

CA CONTROLLED SUBSTANCE RX REFERENCE GUIDE

December 2005

This FREE guide is a resource noting requirements and clarifications about California controlled substance prescriptions for prescribers and pharmacists. As questions and issues arise and are answered, the answers are published in each update.

*Please forward to all California prescribers, pharmacists,
and healthcare facilities who may benefit from it.*

NEW

Preprinted Prescriptions Save Time

Many prescribers write the same set of prescriptions regularly and save time when these are preprinted on their Rx forms. A new form is available on which you may preprint or handwrite up to six (6) prescriptions.

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The image shows a sample of a California Controlled Substance Prescription form. At the top, it identifies the prescriber as ABC Medical Group Practice, 1234 Main Street, Suite 100, Sacramento, CA 95825, with phone (916) 441-1234 and fax (916) 441-5678. The form is for Patient Name [Redacted] and Address [Redacted]. It features a grid for prescribing controlled substances, with columns for the drug name and checkboxes for various quantities and durations. The grid is organized into four quadrants: KX, L, S, M, U, D, T, B, N, P, O, Q, R, V, W, X, Y, Z. The bottom of the form includes a section for 'There are 6(6) prescriptions on this form. There is one for controlled substances.' and a footer with the text 'FORM 10/05/05' and '© 2005 Pro Document Solutions and International Security Products (ISP)'. The form is marked as 'Approved for Controlled Substance Prescriptions'.

REQUIREMENTS BY PRESCRIBER TYPE

Who needs these forms?

Dentists, Nurse Practitioners & Certified Nurse Midwives, Optometrists, Osteopathic Physicians, Physician Assistants, Physicians & Surgeons, Podiatrists, Veterinarians, Pharmacists as a part of multidisciplinary healthcare group, and Naturopathic Doctors.

Who can appear on them?

Every prescriber appearing on a controlled substance prescription blank MUST have an active DEA controlled substance registration number. Without it, they cannot be on the form.

What must be preprinted?

- 1) **All Prescribers** The security printer must preprint the prescriber's name, category of licensure (i.e. MD, DDS, NPF, NMF, OD, PA, etc.), California license number, and DEA registration number. There is no statute requiring that the name be an exact match of the DEA registration or practice license name, however, Sections 11173 & 11174 require the use of a name that can be properly validated. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf page 164) In addition, the prescriber's address and phone number are required to be on the form to be a valid prescription; therefore, the board recommends this information be preprinted as well. However, locum tenens physicians or other physicians that substitute at various facilities may opt not to preprint the address and phone number, but instead stamp or handwrite this information at the time the prescription is written. If address and phone number are not preprinted, preprinting underscores will show that an address and phone number need to

Authorized Distributor of CA Security Prescriptions for Pro Document Solutions and International Security Products (ISP)

be added to make the prescription valid. **NOTE:** Adobe Acrobat Reader is required to view online Pharmacy Lawbook. FREE download link at www.cpr4rx.com.

- 2) **All Prescribers** License numbers printed on the form should always include its license type, usually identified by 1 to 3 prefix letters, but sometimes it is a letter within the license number. Separate from that is the category of licensure, which is usually the prescriber's professional credentials. For example, John Jones, M.D. and his license number A12345; the license type (A) and category of licensure (M.D.) are two separate things.
- 3) **Nurse Practitioners & Nurse Midwives** need to preprint their furnishing numbers as NPF or NMF followed by the number. This is the number that identifies whether they can write C-II prescriptions as part of their license verification listing under Midwives and Registered Nursing at [http://www2.dca.ca.gov/pls/wllpub/wllquery\\$.startup](http://www2.dca.ca.gov/pls/wllpub/wllquery$.startup).
- 4) **Physician Assistants** need to preprint the information required in item 1) for both PA and supervising physician(s).
- 5) **Pharmacists** who are part of a multidisciplinary healthcare group have no additional requirements for their prescription forms but may want space on the form to record the supervising physician.
- 6) **Institutional Forms** are only for healthcare facilities licensed by the Dept. of Health Services under Section 1250. The licensed facility's name, address, phone, and DHS license number as well as the designated prescriber's name, category of licensure, license number and DEA number are required to be preprinted on the form. Designated prescribers are responsible for ordering, distributing, and keeping a record of those who possess and use these forms. This record must be maintained for three years. The designated prescriber may delegate these tasks but remains the responsible party.

FEATURES

True Watermark Security Paper – Though not a new feature for us, it bears repeating. Those willing to go to the trouble can easily replicate all of the security features required by law. For added safety at no extra charge, all of our prescriptions are printed on paper with visible fibers and a true watermark that reads Verify First and SAFE and shows a padlock graphic. To view these images, look through the paper at a strong light. This paper has a secure chain of custody from the time it is made until the user receives it. Because this paper is unavailable except to selected security print manufacturers, it is the most secure protection and also easiest to check.

Logo on Form – Centered single prescriber forms have an online logo upload function that allows you to add your logo to your form if desired. Custom forms can also include your logo.

Customize Without a Custom Form - Forms have a variety of personalization options. Users now have the ability to add information into new areas on their form to customize without the need for a custom form.

Script Sponsor Text Areas – Certain business entities may want to provide prescription forms to prescribers for various reasons. The new customization features provide space to print sponsor messages.

Free Text Areas - These spaces can contain sponsor messages, custom notes or check boxes to suit your specific needs or can be left blank.

Preprint Rx Area – This space can be left blank or you can preprint prescriptions and instructions on every Rx form for drugs that you prescribe on an extremely regular basis. Some or all prescription info may be preprinted with the remainder handwritten by the prescriber or his/her agents. Prescribers are required to sign and date prescriptions in ink. See Q&A below about the requirements for [Preprinting the Prescription Itself](#).

Special Notes Near Signature Area – This space can be left blank or completed to suit your needs.

Customer Form ID# Area – Many organizations have internal form ID numbers that print on their forms for easy identification. This space is provided to print those numbers or may be left blank.

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FORM CHOICES for Controlled Substances

Single Sheet Preprinted 6 Rx Form – This 8 ½ x 11 sheet provides space for up to 6 preprinted and/or handwritten prescriptions. It saves time for those who regularly prescribe the same suite of drugs.

Regular Controlled Substance Rx Forms – Single prescriber with one address with your choice of left side or centered prescriber information; Multiple prescribers & addresses up to a total of 9; Either 1 or 3 prescribing spaces per blank for all designs. 1-, 2- or 3-part pads and 2- or 3-part pads with covers that separate form sets when writing.

Computer Forms for Laser Printers – Single prescriber with one address or up to 6 locations and 28 prescribers with preprint at either top or bottom; Single prescriber for Windent software; Institutional forms for up to 9 locations preprinted at either top or bottom; Custom forms designed for your computer/software.

Pharmacy Forms – Telephone Rx forms & Skilled Nursing Facility Rx forms have a place to obtain the required signature. Designed for internal and external use. Your choice of heading.

Institutional Forms – Single address with 1 or 3 Rx spaces per form; Multiple locations up to 6 per form with 1 or 3 Rx spaces per blank; multiple locations up to 9 per form with 1 or 3 Rx spaces per form. (total of 6 design styles) 1-, 2-, or 3-part pads and 2- or 3-part pads with covers.

Custom Forms – Custom developed per your instructions to meet your needs. 1-, 2-, or 3-part pads and 2- or 3-part pads with covers that separate form sets when writing.

NEW

CONTROLLED SUBSTANCE FACTS

Effective January 1, 2005 all written prescriptions for Schedule II-V controlled substances must be on tamper-resistant prescription forms. These forms can be used to prescribe any drug or device. Prescribers must have a valid DEA number in order to obtain or appear on the controlled-substance prescription forms.

The state-approved security printer must preprint the name, category of licensure, license number and DEA number of the prescriber on the form. http://www.pharmacy.ca.gov/consumers/controlled_sub.htm
Schedule II prescriptions are never refillable and can only be written on tamper-resistant prescription blanks unless 11159.2 exempt.

Controlled and non-controlled substances may be written on the same multiple-drug tamper-resistant prescription form. More than one Schedule II prescription can be written on the same blank, however they must be for different drugs.

Schedule II prescriptions for terminally ill patients may continue to be written on regular prescription blanks with the terminal illness "Exemption 11159.2" noted. This exemption is for Schedule II drugs only.

Schedule III-V written prescriptions for terminally ill patients must be written on the new forms.

Prescribers or their agents may transmit Schedule III-V prescriptions by telephone as in the past.

Prescribers or their agents may transmit written Schedule III-V prescriptions on regular prescription blanks via fax. Prescribers should ensure that all fax-transmitted prescriptions are date- and time-stamped and show the originating header of the fax so the receiving pharmacy can authenticate the transmission.

Prescribers are encouraged to phone or fax Schedule III-V prescriptions if they have not yet received their new prescription forms or if they run out of the forms temporarily. However, in some circumstances phoning or faxing may not be a viable option, therefore pharmacies may receive a Schedule III-V prescription with the notation "11167 exemption". The Board recommends that pharmacists fill these prescriptions by contacting the prescriber to verify and converting the prescription to a telephone order.

Schedule III-V prescriptions may also be transmitted by telephone, fax, or electronically transmitted prescriptions (i.e. Relay Health, Auto Fax etc. with secure digital electronic signature of the prescriber).

For Schedule III-V prescriptions, if the patient can "touch" the prescription form at any point of the process from the prescriber to the pharmacy, it must be written on a controlled-substance tamper-resistant Rx form.

All controlled-substance prescriptions for **Schedules II-V are valid for 6 months** from the date written

unless the prescriber notes an earlier expiration date on the blank. Consequently, Schedule II medications written on either the new tamper-resistant prescription form or an old triplicate prescription form – OR – Schedule III-V medications on a regular plain prescription form that was written before January 1, 2005 can be filled as long as it is before the expiration date. (Health & Safety Code 11166)

The tamper-resistant prescription forms themselves are not tracked, but all Schedule II and Schedule III controlled substances are electronically reported to CURES, the Controlled-Substance Utilization Review and Evaluation System, a joint effort by the California Department of Justice and Board of Pharmacy. Multiple prescribers can be on the same tamper-resistant prescription form with check boxes to note which prescriber is writing the prescription.

“Prescription is void if more than one controlled substance is written per blank” – OR – “Prescription is void if the number of drugs prescribed is not noted” must be printed at the bottom of the new prescription blanks. Forms with the latter statement must include a space to write the number of drugs prescribed.

For forms that allow for more than one prescription, there is no stated limit of how many drugs can be written on the same blank. The required security features below, however, must be present for each drug:

- Quantity check boxes 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over (to match actual quantity)
- A place to indicate units of measure when the drugs prescribed are not in pill or tablet form
- A check box indicating the prescriber’s order not to substitute
- A place to indicate the number of refills authorized. The new forms are designed to support all prescriptions and Schedules. Schedule II drugs, as always, cannot be refilled.

Other required security features are:

- A background pattern that shows “void” when copied or scanned
- White printing (artificial watermark) of “California Security Prescription” on the back
- Tamper-evident chemical sensitivity
- A “thermo-chromic” feature printed in ink that changes color with changes in temperature
- Microprinting or reverse print that appears as a line or smudge or disappears when copied
- A batch or job number for each set of forms produced
- A sequential number always starting with the numeral 1 for each job produced

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Q&A for CONTROLLED SUBSTANCES

California Board of Pharmacy Prescriber and Dispenser Q&A and Information

http://www.pharmacy.ca.gov/consumers/prescribe_dispense.htm

Preprinting the Prescription Itself

Question: Can controlled substance medications be preprinted onto a controlled substance prescription form?

Answer: Only if done the right way. California Code of Regulations Section 1717.3(a) PROHIBITS preprinted multiple check-off prescription blanks for any controlled substance. CA Health and Safety Code 11164(a) (1) requires prescribers to sign and date controlled substance prescriptions in ink but allows all other information to be completed by the prescriber's agent(s). (See pages 102 and 161 respectively at http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.) A preprinted controlled substance prescription is legal if it is preprinted for a single prescription, and therefore has no check-off boxes, and if it complies with all legal requirements for prescribing a controlled substance. Any information not preprinted would need to be written by the prescriber or his/her agent(s). Non-controlled substance prescriptions can be preprinted with multiple check-off boxes. A list of all controlled substances and schedules can be found at <http://www.deadiversion.usdoj.gov/schedules>.

Local Printer

Question: Can my local printer produce controlled substance prescription forms for me?

Answer: Only state-approved security printers are allowed to produce these forms.

Advertising on Rx Forms

Question: Can a pharmaceutical manufacturer or other entity place an order for prescription pads on behalf of a prescriber and pay for it? If so, can they be listed on the prescription form for advertising purposes?

Answer: Policy for payment of the new controlled substance prescription forms is up to the approved security printer. The forms cannot be shipped to the third party that is paying for the order. The prescription forms must be delivered to the prescriber's address and a signature upon delivery is required. It is acceptable to incorporate advertising information on the form and/or within a pad of forms.

Computer-generated Prescription Forms

Question: Can prescribers use blank security stock to print CA controlled substance prescriptions on the computer printer in their office?

Answer: No. The security printer is required to preprint the required information on approved CA controlled substance prescription blanks. The prescriber's name, etc. can be printed by the user's software to identify the prescriber if more than one prescriber is listed on the form but this is in addition to the required preprinted information and security features.

SNF, Intermediate Care, and Hospice C-II Oral and Fax Prescriptions

Question: I'm a pharmacist in northern California in a retail setting and we service Hospice patients. MDs call in medications all the time and quite often they involve Class II drugs. If these patients are classified as 11159.2 patients, can the MD call in these meds or do they have to fax the written RX to us so we have a hard copy for the files?

Answer: Exemption 11159.2 for terminal illness does not apply for phone or fax prescriptions; it allows a Class II to be written on a regular form for terminally ill patients. Section 11167.5, found on page 164 at

http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf, allows for oral or electronically transmitted prescriptions for Class IIs for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice. I recommend reading the entire section for the specific requirements. Drugs delivered pursuant to Section 11167.5 require the specific information listed, including the pharmacist endorsement and the signature of the person receiving the drugs, to be recorded on the original prescription. We have developed a form for this purpose, which can be seen on the following pages.

Emergency Department Dispensing When Pharmacy is Closed

Question: Regarding schedule III-V medications... our ED physicians dispense a "six-pack" of Vicodin tabs directly to their patients. They do not fill out a prescription. The dispensation is charted in the medical record. Are they legally required to fill out a tamper-resistant prescription form?

Answer: Section 4068 of the Business and Professions Code is noted below:

4068. (a) Notwithstanding any provision of this chapter, a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply:

- (1) The hospital pharmacy is closed and there is no pharmacist available in the hospital.
 - (2) The dangerous drug is acquired by the hospital pharmacy.
 - (3) The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
 - (4) The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.
 - (5) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.
 - (6) The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.
 - (7) The prescriber shall ensure that the label on the drug contains all the information required by Section 4076.
- (b) The prescriber shall be responsible for any error or omission related to the drugs dispensed.

In other words, the medication dispensed is purchased by the pharmacy and dispensed as six packs through the ER under the conditions stated above. The medication must be labeled appropriately (4076), proper information about the drug provided to the patient (4074) and the dispensing information provided to the pharmacy when it opens. The pharmacy is required to report C-II & C-III meds dispensed to the Dept. of Justice CURES Program, including the 6-packs dispensed from the ER. They do not have to complete a controlled substance Rx form but all of the same information must be provided to the pharmacy so they can report the dispensing info to CURES.

Sale of Scheduled Drugs for Use in Office

Question: What documentation (prescription or other) is required for a retail pharmacy to sell scheduled drugs to a doctor's office to keep in stock for office use?

Answer: There are several issues involved in answering this question.

1. Is the prescriber authorized to possess/purchase the controlled substance requested? To determine this, the pharmacist must determine that the prescriber is authorized to purchase the particular controlled substance - request a copy of the DEA registration.
2. How is the sale/furnishing documented? The furnishing must be done via an invoice/sales and purchase order. The requirements can be found in Business and Professions Code section 4059 subdivision (b).
3. Section 11250 (and 11251) states that no prescription is required in case of the sale of controlled substances at retail (at wholesale in section 11251) in pharmacies by pharmacists to any of the

following: physicians; dentists; podiatrists; veterinarians; pharmacists, registered nurses, and physician assistants acting under Article 1, etc.; and optometrists.

See http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf page 169 for exact reference.

Other guidance can be found in 21 Code of Federal Regulations (CFR) sections 1307.11 and 1304.22.

What qualifies as separate C-II prescriptions?

Question: In a previous newsletter, it was noted that more than one Class II drug prescription can be written on the same form if the form meets the legal requirements for multiple prescriptions and that two Class II prescriptions on the same blank must be for different drugs. The reason for this is that multiple Class II drugs on the same form would violate the ban on refilling C-II drugs. This raises the question: Does this mean different active ingredients or just different strengths? For example, can two kinds of morphine sulfate or two strengths of Oxycontin be on the same prescription blank?

Answer: If both prescriptions for different strengths or form of medication of the same active ingredient were to be taken by the patient during the same time period for separate medical reasons, then each would be a separate prescription and could not be considered a C-II refill. If there is any question, a call to the prescriber would be the safe approach and would demonstrate due diligence. C-II prescriptions for sequential, successive time periods are not allowed. For example, one Rx for January, another for February, another for March for the same drug would not be allowed on the same Rx blank.

Licensed Healthcare Facility Computer-Generated "Institution" Style Forms

Question: Can a licensed healthcare facility computer generate "institution" style controlled-substance prescriptions to print on a shared laser or dot matrix printer within the facility?

Answer: Yes, a licensed healthcare facility can purchase custom "institution" style prescription blanks that can be used to computer generate prescriptions to print on a shared laser or dot matrix printer within the facility. These custom "institution" style laser or dot matrix forms must adhere to all of the provisions for "institution" style forms, including preprinting the designated prescriber's information, and the forms must incorporate the required security features pursuant to Health and Safety Code Section 11162.1 et seq. However, provisions were added to subsection (c), as a result of Assembly Bill 30 (Richman, Statutes of 2003), that are specifically limited to licensed healthcare facilities that computer generate prescriptions using an "institution" style prescription form to print on a shared laser or dot matrix printer and, as a result, these forms only:

§ **Do not require** the six quantity check boxes;

§ **Do not require** the facility's "designated prescriber" to maintain a record of the prescribers to whom these forms are distributed, but recommend keeping a record of forms ordered, received and used; and

§ **Do allow** the computer software to print the actual prescriber's name, category of licensure, DEA registration number, license number, and the date the prescription is written, in addition to the patient and prescription information.

NOTE: These exceptions do not apply to laser or dot matrix style controlled-substance prescription forms for use by a prescriber, group practice, clinic, or any other outpatient setting. R05-2005

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