

Technical Assistance Guide

History of Prescription Drug Monitoring Programs

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Brandeis University The Heller School For Social Policy and Management



Introduction

Prescription drug monitoring programs are designed to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of prescription drugs within a state. An overriding goal of PDMPs is to uphold both the state laws ensuring access to appropriate pharmaceutical care by citizens and the state laws deterring diversion.

The earliest PDMPs were established primarily as enforcement and regulatory tools providing data to officials responsible for enforcing drug laws and overseeing the prescribing and dispensing of these drugs by health care professionals. While this role continues in almost all current PDMPs, the focus of PDMPs has, for the most part, shifted to enhance patient care and assist in developing drug abuse prevention and treatment strategies

Forty-nine (49) states, District of Columbia, and one (1) U.S. Territory (Guam) currently have PDMP legislation in place. The only state without enacted PDMP legislation is Missouri. Recently, St. Louis County implemented a PDMP and has made the program available to any other Missouri county or city wanting to join. At this time, the St. Louis County PDMP serves more than half the population of Missouri.

The state agency which houses the PDMP can vary from state to state and falls into four (4) major categories: public health, law enforcement, licensing or regulatory boards, and substance abuse facility licensing authorities. Regardless of which agency houses the program, PDMPs share common goals, including enhancing patient care, education and information, curtailing the abuse and diversion of controlled substances, and enhancing prevention and treatment programs.

While in recent years PDMPs have gained notoriety and have been recognized as important programs, it was not always that way. The history of PDMPs spans almost a century and is riddled with opposition, misperception, and misinformation regarding their purpose and value.

Early PDMPs faced many legal and political battles as they tried to establish their programs. Opposition from the pharmaceutical industry, practitioner organizations, and various advocacy groups eventually led one state to take the fight to the US Supreme Court.



Role of the Federal Government

During the early years of PDMPs, only one federal agency supported PDMPs: the Drug Enforcement Administration (DEA). Later, the federal Department of Justice (DOJ) would play a significant role in the establishment and growth of PDMPs. In 2003, DOJ began the Harold Rogers Prescription Drug Monitoring Grant Program (HRPDMP). DOJ, through its Bureau of Justice Assistance (BJA), made funding available to states that were interested in establishing, implementing, and enhancing PDMPs. The availability of federal funds through the HRPDMP played an integral role in the proliferation of PDMPs.

Today, major federal agencies (i.e., SAMSHA, ONC, ONDCP, VA, IHS) and others recognize the value of PDMPs and fully support their mission. Additionally, they have established policies and enacted laws and regulations which allow participation into PDMPs and provide their own funding for the enhancement of existing PDMPs.

The First PDMP (1918)

The origin of PDMPs goes back to the early 20th century. In the early 1900's, drugs such as heroin and cocaine were allowed by federal and state laws to be prescribed by doctors and dispensed in pharmacies. In 1918, New York State became concerned with a growing drug problem and passed sweeping drug legislation to address the crisis. One part of the laws required a doctor prescribing a certain quantity of heroin, cocaine, morphine, opium, or codeine to use "serially numbered official prescriptions blanks" issued by the state health department. A pharmacy was then required to send a copy of the prescription to the health department within 24 hours of dispensing the drug. These laws remained in effect for three (3) years until they were rescinded. Even though the program was eliminated, New York State had drawn the blueprint for what years later would become known as prescription drug monitoring programs.

Early PDMPs (1939-1989)

Established in 1939, California is the oldest continuously operated PDMP program in the country. The 1939 law placed the administration of the PDMP in a newly created Bureau of Narcotic Enforcement. It was followed by Hawaii (1943) which housed their program in the state Narcotic Enforcement agency. Eighteen years later Illinois (1961) established their program and was the first program to be housed within a Department of Health. In 1967, Idaho was the first to house the PDMP in a Board of Pharmacy

The 1970's saw three (3) additional programs come into existence: Pennsylvania (1972) which was originally housed in the Attorney General's Office and moved to the state health department in 2016;

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New York (1973); and Rhode Island (1978). In the 1980's, two (2) additional programs were established: Texas (1981) and Michigan (1988).

During these first 50 years, all of the PDMPs had the same characteristics:

- A tool for the enforcement of drug laws;
- Collected prescription information only on Schedule II controlled substances;
- Required multi-copy (duplicate or triplicate) state issued prescription forms to prescribe and dispense Schedule II medications; and
- Required sending prescription information to the state within 30 days from the time the drug was dispensed.

Official Prescription Forms

The early PDMPs relied on state-issued prescription forms to obtain data. These forms, known as multicopy prescriptions, came in both a three-part form (triplicate prescription) and a two-part (duplicate) form. The triplicate form consisted of an original copy, which was the top form doctors would write on and two additional forms. One form would stay with the practitioner, one with the pharmacy and one would be mailed to the PDMP. The duplicate form contained one original and the state copy. These forms were serialized and purchased by practitioners and health care institutions. A "book" of official prescriptions generally included 25 to 100 prescriptions at a cost of approximately five cents per form. Some PDMPs were able to use the monies obtained through the sale of the forms to fund the PDMP. It was a generally accepted practice for the PDMP to contract the printing of these forms to an outside vendor, but the actual distribution to the doctors would occur by the state. The PDMP recorded the serial numbers issued to a practitioner or institution. Several PDMPs actually had one form for a practitioner and a separate form for institutions. Different color prescriptions and serial number sequence would distinguish practitioner's prescriptions from institutional ones. Practitioners and institutions were required to report to the PDMP any of these forms which were lost or stolen. The PDMP would record the serial number of the lost or stolen prescriptions and would provide that information to a pharmacist upon request.

When a practitioner prescribed a Schedule II controlled substance, he/she would write the prescription using an official prescription form. If it was a triplicate form, a prescriber would keep one copy and give the patient the other two. The patient would then take the other two parts to the pharmacy where the pharmacist would dispense the medication to the patient. The pharmacist would file one copy in the pharmacy and mail the third copy to the state. In states that employed the duplicate official form, the practitioner would give both copies to the patient and the pharmacist would keep one copy and mail the other copy to the state.

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State issued paper prescription forms were used by all of existing PDMPs (1939-1989) because it was a means by which information was sent through the mail to the agency housing the PDMP. The state agency would then enter the data into a state database and reports generated; modern technology and World Wide Web were just starting to take hold.

Taking advantage of emerging technology, Oklahoma (1990), broke the mold of previous PDMPs with its landmark legislation requiring electronic transmission of prescription data from a pharmacy directly to the state. As time went on, the majority of the earlier PDMPs, who had state issued paper forms, eliminated the forms in favor of electronic transmission. Today, only Texas and New York continue to employ, in a limited capacity, state issued forms.

The Oklahoma experience opened the door for other states to consider establishing a PDMP because electronic transmission lowered the cost to operate such a program by eliminating the costs associated with the printing and distribution of the forms and data entry.

The Nineties also saw another major change in PDMPs operations when Nevada (1995) became the first state to require its PDMP to collect prescription data for Schedules II through V controlled substances. Many existing PDMPs were aware of the problem with only collecting Schedule II controlled substance data. Unscrupulous individuals turned to other controlled substance schedules to divert. Knowing these were not being monitored by the state, the diversion of these drugs went either undetected or were difficult and time consuming to investigate.

Along with Oklahoma and Nevada in 1990's, five (5) other states passed PDMP legislation: Massachusetts (1992), Utah (1995), Indiana (1997), Guam (1998), and Kentucky (1998).

In this last decade of the 20th century, seventeen (17) PDMPs were operational (Guam's program became operational in 2013), almost the same number of programs as established in the entire first half of the century.

U.S. Supreme Court Decision

In 1972, New York State passed its Controlled Substance Act commonly referred to as the Rockefeller Laws. The newly enacted laws were nationally known for the mandatory sentencing of drug offenders. A part of these laws allowed the Commissioner of Health to establish a PDMP. Immediately upon passage of the law, court challenges ensued that questioned the legality of such a program. This question would be argued in various state and federal courts until it was finally brought before the US Supreme Court.



The issue before the Supreme Court was whether New York State had the legal authority to collect information on the prescribing and dispensing of controlled substances and whether patient confidentiality was being violated under the U.S. Constitution. While the arguments for and against the PDMP program were specific to New York State, any decision contrary to New York would have had a devastating ripple effect to existing PDMP programs and would possibly have eliminated future PDMPs from being established in other parts of the country or, at the very least, considerably delayed their establishment.

The Supreme Court ruled (*Roe v. Whalen*, 1977) that New York State does have the authority to collect the information as part of its "police powers." The Supreme Court went further to state the PDMP was not unconstitutional and did not violate patient confidentiality. The decision allowed continuation of New York's program and, in an indirect way, confirmed the legitimacy of the other existing programs and opened the door for other states to consider passing PDMP laws.

21st CENTURY

By the beginning of the 2000's, PDMPs began to take root around the country. The old mantra by detractors of how PDMPs were detrimental to patient care in that their mere existence produced a chilling effect on prescribers and dispensers was still being tried, but was no longer effective. Research into the effectiveness of PDMPs began to provide evidence that PDMPs were a valuable instrument for providing patient safety and identifying patients at risk for drug overdose. Drug manufacturers, who once vigorously opposed PDMPs, began to publicly support them.

The first decade of the 21st century saw the largest number of states implementing PDMPs. A total of 27 PDMPs were established from 2000-2010. In 2002, the state of Virginia passed legislation to implement a PDMP; this was followed in 2003 by Maine and Tennessee. New Mexico, Wyoming and Alabama passed legislation in 2004. In 2005, five (5) states passed legislation including Colorado, North Dakota, Ohio, Mississippi, and North Carolina. In 2006, five (5) more states enacted PDMP legislation which included Connecticut, Vermont, Iowa, Louisiana, and South Carolina. In 2007, Arizona, Washington, and Minnesota saw their legislation become effective. Finally, the last three (3) years of the first decade saw eight (8) additional states pass laws: New Jersey, Alaska, and Kansas in 2008; Oregon and Florida in 2009; and Delaware, South Dakota, and Wisconsin in 2010.

By 2010, there were 44 PDMPs with more still to come. In 2011, Arkansas, Georgia, Montana, Maryland and Nebraska passed their laws. The last New England state to implement a PDMP law was New Hampshire in 2012 followed two (2) years later by the District of Columbia (2014). By 2015, Missouri became the only state without PDMP legislation; however, in 2016, St. Louis County, MO passed legislation to implement a PDMP. The law allowed other Missouri counties or cities to



participate in the PDMP. This was the first and only time that a PDMP was being operated under a local jurisdiction and not at the state level. The most recent PDMP legislation was passed by Puerto Rico (2016). Seventy (70%) percent of all current PDMPs were established in the first 15 years of this century.

Building on the experience and knowledge of earlier programs, more recent PDMPs have been implemented faster, employing best practices, and breaking new ground themselves in bringing PDMPs to their full potential. PDMPs continue to evolve into one of the most efficient and effective tools in the battle to reduce prescription drug abuse and diversion. States are continuously improving their programs and being more responsive to stakeholders with more timely and accurate information. In contrast to early programs, today's PDMPs are recognized as an important tool in addressing the drug abuse epidemic. Health care professionals, regulatory boards, and the law enforcement community all look to PDMPs to provide them with information. All PDMPs allow access to their data by prescribers and dispensers. Some PDMPs are now allowing other non-traditional stakeholders to access their data (i.e. drug courts, medical examiners, drug abuse counselors). Starting with Oklahoma in 1990, 44 states have reduced their data collection intervals to one business day or less. In 2010, five (5) states (CO, DE, LA, NV and OK) had mandatory query laws, and today 40 states have such requirements. In 2010, Utah was the only state that allowed prescribers to have delegates to access the PDMP on their behalf and today a total of 49 states have delegate legislation in place. PDMPs in some states have become more than just a repository of prescription information. Wisconsin (2016) and Utah (2016) collect data on individuals who have overdosed and those who have been found guilty of a drug violations and report this information to doctors querying the PDMP. Other improvements and best practices have been put in place which includes interstate data sharing (now available in 47 states) and integration of PDMP data with health information exchanges (HIEs), electronic health records (EHRs), and pharmacy dispensing systems (PDS).

The effectiveness of PDMPs and the role they are playing in reducing drug abuse and diversion is very evident. <u>Studies</u> provide proof of the impact PDMPs have had in curtailing the prescription drug problem. What started as embattled and fragile programs among a small number of states has grown into one of the most effective resource tools in the fight against prescription drug abuse and diversion. The future of PDMPs is on solid ground, and the full impact of these programs is just now beginning to be realized.