

## **MORE SB 151 QUESTIONS AND ANSWERS**

### **Can a California pharmacy fill a controlled substance prescription from an out of state prescriber for a patient in California?**

California Code of Regulations section 1717(d), in accordance with Business and Professions Code section 4005(b), allows written and oral prescriptions from out-of-state prescribers. Pharmacies must verify the prescription. The pharmacist should use his or her best professional judgment when filling out-of-state prescriptions.

### **Can the new tamper-resistant security prescription form be preprinted with more than one prescriber; for example, a group practice setting?**

Yes. The forms should include check boxes or some other means to identify the specific prescriber's name, category of licensure, state license number, and DEA number.

### **What should a prescriber do if he or she is out of the triplicate prescription forms and/or has not yet received his or her new tamper-resistant security prescription forms but needs to write a controlled substance prescription?**

The Board of Pharmacy is most concerned that the healthcare needs of legitimate patients be met during the transition to the new tamper-resistant prescription form and has issued a memo dated August 11, 2004, that supports prescribers' temporary use of the exception to the special form requirement in Health and Safety Code section 11167. Prescribers must make good faith efforts to obtain the new prescription forms in compliance with the law. Prescribers must write "11167 exemption" on the prescription and pharmacists' should exercise their professional judgment when filling these prescriptions with the highest priority given to evaluating whether a prescription is authentic and issued for a legitimate medical purpose. Health and Safety Code section 11167 allows, in an emergency, where failure to issue the prescription could result in loss of life or intense suffering, an order for a controlled substance to be dispensed on an oral, faxed or plain paper prescription as long as the order contains all of the required information. Written orders must be signed and dated by the prescriber. The pharmacist must reduce oral or faxed prescription orders to hard copy form. The prescriber is required to provide a written prescription on the appropriate prescription form by the 7th day following the order. The pharmacist must notify the Bureau of Narcotic Enforcement within 144 hours of the prescriber's failure to do so, including the date and method of notification.

### **What are the quantity check-off boxes on the new tamper-resistant prescription forms?**

The quantity check-off boxes are a security feature that ensures the quantity, for which the prescription is written, is not tampered with in any way. The prescriber writes the prescription as usual, including the quantity, in the body of the prescription. In addition, the prescriber checks the box next to the applicable quantity range confirming the quantity for each prescription written. If the prescription is for anything other than tablets or capsules, the prescriber must also designate the units referenced in the quantity range.

### **How does a prescriber mark the quantity check-off boxes on the new tamper-resistant security prescription form when writing a prescription for multiple drugs on one prescription form?**

Some of the new tamper resistant prescription forms provide separate sections for writing multiple drug prescriptions, which include separate quantity check-off boxes for each. However, some form designs include

only one set of quantity check-off boxes. Prescribers' check the appropriate quantity range confirming the quantity for each prescription written. For example, if a prescriber writes one prescription for 100 tablets and, on the same form, writes another prescription for 25 tablets, the prescriber would check the quantity ranges 75 to 100 and 25 to 49. If the quantity of more than one prescription falls within the same range, simply check the quantity range once. For example, if the prescriber writes three prescriptions and two are for 100 tablets each and one is for 300 tablets, the prescriber would check the quantity ranges 75–100 and 151 and over

**Does my facility qualify as a “licensed health care facility” so that we can order “institution” style tamper-resistant prescription forms?**

*“Licensed health care facility”* means a facility licensed pursuant to Article 1 (commencing with section 1250) of Chapter 2 of Division 2 of the California Health and Safety Code, such as, a general 24-hour acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility

**Where can I find a list of all controlled substances including the drug schedule?**

California controlled substance standards and drug schedules, along with a corresponding list of drugs, are found in Chapter 2 of Division 10 of the California Health and Safety Code (commencing with section 11053). A Federal list of controlled substances, including the drug schedule, can be found on the Drug Enforcement Administration’s website at <http://www.dea/diversion.usdoj.gov/schedules>.

**Can a Schedule II controlled substance prescription be refilled?**

No. Prescribers should mark zero (0) or no refills (NR). The new tamper-resistant forms include an area for refills because the form can be used for any controlled or non-controlled substance prescription

**Can more than one Schedule II medication be written on the same form?**

Yes. As long as the new prescription form has the statement at the bottom that reads, “Void if the number of drugs is not noted” and a line provided for the physician to write in the number of drugs prescribed

**Can a pharmacist fill a prescription for a controlled substance if an error is found on the prescription?**

The prescriber’s signature and the date written are required to be written by the prescriber. Everything else can be written by the prescriber or his or her agent. Therefore, the pharmacist can make changes to any other information on the prescription as long as the pharmacist verifies the change with the prescriber first.

**Is the pharmacy still required to keep a separate record for Schedule II prescriptions filled? If so, what if there is more than one prescription on the form?**

Pharmacies are required to keep a separate record in the pharmacy of Schedule II prescriptions filled regardless of whether or not the prescription includes other non-Schedule II medications. Additionally, the

pharmacy is required to submit the Schedule II prescription information to CURES electronically or on disk, and effective January 1, 2005, must submit both Schedule II and III prescription information to CURES.

**Can a prescriber electronically transmit a Schedule III through V controlled substance prescription from a computer or personal digital assistant (PDA) to a pharmacy's computer or fax machine?**

Yes. Advice from the Drug Enforcement Administration in a letter from Patricia M. Good, Chief of the Liaison and Policy Section, Office of Diversion Control for the U.S. Department of Justice dated September 28, 2001, states that current DEA regulations allow for Schedule III, IV, or V controlled substances that are electronically created or transmitted, which includes PDA's, either directly to a computer or via facsimile machine, be treated as an oral prescription. This means the prescription must be reduced to hard copy form by the pharmacist and retained for at least three years. Additionally, a pharmacist that receives an electronically transmitted prescription via facsimile, or other methods, must ensure the validity of the prescription prior to dispensing the controlled substance (Title 21, Code of Federal Regulations section 1306.21). Electronically transmitted prescriptions, including those sent via PDA, must contain an electronic signature of the prescriber. Pharmacies must ensure the authenticity, integrity, nonrepudiation, and confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered in the course of transmission. Nonrepudiation means ensuring that a party to the transaction cannot later disclaim it. Moreover, a pharmacist has an affirmative obligation to verify a prescription when appropriate to do so. The pharmacy must also ensure that a prescription has been electronically transmitted to the pharmacy of the patient's choice. This may be done a number of ways, including, but not limited to, an affirmative statement on the prescription that the prescriber advised the patient of this right.

## **SENATE BILL 151 QUESTIONS AND ANSWERS**

### **TRIPLICATES OUT – NEW TAMPER-RESISTANT SECURITY PRESCRIPTIONS IN**

**What are “tamper-resistant security prescription” forms?**

The tamper-resistant security prescription forms are specialized prescription forms that have at least ten required security features pursuant to Health and Safety Code section 11162.1. As of July 1, 2004, the triplicate prescription forms, used for Schedule II controlled substances, is being phased out with a new tamper-resistant security prescription form that prescribers are required to purchase from designated security printers that have been approved by the Board of Pharmacy and the Department of Justice. By January 1, 2005, nearly all written controlled substance (Schedule II – V) prescriptions are required to be on these forms.

**What is an *approved* “security printer”?**

A *security printer* is a printing company that has applied to and been *approved* by the Department of Justice to produce the new tamper-resistant security prescription forms for use by authorized prescribers. If the security printer is not listed on the Department of Justice website at [www.ag.ca.gov/bne/security\\_printer\\_list.php](http://www.ag.ca.gov/bne/security_printer_list.php), it is not approved, and cannot legally print the new security prescription forms.

**How do I find an approved security printer to order the new tamper-resistant security prescription forms?A**

Visit the Department of Justice website at [www.ag.ca.gov/bne/security\\_printer\\_list.php](http://www.ag.ca.gov/bne/security_printer_list.php), choose a printing company from the list of approved security printers, and contact them directly to order the new prescription forms. Please have a copy of the prescriber's state license and DEA registration available when you order. Prices differ and are set by each printer. If a company you wish to use is not listed on the Department of Justice website, it is not an approved security printer and cannot legally print the new tamper-resistant security prescription forms. Unapproved printers can apply to the Department of Justice for approval by completing the application found at [www.ag.ca.gov/bne/security\\_printer\\_list.php](http://www.ag.ca.gov/bne/security_printer_list.php).

**Are triplicate prescription forms valid after July 1, 2004?**

Yes, triplicate prescription forms are valid through December 31, 2004. Prescribers can use either the triplicate prescription form or the new tamper-resistant security prescription form during the phase in period of July 1, 2004 through December 31, 2004 for Schedule II prescriptions. After January 1, 2005, nearly all written controlled substance prescriptions (Schedule II-V) must be on the new tamper-resistant security prescription form. Fax and oral prescriptions are still acceptable for Schedules III-V controlled substance prescriptions. However, a security feature on the new security form prints VOID across the face of the prescription when faxed, please use a regular prescription form for faxed prescriptions.

**After January 1, 2005, what should prescribers do with their unused triplicate prescription forms?**

Please return unused triplicates to the Department of Justice, Triplicate Prescription Program, 4949 Broadway, Sacramento, California 95820 by certified or registered mail for destruction. For more information, please call (916) 227-4051.

**How long is a controlled substance prescription valid?**

Since January 1, 2004, prescriptions for **all** controlled substances (Schedules II-V) are valid for 6 months from the date written. Pharmacists can disregard the 14-day restriction currently printed on the triplicate prescription form for Schedule II drugs; it is no longer correct.

**Do I still have the option of faxing or phoning in a prescription for a Schedule III – V controlled substance?**

Yes, prescribers can fax or phone in a prescription for a Schedule III – V controlled substance. However, a security feature on the new tamper-resistant security prescription form prints VOID across the face of the prescription when faxed, please use a regular prescription form for faxed prescriptions. Pharmacies will have to validate the faxed prescriptions.

**Can prescribers write a prescription for a non-controlled substance on the new tamper-resistant security prescription forms?**

Yes.

**Can a prescriber write a non-controlled and a controlled substance prescription on one tamper-resistant security prescription form?**

Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement "Prescription is void if the number of drugs prescribed is not noted" and 2) the total number of drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1, subdivision (a)(8).

**Can a prescription include more than one controlled substance (Schedules II - V) on the same tamper-resistant security prescription form?**

Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement "Prescription is void if the number of drugs prescribed is not noted" and 2) the total number of drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1, subdivision (a)(8).

**Can a Schedule II controlled substance and a Schedule III controlled substance be written on the same tamper-resistant security prescription form?**

Yes, as long as 1) the prescriber uses the security prescription blank that comes preprinted with the statement "Prescription is void if the number of drugs prescribed is not noted" and 2) the total number of drugs are written in the designated space on the security prescription form. See Health and Safety Code section 11162.1, subdivision (a)(8).

**What replaces a skilled nursing facility/hospice pharmacy-generated triplicate prescription form (SNF form)?**

As of July 1, 2004, the pharmacy can use a form of its own design for those drug orders.

**Can a California pharmacy fill a prescription for a Schedule II controlled substance that was written by an out-of-state prescriber for an out-of-state patient? What about Schedule III thru V controlled substances?**

Yes, so long as the prescription conforms to the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed. The prescription must be delivered to the patient in the other state. Prescriptions for Schedule II controlled substances must be reported to CURES and effective January 1, 2005, prescriptions for both Schedule II and III must be reported to CURES.

**Is a federal controlled substance registration number the same thing as a DEA registration number?**

Yes

**With the triplicates, the Department of Justice verified that a prescriber could write Schedule II controlled substance prescriptions prior to filling an order for triplicate forms. How does a pharmacist know that a prescriber has the authority to write controlled substance prescriptions using the new tamper-resistant security prescription form?**

Pursuant to Health and Safety Code section 11161.5 et seq., the approved security printer is required to verify that the prescriber ordering the new tamper-resistant security prescription forms, holds a valid unexpired license and has the authority to write controlled substance prescriptions (any or all Schedules II - V). If a pharmacist is concerned that a prescriber is not authorized to specifically write a Schedule II controlled substance prescription, the board recommends that the pharmacist ask the prescriber to provide a copy of his or her DEA registration, which lists the schedules of controlled substances that he or she is authorized to prescribe.

**After January 1, 2005, can a prescriber use the Health and Safety Code section 11159.2 exemption for a terminally ill patient to write a prescription for any controlled substance (Schedule II – V) on a regular plain prescription form as long as the prescriber makes the notation “11159.2 exemption”?**

No, only Schedule II prescriptions for terminally ill patients can be written on a plain prescription form; there is no terminally ill exemption for Schedule III - V controlled substances. Effective January 1, 2005, prescriptions for Schedule III - V controlled substances for terminally ill patients must be either on a tamper-resistant security prescription form, telephoned, or faxed in to the pharmacy. The intent of the 11159.2 exemption is to make it easier for terminally ill patients to obtain strong pain medication. The exemption applies to Schedule II drugs, which can be written on a plain prescription form with the notation “11159.2 exemption”.

**It appears that a pharmacist’s ability to correct an error or errors on a Schedule II prescription is eliminated on January 1, 2005, is that true?**

No, as of July 1, 2004, Health and Safety Code section 11164, subdivision (a)(5) allows a pharmacist to fill a Schedule II prescription containing errors if the pharmacist notifies the prescriber of the errors and the prescriber approves any correction. The prescriber must fax or mail a corrected prescription to the pharmacist within 7 days of the drug being dispensed. As of January 1, 2005, a Schedule II prescription containing errors should be handled as any other prescription that is uncertain, unclear, and/or ambiguous: the pharmacist must contact the prescriber to obtain the information to validate the prescription (Title 16 of the California Code of Regulations section 1761, subdivision (a).)

**Do prescriptions for all controlled substances have to be entirely in the prescriber’s handwriting?**

No, the prescriber is only required to sign and date controlled substance prescription, with limited exceptions.

**Who can authenticate a controlled substance prescription? For example, verify a stamped signature, verify a prescription that appears to be copy, verify a typewritten date on a controlled substance prescription, or verify the source of new faxed-in prescription.**

Pharmacists using their professional judgment and training are responsible for interpreting and evaluating a prescription. However, at a pharmacist’s direction a pharmacy employee may contact the prescriber’s office to verify/clarify non-clinical information contained on a prescription; for example, is the fax/phone number that of the prescriber? Of course, a telephoned prescription must be received only by a pharmacist or pharmacist

intern (under the supervision of the pharmacist). The pharmacist is responsible for the accuracy of all information on the prescription documents and the prescription medication dispensed.

**If a prescriber has several offices, can he or she order the new tamper-resistant security prescription forms preprinted with all of the addresses listed?**

Yes, multiple addresses for one prescriber may be listed on the form. The forms may include a check box or some other means to identify the specific address where the patient was seen.

**Can a prescriber purchase stock prescription blanks for a laser or dot matrix printer that comes with all of the security features except for the preprinted prescriber name, category of licensure, DEA number and state license number.**

No, the preprinted prescriber information is one of the security features and therefore, must be provided by an approved security printer. However, an approved security printer could offer for sale tamper-resistant security prescription blanks designed for laser or dot matrix printers as long as they are preprinted with the prescriber information before shipping to the prescriber. The prescriber could then send the patient and prescription information electronically to print on the laser prescription blank. The prescriber must sign and date the prescription.

**Note:** Although the prescriber address is not required to be printed on the prescription form by the approved security printer, the pharmacist cannot fill the prescription without the prescriber address on the form. Therefore, the board recommends that prescribers' order the new tamper-resistant security prescription forms with the address printed on the form. Multiple addresses are acceptable.

## **ORAL AND FAXED PRESCRIPTIONS**

**Can a prescriber call in or send a fax prescription for Schedule III – V controlled substances?**

Yes. For prescriptions called in to the pharmacist, the pharmacist must reduce the prescription to hard copy form using a form of the pharmacy's own design, and sign and date the prescription in ink. For faxed prescriptions, the pharmacist must produce the prescription in hard copy form, and sign and date the prescription in ink.

**Note:** One of the security features on the new tamper-resistant prescription forms will print "void" across the face of the security prescription when faxed or copied, prescribers are encouraged to use a regular prescription form when faxing prescriptions.

**Can a prescriber call in or send a fax to a pharmacy for a Schedule II controlled substance?**

No, with two exceptions. A licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice can call in an order or send a fax prescription for Schedule II - V controlled substances. The pharmacist must reduce the prescription to hard copy on a form of the pharmacy's own design or produce the fax in hard copy form, and in both instances, must sign and date the prescription. (Health and Safety Code, section 11167.5.) The other exception is for an emergency where loss of life or intense suffering may occur by not issuing the prescription pursuant to Health and Safety Code section 11167. In this instance, the prescriber may call in or fax the prescription to the pharmacy. The pharmacist must reduce the telephoned

prescription to hard copy form, or produce the fax in hard copy form, and in both instances, sign and date the prescription. The prescriber must, within 7 days, provide a written prescription on the new tamperresistant security prescription form (or triplicate form between July 1, 2004 and December 31, 2004). The pharmacist must notify the Bureau of Narcotic Enforcement within 144 hours of a prescriber's failure to do so, including the date and method of notification.

**Can a prescriber's staff person call in or send a fax for a Schedule III – V prescription?**

Yes, however, the prescription must include the name of the person calling in or faxing the prescription. A pharmacist or pharmacist intern must receive a telephone order. In addition, the pharmacist must authenticate the validity of the prescription. **LICENSED HEALTH CARE FACILITIES**

**Can a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice call in or fax a Schedule II controlled substance order for a patient? What if the patient is being discharged and wants to pick up the prescription on the way home at the pharmacy?**

An order for a Schedule II controlled substance for a patient of a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or a licensed hospice can be phoned in or faxed pursuant to Health and Safety Code section 11167.5. Phoned in orders must be reduced to hard copy and signed and dated by the pharmacist. Faxed orders must be produced in hard copy form, and signed and dated by the pharmacist. The prescription must include the signature of the person receiving the controlled substance prescription on behalf of the facility. The facility must forward a copy of any signed telephone orders, chart orders, or related documentation to the pharmacist. Discharged patients receive a written prescription as outpatients; therefore, the prescription must be written on the new tamper-resistant security prescription form or the triplicate form from July 1, 2004 through December 31, 2004. After January 1, 2005, the order must be written on the new tamperresistant security prescription form.

**What is an "institution" form for a qualified licensed health care facility?**

A *licensed health care facility* has the option of designating a prescriber to represent the health care facility. The designated prescriber's name, state license number, category of licensure, and DEA number are preprinted on the prescription form along with the facility name, address, state license number, and category of licensure. The form also includes a blank space for the actual prescriber to handwrite, type, or stamp his or her name, state license number, category of licensure, and DEA number. The forms are delivered to the designated prescriber who is responsible for distributing the prescription forms to prescribers authorized within the facility. The designated prescriber must maintain a record that includes the name, category of licensure, state license number, DEA number, and the quantity of forms issued to each prescriber and maintain the record in a readily retrievable format for 3 years. The designated prescriber may delegate any or all of these tasks to staff; however, the designated prescriber will be held accountable for compliance with these requirements. The board recommends that the prescriber also record the batch/lot numbers of the forms distributed. (Health & Safety Code section 11162.1, subdivision (c).) **CALIFORNIA UTILIZATION, REVIEW, AND EVALUATION SYSTEM (CURES)**

**What is CURES?**

The Department of Justice, Bureau of Narcotics Enforcement maintains the California Utilization, Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances dispensed to patients in California pursuant to Health and Safety Code section 11165. The CURES database captures data from all Schedule II controlled substance prescriptions filled as submitted



by pharmacies, hospitals, and dispensing physicians. Beginning January 1, 2005, CURES will capture Schedule III data as well. Law enforcement and regulatory agencies use the data to assist in their efforts to control the diversion and resultant abuse of Schedule II and III drugs. Prescribers and pharmacists may request a patient's history of controlled substances dispensed in accordance with guidelines developed by the Department of Justice.

### **Who is required to report to CURES?**

All dispensing pharmacies authorized to **dispense** Schedule II drugs are required to report to CURES in a frequency and format specified by the Department of Justice, Bureau of Narcotic Enforcement (BNE). BNE requires pharmacies to submit data in an electronic format by the 18th of every month, the data collected from the previous month. Beginning January 1, 2005, both Schedule II and III prescriptions filled must be reported to CURES. The BNE directs pharmacies to contact the CURES data collection vendor, Atlantic Associates, at 1-888-492-7341 for information on how to submit data. As of July 1, 2004, physicians that dispense Schedule II drugs from their offices directly to patients must report to CURES in hard copy or in an electronic format, and beginning January 1, 2005, all Schedule III drugs dispensed must also be reported. Dispensing physicians should contact the Department of Justice, Bureau of Narcotic Enforcement, at (916) 227-4051 for more information.

### **How does a pharmacy submit data to the CURES system?**

The Department of Justice, Bureau of Narcotic Enforcement specifies pharmacies to submit data for the previous month to CURES no later than the 18th of every month. Pharmacies must report electronically or via disk accompanied by a completed CURES Program Transmittal form. Pharmacies are required to report even if they did not fill any Schedule II prescriptions; reported as zero on the CURES Program Transmittal form. BNE directs pharmacies to contact the data collection vendor, Atlantic Associates, toll free at 1-888-492-7341 for more detailed information and data format specifications.

### **How does a prescriber or pharmacist request a patient history of controlled substances prescriptions from the CURES system?**

A prescriber or pharmacist can download a Patient Activity Report (PAR) request form by clicking on one of the following links:

prescriber - <http://caag.state.ca.us/bne/pdfs/BNE1176.pdf>

pharmacist - <http://caag.state.ca.us/bne/pdfs/BNE1177.pdf>

Complete the appropriate PAR form and fax it to the Department of Justice, Bureau of Narcotic Enforcement at (916) 227-5079.

### **Do I need to enter the batch/lot number on the new tamper-resistant security prescription form into CURES?**

No, the batch/lot number is not tracked by the State. The batch number is not reported to the CURES system. Prescribers might consider using the batch number to track their forms internally for inventory purposes, and security printers might consider using the number to account for forms during the production process.

### **Can a physician have more than one DEA number?**

Yes. A physician who administers or dispenses controlled substances directly to their patients in the office, pursuant to Business and Professions Code section 4170, are required to have a separate DEA registration number for every address from which he or she practices. If the physician only writes prescriptions for their patients to take to a pharmacy to dispense, then he or she is only required to have one DEA number for all practice addresses.

**I am a prescriber who dispenses controlled substance prescriptions to patients in my office. Do I need to report the information to the CURES system? If so, how do I report to CURES?**

As of July 1, 2004, prescribers that dispense Schedule II drugs directly to patients in their office are required to report to CURES in a hard copy or electronic format, and effective January 1, 2005, all Schedule III drugs must be reported as well. Prescribers, such as medical doctors, dentists, podiatrists, veterinarians, optometrists, midwives, and nurse practitioners, must meet all of the requirements for dispensing controlled substances pursuant to Business and Professions Code section 4170, such as labeling and packaging requirements, and providing patients the option of receiving a prescription. The Department of Justice, Bureau of Narcotic Enforcement (BNE), is in the process of developing a method for dispensing prescribers to submit data to CURES. For more information, please contact the BNE at (916) 227-4051.

**Note:** Prescribers that provide their patients written prescriptions to take to the pharmacy, or sends a fax or phones in prescriptions to a pharmacy are not required to report to CURES. The pharmacy is required to report those prescriptions to CURES.

**Our pharmacy's volume of Schedule II controlled substances dispensed is less than 25 per month and sometimes-even zero for a month; do I still need to report to CURES?**

Yes, currently all Schedule II prescriptions dispensed, and effective January 1, 2005, all Schedule II and III prescriptions dispensed, must be reported to CURES. The Department of Justice, Bureau of Narcotic Enforcement (BNE) requires pharmacies to submit data in an electronic format. Pharmacies must also report any month that they did not fill any Schedule II or III prescriptions by marking zero under the "*Total number of prescriptions included*" on the CURES Program Transmittal Form. For more information or to obtain blank transmittal forms, BNE directs pharmacies to contact the data collection vendor, Atlantic Associates, at 1-888-492-7341.

**Does the pharmacy still need to send a copy of the Schedule II prescription to the Department of Justice?**

During the phase in period, July 1, 2004 through December 31, 2004, if the pharmacy receives a Schedule II prescription on a triplicate form, the pharmacy must send the copy to the Department of Justice as well as report the data in an electronic format to CURES. If the pharmacy receives the prescription on the new tamper-resistant security prescription form, only the data is transmitted to CURES.

**What does a pharmacist enter into the triplicate number field in CURES when the prescription is written on the new tamper-resistant security prescription form?**

Between July 1, 2004 and December 31, 2004, if the Schedule II prescription is written on a triplicate prescription form, enter the triplicate number into CURES. If the prescription is written on the new tamper-resistant security prescription, enter all zeros or leave the triplicate field blank.

## **TIMELINE FOR MAJOR CHANGES TO CALIFORNIA PRESCRIBING LAWS**

On September 16, 2003, the Governor signed Senate Bill 151 (Burton, Chapter 406, Statutes of 2003), repealing California's longstanding requirement for state-issued triplicate prescription forms for Schedule II controlled substances. In place of the triplicate, prescribers will use a tamper-resistant prescription pad that will be available from private printing companies that have been approved by the Board of Pharmacy and the Department of Justice. Senate Bill 151 is a complex bill that makes substantial changes to California law regarding the prescribing of controlled substances, and these changes will be phased in over the next year:

### **Effective January 1, 2004**

- Controlled substance prescriptions (Schedules II-V) are valid for six months.
- All pharmacies are required to report Schedule II controlled substance prescriptions to the CURES program in a time and manner established by the Department of Justice.
- Pharmacies are no longer required to enter the triplicate prescription number into CURES.
- Schedule II-V controlled substance prescriptions are required to be signed and dated only by the prescriber. Other information required on a prescription form may be printed or written in by the prescriber's staff.

### **Effective July 1, 2004**

- The Department of Justice will no longer produce or distribute triplicate prescription forms.
- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.
- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.
- Prescribers dispensing Schedule II controlled substances are required to begin reporting these prescriptions to the Department of Justice.

### **Effective January 1, 2005**

- Triplicate prescriptions are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are permitted) shall be on controlled substance prescription forms.

- Pharmacies must report Schedule III controlled substance prescription information to the CURES program.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the Department of Justice.

## **TRIPPLICATES TO BE REPLACED WITH TAMPER-RESISTANT PRESCRIPTION FORMS**

The triplicate prescription form required to prescribe Schedule II medications is being replaced. Effective July 1, 2004, a new form may be used to prescribe Schedule II medications, although triplicate forms can still be used for six more months.

On January 1, 2005, all *written* controlled substance prescriptions (for Schedules II-V) must be on the new, tamper-resistant prescription form. Phone and fax orders for Schedules III-V medications will still be permitted. Fax orders should not be on the tamper-resistant forms (use of the new forms will result in a voided prescription) but on an ordinary prescription form. If the tamper-resistant form is used for a fax prescription resulting in a “voided” prescription, the pharmacy will have to contact the prescriber to ensure the prescription’s authenticity.

The tamper-resistant form will be available from private printers who must be approved by both the Board of Pharmacy and the Department of Justice. Prescribers can obtain these forms from any approved security printer in any quantity or format they desire.

The new forms must have a number of different security features:

- Void protection to prevent duplication or chemical washing to alter prescriptions;
- Watermark on the backside of the prescription with the text “California Security Prescription;”
- Thermo-chromic ink that changes color when exposed to heat;
- A description of the security features printed on each prescription form;
- Quantity check-off boxes; and
- The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

The pharmacy-generated triplicate for patients in skilled nursing, intermediate care, and hospice settings is also being replaced. Beginning July 1, 2004, pharmacies may replace the pharmacy-generated triplicate with a form of their own design. In addition, pharmacies may now take oral and electronic Schedule II orders for patients in any home health care setting and patients served by a licensed hospice.

Hospitals and other licensed health facilities will use a variation of the tamper-resistant forms that does not require the prescriber’s information (name, license number, etc.) to be preprinted on the form. Instead, these “institutional forms” require the prescriber to write, print or stamp that information on the form before it is a valid prescription.

## **SCHEDULE III IS ADDED TO THE CURES REQUIREMENT**

On January 1, 2005, all pharmacies will have to begin submitting Schedule III prescription information to the Controlled Utilization Review and Evaluation System (CURES) program. The CURES program compiles prescription data in a statewide database to assist state law enforcement and regulatory agencies in their efforts to reduce prescription drug diversion. That data is also available for prescribers and pharmacists who wish to obtain a patient drug history for someone under their care.

Currently, pharmacies are required to electronically transmit only Schedule II prescription information to the CURES program. New legislation, Senate Bill 151 (Burton, Chapter 406, Statutes of 2003), will require the same information be transmitted for Schedule III prescriptions. For most pharmacies, this means that their software must be modified so that Schedule III (as well as Schedule II) prescription information is transmitted to the Department of Justice via their data collector, Atlantic Associates.

In addition to requiring submission of Schedule III prescription information, the bill requires prescribers dispensing these drugs to submit prescription information to the CURES program beginning on July 1, 2004. Both pharmacies and dispensing prescribers must submit the following information for each prescription filled:

- Full name, address, gender, and date of birth of the patient;
- Prescriber's category of licensure, license number, and federal controlled substance registration number;
- Pharmacy prescription number, license number, and federal controlled substance registration number;
- NDC (National Drug Code) number of the controlled substance dispensed;
- Quantity of the controlled substance dispensed;
- ICD-9 (diagnosis code), if available;
- Date of issue of the prescription; and
- Date of dispensing of the prescription.

## **APPROVAL PROCESS FOR PRINTERS OF TAMPER-RESISTANT PRESCRIPTION FORMS**

Senate Bill 151 (Burton, Chapter 406, Statutes of 2003) requires that the new, tamper-resistant prescription forms be produced by "security printers" who are approved by both the Board of Pharmacy and the Department of Justice. Applications for approval are available from the Board's Web site ([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)) with complete instructions attached.

To become a security printer, the printer must apply to the Board of Pharmacy for approval. If approved, the application is then forwarded for consideration by the Department of Justice, which has 30 days to approve or deny the application.

Generally, applicants are screened for prior criminal history and the adequacy of their policies and procedures to ensure that prescription forms are produced and distributed only to appropriately licensed practitioners. The new law requires that security printers have a means for confirming the licensure and prescribing privileges for any person requesting controlled substance prescription forms.

Once a security printer is approved, the printer is authorized to produce prescription forms for appropriately licensed practitioners. The Board of Pharmacy will maintain a list of approved security printers on its Web site.

## **CHANGES TO CONTROLLED SUBSTANCE PRESCRIPTION FORMS (SENATE BILL 734)**

### **What changes to controlled substance prescription forms resulted from Senate Bill 734 (Torlakson, Statutes of 2005)?**

Senate Bill 734 makes several changes to the application process for security prescription printing vendors seeking approval to produce controlled substance prescription forms, makes the Dept. of Justice solely responsible for the review and approval of security prescription printing vendors, and makes the following policy and format changes for controlled substance prescription forms:

- Expands the use of "institution style" controlled substance prescription forms to clinics as specified under Health and Safety Code section 1200, and clinics as specified under subdivision (a) of section 1206 that has 25 or more physicians or surgeons, in addition to hospitals as specified under section 1250. (Health and Safety Code section 11162.1[c])

**SB 734 also makes the following format changes to controlled substance prescription forms. However, these new requirements do not invalidate controlled substance security prescription forms produced prior to these new requirements. Pharmacists should simply be aware of these changes as security prescription vendors begin to transition to the new form style and prescribers replenish their prescription pad stock.**

- All controlled substance prescription forms must have the statement "Prescription is void if the number of drugs prescribed is not noted" printed on the bottom and a line provided for the practitioner to write in the number of drugs prescribed. (Health and Safety Code section 11162.1 [a][8]) This change phases out the single drug prescription format.
- The controlled substance prescription forms must include an identifying number assigned by the Department of Justice to the approved security prescription vendor. (Health and Safety Code section 11162.1 [a][11])
- The security prescription forms must include a check box next to the name of each prescriber when the form lists multiple prescribers. The prescriber signing the prescription form must check the box next to his or her name for identification purposes. (Health and Safety Code section 11162.1 [a][12])
- The Department of Justice, Bureau of Narcotic Enforcement will have sole responsibility for the review of applications from security prescription vendors seeking approval to produce controlled substance prescription forms. The Board of Pharmacy is no longer involved in the approval process.

Effective January 1, 2006, new security prescription vendor applications and questions relating to the production of controlled substance prescription forms should be directed to:

Department of Justice, Bureau of Narcotic Enforcement  
CA Security Prescription Printers Program

P.O. Box 161089  
Sacramento, California 95816-1089  
Phone: (916) 319-9062 Fax (916) 319-9448  
Website: [www.ag.ca.gov/bne/prescriptions.php](http://www.ag.ca.gov/bne/prescriptions.php)  
(Health and Safety Code section 11161.5[a])

Senate Bill 734 also makes various changes to the application process and requirements for security prescription printing vendors seeking approval to produce controlled substance prescription forms. For additional information or to obtain an application to become an approved security prescription printing vendor, please contact the CA Security Prescription Printers Program as indicated above.

View [Senate Bill 734](#) in its entirety.

## **NEW LAWS FOR SECURITY PRESCRIPTION VENDORS, APPLICANT VENDORS, AND CONTROLLED SUBSTANCE PRESCRIPTION FORM FORMAT (SB734 TORLAKSON)**

As a result of [Senate Bill 734 \(Chapter 487, Statutes of 2005\)](#), several changes were made to the laws pertaining to controlled substance prescription forms and to the application process for security prescription vendors applying for approval to produce these forms (Health and Safety Code sections 11161.5 and 11162.1 et seq).

### **Security Prescription Vendor Applicant Changes/Additions (effective January 1, 2006)**

- The Department of Justice, Bureau of Narcotic Enforcement will have sole responsibility for the review of applications from security prescription vendors seeking approval to produce controlled substance prescription forms. The Board of Pharmacy is no longer involved in the approval process. Effective January 1, 2006, new applications and questions relating to the production of controlled substance prescription forms should be directed to:
- Department of Justice, Bureau of Narcotic Enforcement  
CA Security Prescription Printers Program  
PO Box 161089  
Sacramento, California 95816-1089  
Phone: (916) 319-9062 Fax (916) 319-9448  
Website: [www.ag.ca.gov/bne/prescriptions.php](http://www.ag.ca.gov/bne/prescriptions.php)

*Note: All pending applications have been forwarded to the Department of Justice for final review and approval.*  
(Health and Safety Code section 11161.5[a])

- Expands criminal background checks for security prescription vendor applicants to include state, federal, and foreign level convictions and arrests. (Health & Safety Code section 11161.5 [b][5][A] & [B])
- Allows the Department of Justice to deny a security prescription vendor application, if the applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has ever been convicted of a crime. (Health and Safety Code section 11161.5[d][1])

- Allows the Department of Justice to assess a fee sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks on security prescription vendor applicants. (Health & Safety Code section 11161.5 [b][5][D])
- As a condition of approval, security prescription vendor applicants must authorize the Department of Justice to make any examination of books or records of the applicant, or to visit and inspect the applicant premises. (Health and Safety Code section 11161.5 [d][7])
- Requires approved applicants to submit an exemplar of a controlled substance prescription form, with all of the security features, to the Department of Justice within 30 days of initial production. (Health and Safety Code section 11161.5 [e])

### **Controlled Substance Prescription Form Changes/Additions**

- Expands the use of “institution style” controlled substance prescription forms to clinics as specified under Health and Safety Code section 1200, and clinics as specified under subdivision (a) of section 1206 that has 25 or more physicians or surgeons, in addition to hospitals as specified under section 1250. (Health and Safety Code section 11162.1[c])

**SB 734 makes the following format changes to controlled substance prescription forms. However, these new requirements do not invalidate controlled substance security prescription forms produced prior to these new requirements. Pharmacists should simply be aware of these changes as security prescription vendors begin to transition to the new form style.**

- All controlled substance prescription forms must have the statement “Prescription is void if the number of drugs prescribed is not noted” printed on the bottom and a line provided for the practitioner to write in the number of drugs prescribed. (Health and Safety Code section 11162.1 [a][8])
- The controlled substance prescription forms must include an identifying number assigned by the Department of Justice to the approved security prescription vendor. (Health and Safety Code section 11162.1 [a][11])
- A check box next to the name of each prescriber must be included when the prescription form lists multiple prescribers. Requires the prescriber signing the prescription form to identify himself or herself by checking the box by their name. (Health and Safety Code section 11162.1 [a][12])

Please visit [www.leginfo.ca.gov](http://www.leginfo.ca.gov) or view [Senate Bill 734](#) in its entirety. For additional information or to obtain an application to become an approved security prescription vendor, please contact the Department of Justice at (916) 319-9062.