

Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain

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ABSTRACT

Social policies have evolved to address the associated concerns related to the public health crises of drug abuse and undertreated pain. Prescription monitoring programs (PMPs) have been used for many years in this effort but are undergoing re-evaluation and restructuring in light of changes in technology as well as changes in our understanding of the collateral impact of such programs. We reviewed the state of PMPs in the United States and highlighted recent changes in these programs that have occurred nationally. The current changes occurring in California, with the most physicians of any U.S. state as well as the oldest triplicate-based serialized prescription program, are reviewed, with focus on the transition to tamper-resistant prescriptions that use security paper forms. Future trends for PMPs are described, including the potential for widespread use of electronic prescribing, which is gaining favor with the Drug Enforcement Agency.

Key Words. Prescription; Monitoring; Programs; Triplicates; Opioid; Diversion; Abuse; Tamper-Resistant; Security Paper

Introduction

Drug abuse and the undertreatment of pain are prominent public health concerns in the United States. These are fundamentally important issues whose policy solutions have been frequently contradictory. These contradictions can lead to the conclusion that the war on drugs is directly in opposition to the war on pain. This conflict has resulted in a variety of regulations that are intended to prevent drug abuse, but have inadvertently created barriers to the appropriate treatment of pain [1]. This does not conform to the philosophy of national and international policies recognizing that efforts to control abuse and diversion of pain medications must not interfere with their availability for legitimate medical pur-

poses. Some believe removing these regulatory barriers to chronic opioid prescribing is a step toward increasing drug abuse and diversion [2,3]. Therefore, these barriers must be removed without making drug diversion more possible. The current obstacles within the drug regulatory systems offer the opportunity to work with policymakers to revise current laws and regulations, concomitantly improving control over prescription drug abuse while reducing barriers to pain relief [4]. Without special training in this complex subject matter, regulators and investigators cannot be expected to differentiate acceptable prescribing from misuse and diversion. Also, lawmakers cannot be expected to anticipate the negative impact of laws that are meant to help advance the cause of pain relief [5].

In recent years, the health care system has become increasingly intolerant of undertreated pain. In 2001, a California jury found an internist guilty of elder abuse for undertreating the pain of a dying man and was ordered to pay \$1.5 million to the patient's surviving family members [6]. A

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second similar case was recently settled and resulted in the Medical Board of California formally sanctioning the physician involved. Physicians have long been concerned that prescribing for prolonged periods or for large amounts could lead to unwarranted disciplinary actions taken against them, but these landmark cases suggest that the opposite may be just as punishable. Although the medical boards of Oregon and California are presently the only state medical boards to have sanctioned physicians for undertreating pain, there may be more in the future. Other states and national organizations, including the Federation of State Medical Boards, are responding to undertreated pain as an important public health problem. The Veterans Affairs (VA) medical system began this trend by designating pain as the “fifth vital sign” in all their hospitals [7]. The Joint Commission on Accreditation of Healthcare Organization followed suit and now requires hospitals to provide organized pain assessment and treatment in order to be accredited [8]. While it is rare for lawmakers to mandate specifics of medical education, the same civil lawsuit that found the internist guilty of elder abuse for undertreating pain also prompted the California state legislature to pass a law requiring physicians to participate in specific pain and end of life care related continuing medical education [9]; the California state legislature previously had mandated a curriculum in pain and palliative care for all medical schools [10]. West Virginia and Oregon have since passed similar legislation and several other states are considering doing so as well [11]. In addition, the National Institutes of Health have designated a focused initiative in pain research, and a recent act of Congress designated 2001–2010 as “The Decade of Pain Control and Research” [12–14].

Although physicians are encouraged to prescribe opioids to treat pain when they are the best treatment choice, they are largely hesitant to prescribe opioids, because they believe that doing so places them at risk for unwarranted regulatory oversight [15,16]. Twelve state legislatures have attempted to improve pain care by passing Intractable Pain Treatment Acts (IPTAs) that provide immunity from regulatory discipline to physicians who prescribe opioids within the requirements of the statute. Ironically, some IPTAs may also create possible barriers to appropriate pain management [17].

Laws and regulations governing the medical use of controlled substances are the result of long-

standing concerns regarding prescription drug abuse and diversion of psychoactive agents in the United States [18]. Although it is difficult to know the exact extent of prescription drug diversion, a national survey estimated that prescription drugs are the main drug of abuse for nearly one out of every ten patients who receive such treatment in the United States [19]. Extensive regulations are often placed on particular controlled substances, such as opioids, amphetamines, and benzodiazepines, due to their abuse potential [19]. It stands to reason that abuse rates for opioids should rise as opioid analgesics are increasingly available for medical use. Joranson et al. retrospectively reviewed hospital emergency department admissions resulting from abuse of opioid analgesics through the Drug Abuse Warning Network (DAWN) and compared them with their medical use from the Automation of Reports and Consolidated Orders System [20]. They found that, although medical use increased for those opioids most therapeutically relevant for the treatment of severe pain, the proportion of opioid abuse events relative to total drug abuse mentions remained stable [20]. However, later work by this group indicates that abuse of opioid analgesics has indeed increased since 1997 [21].

The authority to regulate medical practice is held by states rather than the federal government. However, the federal government maintains a substantial interest in matters of controlled substances and drug abuse and diversion [22]. This interest led to the 1914 Harrison Narcotic Act, which established a mechanism for distribution of narcotic drugs and was followed by a variety of laws conferring the federal authority to regulate the manufacture, distribution, and labeling of pharmaceuticals [23]. This was followed by the Controlled Substances Act of 1970, which determines our current drug-control system, including classifying drugs as Schedule I through V based upon their individual abuse potential and medical utility (Table 1) [22,24,25].

During the past century, several states have taken further steps to prevent prescription drug abuse by establishing prescription-monitoring programs (PMPs). The most common goals of PMPs involve education, delivery of information, execution of public health initiatives, early intervention and prevention of diversion, investigation and enforcement of abuse, and protection of confidentiality [25–27]. The majority of these diversion-control programs emphasize Schedule II drugs, which are deemed to have the greatest

Table 1 Federal controlled substance schedules

	Description of criteria	Examples
Schedule I C-I	High potential for abuse; lack of accepted safety; no currently accepted medical use	Heroin, lysergic acid, marijuana, mescaline, methaqualone
Schedule II C-II	High potential for abuse; severe psychological or physical dependence liability; currently accepted medical use	Morphine, hydromorphone, methadone, oxycodone, cocaine, amphetamine, methylphenidate
Schedule III C-III	Less abuse potential than I or II; moderate or low physical dependence or high psychological dependence; currently accepted medical use	Opioids combined with non-narcotic drugs (e.g., hydrocodone/acetaminophen, codeine comb), dronabinol, anabolic steroids, benzphetamine
Schedule IV C-IV	Less potential for abuse than I–III; limited physical or psychological dependence; currently accepted medical use	Benzodiazepines, chloral hydrate, dextropropoxyphene, phenobarbital, fenfluramine
Schedule V C-V	Low abuse potential; limited physical dependence or psychological dependence relative to I–IV; currently accepted medical use	Dephenoxylate in combination with atropine (antidiarrheals), antitussives with limited amounts of narcotics (e.g., codeine)

From: Fujimoto D. Clin Geriatr Med 2001;17:537–51 [24].

potential for abuse [19]. PMPs originally operated by transmitting copies of prescriptions to law enforcement and government health agencies; these programs are called multiple copy prescription programs (MCPPs) because they use government-issued duplicate or triplicate prescription forms. Most PMPs have recently begun to use advanced computerized monitoring systems called electronic data transmission (EDT) systems. EDT systems are believed to be the most comprehensive and effective types of PMPs for controlling prescription drug diversion [19,28].

Despite great efforts and good intentions, non-computerized PMPs are considered by many in health care to have a collateral negative impact on other areas of legitimate medical care [19]. Weissman and Johnson describe four potential means by which the regulation of controlled substances adversely affects medical care: 1) By placing restrictions on physician practice, 2) By affecting patient access to opioids, 3) By stigmatizing patients, and 4) By negatively impacting physician perceptions of regulations, resulting in modified medical practices [28]. PMPs have, thus, been seen as contributing to a “chilling effect” on practitioner prescribing practices. This effect is apparent from physician reporting of self-protective behaviors, where prescribing around PMP guidelines results in prescribing shifts from more restricted scheduled drugs to drugs that are not monitored. Despite all good intentions, such PMPs can have consequences that far exceed their effectiveness [25].

Since drug regulation policies for monitoring prescribing patterns are evolving in many states, we reviewed the history and current status of PMPs and their impacts on analgesic prescribing.

We reviewed several potential changes at state and federal levels that include security paper prescribing, which is now required by several states, and a novel electronic prescribing system that is under development by the Drug Enforcement Agency (DEA).

Prescription Monitoring Programs: From Then to Now

PMPs have a long and diverse history. They vary between states, as each state government solely determines the goals and structure of the program to best suit its needs. The earliest programs required physicians to use multiple copy forms (duplicate or triplicate) when prescribing Schedule II controlled substances. New York started the trend when it implemented the first PMP in the 1910s as a duplicate prescription model [27]. California and Hawaii followed suit and began their own MCPPs by the 1940s. By the 1990s, seven more states had enacted legislation or regulations for PMPs of some type, and nine of the states' PMPs were MCPPs [27]. Table 2 lists and summarizes the experiences of individual states and their PMPs.

Nineteen states have implemented legislation or statutory regulations for PMPs of some type, and nine of those states adopted MCPPs. Currently, 19 states have some sort of PMP in place (Table 3). During the last decade, some states began using computer technology to collect PMP data, precluding the need for government-issued prescription forms [27]. Since then, of the nine states that had enacted MCPPs, all have terminated their multiple copy prescription component except for California, which has a triplicate PMP in place that

Table 2 Summaries of state opioid prescribing laws and regulations

California	<p>California lays claim to the oldest, continually operational MCPP, with its triplicate prescription program that began in 1939 [29]. This early legislation applied only to selected “narcotics,” such as opium, hashish, marijuana, and cocaine, which limited physicians to issuing no greater than 100 prescriptions for these drugs in a 90-day period [62]. These restrictions were eliminated in 1945 [62].</p> <p>In 1972, California legislation mandated that all prescriptions for Schedule II narcotics be issued on a multiple copy prescription form and, in 1981, the requirement was made to include any non-narcotic Schedule II controlled substance as well [62]. A Controlled Substance Prescription Advisory Council was established in 1992 to study the Triplicate Prescription Program and make recommendations regarding program improvements and modernization [62]. This council led the legislature to enact a bill in 1996 that established prescription serialization and an electronic-monitoring system [29,62].</p> <p>This present electronic-monitoring component of the California PMP, named CURES, was implemented as a pilot project to evaluate the efficacy of electronic monitoring of the prescribing and dispensing of Schedule II controlled substances. CURES was intended to end on July 1, 2003 but was extended by 2001 law AB 2655, which set a termination date of July 1, 2008 [63]. Recently passed legislation eliminated serialized triplicates in favor of nonserialized security paper prescriptions that include all scheduled drugs (see below) by January 1, 2005. It would also make CURES a permanent program, extending its monitoring to include Schedule II and III controlled substances [63].</p>
Florida	<p>Starting July 1 of 2001, medical practitioners of Florida were required to use a counterfeit-proof prescription blank when writing a hard copy prescription order for Medicaid patients [64]. This regulation extends to all covered services under the Florida Medicaid Prescribed Drug Services Program, including drugs, syringes, nutritional supplements, and test strips [64]. The Florida Medicaid program enacted this requirement as part of their effort to combat fraud and abuse. These counterfeit-proof prescription blanks must be produced by a state approved vendor [61]. A specific layout, format, or style is not required when a vendor produces the blank, and prescribers may choose to customize their prescription layout and use them for non-Medicaid patients as well [64].</p> <p>In 2002, policies were enacted in the Florida State Senate to begin development and initiation of a program requiring all prescribing practitioners to use a counterfeit-proof prescription pad for their Medicaid prescriptions only [65]. In early 2003, legislation was proposed that would create a Schedule II, III, and IV controlled substance prescription tracking program [66]. Purdue Pharma, the Connecticut-based manufacturer of OxyContin® (oxycodone), had previously pledged \$2 million toward financing the development of software needed to operate a tracking program at the conclusion of an investigation into marketing practices of the company by the State Attorney General's office [66,67]. The proposed tracking legislation was rejected near the end of the Florida legislature session, leaving no future plans for the program or the \$2 million pledge from Purdue Pharma [68]. Opponents may have purposely hurt the bill by tacking on several unrelated amendments in the final moments of the Senate, making it the second year in which the legislators of the state have considered then rejected legislation on such a program [66].</p>
Hawaii	<p>In 1943, the first PMP was enacted by the territory of Hawaii as a duplicate prescription program [29]. Hawaii's Narcotic Enforcement Division (NED) was given a federal grant to develop an electronic point-of-sale prescription monitoring program, Hawaii Schedule Two Electronic Monitoring (HISTEM), in 1992 [62]. This was a voluntary program until NED passed legislation in 1996 requiring that HISTEM be mandated in the Hawaii Revised Statutes in accordance with the proposed “Electronic Prescription Accountability Act” [62]. In 2002, Hawaii eliminated the multiple copy prescription requirement and now has only the electronic monitoring program in place, which covers Schedule II, III, and IV controlled substances [29].</p>
Idaho	<p>Idaho enacted its first PMP, a triplicate prescription program, in 1967 [29]. In 1997, this program was changed to a duplicate prescription program with electronic prescription monitoring added [29]. In 2001, Idaho ended its MCPP and instated an electronic prescription monitoring program in its place, which covers Schedules II through V controlled substances [29]. Idaho law mandated that all written prescriptions for controlled substances, Schedules II through V, must be on “noncopyable” security prescription blanks [69]. A list of necessary security features and other requirements are noted in the regulation [69].</p>
Illinois	<p>Illinois began a triplicate prescription program in 1961 [29]. In 1999, Illinois eliminated their MCPP and began an electronic prescription monitoring program, covering Schedule II controlled substances only [29].</p>
Indiana	<p>The Indiana State Police (ISP) first laid the groundwork for the state's MCPP in the early 1980s, but was met with heavy opposition from the State Medical Association, Pharmacists Association, and pharmaceutical industry [62]. It took more than three legislative sessions to narrowly pass the MCPP legislation and, in 1987, Indiana began its triplicate prescription program [29,62]. The law required that practitioners use a state-issued, triplicate, noncarbon prescription pad when prescribing Schedule II controlled substances for any patient outside an institutional setting [62]. Original legislation included an expiration date of 1993 and came up to be renewed at that time [62]. The Indiana State Medical Association (ISMA) still opposed the MCPP and proposed an alternative program, based on the Oklahoma Electronic Prescription Monitoring Program, which would require the electronic transmittal, by pharmacists, of all Schedule II prescription data, instead of a multiple copy prescription blank [62]. MCPP proponents, knowing that they would be defeated, attempted to compromise and try to make the electronic program the best alternative, thus agreeing on single-copy, nonduplicative prescriptions and that pharmacists would be required to obtain positive identification of the person presenting the prescription before filling it [62]. All parties agreed on this alternative program in its final form in 1994, which changed it to an electronic prescription monitoring program, named the Indiana Schedule Two Electronic Prescription (INSTEP) program, covering Schedule II controlled substances only [29]. INSTEP was transferred to the Indiana State Police in 1999 and expanded to include Schedule III and IV controlled substances [70].</p> <p>Effective January 1, 1996, all controlled substance prescription blanks used by licensed practitioners of Indiana to write prescriptions for controlled substances will contain minimum standards for security features as listed in the Indiana Administrative Code [71].</p>

Table 2 Continued

Kentucky	<p>In 1998, the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program was enacted to combat prescription drug abuse [72]. The KASPER program allows the state health department to track prescriptions of all schedule II, III, IV, and V drugs dispensed by all physicians and others who are authorized to dispense controlled substances [72]. The KASPER program is able to detect multiple prescriptions fills for the same drug at different locations, which could indicate misuse [72]. The start-up cost for this program was \$415,000 in Kentucky, with an estimated annual operating cost of \$500,000 [74].</p> <p>At the start of 1999, law mandated that all written prescriptions for controlled substances, Schedules II through V, must be on security prescription blanks [74]. A list of necessary security features and other requirements are noted in the regulation.</p>
Maine	<p>Starting on January 1, 2003, all prescriptions issued by health care providers for Schedule II drugs must be written on security prescription blanks [75]. This new regulation was recommended by the Substance Abuse Services Commission at the conclusion of a half-year study on the abuse of oxycodone in the state [76]. The bill had failed in the previous legislative session, a lack of funding playing a role, but the state will take advantage of the federal grants now available to implement such a program [76].</p>
Massachusetts	<p>Efforts to establish a PMP were initiated by the Massachusetts Department of Public Health in 1982 [62]. These efforts to initiate a paper-based system faced powerful resistance in 1990 and, therefore, began looking into an EDT alternative in 1991 [62]. In 1992, Massachusetts began operating an EDT system, collecting all Schedule II prescription data [70]. This new EDT system did not result in a decrease in the number of prescriptions for Schedule II controlled substances [70].</p>
Michigan	<p>In 1988, the state of Michigan enacted the triplicate prescription program, as part of an anticrime package, which required that all Schedule II controlled substances be written on triplicate forms [77–79]. This law was intended to reduce drug diversion and substance abuse [78,79], while also forming a Controlled Substances Advisory Commission to hold the responsibility of monitoring the program [79], and included a sunset provision requiring the Legislature to reevaluate it at 5-year intervals [77]. When the issue was revisited in 1993, the Legislature decided to replace the program with the Official Prescription Program [77]. This new program substituted a single-sheet official prescription form, eventually replacing the triplicate form, in 1995, that had been used previously [77].</p> <p>Michigan then passed legislation in the 2002 session amending the Public Health Code to repeal the Official Prescription Program and establish an electronic drug-monitoring system for Schedule II through V controlled substances [29,77,80]. In addition, Michigan passed legislation to create and distribute an informational book on pain and to develop and conduct educational programs for health professionals who dispense controlled substances, which must include information on processing allegations of wrongdoing and the disciplinary process [80]. Finally, legislation was passed to establish the Pain Management Education and Controlled Substances Antidiversion Fund, to replace the Official Prescription Program (OPP) fund [77,80].</p> <p>The Michigan Automated Prescription System (MAPS) replaced the OPP at the start of January, 2003 [81]. MAPS requires the electronic reporting of all Schedule II through V controlled substances that are prescribed by practitioners in the state [81]. The new MAPS program does not require practitioners to use security paper or serialized forms when prescribing controlled substances, and serialized prescription forms will not be supplied after the first of the year [81]. Currently, Michigan is reviewing the option of instituting security paper prescriptions [82], although much debate exists over whether or not this is the best option.</p>
Nevada	<p>The Nevada State Legislature of 1995–96 passed the Nevada Revised Statute (NRS) requiring that the Nevada State Board of Pharmacy, the Nevada Division of Investigation, and the Bureau of Alcohol and Drug Abuse develop a computerized program to monitor prescriptions of controlled substances and also established the Controlled Substance Abuse Prevention Task Force to coordinate implementation of the project [62]. This group included representatives from the three state agencies, health care practitioner boards and associations, pain management specialists, and prosecuting attorneys [62]. This Task Force developed the Controlled Substance Tracking Program to prevent inappropriate distribution and use of controlled substances [62]. This program monitors Schedules II, III, and IV controlled substances [29].</p>
New Jersey	<p>Effective January 6, 1997, all licensed prescribers in the state of New Jersey were required to use non-reproducible, nonerasable safety paper New Jersey Prescription Blanks that contain the prescribing practitioner's license number whenever the practitioner issues a prescription for a controlled dangerous substance, a prescription legend drug, or other prescription item [83]. These prescription blanks must be obtained from a vendor approved by the Division of Consumer Affairs in the Department of Public Safety [83].</p>
New Mexico	<p>In July of 1994, legislation was passed in the state of New Mexico allowing an electronic prescription monitoring program to be administered by the New Mexico Board of Pharmacy. The New Mexico Board of Pharmacy did not approve the electronic prescription monitoring program until May of 2004. Currently, New Mexico is implementing the electronic monitoring program for Schedule II–IV drugs and anticipates having the program running in full operation by the summer of 2004 [62].</p>
New York	<p>The Boylan Act of 1914 mandated that New York State physicians be provided with state-issued order blanks for the prescribing of “chloral, opium, or any of its salts, alkaloids or derivatives or any compound or preparation of any of them . . .” [84]. These duplicate prescription blanks were serially numbered, with one copy given to the patient and the other kept on file with the doctor for 5 years to be available for inspection by state authorities at any time [84]. In addition, a physical examination was also required before a prescription for a controlled narcotic could be issued [84].</p> <p>Superseding the Boylan Law, the Whitney Law, signed by the governor in May of 1917, allowed physicians the ability to prescribe for the “comfort of addicts,” in addition to requiring registration of addicts [83,85]. This first Whitney Law stated that any licensed physician could administer or prescribe to any person whom presents, in a mandatory physical exam, as “addicted to the use of any habit-forming drug . . . provided that such physician acts in good faith, solely for the purpose of relieving physical stress or of effecting a cure of such habituates” [85]. The Second Whitney Act, in May of 1918, established the independent State Commission of Narcotic Drug Control, with authority to issue and modify regulations as it sees desirable [85]. This reflected the contemporary view of addiction as a medical issue, but this trend toward medical control of addiction was short lived due to the rise of Prohibition [83].</p>

Table 2 Continued

	<p>By early 1919, a strict ruling by the Supreme Court and increasing federal control basically outlawed addiction throughout the country, with reduction and outpatient methods even being forbidden [83]. The idea of triplicate prescription came about in New York in 1959 and was hotly debated until 1972, when it became law within the state's Controlled Substances Act [83]. New York State physicians opposed the burden of triplicate prescriptions seen as interference by the state on medical practice and an infringement on physician/patient confidentiality [83]. Enforcement of the law was put on hold until a Supreme Court ruling in favor of the state department of health allowed the triplicate prescription program to begin [83].</p> <p>In 1989, after 2 years of debate, benzodiazepines (Schedule IV controlled substances) were added to the triplicate prescription program [23]. The Medical Society of the State of New York and much of the New York medical community continued to battle the triplicate prescription law [83]. The triplicate prescription law was ultimately converted to a single form in 1998 [29]. The new law requires physicians to document the following in the patient's medical record: prescribed controlled substance name, prescribed date, prescribed quantity, and prescribed directions for use, but does not require the physician to keep a copy of the official prescription [86]. Although this new legislation states that one of its purposes is to recognize the use of controlled substances for medical practice and pain management, it does not relax legal requirements for prescribing and dispensing controlled substances.</p>
Oklahoma	<p>The Oklahoma Bureau of Narcotics (OBN) instituted the first electronic monitoring system, Oklahoma Schedule Two Abuse Reduction (OSTAR), in 1990 [62]. Previously, OBN had attempted to implement an MCPP, but, from 1986 to 1989, several versions of PMPs were presented to the Oklahoma legislature and each attempt failed [62]. To prepare for the 1990 legislative session, a study confirmed the belief that the state ranked extremely high in the use of several Schedule II controlled substances with no logical explanation behind these numbers [62]. These results were used to support testimony for the Anti-Drug Diversion Act, which contained provisions for an electronic prescription monitoring program [62].</p>
Rhode Island	<p>Rhode Island's first PMP was initially intended to be a triplicate prescription program, as proposed in 1975, but a duplicate prescription program was adopted in 1978 as a compromise with the medical and dental societies, which opposed the retention requirement and system monitoring [62]. In 1997, Rhode Island decided to change to an electronic prescription monitoring program, covering Schedules II and III controlled substances (and needles and syringes) [29,62].</p>
Tennessee	<p>In 2003, Tennessee enacted an electronic prescription monitoring program to monitor Schedules II, III, and IV controlled substances [29].</p>
Texas	<p>Texas adopted its first triplicate prescription program for Schedule II controlled substances in 1981 [87]. This triplicate prescription program reduced prescribing of schedule II controlled substances by approximately 60% from 1981 to 1982, while the total number of prescriptions for all medications increased by 23% [45,78,88]. The contrast between the two numbers raises some red flags about what really happened when the regulation was implemented. In 1997, legislation passed in Texas to implement its current single-copy, serialized, and electronically monitored prescription program [29]. Triplicate prescriptions were replaced by single blanks to which prescribers will affix a sticker if the prescription is for a Schedule II controlled substance [62].</p>
Utah	<p>The state of Utah considered adopting a triplicate prescription program citing their nationally high per capita consumption of certain controlled drugs. Based on the belief that triplicate prescription programs unnecessarily intrude into the conscious process of a practitioner's decisions with respect to treatment of a patient, Utah decided that the triplicate prescription program was not its best option [89]. Instead, an electronic prescription monitoring program, for Schedules II through V controlled substances, was enacted in 1995 [29].</p>
Virginia	<p>In 2002, Virginia implemented an electronic prescription monitoring program as a 2-year pilot [29]. This program only covers Schedule II controlled substances and is limited to the southwest area of Virginia (approximately 300 pharmacies) [29].</p>
Washington	<p>Originally, the Washington State triplicate prescription program was supported as a full triplicate program [62]. Due to insufficient support and economic troubles in the state, a limited triplicate prescription program was adopted instead [62]. The triplicate program in the state of Washington is currently used for disciplinary purposes only [29].</p>
West Virginia	<p>In 1995, West Virginia implemented its Schedule II electronic monitoring program, the West Virginia Schedule Two Monitoring Program (WV-STMP) [62]. It was originally a voluntary system and became mandatory on December 1, 1996 [62]. Currently, electronic monitoring in West Virginia covers Schedules II, III, and IV [29].</p>
Wyoming	<p>In July of 2004, Wyoming implemented an electronic prescription monitoring program to monitor Schedules II, III, and IV controlled substances [90].</p>

will be terminated by 2006 [29]. Only two other states, New York and Texas, currently maintain a single-copy, serialized prescription program in conjunction with an EDT system [29]. The remaining five states with original MCPPs have now all transitioned to an EDT system that does not require a special government-issued prescrip-

tion form [29]. The Pain & Policy Studies Group of the University of Wisconsin has reviewed the recent trends in state PMPs as seen in Figure 1.

In the federal fiscal year of 2003, Congress approved \$7.2 million for the U.S. Department of Justice to support the Harold Rogers Prescription Drug Monitoring Program to establish or enhance

Table 3 States with prescription monitoring programs

State	Year program was enacted	Current program type	Schedules/drugs covered	Initial program(s) type	Year of previous program enactment
California*	1996	Triplicate, serialized/ electronic	C-II	Triplicate	1939
Hawaii	2002	Electronic	C-II, III, IV	Duplicate/ Electronic Duplicate	1996 1943
Idaho	2001	Electronic	C-II, III, IV, V	Duplicate/ Electronic Triplicate	1997 1967
Illinois	1999	Electronic	C-II	Triplicate	1961
Indiana	1994	Electronic	C-II	Triplicate	1987
Kentucky	1998	Electronic	C-II, III, IV, V		
Maine	2003	Electronic	C-II, III, IV		
Massachusetts	1992	Electronic	C-II		
Michigan	2002	Electronic	C-II, III, IV, V	Single-copy, serialized, Electronic Triplicate	1993 1988
Nevada	1995	Electronic	C-II, III, IV		
New York*	1998	Single-copy, serialized/ Electronic	C-II and benzodiazepines	Triplicate	1972
Oklahoma	1990	Electronic	C-II		
Rhode Island	1997	Electronic	C-II, III	Duplicate	1978
Tennessee	2003	Electronic	C-II, III, IV		
Texas*	1997	Single-copy, serialized/ Electronic	C-II	Triplicate	1981
Utah	1995	Electronic	C-II, III, IV, V		
Virginia (limited)†	2002	Electronic	C-II		
West Virginia‡	1995	Electronic	C-II, III, IV		
Wyoming	2003	Electronic	C-II, III, IV		

Notes: Current as of August 8, 2003; prescription monitoring programs are subject to change; does not include Washington State's triplicate program that is used for disciplinary purposes only.

* Indicates physicians are required to obtain state-issued prescription forms.

† The Virginia program is a 2-year pilot, limited to southwest Virginia (approximately 300 pharmacies).

‡ The West Virginia program was discontinued in 1998, but re-authorized in 2002.

Sources: U.S. General Accounting Office, Prescription drugs: State monitoring programs provide useful tool to reduce diversion, May, 2002; Drug Enforcement Administration, Prescription accountability resource guide, September 1998; and updated information from states.

From: Pain & Policy Studies Group [91].

state-run PMPs to address issues of controlled substance diversion [30,31]. Main objectives of the program include: Creation of data collection and analysis systems, improvement of these systems through the use of enhanced technology, development of real-time information technology systems, and assessment of PMP efficiency and effectiveness [31].

In light of growing consternation over the need for drug monitoring that is effective without inhibiting appropriate opioid prescribing, the American Alliance of Cancer Pain Initiatives (AACPI) has urged states to adopt balanced initiatives in the war against abuse and diversion of prescription pain medications [32]. The AACPI recommends that states consider fully using existing resources to identify sources of diversion to support the need for a PMP and involve a multi-disciplinary medical review group in the develop-

ment, review, and evaluation of any such program [33]. It is suggested that PMPs should be considered only when there is evidence that medication diversion and abuse results from forged prescriptions or by actions from within the health care community; initial efforts must be made to determine the extent that drugs are diverted by criminal means, such as through pharmacy theft or robbery, which would not be addressed by implementing a PMP. The AACPI stresses that states must ensure that their PMPs: 1) Are administered by the state agency regulating health care, 2) Do not include special government-issued, serialized prescription forms, 3) Cover all controlled substances in Schedules II through IV, and 4) Protect patient confidentiality [33]. Also, educational programs should be developed to address the perceptions that health care professionals have about PMPs and to minimize concerns regarding regu-

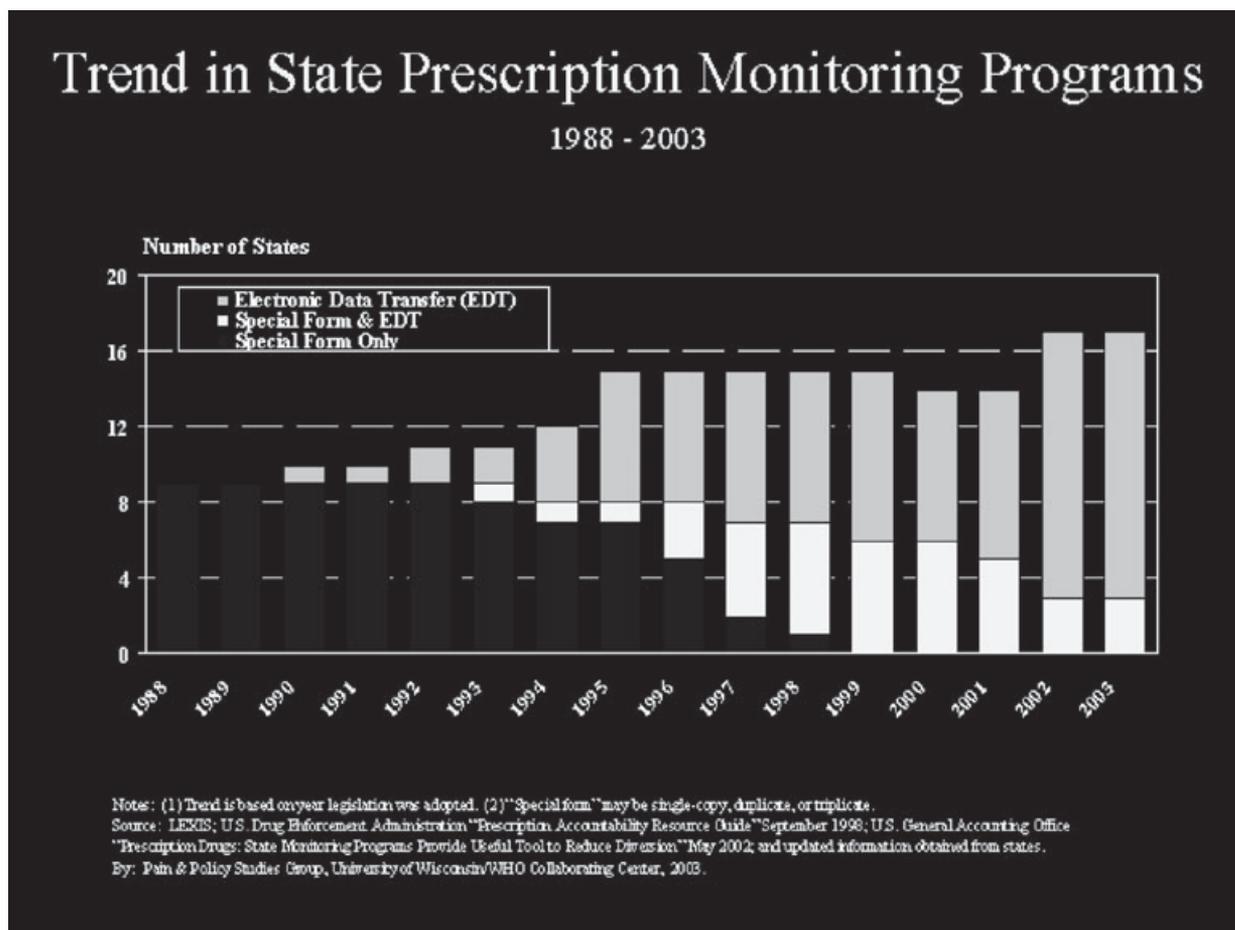


Figure 1 Trend in state prescription monitoring programs, 1988–2003.

latory scrutiny [33]. Very few PMPs have been adequately evaluated to determine their impact on the availability of controlled substances for legitimate medical purposes or the subsequent incidence of drug abuse and diversion [30].

The Impact of Opioid Regulation on Prescribing Patterns

The varieties of restrictions imposed upon controlled substances have created fear in both physicians and patients. PMPs are believed to have adverse effects on the legitimate prescribing of controlled substances, including the inappropriate substitution of nonregulated drugs [34,35]. Some physicians feel this way because they would rather not be bothered by the extra paperwork involved, while others fear that stocking special prescription pads leaves them open to being burglarized. Physicians worry about being labeled as an overprescriber, raising red flags to regulators, or feel

that drugs needing a special prescription must be more dangerous and should be avoided at all cost. Patients report that they fear possible loss of confidentiality and stigmatization by having their names tracked [36–38], as well as an increased difficulty in obtaining needed medications because many physicians will not prescribe drugs that are monitored by a PMP [36]. Patients also worry about the increased costs of the extra doctor visits needed to obtain these prescriptions as they are limited to short periods of time (usually 30 days) without the possibility of refills [36]. In addition, problems may arise when one state has a PMP in place, but nearby states have no such regulations, leading to the persistence of “doctor shopping” [39].

Gilson and Joranson found that medical regulators, most of whom were physicians, believed that the potential for regulatory scrutiny negatively impacted appropriate opioid prescribing [40]. No matter how clinically defensible, physi-

cians fear that their prescribing patterns of these heavily regulated drugs will be intensely monitored by legal authorities [34,37,41]. A group of Wisconsin physicians were surveyed in 1991, and it was found that more than half the respondents at times reduced the drug dose or quantity of refills or prescribed a drug in a less-regulated schedule in response to concerns of overzealous regulatory scrutiny [42,43]. In that same year, 40% of responding physician members from the American Pain Society (APS) reported that fear of regulatory review led them to avoid prescribing opioids for patients with chronic noncancer pain [42,44]. Some physicians may respond to multiple copy prescription requirements by simply not obtaining them. For example, as of April 2001, in California, only 57.6% of physicians had triplicates issued to them, leaving 42.4% of California physicians without the means to prescribe Schedule II medications [24,33].

The implementation of PMPs has been demonstrated to decrease the prescribing of Schedule II controlled substances [5,45,46]. After initiation of such a program, prescribing decreased by 50% in Idaho, 54% in New York, 57% in Rhode Island, and 64% in Texas [47]. U.S. data for 1989 show the “substitution effect” in action. In states with MCPPs, 1.8% of all prescriptions were for Schedule II controlled substances, while in non-MCNP states this percentage was 4.7% [35]. In contrast, Schedule III controlled substances in states with MCPPs were 19.6% of all prescriptions, while in non-MCNP states they were only 14.4% [35]. It stands to reason that many physicians were seeking to avoid the risk of being monitored by avoiding drugs that require the use of multiple-copy or serialized forms [5,46]. These data suggest that physicians who are faced with barriers to prescribing a certain type of medication will often prescribe around that barrier by prescribing drugs that are perceived as less scrutinized, even if they are less efficacious and/or potentially harmful [34,35,46,48,49].

The substitution effect was clearly illustrated by the experience in New York when benzodiazepines were added to drugs that require a triplicate prescription in 1989. Following this change, benzodiazepine prescriptions decreased, but increases were seen in alternative drugs that were often therapeutically less optimal, held a greater chance of toxicity, and carried equal or greater abuse potential [46,48,50–52]. Prescriptions for meprobamate declined by 9% nationally but jumped 125% in New York [46,49]. Likewise, methyprylon pre-

scriptions decreased by 15% nationally but grew by 84% in New York [46,49]. Prescribing of butabarbital was also down 15% nationally but increased by 31% in New York [46,49]. Use of chloral hydrate dropped off by 0.4% nationally but inflated by 136% in New York [46,49]. Although the total number of benzodiazepine overdoses slightly decreased, from 1,294 in 1988 to 1,265 in 1989 (a 2.2% decrease), there was a significant increase in nonbenzodiazepine sedative-hypnotic overdoses, from 111 in 1988 to 144 in 1989 (a 29.7% increase) [53]. These data suggest that the New York triplicate prescription program inclusion of benzodiazepines may have influenced a slight reduction in benzodiazepine overdoses, which was negated by the resultant rise in overdoses from nonbenzodiazepine medications that did not require using a special form, leaving the overall number of overdoses nearly unchanged; 1,405 in 1988 versus 1,409 in 1989 [53].

Since benzodiazepines and alcohol interact with similar central nervous system pathways, it is useful to consider the impact of alcohol consumption, prior to and in response to the New York triplicate prescription inclusion of benzodiazepines [23]. Alcohol consumption had declined in the years immediately preceding the new benzodiazepine triplicate regulations but began to rise again when the new regulation took effect [23]. This upward trend suggests that some patients began self-medicating with alcohol in response to the prescription barrier, using alcohol as a substitute for benzodiazepines that were now less available.

Nonetheless, while the relationship between PMPs and prescribing patterns seems clear, debate continues around the true cause behind these changes. Proponents of MCPPs suggest that these regulations are able to reduce inappropriate prescribing of targeted drugs [3,34]. It is believed that psychotherapeutic drugs are commonly diverted in large amounts [18]. In states where these MCPPs have been instituted, prescriptions written for psychotherapeutic agents have been approximately cut in half [18]. Law enforcement and other state regulators assert that these statistics demonstrate that regulated controlled substances were formerly being misprescribed and overprescribed, and have now returned to more acceptable levels [22]. It is also maintained that these noted reductions are the result of a decrease in prescription forgeries and “doctor shopping” [47]. Thus, a decrease in the amount of medication prescribed is interpreted as the single direct measure

of program success. Access to information derived from these programs is also believed to enhance investigations or prosecutions of misprescribing practitioners and pharmacists [50]. Opponents of MCPPs challenge these claims, citing that this hypothesis stands with no supporting data while convincing data reveal that pain is still undertreated [5,54]. What else could possibly explain these drastic changes in prescribing? Could New York State physicians have been so heavily misprescribing before the law took effect? Conversely, were the citizens of New York in need of greater prescribing of meprobamate, methyprylon, butabarbital, or chloral hydrate than the rest of the country?

Although the overall goal of a successful PMP must be to improve public health, law enforcement's responsibilities are to find solutions to the problem of prescription drug abuse that do not negatively impact legitimate opioid prescribing for pain. Simply assessing decreased rates of prescriptions for controlled substances does not warrant the conclusion that a PMP has succeeded. If PMPs are implemented merely to reduce the amount of prescribed controlled substances covered by the program, then they have attained that objective. However, since it is well established that pain is undertreated, such a goal is squarely at odds with the population that continues to suffer from pain. Any claimed achievement by sheer virtue of decreased prescription numbers is accomplished at the expense of patients in pain.

EDT and Secure Prescription Forms

Prescription monitoring programs can use a number of mechanisms to monitor the use of controlled substances. Multiple copy prescription pad requirements (e.g., duplicates and triplicates) for Schedule II medications were an early tool of the PMP, which typically served to restrict access to prescription forms and provide law enforcement agencies and government regulators of health professionals with a copy of each prescription as a means of identifying potential abuse of prescribing authority. MCPPs indeed garnered the intended effect of sensitizing prescribers to the use of specific categories of drugs, which further reduced their availability. However, the nearly universal use of computers to automate pharmacy practice in the recent past has created an opportunity to gather the same information about a broader category of medications without the necessity of MCPPs.

EDT programs that do not require use of government-issued prescription forms make prescription monitoring transparent to the prescriber through the periodic transfer of prescription data from pharmacy computers to the relevant state agency. These programs have the advantage of both removing the stigma attached to prescribing drugs that require special forms and automating a process that generates far too much information to be effectively handled by a paper-based system. California serves as an example of the administrative burden of an MCPP. According to data reported by the California Board of Pharmacy, more than three and a half million Schedule II prescriptions are written in California each year and are filled by more than five thousand pharmacies. This is far too much data to compile and analyze effectively with a paper-based system. EDT systems reduce the administrative workload and provide a database that is more amenable to analyses that can identify potential diversion and abuse of controlled substances.

The principal limitation of EDT systems from a drug control standpoint is that they address abuse after it has already occurred. Such "backend" analysis can be very effective in directing enforcement resources, but it provides minimal benefit to the "front end" of the transaction. Secure prescription forms, which essentially constitute prescription paper with security features that prevent forgery, have been advanced to address the need for "front-end" prevention of prescription drug fraud. In combination with an EDT program, a secure prescription form offers a more complete PMP than either a secure prescription form or EDT program alone.

The safeguards established for secure prescription forms have been selected to strike a balance between preventing forgery and counterfeiting and making the form affordable and easy to use. The secure prescription form increases confidence in the integrity (the contents of the prescription reflect the prescriber's order) and authenticity (the patient and prescriber are who they say they are) of the prescription at the point of transaction. 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 demonstration of their ability to consistently deliver secure prescription pads only to appropriately licensed practitioners.

- Security printers authentication of the identity of any practitioner ordering secure prescription forms.
- Security printers maintenance of records of the sale of secure prescription forms which preserves a trail of accountability.
- Secure prescription forms including quantity check boxes. These check boxes prevent much common prescription fraud. 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 hydrocodone/acetaminophen becomes a prescription for 130 tablets.
- Secure prescription form including preprinted prescriber information (name, address, license number, DEA registration number).

There are a range of technological safeguards that can be included in a secure prescription form to reduce the likelihood of tampering. Many of these safeguards are listed in Table 4. 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. This balance can mutually serve the needs of government and practitioners providing appropriate pain treatment to their patients.

The secure prescription form is superior to an MCPP by removing those features of MCPPs that were most troubling to prescribers. First, secure prescription forms can be provided by approved private printers. This immediately reduces the barrier to appropriate prescribing by making the forms available without the administrative hassle and fear factors associated with applying to a law enforcement agency to receive forms. The removal of a serial number from each prescription also serves to remove the perception that 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.

Currently, six states have mandated use of security paper prescription blanks. These are Florida, Idaho, Indiana, Kentucky, Maine, and New Jersey. Little is published on the specifics of these programs. Written and phone queries for information on the nature and rules of their state's particular

Table 4 Technical safeguards for security paper

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	The word void appears repetitively when the form is exposed to chemicals designed to wash the ink from the existing prescription to permit a forger to write a new prescription.
Thermochromic ink	Special ink that changes color when exposed to heat by rubbing the feature with your finger.
Invisible ink	Special ink producing an image or pattern that is invisible unless exposed to a particular wavelength of light.
Embossing	Pattern or logo formed into paper resulting in raised or three dimensional image. Gives a distinctive and affluent appearance to documents, especially when combined with foil stamping. Tactile property of feature provides immediate verification.
Microprinting	Miniature print or text that appears as screened line or border. Type commonly consists of a company name or warning message. Verified with magnifying glass. Copied or scanned attempts appear plugged and/or unreadable.
Bleed-through MICR and Arabic numbers	Aniline dye in ink results in penetration into paper, developing into visible, ghosted or blurred image on back of document. Provides immediate verification of authenticity
Foil stamping	A hot stamped decorative feature difficult to copy or scan. If attempted, copied or scanned image will appear mostly black due to reflection effect. Available in solid color or as rainbow
Holographic foil stamping	A hot-stamped foil image appearing as three dimensional or rainbow colored to the document handler. Unique and distinctive as a document feature, it simultaneously serves as a safeguard. Copying and scanning resistant.
Fluorescent fibers	Embedded in the paper, fibers are detectable by black light (UV) and cannot be reproduced by copiers or scanners.
Solvent dye reaction	Adulteration attempts with solvent-based ink eradicators show up by the appearance of black and blue specks in each prescription pad.
Brownstain	Protects against the use of chlorine-based eradicators (bleach), causing the altered area on paper to turn brown.

security paper prescription program was met with varying levels of assistance and knowledge. Some states appeared to have difficulty finding their own regulations. While all of these state programs vary, Florida differs the most in that security paper prescription blanks are required only for the state's Medicaid patients.

The Bellwether State: California 2003

As the first state with a triplicate-based MCPP, California now has the distinction of being the last state with such a system. California law enforcement has testified to the state legislature that the principle example of the success of its triplicate prescription program is the limited problem with Schedule II opioids, such as oxycodone. However, the California triplicate program does not include drugs such as hydrocodone with acetaminophen. Similar to the experience in New York, California physicians have prescribed around the triplicate barrier to Schedule II prescribing. However, Schedule III opioids are often inadequate for many patients in severe or chronic pain, and overprescribing adds the risk of acetaminophen or non-steroidal anti-inflammatory drug toxicity. Moreover, the problem of abuse with Schedule III opioids, such as hydrocodone/acetaminophen, is more significant than those for Schedule II drugs, such as oxycodone [21]. Thus, the California triplicate program may well have converted the problem of Schedule II opioid abuse to a Schedule III problem that goes unmonitored by the current MCPP.

As stated earlier, since 2000, less than 60% of licensed prescribers in California have obtained the required triplicate prescription pads for Schedule II controlled substances [24,33]. In addition, very few triplicates are ever entered into the manual system. For instance, in 1998, only 1.7% of Schedule II drug prescriptions had been entered in California [33]. Taken together, this adds up to an inefficient system that has good intentions but poor outcomes.

Several attempts have been made to repeal the triplicate MCPP for a new program that can balance the law enforcement requirement of preventing forged or otherwise abused prescriptions with patient demand for appropriate analgesics [55–57]. Each attempt has failed due to a lack of support from law enforcement based on their concern that, without triplicates prescriptions, Schedule II abuse and particularly forgery would increase. In recent years, California developed a

computer-tracking program for Schedule II prescriptions, called the Controlled Utilization Review Evaluation System (CURES), which essentially deals with all the functions of triplicate prescriptions except for forgery. Preventing forgery became the last rationale for California's triplicate prescription program. Finding a way to eliminate triplicates required also preventing forged Schedule II prescriptions.

In California's Controlled Substances Act, it is stated that "the Medical Board of California has recognized that pain is undertreated in California in part due to physicians' concern about undergoing investigation for overprescribing." Although somewhat inaccurate, it also states that "Forty-five states in the nation have no requirement for triplicate prescriptions" [58]. It was apparent to the authors of Senate Bill 151 (SB 151) that new solutions were necessary to ensure that all patients are able to receive adequate pain management and society is protected from as much risk of drug abuse as possible. SB 151 was introduced in the California Senate in February 2003 to eliminate triplicate prescriptions in California and establish requirements for the use of tamper-resistant security prescription paper for all scheduled drugs. The bill passed both houses without opposition in August 2003 and was signed into law the following September. This new law phases in a requirement of forgery-resistant prescription pads (tamper-resistant) to be used for all scheduled drugs by January 1, 2005. The Department of Justice will be omitted from the day-to-day prescribing of opioids because the security paper prescriptions will come to physicians from printers, rather than the current arrangement of triplicate prescriptions ordered through an agency of the Department of Justice. Moreover, it is expected that the practice of prescribing Schedule III opioids only because they are perceived to be easier or less risky, but which are less optimal for severe pain than Schedule II opioids, will decrease when all opioids come under the same security paper requirements; phone-in and electronic transmissions will continue to be limited to Schedule III medications. Additionally, safeguards will be added to deal with the abuse of Schedule III drugs.

In addition to security paper requirements, California SB 151 law establishes the present computerized drug monitoring program (CURES) as a permanent program [59]. EDT systems, such as CURES, can achieve the same results as an MCPP by working in the background to monitor pre-

scribing practices, but without being overly burdensome and intrusive on the practitioner. They also permit federal regulators to monitor prescribing activity without becoming overly involved in matters of the state [22]. Brushwood argues, "The maximum value from electronic prescription monitoring programs will be realized in states that design them as health care programs with significant law enforcement benefits." [60]. The combination of an EDT system that monitors prescribing practices with a forgery-resistant, security paper prescription program for all prescription drug schedules appears able to balance the usually disparate needs of patients, law enforcement officials, and physicians. In a remarkable turn of political events, California citizens now have increased protection from improper prescribing and abuse of controlled substances and improved access to appropriate use of analgesic medications [54,59].

On the Horizon: Electronic Prescribing and the DEA

Physicians and pharmacists in many states are already using electronic data interchange technology to route prescriptions for noncontrolled substances, but as of yet, this technology cannot be used for controlled substances. The DEA currently prohibits electronic transmission of controlled substance prescriptions, but it is currently working on a system for secure electronic transmission of Schedule II drugs, which it calls the Electronic Prescriptions for Controlled Substances (EPCS) project [61]. For such a system to succeed, it will need to provide high levels of security and accuracy.

The EPCS project promises to allow electronic transmission of prescriptions for controlled substances in addition to, but not in replacement of, the current paper-based system [61]. All persons authorized to prescribe controlled substances would be issued digital certificates by the DEA, which function as authentication of a practitioner's authority to prescribe and digitally sign prescriptions for controlled substances [61]. The DEA believes that the EPCS project will produce several benefits to both patients and the health care community, including reduced medical mistakes, improvement of health care efficiency, and reduced prescription forgery [61]. Guidelines for the program are still evolving, and the DEA is currently working with the VA to appraise the performance of this concept in the controlled setting

of a VA facility [61]. The DEA anticipates that, following evaluation of the results from the pilot sites, they will establish and issue modified regulations to permit the electronic transmission of Schedule II prescriptions [61]. Use of this electronic system will likely not be mandated by the DEA, but will serve as an alternate means through which controlled substances can be sent to pharmacies [61].

Conclusions

Medication diversion and pain are unfortunate facts of life. Managing one of these problems should not impair society's ability to manage the other. Physicians must recognize that they have a dual obligation to treat pain while adopting clinical risk-management methods to reduce abuse and diversion of pain medications. Alternatively, law enforcement and regulators must effectively assess and stop diversion without interference with legitimate medical practice.

New advances in prescribing controlled substances to appropriate patients and advanced monitoring programs hold the promise of improving health and public safety. Nonetheless, the concurrent war on drugs continues to collaterally damage the war on pain. While we must implement new programs with potential solutions, we must also continue to periodically examine their effectiveness and the possibility that our efforts may continue to impair access to pain relief.

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