equivalent:

  By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above.

(21 C.F.R. §1311.120 and 21 C.F.R. §1311.140.)

Authentication

29. How do I obtain a two-factor authentication?

A physician must obtain a two-factor authentication by submitting identity proofing information to either a credential service provider or authentication authority. The requirements for these providers include:

- A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800–63–1.
- For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.

(21 C.F.R. §1311.105.)

30. What are the requirements for a two-factor authentication?

To sign a controlled substance electronic prescription, the electronic prescription application must require the physician to authenticate to the application using an authentication protocol that uses two (2) of the following three (3) factors:

- Something only the practitioner knows, such as a password or response to a challenge question.
- Something the practitioner is, biometric data such as a fingerprint or iris scan.
- Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1 for cryptographic modules or one-time-password devices. (21 C.F.R. §1311.115.)

Signature

31. How do I "sign" an electronic prescription?

A physician must obtain a two-factor authentication credential from certain federally approved credential service providers or certification authorities. (21 C.F.R. §1311.105.)

The credential service provider or certification authority must issue the authentication credential using two (2) channels (e.g., email, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the physician has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two (2) pieces of information used to generate or activate the authentication credential using two (2) channels. (*Id.*)

When the physician indicates that one or more prescriptions are "ready to be signed," the application must prompt him/her to begin the two-factor authentication protocol.

The two-factor credential constitutes the legal signature of the DEA-registered prescriber. (21 C.F.R. §1311.120.) When the credential is used, the application must digitally sign and archive at least the DEA required information contained in the prescription and archive the digitally signed record. A physician may also sign the prescription with his/her private key meeting certain elements. (*Id.*; *see also* 21 C.F.R. §1311.145.)

For more information on electronic signatures, *see* CMA ON-CALL document #0400, "Electronic Signatures."

32. Can I alter the information after I indicated that the prescription is ready to be signed?

No. The DEA clarified that this prohibition only applies to changes to the content (not format) by intermediaries, not to changes that may be lawfully made at the pharmacy after receipt pursuant to state and federal law. (76 Fed.Reg. 16236 (March 31, 2010).)

Multiple Prescriptions

33. Can a physician simultaneously issue multiple prescriptions for multiple patients with a single signature?

No. (21 C.F.R. §1311.120.)

34. What about multiple prescriptions for a single patient?

That activity is allowed so long as each controlled substance prescription is indicated as "ready for signing." A single execution of the two-factor authentication protocol can then sign all prescriptions for a given patient. (21 C.F.R. §1311.120(b)(13).)

Security Protections

35. What security protections must I follow for electronic controlled substance prescriptions?

The physician must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The physician must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. A physician's failure to secure the hard token, knowledge factor, or biometric information provides a basis for revocation or suspension of DEA registration. (21 C.F.R. §1311.102(a).)

36. What if my hard token is lost/stolen or the authentication protocol is compromised?

The physician must notify the individuals designated to manage access control to the application pursuant 21 C.F.R. §1311.125 or 21 C.F.R. §1311.130 within one business day of discovery that the hard token has been lost, stolen, or compromised or the authentication protocol has been otherwise compromised. A physician who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential. (21 C.F.R. §1311.102(b).)

Mandatory Electronic Prescribing

Assembly Bill (A.B.) 2789, Stats. 2018, ch. 438, requires that on and after January 1, 2022, health care practitioners authorized to prescribe pursuant to Business & Professions Code §4040 have the capability to transmit electronic data transmission prescriptions. Likewise, the law requires that on and after January 1, 2022, pharmacies and prescribers authorized to dispense prescriptions have the capacity to receive electronic data transmission prescriptions. (Business & Professions §688(a)–(d).) Prescribers will be required on and after January 1, 2022 to use electronic prescribing unless one of the following exceptions is met:

- The prescription is for a pain medication issued pursuant to §11159.2 of the Health and Safety Code.
- An electronic data transmission prescription is not available due to a temporary technological or electrical failure. "Temporary technological or electrical failure" means 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 affecting the certified electronic data transmission prescription application used to transmit the prescription. For controlled substances, the prescriber who issues but does not transmit the prescription must document the reason in the patient's medical records as soon as practicable and within 72 hours of the technological or electrical failure.
- The prescribing health care practitioner is issuing a prescription to be dispensed by a pharmacy located outside California.
- A prescription shall be electronically issued but does not require electronic transmission and may be provided directly to the patient when the prescription is issued in a hospital emergency department or urgent care clinic and one 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.
- 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 by a prescribing health care practitioner in circumstances where the practitioner reasonably determines that it would be impractical for the patient to timely obtain substances prescribed by an electronic data transmission prescription and the delay would adversely impact the patient's medical condition.
- The prescription that is issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard, as amended from time to time.
- Health care services are being provided to an inmate, individual on parole, or youth under the jurisdiction of the Department of Corrections and Rehabilitation

(Business & Professions §688(e), (f), (k).) (g) Pharmacies that receives electronic data transmission prescription from a prescriber who has issued the prescription but has not dispensed the medication to the patient shall, at the request of the patient transfer or forward the electronic data transmission prescription to an alternative pharmacy designated by the patient. If a pharmacy is aware that an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, the pharmacy shall immediately notify the prescriber. Pharmacists may continue

to dispense medications from legally valid written, oral, or fax prescriptions. Physicians who fail to comply with electronic prescribing requirements will be referred to the Medical Board. (Business & Professions §688(g)–(j).)

In addition, under the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that was signed into law on October 24, 2018, physicians will be mandated to electronically prescribe controlled substances for Medicare patients after January 1, 2021. (H.R. 6, P.L. 115-271.) Although the federal law was enacted after the state law, the federal mandate goes into effect before the state mandate. As such, there will likely be changes to the state law to conform with the federal law.

MULTIPLE PRESCRIPTIONS AND REFILLS OF CONTROLLED SUBSTANCES

37. I am using a secure prescription pad that includes a box to put the number of refills on the form. Does this mean that Schedule II prescriptions can be refilled?

No. Schedule II prescriptions cannot be refilled. (Health & Safety Code §11200(c).) Schedule II prescriptions are valid for six (6) months from the date of issuance by the prescriber. (Health & Safety Code §11200(a).)

The security prescription forms include an area for refills because the form can be used for any controlled or non-controlled substance prescription. Therefore, for Schedule II prescriptions, prescribers should mark zero (0) or no refill (NR).

Schedule II, and Schedule III, IV, and V controlled substances may be written on the same tamper-resistant security form as long as the prescriber uses the security prescription form that comes pre-printed with the statement "prescription is void if the number of drugs prescribed is not noted." (Health & Safety Code §11162.1(a)(8).)

The DEA clarified its rule for providing individual patients with multiple prescriptions for the same Schedule II controlled substance at a single office visit. The updated federal regulation reiterates the law that refilling of a prescription for a controlled substance is prohibited. However, a physician may issue multiple prescriptions authorizing the patient to receive a total of up to a ninety (90) day supply of Schedule II controlled substance, provided that:

- Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
- The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
- The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
- The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
- The individual practitioner complies fully with all other applicable federal and state laws and regulations.

These subsequent prescriptions cannot be dated with a future date but must be dated as of and signed on the day when issued. (21 C.F.R. §1306.05(a).) There is no requirement that a prescription be filled within a certain amount of time after it was issued. The DEA makes it clear that it is not mandating or encouraging physicians to issue prescriptions in this manner, but that they must use their own medical judgment. (21 C.F.R. §1306.12.)

38. Is there a limit on the number of separate prescriptions per Schedule II controlled substance that may be issued for the 90-day supply?

The rule does not state how many separate prescriptions per Schedule II controlled substance may be issued for the 90-day supply. According to the DEA, it is up to the practitioner to determine how many separate prescriptions to be filled sequentially are needed to provide adequate medical care. For example, a practitioner may issue three 30-day Schedule II prescriptions to cover a 90-day supply or he/she may issue nine prescriptions for the same

Schedule II controlled substance, each for a ten-day supply, having the combined effect of a 90-day supply. In light of the ongoing efforts to reduce the misuse and abuse of opioid medications, some of the regulations are currently under review.

39. Can a physician write prescriptions for more than one Schedule II drug on a single form? Can I use the form for all my prescriptions?

Yes, so long as physicians follow the rules in response to Question 37. More than one Schedule II drug may be prescribed on a single form and the forms may be used for all prescriptions. For more information, visit the Board of Pharmacy website at www.pharmacy.ca.gov/licensees/index.shtml.

40. Is post-dating of multiple prescriptions allowed?

No. Federal regulations have always required that all prescriptions for controlled substances "be dated as of, and signed on, the day when issued." (21 C.F.R. §1306.05(a).)

41. Can a physician refill prescriptions for Schedule III, IV, and V controlled substances?

Prescriptions for Schedule III and IV controlled substances may not be refilled more than five (5) times, nor in an amount that, taken together, exceed a one hundred and twenty (120) day supply. There is no limitation on refills for Schedule V drugs. However, any prescription for a controlled substance is invalid after six (6) months. (Health & Safety Code §11200.)

42. Why are some pharmacies suddenly refusing to refill prescriptions by fax forms?

In a May 2012 letter, the DEA attempted to clarify a pharmacy's responsibilities under existing regulations for the proper prescribing and dispensing of controlled substances. Unfortunately, this "clarification" caused significant confusion for pharmacies and physician offices.

Pharmacies have long faxed "reminder letters" or prescription refill requests to notify prescribers that a previously authorized controlled substance prescription is about to expire. CMA received inquiries from physicians who reported that pharmacies were no longer faxing prescription refills for controlled substances and in some cases that physicians are no longer allowed to fax prescriptions for controlled substances "because of a new DEA regulation."

The DEA has confirmed that there are no new laws or regulations on controlled substance prescription requirements. Rather, the DEA clarified in its letter that "a pharmacy may not initiate a reminder letter to a prescribing practitioner that provides a partially or fully pre-populated [prescription] form" because a controlled substance prescription can only be authorized after the prescriber determines that it is for a legitimate medical purpose. (21 C.F.R. §1306.04.)

Although some pharmacies may be misinterpreting the DEA's statement to be more restrictive than intended, pharmacies are not prohibited from contacting physicians by fax or phone to have the physician authorize a refill of a controlled substances prescription. The clarification was intended to emphasize that the reminder letter cannot contain a pre-populated prescription form. Some pharmacies will need to change how they handle prescription refill requests to ensure that they are in full compliance with the law.

In 2011, CMA's House of Delegates adopted policy to prevent the practice of automatic refills by pharmacies. CMA policy "urges pharmacists, when questioning a patient's prescription, to contact the prescribing physician to clarify the intent of prescription orders." (HOD E-3-11.)

NARCOTIC TREATMENT

43. Are there separate requirements for practitioners who dispense narcotics for addiction treatment?

Under 21 U.S.C. §823(g), except as provided below, physicians who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment must obtain annually a separate registration for that purpose. The Attorney General must register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both) if:

- The applicant is determined to be qualified by the Secretary of HHS to engage in the treatment with respect to which registration is sought;
- The Attorney General determines the applicant will comply with standards established by the Attorney General respecting: i) security of stocks of narcotic drugs for such treatment; and ii) the maintenance of records (in accordance with 21 U.S.C.S. §827) on such drugs; and

- The Secretary of HHS determines the applicant will comply with standards established by the Secretary of HHS (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(21 U.S.C. §823(g).)

The registration requirements cited above are waived in the case of the dispensing (including the prescribing), by a physician, of narcotic drugs in Schedule III, IV, or V or combinations of such drugs for maintenance or detoxification treatment if the physician submits to the Secretary a notification of the intent of the physician to begin dispensing the drugs or combinations for such purpose. The notification must contain the following certifications:

- The practitioner is a qualifying physician, as defined.
- With respect to patients to whom the physician will provide such drugs or combinations of drugs, the physician has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary:

  I) All drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

  II) Appropriate counseling and other appropriate ancillary services.
- The total number of such patients of the physician at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the physician submitted the initial notification, the physician submits a second notification to the Secretary of the need and intent of the physician to treat up to 100 patients.

The Secretary may by regulation change such applicable number and may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting. (21 U.S.C. §823(g)(2)(B).)

Further waiver requirements include:

- The notification is in writing and states the name of the practitioner;
- The notification identifies the registration issued for the practitioner;
- If the physician is a member of a group practice, the notification states the names of the other physicians in the practice and identifies the registrations issued for the other physicians.

(21 U.S.C. §823(g)(2)(D).) A "waiver notification" may be found on the Substance Abuse and Mental Health Services Administration (SAMHSA) website at www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/waiver-form-sma-167.pdf. For more information on medication assisted treatment (MAT), visit the SAMHSA website at www.samhsa.gov/medication-assisted-treatment/treatment#otps.

44. How can a physician qualify for a waiver?

To qualify for a waiver a licensed physician must meet any one or more of the following criteria:

- The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- The physician holds an addiction certification from the American Society of Addiction Medicine.
- The physician holds a board certification in addiction medicine from the American Osteopathic Association.
- The physician has, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate. Such training must include:
  - Opioid maintenance and detoxification;
  - Appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
  - Initial and periodic patient assessments (including substance use monitoring);
  - Individualized treatment planning, overdose reversal, and relapse prevention;

- Counseling and recovery support services;
- Staffing roles and considerations;
- Diversion control; and
- Other best practices, as identified by the Secretary

- The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.
- The physician has such other training or experience as the state medical licensing board (of the state in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients.
- The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients. Any such criteria are effective only for three years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate.

Other qualifying practitioners include nurse practitioners and physician assistants until October 21, 2021. These individuals must complete 24 hours of training to be eligible for a waiver to prescribe and must be supervised by or work in collaboration with a qualifying physician if required by state law. (21 U.S.C. §823(g).) For more information on the scope of practice of physician assistants, *see* CMA ON-CALL document #3007, "Physician Assistants." For more information on the scope of practice for nurse midwives and nurse practitioners, *see* CMA ON-CALL document #3005, "Nurses."

45. Are there specific federal record keeping requirements for office-based opioid therapy?

DEA record keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. Physicians must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment (21 C.F.R. §1304.03(c)). Many physicians comply with this requirement by creating a log that identifies the patient (an ID number may be used instead of name), the name of the drug prescribed or dispensed, as well as the strength and quantity and date of issuance or dispensing. Some physicians comply with this requirement by keeping a copy of the prescription in the patient record.

In some cases, patients return to the prescribing physician with their filled Subutex or Suboxone or approved generic versions of these products prescriptions so that the physician can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, physicians must not store and dispense controlled substances that are the result of filled patient prescriptions.

46. Can a physician provide medication-assisted opioid addiction treatment under California law?

Yes, the law specifically authorizes a physician who is registered with the federal Attorney General pursuant to 21 U.S.C. §823(g) to provide such treatment for addiction. (Health & Safety Code §11223.)

47. Are there any immunities for physicians during addiction treatment?

Yes, the law provides a limited immunity from civil and criminal liability to a licensed health care provider who is authorized by law to prescribe an opioid antagonist, if acting with reasonable care and the opioid antagonist is subsequently dispensed or distributed to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. (Civil Code §1714.22(b).) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may also issue standing orders for the *distribution* of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. (Civil Code §1714.22(c).) Similarly, a licensed health care provider may issue standing orders for the *administration* of an opioid antagonist to a person at risk of an opioid-related overdose to a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose. (*Id.*) A person who is prescribed or possesses an opioid antagonist pursuant to a standing

order must receive the training provided by an opioid overdose prevention and treatment training program defined below. (Civil Code §1714.22(d).) However, a person who is prescribed an opioid antagonist directly from a licensed prescriber is not required to receive such training. (*Id.*) This immunity applies to the licensed health care provider even when the opioid antagonist is administered by and to someone other than the person to whom it is prescribed as long as the appropriate training was received where required. (Civil Code §1714.22(e)–(f).)

For the purposes of this law, an "opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of an opioid overdose. An "opioid overdose prevention and treatment training program" or "program" means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:

- The causes of an opiate overdose.
- Mouth to mouth resuscitation.
- How to contact appropriate emergency medical services.
- How to administer an opioid antagonist.

(Civil Code §1714.22(a)(2).)

48. What is the MBC's advice about treating addiction?

The Medical Board has joined forces with the California Department of Public Health, the Pharmacy Board, and many other State agencies and stakeholders to expand prevention and treatment strategies as well as to decrease the amount of prescription drug misuse. For more information on these efforts, *see* www.mbc.ca.gov/Licensees/Prescribing/OverdosePrevention/. Further, the Board released the updated *Guidelines for Prescribing Controlled Substances for Pain* in November 2014, available at www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf. For more information on pain management and appropriate prescribing of opioids, *see* CMA ON-CALL document #3210, "Pain Management."

ABILITY OF FEDERAL CONTROLLED SUBSTANCE LAW TO REGULATE MEDICINE

49. Does the federal Controlled Substance Act (CSA) regulate the practice of medicine?

In *Gonzales v. Oregon* (2006) 546 U.S. 243, the U.S. Supreme Court ruled as invalid an order by the U.S. Attorney General that banned the prescribing, dispensing and/or administering of federally controlled substances to assist suicide. The order stated that drugs regulated under the federal act could not be dispensed to terminate lives because assisted suicide does not serve a "legitimate medical purpose." In striking down the order, the Court stated that the determination of what constitutes a legitimate medical practice or purpose has traditionally been left to the individual states. State statute, state medical boards, and state regulators control the practice of medicine. The CSA was never intended, and the U.S. DOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board. To allow an attorney general to determine the legitimacy of a particular medical practice without a specific congressional grant of such authority would be inconsistent with Congress' intent in passing the CSA.

We hope this information is helpful to you. CMA is unable to provide specific legal advice to each of its more than 44,000 members. For a legal opinion concerning a specific situation, consult your personal attorney.

For information on other legal issues, use CMA's online health law library, CMA ON-CALL, or refer to the *California Physician's Legal Handbook* (CPLH). CPLH is a comprehensive health law and medical practice resource containing legal information including current laws, regulations and court decisions that affect the practice of medicine in California. Written and updated by CMA's Center for Legal Affairs, CPLH is available in an eight-volume, softbound print format, or as an online subscription to www.cplh.org. To order your copy, call (800) 882-1262 or visit CMA's website at www.cmadocs.org.