



## The End of Triplicates

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SB 151 WAS INTRODUCED in the California Senate in February 2003 to eliminate triplicate prescriptions and establish tamper-resistant security paper prescriptions for all scheduled drugs. It passed through the Legislature without opposition in August 2003 and went into effect in January 2004.

This new law phases in tamper-resistant "security paper" prescription pads that replace triplicates. These new prescriptions will be used for all scheduled drugs by January 1, 2005, and will be obtained by clinicians from printers rather than through an agency of the Department of Justice. All scheduled medications will come under the same security paper requirements. Phone-in and electronic transmissions will continue to be allowed for other than schedule II medications.

The new security pads will not be serialized for tracking, but each individual pad will be numbered, just as in a checkbook. In addition to the security paper requirement, the new law makes the present computerized drug monitoring program (CURES) permanent. CURES works in the background to monitor prescribing practices without being overly burdensome and intrusive to the practitioner.

The California Board of Pharmacy is directing the transition from triplicate to security paper prescriptions. They will be working with private printing firms to make the security paper prescriptions available to prescribers in the summer of 2004. It is anticipated that there will be a six-month period during which prescribers may use either triplicate or security paper prescriptions. After January 1, 2005, triplicate prescriptions are expected to no longer be valid.

### Background

Drug abuse and the under treatment of pain are major public health concerns that too often conflict with each other. These conflicts have resulted in a variety of regulations that are intended to prevent drug abuse, but have subsequently created barriers to appropriate treatment of pain. Physicians are encouraged to prescribe opioids to treat pain when appropriate, but many resist for fear of regulatory or legal scrutiny.

The states regulate most medical practice issues. At one point, 19 states implemented legislation or statutory regulations for prescription monitoring programs (PMPs), and eight of them adopted multiple copy prescription programs (MCPPs). Currently, 17 states have some sort of PMP in place. By the early 1990s, some states began using computer technology to collect PMP data, precluding the need for special prescription forms. The eight states that had enacted MCPPs have all terminated their duplicate or triplicate prescriptions — except for California.

California has had a triplicate PMP in place since 1939. It is now transitioning from a triplicate-based MCPP to a non-serialized security paper based program by the end of 2004. Only two other states, New York and Texas, currently maintain a single-copy, serialized prescription program. The other five states with original MCPPs have now all moved to electronic data transmission (EDT) systems not requiring a special government-issued prescription form.

Despite the good intentions behind them, PMPs are considered by many in the healthcare community to have a collateral negative impact on other areas of legitimate medical care. One author describes four potential ways these regulations adversely affect medical care: (1) placing restrictions on physician practice, (2) affecting patient access to opioids, (3) stigmatizing patients, and (4) negatively affecting physician perceptions of regulations, resulting in modified medical practices.

PMPs have been associated with a "chilling effect" on practitioner prescribing practices. There have been reports describing self-protective behaviors by physicians, who prescribe around PMP guidelines by selecting drugs requiring less regulatory documentation.

The prominent example in California is the avoidance of schedule II opioids such as sustained release morphine in favor of multiple doses per day of schedule III drugs such as Vicodin. The schedule III agents may be perceived as less dangerous but also carry abuse potential and possibly may pose greater side effects such as acetaminophen toxicity. PMPs can have consequences that far exceed their effectiveness.

Implementation of PMPs has been shown to decrease prescribing of Schedule II controlled substances. Following initiation of such a program, prescribing schedule II controlled substances decreased by 50 percent in Idaho, 54 percent in New York, 57 percent in Rhode Island and 64 percent in Texas.

Prescription data for 1989 shows the "substitution effect" in action. In states with MCPPs, 1.8 percent of all prescriptions were for Schedule II controlled substances, while in non-MCPP states this percentage was 4.7 percent. In contrast, Schedule III controlled substances in states with MCPPs were 19.6 percent of all prescriptions, while in non-MCPP states they were only 14.4 percent. It stands to reason that many physicians were avoiding drugs that require the use of multiple-copy or serialized forms. These data suggest physicians will get around barriers by prescribing drugs perceived to be less scrutinized, even if they are less efficacious or potentially harmful.

The substitution effect was most clearly seen in New York in 1989 when benzodiazepines were added to drugs that require a triplicate prescription. As benzodiazepine prescriptions decreased, increases were seen in alternative drugs that were often therapeutically less optimal, had greater risk of toxicity, and carried equal or greater abuse potential. For instance, prescriptions for meprobamate (Miltown) declined by 9 percent nationally, but jumped 125 percent in New York. The sedative methyprylon (Noludar) had decreased use by 15 percent nationally, but grew by 84 percent in New York. Butabarbital prescribing was down 15 percent nationally but increased 31 percent in New York. Use of chloral hydrate dropped by 0.4 percent nationally but increased 136 percent in New York.

Although the total number of benzodiazepine overdoses slightly decreased, from 1,294 cases in 1988 to 1,265 cases in 1989 (a 2.2 percent decrease), there was a significant increase of 29.7 percent in non-benzodiazepine sedative-hypnotic overdoses, from 111 cases in 1988 to 144 cases in 1989. These data suggest that inclusion of benzodiazepines in the New York triplicate prescription program influenced a slight reduction in benzodiazepine overdoses. The reduction in overdoses were negated by the resulting rise in overdoses from non-benzodiazepine medications that did not require using a triplicate form, leaving the overall number of overdoses nearly unchanged: 1,405 cases in 1988 vs. 1,409 cases in 1989.

### **California's experience**

California was the first state with a triplicate based MCPP, and now has the distinction of

being the last state with such a system. It has been asserted that the principal example of the success of our triplicate prescription program is the state's limited problem with Schedule II opioids, such as OxyContin. It must be noted that the California triplicate program does not include drugs such as hydrocodone with acetaminophen (Vicodin, Lorcet, Norco, etc.).

California physicians prescribe around the triplicate barrier to Schedule II drugs. This may seem like a fair trade. However, over-prescribing Schedule III opioids is often inadequate for many patients in severe or chronic pain or accompanies the risk of acetaminophen or NSAID toxicity. Moreover, the problem of abuse with Schedule III opioids, such as Vicodin, may be more significant than those for Schedule II drugs, such as OxyContin. Thus, the California triplicate program may well have converted the problem of Schedule II opioid abuse to a Schedule III problem, which goes unmonitored.

Since 2000, less than 60 percent of licensed prescribers in California had obtained triplicate prescription pads for Schedule II controlled substances. In addition, very few triplicates are ever entered into the manual system. For instance, in 1998, only 1.7 percent of Schedule II drug prescriptions had been entered in California. Taken together, this adds up to an inefficient system with good intentions but poor outcomes.

Several attempts had been made to repeal the triplicate MCPP, each failing because of law enforcement's concern that Schedule II abuse and particularly forgery would increase. In recent years, California developed a computer-tracking program for Schedule II prescriptions - the Controlled Utilization Review Evaluation System (CURES), which essentially deals with all of the functions of triplicate prescriptions except for forgery. Preventing forgery became the last rationale for California's triplicate prescription program.

Electronic data transmission (EDT) systems, such as CURES, have many advantages but can only address abuse after it has occurred. Such "back end" analysis can be very effective in directing enforcement resources, but provides no "front end" benefits for the transaction. However, a secure prescription form can address "front end" prevention of prescription drug fraud. In combination with an EDT program, law enforcement believed a secure prescription form provides a more complete PMP than either a secure prescription form or EDT program alone.

### **Tamper resistant security paper**

Procedural and technological safeguards can create a secure prescription form that balances fraud protection with accessibility, ease of use and affordability for practitioners. Currently, six states mandate use of security paper prescription paper — Florida, Indiana, Kentucky, Maine, New Jersey and West Virginia.

Secure prescription forms attempt to remove most of the troubling features of triplicate prescriptions. First, they will be provided by approved private printers, making the forms available without the administrative hassle and fear associated with applying to a law enforcement agency to receive forms. The removal of a tracking serial number also helps remove the perception that government is scrutinizing each prescription. Lastly, a secure prescription form is a practical requirement for all controlled substances, which eliminates stigmatizing particular schedules or classes of drugs.

The safeguards for secure prescription forms were selected to strike a balance between preventing forgery and counterfeiting while making the form affordable and easy to use. Some of the possible procedural safeguards that may be part of a secure prescription form program include:

- Governmental approval before a private security printer can print secure prescription forms.
- Security printers demonstrate ability to consistently deliver secure prescription pads only to appropriately licensed practitioners.
- Security printers authenticate the identity of any practitioner ordering secure

prescription forms.

- Security printers maintain records of the sale of secure prescription forms that preserve a trail of accountability.
- Secure prescription forms include quantity check boxes to prevent much common prescription fraud. For example, a common tactic is placing a "1" in front of a quantity; thus a prescription for 30 tablets of Vicodin becomes a prescription for 130 tablets.
- Secure prescription forms include preprinted prescriber information (name, address, license number, DEA number).

Technological safeguards can also reduce the likelihood of tampering. They include:

- Special Paper - Embedded watermarks and microfilaments that distinguish genuine documents.
- Latent void - The word "void" appears on any copies made by a color copier or scanning device.
- Printed Watermark - Translucent "watermark" on the prescription form through the use of special security inks.
- Chemical Void - Repetitive "void" appears when the form is exposed to chemicals designed to wash the ink from the existing prescription permitting a forger to "write" a new prescription.
- Thermo-chromic ink - Special ink that changes color when exposed to heat by rubbing the feature with your finger.
- Invisible Inks - Special ink producing an image or pattern that is invisible unless exposed to a particular wavelength of light.

Its ease of use will hopefully encourage all California physicians to use the security paper prescriptions for all prescribing, creating a single prescription pad practice missing in this state since the inception of triplicates. The California Board of Pharmacy has expressed its commitment to making the adoption of security paper prescriptions as easy and convenient as possible.

*Contact SSVMS for a complete set of references for this article.*

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