Repeal of Triplicate Prescribing and the New Security Paper Prescription Requirement in California

By Scott M. Fishman, M.D.

Dr. Fishman is Professor of Anesthesiology and Director of the Division of Pain Medicine in the Department of Anesthesiology and Pain Medicine at the University of California, Davis School of Medicine in Sacramento, California.

This issue of the *Bulletin* initiates an educational series of twelve articles on pain management and end-of-life care. They all shall be CME accredited, and the complete series of twelve will satisfy the CME requirement for physicians set by the California legislature. Each article will be written by a current or former director of a university- based pain management program in California. The full text of each article, along with references, will be accessible through the CSA Web Site <**www.csahq.org**>. For each article, the Web Site also shall contain ten questions that must be answered and submitted to the CSA in order to receive the CME credit. This is a free service for CSA members. Non-members will be charged $25 per CME credit.

The first article in the series is written by Scott Fishman, M.D., Director of the pain management program at UC Davis. This informative article by one of the state's leading experts on the regulatory environment in pain management covers the repeal of the triplicate prescription form law, and its legal and practical implications. It provides the information that anesthesiologists must know when this law takes effect in January 2005. The content in Dr. Fishman's article is essential and timely to those holding DEA prescription-writing privileges in this state.

Joshua P. Prager, M.D., M.S.
Coordinator, CSA *Bulletin* Pain Management Series
Clinical Assistant Professor of Anesthesiology and Internal Medicine
David Geffen School of Medicine at UCLA
Director, California Pain Medicine Center at UCLA Medical Plaza and The Center for Rehabilitation of Pain Syndromes

Introduction

Senate Bill 151 was passed by the 2003 California Legislature to eliminate triplicate prescriptions and establish requirements for the use of tamper- resistant security paper prescriptions for all scheduled drugs.* It went into effect in January 2004. These new prescriptions will be used for all scheduled drugs by January 1, 2005, and they will be obtained by clinicians from printers rather than the current arrangement of triplicate prescriptions that are ordered through an agency of the Department of Justice. All scheduled medications will come under the same security paper requirements, but phone-in and electronic transmissions will continue to be allowed, while schedule II medications will continue to be excluded. 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 establishes the present computerized drug monitoring program (Controlled Utilization Review Evaluation System_CURES) as a permanent program, one which 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. It will be working with private printing firms to make the security paper prescriptions available to California prescribers in the summer of 2004. In order for prescribers to exhaust their current supply of triplicate prescriptions, it is anticipated that there will be a six-month period during which time prescribers may use either triplicate or security paper prescriptions.

Background

Drug abuse and the undertreatment of pain are major public health concerns that too often are associated with solutions that 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.[1] Although physicians are encouraged to prescribe opioids to treat pain when appropriate, many resist because they believe that doing so places them at risk of regulatory or legal scrutiny.[2,3]

The authority to regulate most issues addressing medical practice is held by states rather than the federal government. At some point in their history, nineteen states implemented legislation or statutory regulations for prescription monitoring programs (PMPs), and eight of these states

adopted multiple copy prescription programs (MCPPs). Currently, seventeen states have some sort of

---

- California Health & Safety Code, Sections 11054-11058

PMP in place. By the early 1990s, some states began using computer technology to collect PMP data, precluding the need for special prescription forms.[4] Of the eight states that had enacted MCPPs, all have terminated their multiple copy prescription component (duplicate or triplicate), except for California, which has had a triplicate PMP in place since 1939. California is in the process of 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.[5] The remaining five states with original MCPPs have now all transitioned to electronic data transmission (EDT) systems that do not require a special government-issued prescription form.[5]

Despite the efforts and good intentions behind PMPs, they are considered by many to have a collateral negative impact on other areas of legitimate medical care.[6] Four potential means by which regulation of controlled substances adversely affect medical care are: (1) placing restrictions on physician practice, (2) affecting patient access to opioids, (3) stigmatizing patients, and (4) negatively impacting physician perceptions of regulations, resulting in modified medical practices.[7] PMPs have subsequently been associated with a "chilling effect" on practitioner prescribing practices. This effect is manifested through reports that describe self-protective behaviors by physicians, where they prescribe around PMP guidelines by selecting drugs that need 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 (hydrocodone plus acetaminophen). The schedule III agents may be perceived as less dangerous, but they also carry abuse potential, and they possibly may pose greater side effect risks such as acetaminophen toxicity. Despite good intentions, such PMPs can have consequences that far exceed their effectiveness.[8]

The implementation of PMPs has been demonstrated to decrease by 50-64% the prescribing of Schedule II controlled substances.[9-12] Prescription data for 1989 has shown the "substitution effect" in action. In states with MCPPs, 1.8% of all prescriptions were for Schedule II controlled substances, while in non- MCPP states this percentage was 4.7%.[13] In contrast, Schedule III controlled substances in states with MCPPs

totalled 19.6% of all prescriptions, while in non-MCPP states they were only 14.4%.[13] It stands to reason that many physicians were seeking to avoid drugs that require the use of multiple-copy or serialized forms.[9,10] These data suggest that physicians who are faced with barriers to prescribing a certain type of medication will prescribe around that barrier with drugs that are perceived as less scrutinized, even if they are less efficacious or potentially harmful.[11,13-16]

The "substitution effect" was most clearly seen in New York in 1989 when benzodiazepines were added to the list of drugs that require a triplicate prescription. Following this change, benzodiazepine prescriptions decreased, but increases were seen in alternative drugs (mebrobamate, methyprylon, butabarbital, and chloral hydrate, all of whose use decreased nationally) that were often therapeutically less optimal, had greater risk of toxicity, and carried equal or greater abuse potential.[11,15-19] Although the total number of benzodiazepine overdoses decreased by 2% from 1988 to 1989, there was a concomitant 30% increase in non-benzodiazepine sedative-hypnotic overdoses.[20] These data suggest that inclusion of benzodiazepines in the New York triplicate prescription program effected a slight reduction in benzodiazepine overdoses that was negated by a significant rise in overdoses from non-benzodiazepine medications that did not require using a triplicate form.

The California Experience with Triplicate Prescriptions

As the first state with a triplicate based MCPP, California now has the distinction of being the last state with such a system. It has been asserted that the principle example of the success of our triplicate prescription program is the state's limited problem with Schedule II opioids, such as OxyContin (oxycodone). It must be noted that the California triplicate program does not include drugs such as hydrocodone with acetaminophen (Vicodin, Lorcet, Norco, etc.). Similar to the experience in New York, California physicians prescribe around the triplicate barrier to Schedule II drugs. At face value, 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 acetominophen 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% of licensed prescribers in California had obtained the required triplicate prescription pads for Schedule II controlled substances.[21,22] Several attempts have been made to repeal the triplicate MCPP, each failing due to lack of support from law enforcement based on their concern that, without triplicates prescriptions, Schedule II abuse and_ particularly forgery_would increase.[23-25] In recent years, California developed a computer-tracking program for Schedule II prescriptions (CURES) which essentially deals with all of the functions of triplicate prescriptions except for forgery. Preventing forgery became the remaining rationale for California's triplicate prescription program; therefore, finding a way to eliminate triplicates required also preventing forged prescriptions.

Electronic data transmission (EDT) systems, such as CURES, have many advantages but also have the intrinsic limitation of addressing abuse after it has already occurred. Such "back end" analysis can be very effective in directing enforcement resources, but it provides no benefit to the "front end" of the transaction. The creation of a secure prescription form has been advanced to address the need for "front end" prevention of prescription drug fraud. In combination with an EDT program, California law enforcement believed that a secure prescription form provides a more complete PMP than either a secure prescription form or EDT program alone.

Tamper Resistant Security Paper Prescriptions

Both procedural and technological safeguards can be combined to create a secure prescription form that balances fraud protection with accessibility, ease of use, and affordability for practitioners. Currently, six states have mandated use of security paper prescription paper. These include Florida, Indiana, Kentucky, Maine, New Jersey and West Virginia.

Secure prescription forms attempt to remove most of the troubling features of triplicate prescriptions. First, secure prescription forms will be provided by approved private printers instead of an agency within the California Department of Justice. This reduces the barrier to appropriate prescribing by 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 from each prescription also serves to remove the perception that the government is scrutinizing each prescription. Lastly, a secure prescription form makes it practical to apply a secure prescription form requirement to all controlled

substances, which eliminates stigmatizing particular schedules or classes of drugs. Treating all controlled substances equally in this manner will free prescribers to use the most effective drug for pain control without concern for differential regulatory scrutiny.

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

- 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, which preserves a trail of accountability.
- Secure prescription forms include quantity check boxes. These check boxes prevent much of the prescription fraud commonly encountered. For example, a common tactic is to place a "1" in front of a quantity on the prescription. Thus, a prescription for 30 tablets of Vicodin becomes a prescription for 130 tablets of Vicodin.
- Secure prescription forms include preprinted prescriber information (name, address, license number, DEA number).

There are also technological safeguards that can be included in a secure prescription form to reduce the likelihood of tampering. These safeguards include the following:

- 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, thus 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.

Summary

The adoption of tamper-resistant security paper prescriptions is intended to offer California physicians a deterrent to prescription forgery without the obstacles associated with the triplicate system.[26] These new prescriptions will cover all scheduled drugs which should eliminate the tendency to prescribe around triplicates and even the playing field for all opioids and other scheduled drugs. Moreover, it is hoped that the intended ease of use of this system will encourage all California physicians to use the security paper prescriptions for all prescribing, creating a single prescription pad practice that has been missing from California since the inception of triplicates. The California Board of Pharmacy is overseeing the transition, expressing commitment to making the adoption of security paper prescriptions as easy and convenient as possible. It is expected that the new prescription paper pads will be available by summer 2004. At that time, it is planned to have prescribers use either triplicates or security paper prescriptions so that residual triplicates can be consumed. As of 2005, it is expected that California triplicate prescriptions will no longer be valid, and the tamper resistant security paper program will be in full operation.

For a complete rendition of this article with the references, please contact the CSA office at (800) 345-3691.

For one hour of CME credit for reading the complete article and answering the accompanying questions, go to the CSA Web Site at **www.csahq.org**.

This module is available from March 31, 2004, until March 31, 2007.