

SEP 27 2011

Dear Colleague:

The purpose of this letter is to encourage physicians, physician assistants, nurse practitioners, pharmacists, and other Staff in Opioid Treatment Programs (OTPs) to utilize State Prescription Drug Monitoring Programs (PDMPs) as an additional resource to maximize safety of patient care pursuant to applicable state guidelines. The illicit use of prescription drugs (i.e. opioids, stimulants, and sedatives) is a major public health problem. In addition, prescription drug issues affect patients in OTPs.

Prescription Drug Monitoring Programs (PDMPs) – PDMPs are statewide programs that collect data on various controlled substance prescriptions and enable prescribers (including OTP program physicians), pharmacists, regulatory boards and law enforcement agencies (under certain restrictions) to access this information pursuant to applicable State guidelines. Additionally, PDMPs may aid the care of those patients with chronic, untreated pain or chemical dependency and help to identify patients engaged in prescription drug abuse and diversion. To date, forty-eight states and one US territory have enacted PDMP legislation. Thirty-five states have operational PDMPs and an additional thirteen have enacted legislation to implement a program.

PDMPs can be particularly useful to physicians in OTPs. A “case study” developed by the PMP Center of Excellence at Brandeis University (attached) narrates an OTP medical director’s first-person written account of the physician’s experience using a PDMP as an adjunct in ensuring safe and effective outpatient addictions treatment¹. When accessing the PDMP, the physician found that 23% of their patients were being prescribed significant quantities of opiates, benzodiazepines and other controlled substances by clinicians outside their practice. None of the employees at the treatment center were aware the patients were being prescribed these medications.

OTPs and PDMPs – The Substance Abuse and Mental Health Services Administration (SAMHSA) OTP inspections reveal that PDMP reports are already included in many OTP patient records. At least one State requires OTPs to access the State PDMP for patients admitted to treatment, and periodically through treatment. SAMHSA believes that when OTPs access the PDMP database it would assist them in identifying those few who are engaged in doctor-shopping and spot irregularities with what the patients are reporting with what they are actually

¹PMP Center of Excellence Notes from the Field, “Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting,” 2011.

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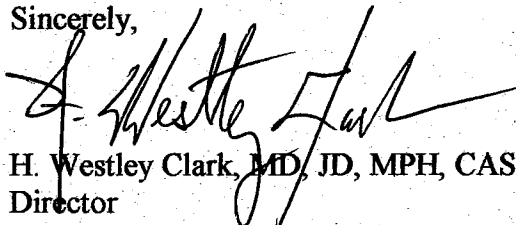
filling. In many cases, monitoring the PDMP may assist the prescriber to revise their treatment plans, possibly preventing a serious adverse event. SAMHSA intends to develop additional guidance on the use of PDMPs in the OTP setting. Until these guidelines are complete, the Agency suggests that OTPs review the enclosed material to help address questions from patients and others.

Confidentiality Requirements – SAMHSA has received questions regarding Federal Confidentiality and how it applies to OTPs and PDMPs. In an attempt to assist with implementation of the rules SAMHSA has prepared the attached guidance. Please refer to Enclosure 1 “OTPs, PDMPs and Confidentiality Issues.” Please note that the Enclosure is intended as educational guidance to assist with the implementation of the confidentiality requirements, however, the information is not legal advice.

In conclusion, SAMHSA urges physicians, physician assistants, nurse practitioners, pharmacists, and other appropriate staff in OTPs to access PDMPs as an invaluable additional resource to monitor patient compliance with treatment protocols.

For additional information or questions, please contact Jinhee Lee, PharmD, Public Health Advisor, at (240) 276-0545 or by e-mail at jinhee.lee@samhsa.hhs.gov

Sincerely,



H. Westley Clark, MD, JD, MPH, CAS, FASAM
Director
Center for Substance Abuse Treatment

Enclosures:

Description of OTPs, PDMPs, and Confidentiality Issues

PMP Center of Excellence Notes from the Field, “Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting”

OTPs, PDMPs and Confidentiality Issues*

SAMHSA has prepared this guidance regarding the implementation of federal regulations at 42 CFR part 2 for educational purposes only. This information is not intended to serve as legal advice.

State PDMPs collect and retain prescription drug information and disclose such information to legally authorized users. Most PDMP state laws require that providers who dispense more than a 48 hour supply of a schedule II-V controlled substance must report that transaction, including patient health information, to the State PDMP. Opioid Treatment Programs (OTP) and Drug Addiction Treatment Act of 2000 (DATA 2000)-Waived physicians are substance abuse treatment programs under the Federal confidentiality rules, therefore, disclosures of patient-identifying information by such programs to State PDMPs are not permitted unless an exception applies consistent with the federal confidentiality regulations.

The legal framework established in the Public Health Service Act (42 U.S.C. 290dd-2) and Federal confidentiality regulations (42 CFR Part 2) protect records relating to a patient received or acquired by a federally-assisted substance abuse program, and include any information that could reasonably be used to identify an individual. Patient records may not be disclosed by federally-assisted substance abuse programs without patient consent, unless an exception specified in the regulations applies.

State laws require PDMPs to establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information is protected and not disclosed to anyone who is not authorized to access this information. In addition, covered entities under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may not use or disclose protected health information except as provided under HIPAA.

How do the Federal confidentiality rules apply to PDMPs?

PDMPs generally do not meet the definition of a federally-assisted substance abuse programs for the purposes of 42 CFR part 2. Therefore, authorized disclosures by State PDMPs would not be considered disclosures of substance abuse patient records and not subject to these regulations.

May an OTP provide patient-identifying information to a PDMP under federal confidentiality rules?

Disclosures of patient-identifying information by federally-assisted programs (including OTPs and DATA-waived physicians) are permitted with written patient consent under 42 CFR part 2. However, redisclosures of such information is prohibited. Since one of the goals of PDMPs is to make information available to authorized users, currently it would not be feasible to ensure that the information will not be redisclosed. Therefore, OTPs and DATA-waived physicians should not disclose patient-identifying information to PDMPs. The question of disclosures of information to PDMPs with patient consent may be considered further by SAMHSA.

Is Patient Consent Necessary to Access Information from a PDMP?

A request for information by an OTP physician from a State PDMP would not be considered a disclosure of patient health information under 42 CFR part 2, therefore, patient consent is not required.

Should patients be notified of PDMP Access?

Programs should consider notifying patients that prescription information is monitored by the State PDMP. This also serves the purpose of facilitating open communication with patients about their prescriptions. Programs can clarify to patients that prescription medication histories are routinely monitored by PDMPs.

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Notes from the Field

2.2 Keeping Patients Safe: A Case Study on Using Prescription Monitoring Program Data in an Outpatient Addictions Treatment Setting

March 2011

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Notes from the Field

Keeping patients safe: A case study on using Prescription Monitoring Program data in an outpatient addictions treatment setting

Summary

A first-person case study is presented on using prescription history data to screen and monitor patients who are opioid addicted for medically unwarranted concurrent use of controlled substances. The Medical Director of a large outpatient opioid addiction treatment program obtained prescription history data on all patients from a newly established state prescription monitoring program (PMP). The Medical Director's analysis of the data indicated that, unknown to clinic medical staff, approximately 23% of patients were being prescribed significant quantities of opiates, benzodiazepines and other controlled substances from providers outside the clinic.

These prescriptions potentially compromised treatment and put patients at risk for dangerous drug interactions, continued addiction, overdose and death. Patients in this group were advised that successful treatment and their own safety required they discontinue seeking unauthorized or duplicate prescriptions. Most patients complied and were retained in treatment, subject to continued monitoring via the state's PMP. This case study suggests that clinical use of prescription history data is a valuable adjunct in ensuring safe and effective outpatient addictions treatment.

All quotations (sections 2-9, indented in text) are taken from the Medical Director's first person written account of the events in question. Anonymity is preserved to protect doctor-patient confidentiality.

1. Background on methadone maintenance and prescription monitoring

Methadone maintenance therapy, often on an outpatient basis, remains the treatment of choice for many of those addicted to opiates, whether heroin or prescription opioid pain relievers. According to the American Association for the Treatment of Opioid Dependence, just over 1,200 methadone clinics are operating in the continental United States, with an estimated combined patient enrollment of approximately 270,000. A concern among clinicians is the illicit use or diversion of controlled substances by some methadone patients. Patients using substances such as prescription opiates and benzodiazepines beyond that indicated for clinically sound addiction treatment are at risk for dangerous drug interactions, continued addiction, overdose and death. A protocol to help reduce illicit drug use and diversion by such patients would be of great value to ensure successful treatment and increase both patient and public safety. The case study presented here suggests that clinical use of PMP data on patients' prescription histories constitutes just such a protocol.

Prescription monitoring programs, underway in the majority of US states (34) and being planned or implemented in ten others, collect data from pharmacies on prescription sales of controlled substances, recording the type of drug, quantity dispensed, customer and/or patient identifying information, prescriber, pharmacy and date of sale. In response to requests by authorized medical providers, almost all PMPs provide reports on the prescription histories of specific patients.

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Providers can, therefore, check to see whether their patients are receiving concurrent prescriptions from other prescribers, an indicator of possible prescription misuse, abuse, fraud or doctor shopping. Most PMPs have or are moving to online systems in which authorized end-users can retrieve data on a patient's prescription history from their offices. The present report suggests that quick, online (but strictly controlled) access to PMP data for medical providers can play a critical role in addictions treatment.

The Medical Director reporting data for this study was the director of a large outpatient methadone clinic. The text in sections 2-9 is drawn verbatim from his written first-person narrative, which takes us from the discovery of his state's newly implemented PMP to the consequences for treatment and patient safety of consulting prescription histories. Italics for entire sentences have been added for emphasis by the PMP Center of Excellence, whereas single words in italics or underlined were emphasized in the Medical Director's original account.

2. Discovering and using the PMP

I first learned about our state's prescription monitoring program (PMP) from an email forwarded to me by one of the administrators at the opioid treatment program (methadone clinic) where I worked. He originally received the information from a person working in the office of the state opioid treatment authority. As soon as I knew we had a functioning prescription monitoring program, I did all I needed to do to get access to this database, which was relatively simple. I had to sign a notarized statement to send to database officials, along with a copy of my driver's license. I was given an ID and a password for the database. *I consider the database one of the best tools I have to help identify and treat opioid addiction.*

Our PMP requires only a patient's first and last name and birth date to obtain database information. There's even an option if you have only an approximation of the birth date, so doctors can still find the needed information. There is a delay between the time a patient picks up a prescription and when that information is uploaded onto the site. In most cases, it takes two weeks or less. When I've had patients use these pharmacies, I've called these pharmacies to explain why it is so important to me that they participate in the PMP.

I'm not particularly computer savvy, but it didn't take long to become proficient in searching the online database. I've become very efficient at this website and can check a patient in about 20 seconds, though much more time is required if I find any prescriptions.

3. The importance of PMP screening: dangers of concurrent substance use during methadone treatment

I feel that it's my obligation to use the PMP to screen all of the patients being admitted to methadone maintenance treatment. Since most people seeking treatment for opioid addiction in our state are addicted to prescription opioids, and not heroin, checking the PMP database was, and is, a goldmine of information. Many of the patients who were opioid addicted got at least part of their opioids by prescription from their doctors, and often were prescribed other

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controlled substances that they used non-medically, or sold. These people often didn't seem to realize how addictive and dangerous prescription medications can be, and mistakenly thought prescription pills were safer than what they considered "hard" drugs.

Methadone is a strong opioid, and can be fatal when mixed with other drugs or medications. Benzodiazepines, combined with methadone or other opioids, have caused many overdose deaths in our state. Many opioid-addicted patients seeking treatment at opioid treatment programs are also addicted to benzodiazepines. By addicted, I mean they use them inappropriately and non-medically, whether they get them by prescription or off the street. Opioids can cause overdose deaths even if not mixed with other drugs. *For this reason, it's critical to make sure we know whether or not the patient is getting another opioid in addition to the methadone we are prescribing.*

4. Findings from PMP data: concurrent prescription use by some methadone patients

When I became the Medical Director of the opioid treatment center I checked all patients' PMP data myself. One of the regulations of our PMP website is that the physician can't delegate this task to anyone else. I was overwhelmed and dismayed about what I found the first time I checked our patients on this database. *Approximately 23% were getting significant prescriptions about which we had no prior information.*

It didn't take me long to decide that, at least for the time being, I would ignore patients getting occasional prescriptions for 20 or 30 hydrocodone pills. As a matter of triage I had to focus on the more serious cases: those getting prescriptions for methadone, Oxycontin, fentanyl, or relatively large amounts of benzodiazepines (e.g., prescriptions for 2 milligrams of Xanax taken twice a day), or combinations of these. Most worrisome were the patients filling prescriptions for methadone, besides dosing with the methadone we prescribed at the clinic. I can recall at least eight or nine doing this. About half of them said they were selling or giving the methadone pills prescribed by community doctors to friends or family. The other half claimed to be taking the extra methadone themselves, with no good explanation about why they hadn't asked for dose increases at our treatment program.

Benzodiazepines were mostly alprazolam, diazepam, or clonazepam. Some patients said they had been taking these prescriptions, and found methods to avoid detection on observed urine drug screens (a fascinating topic of its own), some said they were giving them to friends or family members, and some admitted selling them. None of their community-based physicians knew they were being treated at an opioid addiction treatment program. *No one at our treatment center knew they were seeing another doctor, or what they were being prescribed, prior to access to this data via the prescription monitoring program.* These patients, like all treated by our program, were asked at intake about what medications they were being prescribed, but obviously did not disclose these prescriptions to our staff.

Using PMP data in an outpatient addictions treatment setting**6. Clinical Interventions and patient responses**

There were too many patients for me to meet individually with all of them to discuss results of the database, though I saw many of them. Because of the large number of patients involved, program managers and patient counselors had to help me.

My approach with a patient would be to say, "Look, we have this new way of checking for other powerful prescriptions and this is what I found for you. Can you explain to me what's going on?" There were several common ways patients responded.

The majority of patients said something like, "Yeah, I'm getting them. I know I'm not supposed to, but I didn't think you'd find out." Most patients agreed to sign release of information (ROI) forms allowing me to call the other doctor, or multiple doctors in many cases, to tell them the patient was being treated with methadone for an addiction and consult about the best course of treatment.

If one or more opioid prescriptions were being filled, I had to ask the patient if they were taking these themselves. Many were. These patients needed methadone dose *increases*, since they were still able to feel euphoria from other opioids. This meant their methadone dose wasn't high enough for opioid blockade. *As long as the patient agreed to stop getting other opioids, they could stay in treatment with us, and the patient was better off. Many such patients later said they were glad this had happened. They said it burned the bridge of access to drugs they often misused.*

Other patients acknowledged *filling* the prescriptions, but denied *taking* the medications themselves. I really didn't need to know what they were doing with them (selling or giving them to others), so long as they signed a ROI and stopped getting them. Most did stop. I re-checked these patients a month or so later, to make certain. If I found they were still getting prescription medications even after our talk, and if they refused to sign the ROI, I decided they weren't appropriate for treatment at our program. In these cases, prior to discharge I slowly (e.g., over weeks or months) tapered their methadone to low levels, while advising them of other treatment options, for instance detox or a non medication-assisted program.

Some patients denied they were getting these medications at all. Since pharmacies can make errors when they upload data, I was careful to double-check names, birthdates, and the home addresses, to make sure they matched. If they did, I told the patient that it is possible this was a case of medical identity theft, and I would investigate. Only one time, out of about a hundred of such cases, was there actual medical identity theft. In all the rest of the cases, our patients were lying when they said they had not filled the prescription in question.

Surprisingly, more than a few patients were belligerent and angry. Many declared that their other medications weren't any of my business. I claimed that as long as they were asking me to prescribe methadone for them, it certainly was my business. This is particularly true if they're still filling prescriptions for the very medications to which they were addicted, and for which they had sought treatment.

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6. Patient safety the paramount concern

The issue of patient safety for me was the first consideration. I wanted to keep patients in treatment if it was reasonably safe to do so, and deciding what was "safe" and what wasn't was a judgment call. I talked to the other doctors at our clinic, but as Medical Director, the decision ultimately fell to me. If it had been more than three weeks since the patient last filled the prescription in question, I made sure the patient wouldn't be prescribed that medication again, by talking with her other doctor, and we continued to dose the patient. All take home doses were stopped, or course, and the patient had to come to the clinic every day.

I constantly asked myself if I was handling situations as I should. I felt anger towards these patients, that they weren't taking their recovery seriously, and I worried the anger would color my judgment about the best course of action. I was angrier with long-term patients who were supposedly doing well. Thirty or forty patients on take-home level five or six (meaning they only came to the clinic to be dosed once every week or once every two weeks) were found to be furtively obtaining methadone or Oxycontin or fentanyl, and I felt their deception was greater. I felt they treated our efforts to help them recover from a potentially fatal illness, opioid addiction, with disdain.

My anger cooled after many months of repeatedly checking the PMP database for new patients and old patients. I began to realize this furtive activity of still getting pills was part of the old lifestyle of addiction, and its grasp doesn't release quickly. It doesn't release at all for some people. *Plus, it's still important for me to remember that the majority of methadone patients didn't get prescriptions after entering treatment with us, and did do well in this form of treatment.*

7. Improvements in treatment and public safety: patient and staff perceptions

Many patients voiced appreciation of our efforts. They said after we checked the prescription database, there was much less drug dealing in the parking lot. The majority of patients were dedicated to their recovery and found the drug dealing to be a temptation and a vexation. Much of the parking lot violence was related to this dealing.

Most of the counselors and nurses, who had direct contact with patients, were supportive, and glad to have this new tool to use. *Over and over, counselors said patients who stopped getting covert prescriptions did better in treatment afterward. Many of the patients also thanked us for addressing the issue.* Some felt they were in better recovery, and others enjoyed a safer parking lot.

I've worked in the field of addiction for nine years. *The prescription monitoring database is the best tool I've been given.* I know these databases have saved lives, prevented overdoses, and brought people into treatment. I know there's less drug dealing when the databases are used. This decreased drug dealing was an unexpected but pleasant unintended consequence of using the database.

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8. Ongoing prescription history screening as a clinical tool

I now check patients entering the opioid treatment program on our prescription monitoring database when they are admitted, and several times per year. It's much better to let patients know from the start that we check the database, so it doesn't turn into a kind of "gotcha" situation like it did on the first go-round. I can have an honest conversation about all prescription medications. I can explain why continuing old addictive habits will hurt their recovery. Most patients respond in a positive way. A few decide they don't want to stop getting prescribed opioids, even though they misuse them, run out early, then go into withdrawal. I tell them that if they change their mind, they're welcome back, leaving the door to treatment open.

I also prescribe buprenorphine (better known by its brand name Suboxone) in a private office, treating opioid addiction. The majority of my patients were addicted to pain pills prescribed by doctors. I check each patient on the prescription database the night before I see them, for every visit. *It's a delight to look at the database and see multiple opioid prescriptions from multiple doctors before starting treatment, and after starting treatment, the only opioid they fill is buprenorphine.* Since I check the database before every visit, if the patient has relapsed, the prescriptions don't continue very long before I talk with them about their commitment to their recovery, and what they want to do about their problem.

9. Barriers to PMP participation, recommendations for improvements

The main obstacles to physician use of the databases that I see are avoidance, time restraints, and apathy. Most doctors feel uncomfortable talking to patients about alcohol and drug use. There still is a value judgment attached to this disease. Some doctors think addicts are bad people, not sick people. They have a hard time believing that their "nice" patients could have an addiction. Plus, doctors have to do more and more, in less time per visit. Where would they find time to check the prescription database for everyone they see? And some docs just don't care. If the patient's addicted...so what. Let them take their dirty little habit elsewhere to be cured.

I suggest these improvements: link all states on one database. We had a Suboxone patient who occasionally traveled to a neighboring state. Something seemed off about him. I got permission from two adjoining states to access their databases. He was being prescribed very large amounts of methadone, filled in both of these states. I know for sure he can't be taking both Suboxone and methadone, as he would be in withdrawal, so he must have been selling one of them. This could have been detected months to years earlier if all states' databases were linked.

Make cross-state access relatively easy for physicians. Our office is close to another state, but no physician is permitted access to that state's database unless they have a license to practice medicine in that state. Some states seem to have made it difficult to even find their database online. I searched for over an hour, using search engines, to locate a state's site, to see what their requirements were.

