



Published in final edited form as:

*Health Aff (Millwood)*. 2013 March ; 32(3): . doi:10.1377/hlthaff.2012.0945.

## Measures Such As Interstate Cooperation Would Improve The Efficacy Of Programs To Track Controlled Drug Prescriptions

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### Abstract

In response to increasing abuse of prescription drugs, 44 states have implemented -- and five more states will soon adopt -- monitoring programs to track prescriptions of controlled medications. Although these programs are primarily designed to help law enforcement officials and regulatory agencies spot possible illegal activity, health care providers have begun to use data from them to help improve patient safety and quality of care. We reviewed government documents, expert white papers, articles from the peer reviewed medical literature, and reports of the experiences of local health officials. Although we found some evidence that prescription drug monitoring programs are a benefit to both law enforcement and health care delivery, the programs have strengths and weaknesses, and their overall impact on drug abuse and illegal activity remains unclear. We believe that improving the efficacy of prescription drug monitoring programs will require such changes as more standardization and interstate cooperation, better training of providers, more secure funding, and further evaluation.

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In response to growing concerns about prescription drug abuse, most states have implemented prescription drug monitoring programs. These programs collect data on prescription medications, such as opioids, sedative-hypnotics, and amphetamine-related drugs.

Typically, a centralized database is established to which pharmacies report dispensed medications (by drug name, strength, and quantity), date, prescriber, and patient. The information is then made available to other pharmacists, health care providers, and law enforcement officials in that state.

The primary goals of these monitoring programs are to reduce prescription drug abuse and curtail "diversion," a term that encompasses several forms of illicit activity, including "doctor shopping" (visiting many physicians to obtain multiple prescriptions), outright drug

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In this month's *Health Affairs*, Richard Deyo and colleagues report on their assessment of state monitoring programs to track prescriptions of controlled medications. The programs are primarily designed to help law enforcement officials and regulatory agencies spot possible illegal activity, but health care providers are also using data from them to help improve patient safety and quality of care. The authors conclude that the programs' impact on drug abuse and illegal activity is unclear. But various measures could improve their efficacy and make them even more useful to providers -- such as feeding data collected by the programs into electronic health record systems.

theft from pharmacies, and prescription forgery. Diversion can also involve the illegal sale of prescriptions—or the drugs themselves—by physicians, patients, or pharmacists.

Prescription monitoring programs primarily target drug abusers and prescriber “pill mills.” At the same time, however, health care providers increasingly look to these programs as a tool to improve patient safety and quality of care.

To understand more about the structure and effectiveness of these programs, we reviewed articles from the peer reviewed medical literature, government documents, documents from the Brandeis Prescription Drug Monitoring Program Center of Excellence, material from the National Alliance for Model State Drug Laws, and the reports of the experiences of local health officials involved in developing Oregon's prescription monitoring program.

Based on our review, we constructed a timeline of the evolution of prescription drug monitoring programs, created a snapshot of those programs today, and evaluated and compared their strengths and weaknesses. Our conclusions are presented below, along with possible steps that can be taken to improve the efficacy of these programs.

## Magnitude Of The Prescription Drug Problem

Prescription drug abuse is a national concern. Prescription opioid sales quadrupled between 1999 and 2010,<sup>1</sup> partly in response to concerns about undertreatment of patients receiving cancer care, palliative care, or therapy for acute pain. Prescribing for chronic noncancer pain, however, also increased dramatically during the same time period.

Pharmaceutical industry marketing, along with the industry's sponsorship of pain societies and continuing medical education, may have played an important role in these trends.<sup>2-4</sup> For instance, professional societies for clinicians who specialize in pain management receive substantial financial support from opioid manufacturers, especially for annual meetings and for continuing education courses and seminars aimed at prescribers.<sup>2-4</sup>

With increased prescribing came a parallel increase in opioid-related deaths, reaching 14,800 deaths in 2008,<sup>1</sup> and translating into a mortality rate four times what it was in 1999.<sup>1</sup> Since 2003, the number of prescription opioid-related deaths has exceeded deaths related to heroin and cocaine combined.<sup>1</sup> Although it was previously assumed that high doses of opioids were safe if those doses were achieved gradually, recent studies suggest that opioid doses exceeding a moderate level are associated with a several-fold increase in the risk of overdose or death.<sup>5,6</sup>

Visits to emergency departments for opioid abuse doubled between 2004 and 2008.<sup>7</sup> Admissions to substance abuse treatment programs quadrupled between 1998 and 2008, with prescription opioids second only to marijuana as the cause for these admissions.<sup>7</sup> Increases in opioid use among adolescents and pregnant women (because of the subsequent risk of neonatal withdrawal syndrome) have caused particular concern.<sup>8,9</sup>

Treatment of chronic noncancer pain now accounts for the largest volume of opioid prescribing. Although a small number of patients may benefit from this treatment, randomized trials offer little evidence of the efficacy of long-term opioid use for chronic back pain or osteoarthritis, the most common indications.<sup>10,11</sup> Many people receiving long-term opioid therapy continue to have severe pain.<sup>12</sup> Addiction and misuse appear to be more common than once believed, as are other side effects of long-term opioid therapy, such as sexual dysfunction and—among the elderly—osteoporosis, driving accidents, fecal impaction, falls, and fractures.<sup>6</sup>

It remains unclear how often prescription opioids lead to abuse, but surveys of community practices report that opioid abuse occurs in 4–26 percent of patients receiving these drugs.<sup>6</sup> Among primary care patients with no history of substance abuse who were receiving daily opioid therapy, purposeful over-sedation was reported by 19 percent, unsanctioned dose increases by 33 percent, use for purposes other than pain by 12 percent, hoarding by 10 percent, and obtaining extra opioids from other doctors by 5 percent.<sup>13</sup>

These trends have led to growing alarm, with some physicians advocating reduced opioid prescribing for chronic pain outside of cancer or palliative care.<sup>3,6,14</sup> Alternatives include non-opioid analgesics, physical treatments, and cognitive-behavioral therapy, although insurance coverage is often inadequate for such non-drug therapies.<sup>15,16</sup>

## Prescription Monitoring Programs

Against this backdrop of overuse, abuse, and illegal activity, the role of prescription drug monitoring programs warrants increased scrutiny.

In 1939, long before the current era of doctor shopping, pill mills and the OxyContin epidemic, California launched the nation's first prescription monitoring program.<sup>17</sup> Instead of computers and databases, California physicians and pharmacists used the technology available at that time: carbon copies, forms in triplicate, and the US mail.

Advances in information technology in the 1990s enabled more states to implement prescription drug monitoring programs, and by 2002, seventeen states had such programs. The federal government also initiated a number of programs of support.

In 2002, the Department of Justice created the Harold Rogers Prescription Drug Monitoring Program, named after Congressman Harold Rogers of Kentucky, Chair of the House Appropriations Committee and supporter of the program. The program makes funds available to states to create their own prescription drug monitoring programs. The department had also supported (beginning in 1995) the creation of the National Alliance for Model State Drug Laws, a nonprofit organization that provides assistance to states and facilitates coordination among stakeholders.

In addition, beginning in 2010, the Justice Department supported a Prescription Drug Monitoring Program Center of Excellence at Brandeis University. The center provides analytical support to government agencies, encourages innovative uses of program data, and identifies best practices.

With support from the Harold Rogers Program, more states established prescription monitoring programs, but they did so in a variety of ways and without common standards for program operation, data protection, data reporting, data interpretation, or access.

In fiscal 2009, the Department of Health and Human Services provided additional funding to states to establish or improve prescription monitoring programs and established best practices for prescription monitoring programs as authorized by the National All Schedules Prescription Electronic Reporting Act of 2005. The best practices were established to promote patient safety and quality of care and to provide greater privacy safeguards for patients. However, no funding has been authorized to support these activities since fiscal 2010, so the shift of emphasis to health concerns remains only partially implemented.

In 2011, the White House Office of National Drug Control Policy made prescription monitoring programs a central feature of its plan to control the epidemic of prescription drug

abuse, with the goal of having a program in every state.<sup>18</sup> This action, in addition to the Harold Rogers Program, provided an impetus for the remaining states to create programs.

By January 2013, forty-nine states had laws enabling the establishment of a prescription drug program, with Missouri the only exception. Of the forty-nine states with enabling legislation, only five do not have an operational prescription drug monitoring programs: Arkansas, Georgia, Maryland, New Hampshire, and Wisconsin.<sup>19</sup>

In addition to helping authorities track potential prescription drug abuse, these programs provide clinicians and pharmacists the means to monitor the use of controlled medications to ensure a high level of quality and safety in health care. Data indicating multiple prescribers, multiple pharmacies, early refills, high doses, multiple controlled drugs, or risky co-prescriptions can suggest to clinicians and pharmacists potential drug abuse or diversion on the one hand, or compromised patient safety on the other.

Such data, combined with a clinical assessment, might prompt a physician to avoid prescribing a controlled drug or to refer patients to addiction or mental health services. Similarly, a pharmacist might decline to dispense a controlled drug to a patient in light of data that might signal abuse.

## Design And Variations Among Prescription Monitoring Programs

Although most states now have prescription monitoring programs, these programs vary widely in terms of design, function, and who can access the data (Exhibit 1).<sup>19</sup> Programs are evolving so rapidly that even the reported data for specific states (collected by the National Alliance for Model State Drug Laws in late 2012 and available on the organization's website<sup>19</sup>) may be out of date by the time this article is published. Still, it is useful to categorize and describe general program characteristics for the purpose of comparing and gauging effectiveness.

### Variations In Law Enforcement Access

Thirty-eight state prescription monitoring programs operate under the authority of a state health agency. Six states assign the responsibility for prescription monitoring programs to law enforcement agencies.

Regulations permitting access to prescription data by law enforcement vary. Seventeen states require that law enforcement agencies provide proof of probable cause, a search warrant, a subpoena, or proof of other judicial process in order to gain access to prescription drug data. In twenty-eight states, a law enforcement officer must be engaged in an active investigation to access the state's prescription database. In Pennsylvania, data are available to law enforcement on request, without any judicial or investigative requirements.

### Monitored Drugs

Forty-five states have prescription monitoring authority for drugs listed in Schedules II through IV of the Drug Enforcement Administration's schedules of controlled substances (Exhibit 2). Schedule I includes substances like heroin that are subject to abuse and have no recognized medical use. These are not dispensed by pharmacies and therefore not overseen by monitoring programs. Schedule II includes prescription drugs with the highest risk of abuse, such as morphine, oxycodone, and methadone, and these are monitored in every state program.

Schedule III, IV, and V drugs have progressively lower potential for abuse. Twenty-nine states also grant authority to monitor Schedule V drugs, and thirteen even allow monitoring of certain drugs not on the Drug Enforcement Administration's schedules.

### **Access By Persons Other Than Law Enforcement Officers**

Forty-five states allow prescribers and dispensers of controlled medications to access monitoring program data, and forty-four allow access by state licensing boards. In thirty-five states, an adult patient (or parent or guardian of a minor) may receive personal information collected by the monitoring program on request.

Public insurance carriers (Medicare, Medicaid, or state insurance programs) can access monitoring program data in twenty-nine states. Only fourteen states grant access to medical examiners and four to mental health and substance abuse professionals (with some restrictions).

### **Required Participation In Prescription Monitoring Programs**

In forty-one states, prescriber participation in the program is voluntary. However, eight states require all prescribers to participate. Furthermore, twelve states require that prescribers use the monitoring program under specific circumstances.

For example, Tennessee requires prescribers to check the monitoring program whenever prescribing a controlled substance to a patient for the first time, then annually thereafter. Kentucky requires clinicians to check whenever prescribing a Schedule II or III drug. In all states, regardless of participation requirements, prescribers must register to gain access to monitoring program data.

### **Delegated Access**

Most health care providers delegate some aspect of patient record-keeping and data collection to nonphysician staff. Only twenty-one states, however, allow practitioners to designate an authorized agent to access the state's prescription monitoring database. In the remaining twenty-eight states with enabling laws, the practitioner must personally access the data.

### **Providing Unsolicited Reports**

Twenty states provide unsolicited reports to prescribers, pharmacists, licensing boards, or law enforcement agencies. The intent of such proactive systems is to notify the appropriate party when a pattern of aberrant drug prescribing or dispensing is detected. Thirteen states do not provide unsolicited reports; officials cite cost as a barrier.<sup>20</sup>

## **Controversies Surrounding Prescription Monitoring Programs**

### **Law Enforcement And Health Care**

Prescription monitoring programs emerged from law enforcement concerns about drug abuse and diversion. The concept of using prescription monitoring programs as tools for public health—to limit risky prescribing and facilitate addiction services—arose secondarily.

States where prescription monitoring programs maintain a strong law enforcement component have reported that drug diversion cases involving specific clinicians, pharmacies, or patients take less time to investigate.<sup>20</sup> Physicians, however, confront conflicting pressures.

On the one hand, they might feel pressure to avoid prescribing opioids liberally, even if they believe the prescription is clinically appropriate, because such a prescription pattern detected by a monitoring program could bring legal scrutiny. On the other hand, they might feel pressure to prescribe opioids to meet patient expectations or maintain high patient satisfaction scores on performance evaluations, or because prescribing opioids is the fastest way to address a pain complaint and maintain high patient volume.<sup>21</sup>

### Potential For Inadequate Pain Treatment

Some clinicians and patient advocates believe that prescription monitoring programs have a chilling effect on opioid prescribing and adversely affect pain management.<sup>22,23</sup> Clinicians might withhold or minimize opioids because they fear legal scrutiny. Even though many pain experts now caution against routinely recommending opioids for chronic noncancer pain,<sup>2,3,6,14</sup> prescriptions in the United States continued to increase at least through 2010.<sup>1</sup> This continued increase in prescribing may alleviate concerns about undertreatment, but it raises questions about whether monitoring programs are having the intended effect on opioid diversion or abuse.

### Privacy Concerns

Some prescription monitoring programs, especially those based in law enforcement agencies, did not historically treat their data as protected health information would be treated today under federal and state laws and regulations.<sup>24</sup> Privacy advocates express misgivings about privacy risks raised by prescription monitoring programs.<sup>25</sup> As well, studies show that patients fear the loss of privacy, stigma from being tracked, and increased difficulty in obtaining medication.<sup>23</sup>

In Oregon, legislation creating the state's prescription monitoring program was vigorously opposed by the American Civil Liberties Union, which argued for adequate safeguards to prevent “fishing expeditions” by law enforcement and the inadvertent release of information.<sup>25</sup> Although advocates of the prescription monitoring law prevailed, lawmakers heeded the privacy concerns and included in the law such safeguards as limiting law enforcement access to the database, allowing access only to registered clinicians and pharmacists (not their assistants), and prohibiting unsolicited reports.

### How Quickly Should New Data Be Available?

In some twenty-two states, prescription monitoring programs receive weekly electronic transmissions of information from pharmacies. In six states, however, data are submitted monthly. But vendors of prescription data systems and some program advocates argue for real-time data transmission, with data flowing to monitoring programs as a pharmacist fills a prescription.<sup>26</sup>

Real-time data transmission might be useful in clinical settings, such as emergency departments, where providers and patients do not have a long-standing relationship. A counterargument is that real-time data could increase system costs, impose burdens on pharmacists, and deliver little return on investment.<sup>26</sup> In conversations, some clinicians are less concerned about a potential problem in recent hours or days than about patterns of dispensing to their patients over weeks and months.

But more important than the frequency of transmission from pharmacists to the database is the assurance that practitioners and pharmacists have access to program data on a continuous basis. Four states do not yet have web-based access to their monitoring programs or have installations underway;<sup>26</sup> at present they rely on fax, mail, or e-mail for transmission of data.

This reliance on older technology can limit their access to database information after business hours and on weekends.

## Impact On Individual Patient Care

Do prescription monitoring programs improve patient care? The question is the subject of ongoing investigation.

Little is known about how providers and pharmacists use monitoring program data in clinical practice, what the best techniques are for approaching patients, how to support the use of relevant treatment or screening guidelines, how referral patterns are affected, and what the impact of programs on health care utilization and outcomes has been.

One of the few studies to examine the influence of prescription drug monitoring data on individual doctor-patient interactions came from an emergency department,<sup>27</sup> a setting where many opioid prescriptions originate. The 2008 study, conducted in Toledo, Ohio, found that some patients had filled up to 128 opioid prescriptions from as many as forty different clinicians and twenty different pharmacies in the twelve months prior to their emergency room visit.

After accessing prescription monitoring data, physicians participating in the study indicated that they changed prescriptions in 41 percent of patient encounters. Most of those changes, 61 percent, resulted in less or no opioid medication, but 39 percent resulted in more opioid medication than originally planned. Prescribing more opioids reflected a judgment that the patient would benefit from stronger analgesia, and that there was no evidence of drug misuse. The study results suggested that the monitoring data contributed to limiting prescriptions in questionable situations and improving pain management where there was no evidence of misuse.

A 2011 national survey of 205 physician toxicologists identified barriers to their use of prescription drug monitoring programs and data. These barriers included burdens on their time, perceptions that data would not change clinical practice, and difficulties in accessing and navigating the system.<sup>28</sup>

Anecdotal reports suggest other clinical uses of prescription monitoring programs. For example, some clinicians would be more comfortable checking a monitoring program report than requiring a urine drug screening, which might result in an awkward patient confrontation and disrupt the clinician-patient alliance.<sup>29</sup> Two doctors report their colleagues' experience that when they presented patients with results of a monitoring program search, some of those patients requested admission to rehabilitation programs.<sup>29</sup>

Many physicians have reported experiences where they discovered aberrant patterns of prescription drug use by a patient in which the patient simply chose to change providers, although this phenomenon has not yet been quantified in published research.

In a 2006 survey of program administrators from eighteen states, administrators reported being aware of a few cases in which clinicians discharged patients from care without making any effort to help the patients, a practice that administrators considered inappropriate.<sup>30</sup>

## Population Impacts

Do prescription monitoring programs reduce drug diversion, abuse, and overdoses? It remains unclear whether prescription monitoring programs have reduced opioid-related deaths or substance abuse.

The 2004 President's National Drug Control Strategy advocated for monitoring programs with this observation: "The effectiveness of PMPs [prescription monitoring programs] can be seen in a simple statistic: in 2000, the five states with the lowest number of OxyContin prescriptions per capita all had PMPs ... the five states with the highest number of prescriptions per capita all lacked them."<sup>31</sup> Unfortunately, this assessment did not consider the possibility that states with monitoring might inadvertently shift prescribing to other opioids, and said nothing about rates of abuse or death or other health impacts.

An unpublished 2006 analysis for the Department of Justice compared states with and without prescription monitoring programs, and concluded that the programs reduced the per capita supply of Schedule II drugs.<sup>32</sup> The analysis found states with proactive programs that provided unsolicited reports appeared to be more effective in reducing the per capita supply of Schedule II drugs compared with states that lacked such proactive programs.

The authors of this analysis noted that when admissions to drug abuse treatment programs were used as an outcome measure, states with prescription monitoring programs paradoxically seemed to have higher rates of opioid abuse than states without. One explanation for this finding is that the states with the biggest problems in opioid abuse were most likely to implement monitoring programs.

The study's statistical modeling suggested that although opioid prescribing increased over time in states with monitoring programs, the rate of increase would have been 10 percent higher without proactive programs. The authors suggested that proactive monitoring programs should therefore reduce the probability of prescription opioid abuse.<sup>32</sup> Unfortunately, the study did not investigate whether the monitoring programs prompted doctors to prescribe fewer Schedule II drugs in favor of Schedule III drugs.

A more recent evaluation using 2003–2009 data compared states with and without prescription monitoring programs and supported an association between these programs and diminished opioid misuse. The authors used reports to poison centers to identify "intentional exposures" to Schedule II opioids. Intentional exposures included suspected suicide, withdrawal, abuse, and intentional misuse. In states without a prescription monitoring program, these events increased on average 8 percent per year, but in states with a monitoring program in place, they increased by 0.8 percent per year. Opioid treatment admissions rose 20 percent per year in states without a monitoring program, but just 11 percent per year in states with a monitoring program.<sup>33</sup>

As mentioned previously, there is concern that prescription monitoring programs may decrease prescribing of Schedule II drugs, only to increase prescribing of Schedule III drugs, which prompt less scrutiny, a "substitution effect." There is evidence of such shifts in several states,<sup>22,23</sup> and nationwide data support the concern.<sup>34</sup> A related concern is that if prescribing of controlled drugs is curtailed, more drug abusers will shift to illicit drugs.<sup>22</sup>

The possibility of a substitution effect is supported by the only study comparing overdose deaths in states with and without monitoring programs. Paulozzi and coauthors used data from the Centers for Disease Control and Prevention and the Drug Enforcement Administration to examine "multiple cause of death mortality files produced by the National Center for Health Statistics" in the years 1999–2005, and found that overdose rates from all drugs, and opioid-related overdose rates in particular, rose with or without the presence of a state prescription monitoring programs.<sup>35</sup>

There were no statistically significant differences in mortality between states with and without monitoring programs, but there was a trend toward higher crude mortality rates (unadjusted for age or sex) in states with a program. In keeping with the substitution



hypothesis, use of Schedule II drugs, such as oxycodone, was lower in states with monitoring programs, but those same states had greater use of hydrocodone, a Schedule III drug.

Paulozzi's study found that states with proactive prescription monitoring programs did not have lower drug-related death rates than states whose programs were not proactive. However, three large states, California, New York, and Texas, all with proactive programs, had lower than average overdose rates and smaller increases in opioid prescribing. The authors speculated that this was because of continued use of serialized tamper-resistant prescription forms. However, there is conflicting evidence on the effects of such forms.<sup>36</sup>

Critiques of the Paulozzi study noted that it did not measure use of the monitoring programs by health care providers, and that during the study period, the prescription monitoring programs were mostly used by law enforcement officials.<sup>37,38</sup> Furthermore, during the study period, many states were receiving pharmacy reporting data on only a monthly basis; many monitoring programs were not accessible online; and some states restricted access by physicians, pharmacists, or both.<sup>37,38</sup>

In summary, the effectiveness of modern prescription monitoring programs remains uncertain, as do the effects of various system design features.

## Policy Implications

Forty-four states now have, and an additional five will soon have, a prescription monitoring program. Widespread implementation of the prescription monitoring programs provides opportunities to define optimal program features and create standards that maximize their utility. The near ubiquity of these programs should reduce the shift of drug diversion activities from a state with a monitoring program to adjacent states without one.<sup>20</sup> It also creates greater opportunities to compare the impacts of differing design features.

## Linking State Programs

Ubiquity will foster linkage of state programs. The Council of State Governments has drafted a compact to facilitate sharing of prescription monitoring program data and to address funding, provider education, data security, access, and compatibility.<sup>39</sup>

In 2012, Congressman Rogers of Kentucky introduced legislation to develop national interoperability standards to facilitate interstate exchange of prescription information. Through his and other such efforts, states are already creating the architecture for software that enables the exchange of prescription monitoring information. The National Association of Boards of Pharmacy is coordinating with the software initiative and has provided financial support for a program that links ten state programs.<sup>40</sup>

An unresolved issue is the growth of internet pharmacies offering controlled substances.<sup>41</sup> Many states have statutory authority to require nonresident pharmacies to report to the state monitoring program, but it is unclear how many can enforce the requirement. Interstate agreements that support data sharing may help in this regard.

## Standardizing Monitoring Program Features

Experience to date indicates that certain prescription monitoring program features should be standardized. To avoid the substitution effect, programs should monitor all schedules of controlled substances.<sup>26</sup> All states should allow access to program data by prescribers. The value of immediate clinician access to data argues for web-based electronic access and not reliance on telephone, fax, or mail.

Programs should also standardize the timing of pharmacy reports to the database. Monthly reporting may be suboptimal and real-time reporting burdensome. Weekly intervals for reporting seem reasonable, but further evaluation is appropriate. States should institute regular periodic data-system and program evaluations to ensure data accuracy, assess program impact, and gauge responses to program changes.<sup>24</sup>

### **Proactive Programs**

Monitoring programs, which issue periodic unsolicited reports of suspicious activity, appear to be more successful than programs that do not provide routine reviews.<sup>26</sup> Proactive strategies could use the monitoring program as an epidemiological tool to identify geographic locales, patients, prescribers, or pharmacies with aberrant prescribing or patterns of use.

Monitoring programs also could track standardized outcome measures, such as numbers of patients who fill prescriptions from five or more providers within a six-month period, submit overlapping prescriptions, or receive risky co-prescriptions.<sup>35</sup> Some of this analysis could be automated, but multidisciplinary analytical expertise and judgment would probably be needed for optimal analysis.<sup>24,26</sup>

### **Provider Education**

Because prescription monitoring programs are relatively new, they remain unfamiliar to many providers, and there is little guidance on how they can be used effectively.<sup>26</sup> Some states have begun developing guidelines, but there are few resources to help clinicians interpret data, communicate information to patients in a nonthreatening way, plan clinical interventions, or coordinate care among multiple providers and pharmacists.

### **Integration Into Clinical Workflow**

Prescription monitoring program data remain poorly integrated into clinical workflow.<sup>26</sup> Organizations such as the federal Substance Abuse and Mental Health Services Administration advocate expanding access to the data by provider-appointed delegates in a manner consistent with privacy laws. Enabling physicians to gain access via electronic medical records and providing unsolicited alerts directly to an electronic medical record may facilitate providers' use of monitoring program data. Facilitating their use should be considered when deciding whether to integrate programs with electronic health record systems or to keep them as stand-alone databases provided by vendors outside the health care system.

### **Funding**

Annual operating costs for prescription monitoring programs range from \$125,000 to \$1 million.<sup>40</sup> Current support comes from general state revenues, prescriber and pharmacy licensing fees, state controlled substance registration fees, health insurers' fees, and state and federal grants.<sup>40</sup>

It seems appropriate to continue the Harold Rogers grant program (\$7 million in 2012 appropriations) and to restore the National All Schedules Prescription Electronic Reporting Act. The latter will require Congress to restore funding.

Drug industry support for some activities may be appropriate, given the industry's stake in appropriate medication use. That is, reducing prescription drug overdoses and deaths would reduce the likelihood of more restrictive regulation of certain controlled drugs.

Insurance industry support may also be appropriate, given the high costs of complications from drug misuse, overdose, and addiction therapy, and the potential for reducing those costs.

## Conclusions

Though prescription monitoring programs developed as law enforcement tools, an unrealized value may be in clinical care. Goals of improved patient care and reduced substance abuse are primarily public health priorities. The costs of these programs pale in comparison to the costs of prescription drug misuse, but state and federal governments face extreme budget constraints. With sparse data on efficacy, should states invest further in these programs?

Many potential uses of monitoring program data are just now being explored. As one example, there is little use of programs to alert clinicians to overdose potential from risky co-prescriptions or doses. Programs are likely to become more valuable to clinicians as the information is further embedded into clinical workflow.

The value of prescription monitoring programs cannot yet be assumed, and the most effective system design features and response strategies have yet to be documented. Thus, it seems premature to judge the value of monitoring programs.

Given the infrastructure developed to date, the still-immature nature of most programs, rapid evolution, promising enhancements, and suggestive evidence of both law enforcement and health care benefits, we believe it prudent to support ongoing funding for the programs, enhancements, and further evaluations. The emergence of prescription monitoring programs in nearly every state, suggests that the time is ripe for these developments.

## Acknowledgments

The project described was supported by the National Institutes of Health, National Institute for Drug Abuse through Grant No. 1 R01 DA031208-01A1 and by the National Center for Research Resources and the National Center for Advancing Translational Sciences through Grant No. UL1RR024140. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the participating institutions. Dennis McCarty has Research Service Agreements with Purdue Pharma, LP, and Alkermes, plc.

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Deyo's research interests include measurement of patient function, engagement of patients in clinical decisions, and management of low-back pain. He earned a master's degree in public health from the University of Washington and a medical degree from Pennsylvania State University.

Jessica Irvine is a project manager at Aumentra Health, a nonprofit organization in Oregon that is focused on improving the quality, safety, and value of health care. She currently manages a federally funded study that aims to identify how providers use data from prescription drug monitoring programs to make decisions about prescribing controlled substances. She received a master's degree in psychology from Portland State University.

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Dennis McCarty is a professor in the Department of Public Health and Preventive Medicine at Oregon Health and Science University, where he collaborates with state and federal policy makers as well as community-based programs to examine publicly funded prevention and treatment services for people with substance use disorders. McCarty is also the co-principal investigator for the Western States Node of the National Drug Abuse Treatment Clinical Trials Network, which studies behavioral and pharmaceutical approaches treatment for alcohol and drug use disorders. He earned a doctorate in social psychology from the University of Kentucky.

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**Exhibit 1****Variations In Design And Use Of Prescription Drug Monitoring Programs, December 2012**

<b>PDMP Characteristic</b>	<b>Variations</b>	<b>No. Of States (N=49<sup>a</sup>)</b>
Location of database in state government		
	Health Department, Board of Pharmacy, single state authority	38
	Law enforcement agency	6
	Professional licensing board	2
Drugs that can be monitored		
	Only Schedule II drugs	1
	Only Schedule II and III drugs	2
	Schedule II,III, and IV drugs	45
	Authority to monitor Schedule V drugs	29
Access to law enforcement		
	For probable cause, search warrant, subpoena, other judicial process	17
	Pursuant to active investigation	29
	On request from law enforcement	1
Access other than to law enforcement		
	To prescribers and dispensers	45
	To patient, parent or guardian	35
	To licensing or regulatory boards	44
	To Medicare, Medicaid, or state insurance programs	29
Delegated access		
	Practitioner may designate an authorized agent to access database	21
Provide unsolicited reports		
	None	7
	To prescribers only	2
	To law enforcement only	2
	To prescribers and pharmacists only	5
	To prescribers, pharmacists, law enforcement and licensing entities	20
Notification requirements		
	Require prescribers & dispensers to notify consumers about PDMP	7
Interstate sharing of PDMP data		
	Share data with other PDMPs	19
	Share with users in other states	8
	Share with both other PDMPs and authorized users	15

SOURCE See Note 19 in text.

NOTE PDMP is prescription drug monitoring program.

SOURCE See Note 16 in text.

<sup>a</sup>Totals in each category do not reach 49 because in most categories there are several "other" possibilities or combinations not listed, each with just one or two states. In some cases, the possibilities overlap. The list of possibilities was truncated to shorten the table.

**Exhibit 2**

## DEA Schedules For Controlled Substances

Schedule	Description	Examples
I	Drugs or other substances with a high potential for abuse and no currently accepted medical use in the U.S. They lack accepted safety for use under medical supervision.	Heroin, lysergic acid diethylamide (LSD)
II	Drugs with high potential for abuse, but that have an accepted medical use in the U.S. Abuse may lead to severe psychological or physical dependence.	Morphine, oxycodone, methadone, cocaine, amphetamine-related drugs, some barbiturates
III	Drugs with less potential for abuse than Schedule I or II and an accepted medical use in the U.S. Abuse may lead to moderate or low physical and high psychological dependence.	Certain opioids, especially hydrocodone or codeine in combination with acetaminophen or non-steroidal anti-inflammatory drugs (eg, Vicodin, Tylenol 3), tramadol, buprenorphine; anabolic steroids
IV	Drugs with low potential for abuse relative to those in Schedule III and that have an accepted medical use in the U.S. Abuse may lead to more limited physical or psychological dependence those in Schedule III.	benzodiazepines such as diazepam (Valium); hypnotics such as zolpidem (Ambien)
V	Drugs or other substances with low potential for abuse relative to Schedule IV; and have an accepted medical use. Abuse may lead to limited physical or psychological dependence relative to those in Schedule IV.	cough preparations with small amounts of codeine; anti-diarrheal medications with opioid components

SOURCE Office of Diversion Control, Drug Enforcement Administration. Definition of controlled substance schedules [Internet]. Washington (DC): US Department of Justice; [cited 2013 Jan 17]. Available from: <http://www.deadiversion.usdoj.gov/schedules/index.html#define>

NOTE A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in the United States and its relative abuse potential and likelihood of causing dependence.