

CMA ON-CALL: The California Medical Association's Information-On-Demand Service
Online: www.cmanet.org

Document # 0509

CMA Legal Counsel

The New California Security Prescription Law

November 2004

This document summarizes the requirements of the new California security prescription law (SB 151) and answers questions about how physicians prescribe controlled substances both before and after January 1, 2005, when triplicates are no longer valid and security prescription forms must be used for all controlled substances.

For a more detailed discussion of the laws pertaining to the prescribing and dispensing of controlled substances, *see* **CMA ON-CALL document #0508, “Controlled Substances: Prescribing and Dispensing.”** CMA members have free access to this and other documents from CMA’s vast medico-legal and reimbursement library by logging onto CMA’s website, www.cmanet.org. Non-CMA members can access these documents for \$2 per page at www.cmanet.org/bookstore/cmaoncall.cfm.

OVERVIEW OF THE NEW LAW

1. What is the new California security prescription law? What has changed with this new law?

In 2003, the legislature passed SB 151, which eliminates the use of triplicates as of January 1, 2005 and, instead requires the use of security prescription forms for **all controlled substances—Schedules II, III, IV and V.**

The new security prescription forms must be supplied by printing companies approved by the Department of Justice and the Board of Pharmacy and must include specific security features. *See* Question 3.

The following is a list of the most significant changes to the law related to the prescribing of controlled substances:

- Eliminates triplicates. (Physicians will no longer be required to submit duplicate copies of prescriptions to the pharmacist and Department of Justice.)
- Requires new security prescribing forms for **all** written controlled substance prescriptions—**Schedules II, III, IV and V**, effective January 1, 2005.
- All controlled substance prescriptions (including Schedule II) are valid for six-months. (This new law eliminates the 14-day restriction on Schedule II triplicate forms.)
- Retains the terminal illness exemption for the prescription of Schedule II drugs. (For a detailed discussion of this exemption, *see* **CMA ON-CALL document #0508, “Controlled Substances: Prescribing and Dispensing.”**)

Due to the complexity of this new law and its impact on prescribing practices, the law was phased in during 2004. Effective January 1, 2005, all aspects of this new law (SB 151) will be in place and triplicate prescriptions will no longer be valid.

© California Medical Association 1995-2005
This CMA ON-CALL document is brought to you through the generous support of
physician-sponsored professional liability companies
Medical Insurance Exchange of California, NORCAL Mutual Insurance Company,
and The SCPIE Companies, and by The Doctors Company.

2. Where do I find a current list of controlled substances?

The identity of California controlled substance standards and drugs is codified (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 website at www.deadiversion.usdoj.gov/schedules.

SECURITY PRINTERS

3. How do I find an approved security printer? Has CMA partnered with any security printer to offer a discounted price for CMA members?

On October 29, 2004, the State Board of Pharmacy and the Department of Justice approved RxSecurity, CMA’s sponsored security prescription form, on its list of approved security printers. RxSecurity has been printing secure tamper proof pads for other jurisdictions since 1989 and has an automated authentication process for Medical Board of California and Drug Enforcement Agency licensure. More importantly, Rx’s pricing is superior to most of the publicly posted pricing of other security printers approved by the state, especially for one-part (single prescription) pads. CMA members receive a 15% discount from Rx Security’s already low pricing schedule. Non-CMA members will also find their pricing attractive when compared to other approved printers’ public pricing. Special pricing is also available for hospitals, clinics and other high-volume purchasers.

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

The following is the RxSecurity price list, guaranteed through July 1, 2005:

RxSECURITY	10 Pads	20 Pads	40 Pads	60 Pads	80 Pads	120 Pads	200 Pads	500 Pads	1000 Pads
1-Part Pads (Per Pad)	\$5.60	\$3.60	\$3.20		\$2.80		\$2.50	\$2.30	\$2.20
Per Script	\$0.0560	\$0.0360	\$0.0320		\$0.0280		\$0.0250	\$0.0230	\$0.0220
CMA Member Pricing	\$4.76	\$3.06	\$2.72		\$2.38		\$2.12	\$1.96	\$1.87
	\$0.0476	\$0.0306	\$0.0272		\$0.0238		\$0.0212	\$0.0196	\$0.0187
2-Part Pads (Per Pad)		\$5.40	\$5.10		\$4.80		\$4.50	\$4.25	\$4.00
Per Script		\$0.1080	\$0.1020		\$0.0960		\$0.0900	\$0.0850	\$0.0800
CMA Member Pricing		\$4.59	\$4.34		\$4.08		\$3.82	\$3.62	\$3.40
		\$0.0918	\$0.0868		\$0.0816		\$0.0764	\$0.0724	\$0.0680

RxSecurity pricing is guaranteed through July 1, 2005. RxSecurity pricing is all-inclusive and includes shipping. Orders taken on-line at www.rxsecurity.com/cma.php or an order form may be downloaded and faxed in to RxSecurity at 1-866-667-9723.

4. 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 Board of Pharmacy's website, www.pharmacy.ca.gov/app_sec_printers.htm.

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 Board of Pharmacy website www.pharmacy.ca.gov/app_sec_printers.htm, 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 Medical Board of California. (Health & Safety Code §11162.6.)*

ORAL, FAX AND ELECTRONIC PRESCRIBING OF SCHEDULE II DRUGS

5. Does the new law allow me to orally prescribe Schedule II drugs or fax or electronically send them to the pharmacy?

With some exceptions, prescription orders for drugs classified in Schedule II may not be faxed, emailed or orally prescribed, but must be written in the handwriting of the prescriber (but see question 15) on the official tamper-resistant prescription form. (Health & Safety Code §11164.) State and federal law differ as to allowed exceptions, but generally the exception to this rule relates to prescriptions filled on an emergency basis, for a patient in a skilled nursing facility, intermediate care facility or a hospice patient, and if the original is presented before dispensing. For a summary of these exceptions, please see question 16 below. For a more detailed discussion of the circumstances under which Schedule II drugs can be prescribed other than in written form, see **CMA ON-CALL document #0508, "Controlled Substances: Prescribing and Dispensing."**

USE OF SECURITY FORMS FOR SCHEDULE III, IV AND V DRUGS

6. When do I have to start using the security forms for Schedule III-V prescriptions?

Effective January 1, 2005, all written controlled substance prescriptions for Schedules III-V must be on the tamper-resistant prescription forms and use of the regular prescription forms for written prescriptions are no longer valid.

ORAL, FAX AND ELECTRONIC PRESCRIBING OF SCHEDULE III, IV AND V CONTROLLED SUBSTANCES

7. Can I fax or orally prescribe Schedule III, IV or V controlled substances? What about electronic prescribing of Schedule III, IV or V 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(c); 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. (Health & Safety Code §11164(c).) An oral prescription must be promptly reduced to writing by a pharmacist.

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(c).)

On its face, the comparable federal regulation is silent on the issue of electronically prescribing of Schedule III, IV and V drugs. However, the U.S. Department of Justice Drug Enforcement Administration has issued a written interpretation of the regulation which states that it will treat electronically created and transmitted prescriptions, either directly in a computer or via a facsimile machine, as oral prescriptions. The DEA's interpretation is set forth in a letter dated September 28, 2001 from Patricia M. Good, Chief of the Liaison and Policy Section, Office of Diversion Control for the U.S. Department of Justice, Drug Enforcement Agency.

USE AND DESTRUCTION OF TRIPLICATE FORMS

8. When do I have to stop using triplicates?

December 31, 2004 is the last day physicians may write a prescription on a triplicate form **and** the last day triplicate prescriptions are valid and presentable to a pharmacist for filling. Therefore, if physicians are still using triplicates as of that date, they must advise their patients to **immediately** fill the prescriptions before January 1, 2005. To ensure that patients are able to refill their prescriptions, the Department of Justice and CMA recommend that physicians begin to use the approved security prescription forms as soon as possible, as such prescriptions are now valid for six months from the time they are written.

9. Can I still order triplicate forms from the Department of Justice?

No. The deadline for ordering such prescriptions was November 1, 2004. (Health & Safety Code §11161.)

10. I ordered triplicates before the November 1, 2004 cut-off and haven't received them. What do I do?

During the implementation of SB 151, physicians were allowed to order triplicates until November 1, 2004 and were allowed to use triplicate forms through December 31, 2004. However, physicians may have experienced some delay in obtaining a supply of triplicates from the Department of Justice. Therefore, some physicians have no access to triplicates or new security forms. The Department of Justice recommends that physicians who have run out of the authorized forms, despite good faith efforts to get them, make use of Health & Safety Code §11167, which allows for any written order signed and dated by the prescriber under emergency circumstances. This law requires that the prescriber forward to the pharmacist an authorized prescription form provided or postmarked by the seventh day following the transmission of the initial order. The DOJ has agreed not to pursue enforcement efforts for physicians who

cannot comply with the seven-day rule, if they have documented their situation. The DOJ will not investigate physicians for this technical non-compliance until it is clear to DOJ staff that physicians can fully comply with the law.

With the increased availability of security printers, particularly CMA's new security printer partner, RxSecurity, physicians should have no difficulty obtaining approved forms for the prescription of controlled substances.

Physicians who have not received triplicates that they ordered and paid for before November 1, 2004, may contact the Department of Justice at (916) 319-9062.

11. What do I do with my unused triplicate forms after January 1, 2005?

The new prescription law does not mandate a specific procedure for retiring triplicate prescription forms after January 1, 2005, when triplicate prescription forms will no longer be valid. However, the California Department of Justice (DOJ) has requested that all unused triplicate prescriptions be returned to the Department of Justice Triplicate Prescription Program, 4949 Broadway, Sacramento, CA 94820, by **certified or registered mail** for destruction by the DOJ.

The DOJ believes that the potential for theft and misuse of triplicate prescription forms is still a concern and that triplicates still have a significant "street value" whether or not a physician signs the prescription. Therefore, the DOJ requests that physicians return the triplicate forms to them by certified or registered mail to ensure proper receipt and to allow the Department of Justice to log out all triplicate forms from its system.

Under no circumstances is it appropriate for physicians to simply dispose of triplicate prescription forms by throwing them in the garbage. If a physician elects to destroy unused triplicate forms (rather than return them to the DOJ) the only acceptable methods of destruction are shredding or incineration. However, physicians should be aware that if the triplicate forms are not returned to the DOJ there will be no voiding of the triplicate form number from the DOJ tracking system. Therefore, CMA recommends that physicians return the triplicate prescription forms to DOJ to remove any potential liability on behalf of the physician. Physicians should retain a copy of their receipt of mailing for their records.

MULTIPLE PRESCRIPTIONS AND REFILLS OF CONTROLLED SUBSTANCES

12. I am confused. 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.) The new law provides that Schedule II prescriptions are valid for 6 months from the date of issuance by the prescriber. (Health & Safety Code §11200.)

The new tamper-resistant 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," and the total number of drugs are written in the designated space on the security prescription form. (Health & Safety Code §11162.1(a)(8).)

Alternatively, physicians may elect to prescribe only one controlled substance per form. In that case, the law requires the prescription form to have the pre-printed language, "Prescription is void if more than one controlled substance is written per blank."

13. Can I 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 12. More than one Schedule II drug may be prescribed on a single form and the forms may be used for all prescriptions.

14. Can I 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 times, nor in an amount, for refills of that prescription taken together, exceeding a 120-day supply. (Health & Safety Code §11200.) There is no limitation on refills for Schedule V drugs.

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. (Health & Safety Code §11164(a)(1).)

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

Other than the signature and date by the prescriber in ink, prescriptions for controlled substances must contain the following:

- The prescriber's address and telephone number;
- The name of the person for whom the controlled substance is prescribed;
- The name, quantity, strength and directions for use of the controlled substance prescribed;
- 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).)

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?	E-Mail Allowed?	Oral Prescribing?
Schedule II	Yes , as of January 1, 2005 (Use of triplicates ok through December 31, 2004)	No , except: 1) In an emergency , triplicate (until 1/05) or security form must be sent (postmarked) within 7 days (Health & Safety Code §11167.21); or 2) If patient is in SNF, intermediate care facility, hospice if pharmacist reduces to writing (Health & Safety Code §11167.5, 21 C.F.R. §1306.11(f)(g).) 3) Fax ok if original prescription is presented before dispensing (21 C.F.R. §1306.11(a).)	No (Federal law pre-empts state law.) State law would allow for emergency, long term care (LTC) and hospice (Health & Safety Code §11167.5.)	If an emergency with special qualifications (21 C.F.R. §1306.11(d); Health & Safety Code §11167.) NOTE: California law would allow oral prescribing for LTC and hospice and emergency, but federal law pre-empts Health & Safety Code §11167.5.
Schedule III—V	If written: Yes (effective 1-1-05); 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.)	Under certain circumstances per Federal law (21 C.F.R. §1306.21), DEA treats electronic prescription as an oral prescription. Yes under California law (Health & Safety Code §11164(c),) but federal law preempts state law.	Yes (Health & Safety Code §11164(c); 21 C.F.R. §1306.21.)

August 12, 2004

GROUP PRACTICES

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

No. The new tamper-resistant security prescription forms may be pre-printed with more than one 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.

INSTITUTIONAL PRESCRIPTION FORMS FOR LICENSED HEALTH FACILITIES

18. I am employed by a hospital. Do I have to use my own pre-printed prescriber information?

A prescriber designated by a licensed health care facility (a general 24-hour acute care hospital or acute psychiatric hospital, licensed pursuant to Health & Safety Code §1250), may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information of each prescribing physician. 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 prescribers shall 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. These records must be maintained in the health facility for three years.

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.)

We hope this information is helpful to you. CMA is unable to provide specific legal advice to each of its more than 30,000 members. For a legal opinion concerning a specific situation, consult your personal attorney.

For information on other legal issues, use CMA ON-CALL, or refer to CMA's California Physician's Legal Handbook. This book contains legal information on a variety of subjects of everyday importance to practicing physicians. Written by CMA's Legal Department, the book is available on a fully searchable CD-ROM, or in a six-volume, softbound format. To order your copy, call (800) 882-1262 or visit CMA's Bookstore at www.cmanet.org.