Leveraging Prescription Drug Monitoring Program (PDMP) Data in Overdose Prevention and Response

March 2021

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

Overdose Data to Action (OD2A)

Overdose Data to Action (OD2A) is a cooperative agreement administered by the Centers for Disease Control and Prevention's (CDC's) Division of Overdose Prevention. OD2A began in September 2019 and focuses on the complex and changing nature of the drug overdose epidemic and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. Funds awarded as part of this agreement support state, territorial, county, and city health departments (totaling 66 jurisdictions) in obtaining high quality, more comprehensive, and timelier data on overdose morbidity and mortality and using those data to inform prevention and response efforts.

One of the main purposes of OD2A funding is to support recipients as they implement strategies to advance the development and expansion of existing PDMPs and increase their utilization as public health surveillance and clinical decision-making tools. This document was created to highlight the value of Prescription Drug Monitoring Programs (PDMPs) as public health tools and to support OD2A recipients, PDMP administrators, state and local policymakers, and public safety officials in utilizing PDMP data to inform public health interventions and clinical decision-making.

Document Information

Funding Support

This document was developed in March 2021 by CDC, ICF, and the Network for Public Health Law with support under contract #GS00Q140ADU119 order #75D30119F05503, funded by CDC.

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Acknowledgements

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Disclosure

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC. Mention of trade names, commercial products, or organizations does not imply endorsement by the U.S. Government.

Recommended Citation

Centers for Disease Control and Prevention. Leveraging Prescription Drug Monitoring Program (PDMP) Data in Overdose Prevention and Response. 2021. National Center for Injury Prevention and Control, Division of Overdose Prevention, Atlanta, GA.

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Introduction

Public health departments need accurate and timely data to save lives and prevent opioid misuse, opioid use disorder, and overdose. Accurate and timely information on the dispensing of controlled substances is a critical piece of data for these purposes. In almost all states[§], territories, and the District of Columbia, these data are collected and managed by PDMPs. PDMPs were originally conceived[1] as regulatory and law enforcement tools. As a result, most early state PDMP laws did not permit identified PDMP data to be provided to public health officials. However, PDMPs are now widely recognized for their value as public health tools. PDMP data can be used by clinicians, pharmacists, and others to improve prescribing practices and reduce prescription opioid-related harms, while health departments across the country are utilizing PDMP data to inform public health interventions.

This document offers key information about PDMPs and also highlights examples of how some OD2A recipients are using PDMP data in their prevention and response work. The examples include:

- How Kentucky uses PDMP data to share overdose information with clinicians, to prevent disruption of patient services, and to identify geographic patterns of opioid prescribing.
- How Pennsylvania shares PDMP data with state, county, and municipal health departments to enable them to better target interventions and uses PDMP data to prevent disruption of patient services.
- How West Virginia integrates emergency medical services (EMS) data into the PDMP, shares suspected overdose information with clinicians, and provides clinicians with information on evidence-based actions they can take to reduce overdose risk.

The purpose of this document is to provide key information to CDC's OD2A recipients (OD2A overview), PDMP administrators, state and local policymakers, and public safety officials about:

- PDMP history
- Why access to PDMP data is important
- Considerations for increasing access to and utilization of PDMP data
- Implications for PDMPs located in the state health department
- Implications for when the PDMP is located outside the state health department

[§] Missouri does not have a state-wide PDMP; however, the St Louis County PDMP covers 85% of the population and 94% of state clinicians.

This document provides general information that is not specific to any state. It is not intended to supersede state law or substitute for advice from state or organizational legal counsel.

PDMP Overview and Brief History

PDMPs are databases that collect information about dispensed prescription drugs. In most states, these data are received from retail pharmacies and dispensing clinicians, and are limited to some or all controlled substances depending on the state.[3] State law permits PDMP data to be accessed only by authorized users. Although the types of individuals[3] who may be authorized and the data that are permitted to be accessed vary widely between states, all states with PDMPs permit clinicians and pharmacists to access identified PDMP data. All but one PDMP permit regulatory boards to access PDMP data, and most provide access to law enforcement officials as well.

PDMPs in the OD2A Program

As the Overdose Data to Action Notice of Funding Opportunity[2] (NOFO) notes, "PDMPs are vital public health surveillance and clinical decision-making tools in preventing opioid misuse, use disorder, and overdose." In support of these ends, OD2A includes a strategy specific to PDMPs (Strategy 4). A key goal of this strategy is to support recipients as they implement activities to advance the development and expansion of existing PDMPs to serve those ends. Strategy 4 of the OD2A NOFO notes that the program also aims to "incentivize and improve nationwide overdose tracking systems that will help resources to be rapidly deployed to hard-hit areas."

In Strategy 3 of the OD2A NOFO, CDC requires all recipients to propose and demonstrate their capacity to enhance or implement at least one innovative surveillance system. One of these priority areas involves linking PDMP data with other datasets including State Unintentional Drug Overdose Reporting System (SUDORS), EMS data, and Medicaid data. Additional funding is available to states that propose to integrate PDMP data with other health system data.

Initially, the development and operation of PDMPs was funded largely by the Drug Enforcement Administration[1]. The central goal of early PDMPs was to support regulatory and law enforcement activities, not public health data collection. For this reason, most early PDMP laws did not permit identified PDMP data to be provided to public health officials.

View the PDMP Training and Technical Assistance Center's (TTAC's) History of PDMPs.[1]

As late as 2014, a review of state PDMP laws[4] found that they most frequently included law enforcement and regulatory goals, including reducing misuse and diversion of prescription drugs and aiding investigations. These types of legislative goals were much more common than health-focused goals such as using the data to refer patients to treatment or using data for public health purposes. Similarly, a 2013 review[5] of PDMP websites found that most sites did not mention overdose reduction or public health goals either.

Utilization of PDMPs as a public health tool has grown with the increase in overdoses related to prescription opioids, improvements in health information technology, and a growing understanding that a robust public health response is necessary to address the opioid overdose epidemic. Health department staff are highly skilled in using data to address public health problems. As detailed in the examples in this document, increasing access to PDMP data can enable health departments to respond to and reduce opioid-related harms more effectively by providing data on opioid prescribing "hot spots" to local health departments, coordinating with other agencies to ensure that patients receiving opioids are directed to appropriate clinicians if and when their clinician stops prescribing opioids, and linking PDMP data with other datasets to improve surveillance, prevention, and response.

"Increasing access to PDMP data can enable health departments to respond to and reduce opioid-related harms more effectively."

The Health Insurance Portability and Accountability Act (HIPAA), the federal law that governs access to and sharing of protected health information, does not generally limit the sharing of PDMP data[6] for public health purposes. See Appendix A for more information about HIPAA and PDMPs, and always consult with your organization's counsel or a qualified attorney in your jurisdiction for information regarding state or local laws which may also apply to patient health data.

Why is Access to PDMP Data Important for Public Health?

Given their history of using data to better respond to a wide variety of threats to public health, health departments have become the backbone of the response to the opioid overdose epidemic. By accessing and using high quality, timely data, health departments can successfully deploy personnel and resources to reduce overdose and other opioid-related harms effectively and efficiently.

PDMP data can enable public health officials to apply similar tools and strategies that are routinely deployed to address other epidemics, like targeting risk-reduction strategies and tailoring educational resources to at-risk individuals. In the overdose epidemic, these types of data-informed interventions can include academic detailing for clinicians, the provision of naloxone, and informed referrals to pain or treatment specialists for patients. PDMP data can also help public health officials develop unique tools and strategies specific to reducing overdoses and other opioid-related harms.

However, there is often a disconnect between those who have access to PDMP data and those best positioned to use it to inform public health activities. In most states, intervention activities are largely undertaken by local health departments, while identified PDMP data – when available at all – are often available only to the state health department. It is therefore important that PDMP data is shared with local health departments or agencies, either directly from the PDMP itself or via state health departments. In order to maximize the utilization of PDMP data by health departments, training and technical assistance related to PDMP data use best practices should also be provided

Public Health Departments Have Expertise in Appropriate Use of Health Data

Health departments are trained, skilled, and experienced in appropriately obtaining, analyzing, and protecting confidential health data. For example, mandatory reporting of infectious diseases permits health departments to investigate reported cases, connect affected individuals with appropriate treatment, and implement focused preventive measures. Every state requires that health providers report such data, which often includes extremely sensitive information such as the names of individuals with sexually transmitted infections. Health departments have developed robust technology and training to ensure that such data are stored securely and used strictly for legislatively authorized public health purposes.

to local health departments when possible. The following sections describe two general types of PDMP data—those at the aggregate level and those at the individual level— that may be used by state and local health departments in accordance with state law to inform their opioid overdose prevention and response efforts.

Access to Aggregate PDMP Data

Aggregate PDMP data are data from many people that have been combined and therefore cannot be used to identify specific individuals. Examples include the number of prescriptions dispensed in a county or prescribed by a particular medical specialty. Aggregate data can be used for many purposes, including targeting healthcare clinician outreach and education to specific specialties or broad locations. They can also be used to assess whether public health interventions are having the desired impact at the state, regional, or county level, depending on the granularity of data available. Many states are currently using aggregate data for activities like creating data dashboards and compiling reports to provide general information on prescribing trends. Dashboards and other presentations of aggregate data can inform state and local partners to direct resources for targeted education and risk reduction activities, and to provide information to public officials and other interested parties.

Access to Individual-level PDMP Data

"Where state law permits, individual-level PDMP information can be used to inform clinical decision-making and prescribing."

Compared to aggregate data, individual-level PDMP data provide clinician- or patient-level information. Individual-level PDMP data can be used alone or combined with data from other entities. Where permitted by state law, individual-level PDMP data can be used retrospectively to identify past negative outcomes, identify potential means for reducing those harms in the future, and inform prevention activities designed to reduce the number and severity of fatal and non-fatal overdoses. For example, where state law permits, individual-level PDMP information can be used to inform clinical decision-making and prescribing in the following ways:

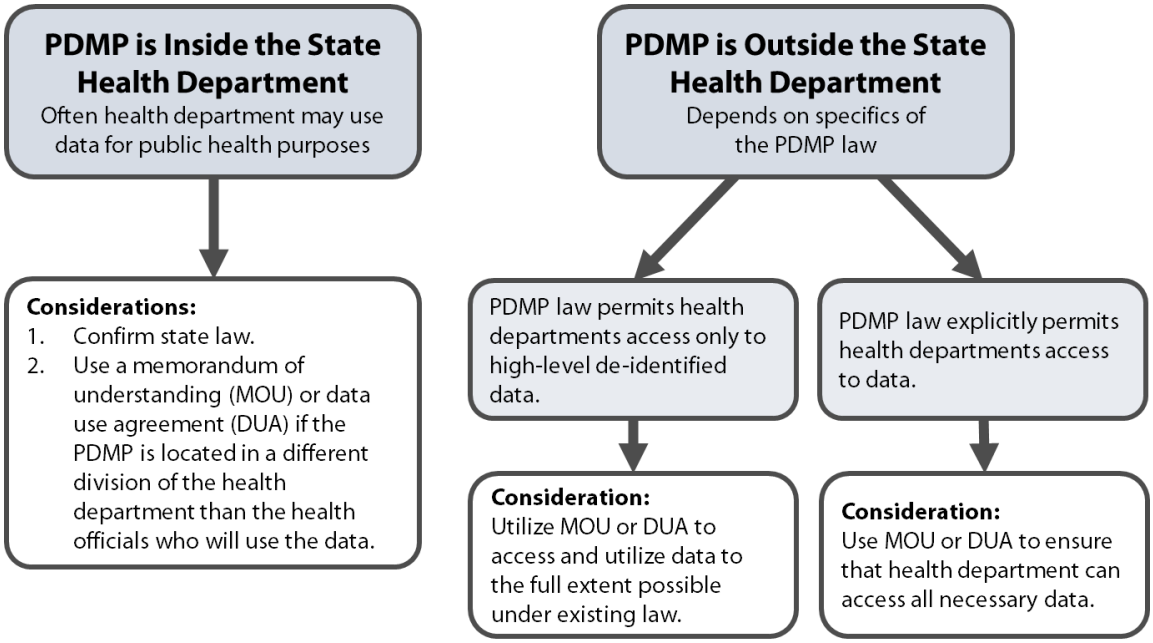
- Identify clinicians who appear to be prescribing potentially inappropriate amounts of opioids or opioids in combination with other medications (e.g., benzodiazepines), or prescribing opioids when nonpharmacologic therapy or nonopioid pharmacologic therapy is recommended as first line therapy. These clinicians can be offered training, academic detailing, educational information, and other evidence-based interventions.

- Identify patients prescribed amounts of opioids or opioids in combination with other medications (e.g., benzodiazepines) at levels that could increase their risk of overdose.
- Equip clinicians with information to assist in reducing overdose risk by providing high-risk patients with education, prescriptions for naloxone or medications for opioid use disorder, or referral to a pain treatment specialist for prescribing as appropriate.
- Inform clinicians that one of their patients has experienced a fatal overdose and provide them with evidence-based solutions to reduce prescribing-related risk.

What are the Considerations for Increasing Access to and Utilization of PDMP Data?

The laws and regulations that govern how PDMPs operate vary widely from state to state. This section provides information on how PDMP data may be accessed, shared, and utilized depending on the agency where the PDMP is administratively located and the type of data the existing laws permit the health department to access. Figure 1 below presents a summary of these considerations. This section also provides examples of states that are integrating PDMP data with data from other sources and using those data in innovative ways at both the state and local levels.

Figure 1 ■ Considerations for Accessing and Utilizing PDMP Data, Based on PDMP Location and PDMP Law



When the PDMP is in the State Health Department

In approximately 17 states, the PDMP is administratively located[3] in the state health department. Although memoranda of understanding (MOU), which are also known as data sharing or data use agreements (DUA), may be useful or necessary when the PDMP is located in a different division than health officials who will use the data, specific legal authorization is often not required.[7-12] However, cooperation and buy-in from different agencies is necessary for PDMP data to be linked with data from other agencies, such as the state medical examiner or department of corrections.

Kentucky: Integration of Overdose Data into PDMP, Use of PDMP Data to Correlate Neonatal Abstinence Syndrome Risk

The Kentucky PDMP is located within the Cabinet for Health and Family Services, which also houses the state health department. State law[7] directs the Cabinet to "proactively use the data compiled in [the PDMP] for investigations, research, statistical analysis, and educational purposes and… proactively identify trends in controlled substance usage and other potential problem areas." With that law and data use agreements with numerous organizations, Kentucky has used PDMP data in several innovative ways.

Kentucky has integrated both de-identified and identified health data with PDMP data. For example, the Cabinet has used aggregate PDMP data combined with de-identified data from the Department for Public Health's Division of Maternal and Child Health. With these combined data, they can compare[8] geographic patterns of neonatal abstinence syndrome in the state with opioid prescribing. They also use PDMP data to generate quarterly trend reports[9] at the county and 3-digit ZIP code level.

The Cabinet for Health and Family Services also uses identified PDMP data to integrate health information into the PDMP. Under Kentucky state law[10], many hospitals are required to report to the Cabinet "all positive toxicology screens that were performed by the hospital's emergency department to evaluate the patient's suspected drug overdose." The patient PDMP record permits a provider to view whether the patient has experienced a recent overdose. Providers, upon seeing this information, can then log in to the statewide Health Information Exchange[11] portal and, in many cases, read the details regarding the overdose. The Cabinet is working to integrate the statewide treatment locator, findhelpnowky.org, into the PDMP reports so that a provider can directly link a patient to the nearest appropriate treatment facility via the PDMP. Finally, a law passed in[12] March 2020 permits the Cabinet to use PDMP data in the event that the office or clinic of a practitioner closes "to issue notification as soon as practicable to the practitioner's patients to help prevent the disruption of medical treatment and promote continuity of care."

Pennsylvania: Recent PDMP Law Amendments Modify Health Department Access, PDMP Data Help Connect Patients with Services, and Data Linking Project to Reach At-Risk Areas

The Pennsylvania PDMP is located within the state Department of Health. The Department has successfully used the data in its possession, both in aggregate and at the individual level, for a variety of public health purposes.

The state Department of Health has successfully utilized identified PDMP data[13] in several ways. In one novel initiative, the Department proactively attempted to ensure that, where a provider is unable to continue to prescribe controlled substances due to regulatory or law enforcement action, the clinician's patients are connected with appropriate medical services. The Department works with regulatory agencies and law enforcement officials so that they are notified either before or shortly after a clinician stops prescribing. It then notifies the patient's health insurer, which works with the patient to find another source of pain management or opioid treatment, as appropriate.

Pennsylvania law[14] was changed in February 2020 to permit authorized employees of the state, county, and municipal health departments to access identified PDMP data. The purpose of this access is to develop educational programs and public health interventions and for conducting analyses on prescribing trends. Some local departments intend to use identified PDMP data for activities such as academic detailing, local-level analyses of prescribing and dispensing, and the provision of data to overdose fatality review[15] panels. They will do this under the terms of data sharing agreements approved by the state Department of Health's legal office.

When the PDMP is Outside the State Health Department

In more than half[3] the states, the PDMP is located in a board or agency other than the one that houses the health department. For example, in approximately 27 states the PDMP is administratively located in the state board of pharmacy or other professional licensing agency and in five states, it is located or co-located in a law enforcement agency. To access PDMP data in those cases, the health department must rely on permissions granted under state law as well as agreements with the agency in which the PDMP is located. Some PDMP laws permit health departments to access only aggregate or de-identified data. In those states, MOUs or DUAs can be used to clarify the statute that governs the parties to whom PDMP data may be released and the purposes for which it may be used to permit health departments to access and utilize identified PDMP data.

However, many states now recognize the value of PDMP data to inform public health actions, and several have changed their laws to explicitly permit health departments to access and use those data. Examples of supportive PDMP laws are provided in Appendix B.

In instances where laws are written in general terms, an MOU or DUA can clarify the specific ways in which the health department can access PDMP data and use those data to inform public health initiatives.

MOUs and DUAs can help clarify the scope of data that can be shared and the purposes for which it can be used. For example, some state statutes provide for health department access to PDMP data for "statistical, research, and educational" purposes, or words to that effect. Others may permit "de-identified" data to be shared, without specifying what that term is intended to mean.

MOUs and DUAs can also be useful in states that permit identified data to be shared with and used by the health department for public health purposes. In these cases, MOUs and DUAs can help codify roles and ensure that the health department is able to access data to the full extent permitted by law, consistent with the needs of the department. MOUs and DUAs can also ensure that all necessary data protections are in place and improve interoperability across agencies and departments.

MOUs and DUAs will usually contain information regarding:

- the data to be shared
- the individuals who can access the data
- the purposes for which the data can be used
- the security measures to be taken to ensure that the data are kept secure and confidential

There is no "one size fits all" MOU or DUA, and each state health department likely already has MOUs and DUAs in place with other entities that can be used as templates for accessing and using PDMP data. Before beginning the process of creating an MOU or DUA, the health department should carefully consider which data would be useful to the department and ensure that, to the extent possible under state law, the MOU or DUA reflects those needs. Appendix C provides a list of considerations for MOUs or DUAs, including that they contain a clear statement of which data are to be shared, the format in which the data will be shared and how they will be transferred, and confidentiality provisions. Examples are available in Appendix D.

West Virginia: Improved PDMP Data Access Through a Data Use Agreement, and Provider Notifications of Non-Fatal Overdoses

West Virginia has successfully integrated non-fatal overdose data, provided by the state Office of Emergency Medical Services (OEMS), into the state's PDMP. This success is pursuant to state law[16] and a DUA between the Board of Pharmacy, where the PDMP is located, and the Department of Health and Human Resources, which houses OEMS.

EMS data that meet an OEMS-created case definition for suspected overdose are provided to the Board of Pharmacy. An epidemiologist at the Board of Pharmacy cleans the data and transfers it securely to the state's PDMP vendor, where it is matched to the appropriate entry in the PDMP. In most cases, the information appears in the PDMP within three weeks of the suspected overdose.

When a provider queries the PDMP for a specific patient, a notification appears at the top of the resulting report that the patient has experienced a suspected non-fatal overdose within the previous 12 months. An automated email is also sent by the Board to each prescriber who issued a controlled substance prescription to the patient within the 60 days preceding the suspected overdose. The email contains links to evidence-based opioid prescribing guidelines, counsels the provider to continue to treat pain patients as appropriate, to prescribe naloxone if indicated, and to assess the patient for potential substance use disorder, as suggested by CDC.[17] A sample provider letter is available in Appendix E.

Conclusion

Health departments are trained, skilled, and experienced in appropriately obtaining, protecting, and utilizing confidential health data. Improved sharing and use of PDMP data can further inform tools and strategies for responding to the opioid overdose epidemic. It can also help ensure that evidence-based interventions are efficiently and effectively targeted. Recent successes in Kentucky, Pennsylvania, and West Virginia have shown that PDMP data can be used to share patient overdose information with clinicians, to prevent disruption of patient services, and to target interventions where they are most needed. Health departments may wish to assess current barriers to utilizing PDMP data and, where necessary, consider adopting or amending MOUs and DUAs to enable them to access and use PDMP data to advance public health.

Resources

CDC Guideline for Prescribing Opioids for Chronic Pain[18]

CDC developed and published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

Prescription Drug Monitoring Program Training and Technical Assistance Center (TTAC)[19]

The TTAC provides a wealth of information regarding state PDMPs, including data on state PDMP operating agencies and links to PDMP officials.

PDMP TTAC Searchable Compilation of PDMP Statues and Regulations[3]

Within the TTAC website, this searchable database can be used to find up to date information about the laws and regulations related to PDMPs in each state. Searchable topics include the agency in which the PDMP is located and which individuals and occupations are permitted to access PDMP data.

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Appendix A: HIPAA and PDMPs

The Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule regulates the use and disclosure of protected health information (PHI) by "covered entities," which are defined as health plans, health care clearinghouses, and health care providers that transmit health information in electronic format for certain purposes, as well as their business associates. It is intended to balance patient privacy with legitimate access to PHI. For several reasons, the HIPAA Privacy Rule does not generally limit the sharing of PDMP data for public health purposes.

First, PDMPs are generally not covered entities and are therefore not subject to HIPAA's requirements. Even if a PDMP were deemed to be a covered entity, disclosure of PDMP data for public health purposes likely falls within one or more categories of data that HIPAA permits to be disclosed. Most notably, the Privacy Rule explicitly permits PHI to be disclosed to an authorized public health authority, which is defined as an agency or authority of the federal government, or any state or territory, or political subdivision of any state or territory, as well as Indian tribes that are responsible for public health matters.

Under this broad provision, a covered entity may disclose PHI to any public health authority that is authorized by law to receive that information "for the purpose of preventing or controlling disease, injury, or disability, including public health surveillance, public health investigations, and public health interventions." The HIPAA Privacy Rule also permits data to be disclosed where that disclosure is required by law, so long as the disclosure complies with the relevant law. Where PDMP data are required to be provided to a public health department, that provision should apply.

Please note that although HIPAA does not generally prevent the disclosure of PDMP data for public health purposes, state laws often impose additional restrictions on the use and disclosure of PDMP data, including limitations on whether, when, and how public health officials can access and use those data. OD2A recipients should consult with legal counsel or a qualified attorney in their jurisdiction regarding relevant laws.

Resources on HIPAA and the Privacy Rule

- Leveraging Data Sharing for Overdose Prevention: Legal, Health, and Equity Considerations. (ChangeLab Solutions)
- HIPAA Guidance Materials (US Department of Health and Human Services)
- HIPAA Privacy Rule (Network for Public Health Law)

Appendix B: Examples of Supportive PDMP Laws

Listed below are several examples of state laws that enable health departments to access PDMP data or encourage the use of those data for public health purposes. This document provides general information that is not specific to any state. It is not meant as an endorsement of law or statute. It is not intended to supersede state law or substitute for advice from state or organizational legal counsel. Please also see Appendix C for a list of best practices for creating Memoranda of Understanding for PDMP data sharing.

Pennsylvania: Example of PDMP Located in State Department of Health

(b) Authorized users. The following individuals may query the system according to procedures determined by the board and with the following limitations:

…

(13) (i) An authorized employee of a county or municipal health department or the Department of Health of the Commonwealth may have access to data from the system for any of the following purposes:

(A) Developing education programs or public health interventions relating to specific prescribing practices, controlled substances and the prevention of fraud and abuse.

(B) Conducting analyses on prescribing trends in their respective jurisdictions.

(ii) For purposes of subparagraph (i)(A), a county or municipal health department shall implement appropriate technical and physical safeguards to ensure the privacy and security of data obtained from the system.
35 Pa. Health & Saf. § 872.9

Kentucky: Example of PDMP Located in Same Agency but Different Department than the Health Department

"The Cabinet for Health and Family Services shall proactively use the data compiled in the electronic system created in KRS 218A.202 for investigations, research, statistical analysis, and educational purposes and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the system shall be authorized access to the data and reports under this subsection."
Ky. Rev. Stat. Ann. §218A.240(7)

Utah: Example of PDMP Located in Different Agency than the Health Department

"The division shall make information in the database and information obtained from other state or federal prescription monitoring programs by means of the database available only to the following individuals…

(e) in accordance with a written agreement entered into with the department, employees of the Department of Health:

(i) whom the director of the Department of Health assigns to conduct scientific studies regarding the use or abuse of controlled substances, if the identity of the individuals and pharmacies in the database are confidential and are not disclosed in any manner to any individual who is not directly involved in the scientific studies;

(ii) when the information is requested by the Department of Health in relation to a person or provider whom the Department of Health suspects may be improperly obtaining or providing a controlled substance…"
Utah Code Ann. §58-37f-301(2)(e)

Arizona: Example of PDMP Located in Different Agency Than the Health Department

C. The [pharmacy] board may release data collected by the program to the following: …

…

9. The department of health services regarding persons who are receiving or prescribing controlled substances to implement a public health response to address opioid overuse or abuse, including a review pursuant to [the overdose fatality review law]. Except as required pursuant to subsection B of this section, the board shall provide this information only if the department states in writing that the information is necessary to implement a public health response to help combat opioid overuse or abuse.
Ariz. Rev. Stat. §36-2604

Appendix C: Best Practices for Memoranda of Understanding or Data Use Agreements

*Note: This information was previously developed by Corey Davis at the Network for Public Health Law

Awardees should consider consulting with an attorney employed by or contracted by their department or agency for assistance in crafting a memorandum of understanding (MOU) or data use agreement (DUA) that permits the agency to access data for public health surveillance and response while complying with relevant legal and regulatory requirements. In general, an MOU) or DUA can be designed to permit the health department to access PDMP data to the full extent permitted by relevant law as consistent with the department's needs, including real-time surveillance and active response as appropriate.

For PDMP data sharing, states should consider ensuring that the MOU or DUA contains:

- A clear statement of the parties to the agreement.
- A clear statement of the legal authority permitting the data to be shared.
- A clear statement of the data that will be shared.
- A clear statement of the format in which the data will be shared and the means of transfer.
- A clear statement of the frequency with which data will be shared.
- If some data elements are to be de-identified, a clear statement of which party will de-identify the data, and the mechanism that will be used to do so.
- A clear statement of which individuals or employee classifications will be permitted to access the data.
- A clear statement of the purposes for which the data can be used, including whether they may be linked with other datasets.
- An individual or officeholder on each side who has responsibility for ensuring that the agreement is followed.
- If information protected under state or federal law is to be transferred, a clear statement of how those data will be handled in a manner consistent with applicable laws and regulations.
- The dates that are covered by the agreement, whether one or more parties may terminate the agreement prior to that date, and if so under which circumstances.
- Whether data transferred under the agreement must be destroyed, and if so, the date such destruction is to occur, the party responsible for ensuring destruction, and approved destruction methods.

Appendix D: Examples of Data Use or Data Sharing Agreements

Pennsylvania Data Sharing Agreement

This document provides general information that is not specific to any state. It is not meant as an endorsement of law or statute. It is not intended to supersede state law or substitute for advice from state or organizational legal counsel. This is an example of a Data Sharing Agreement that permits the state Department of Health to share identified PDMP data with local health departments and other entities as permitted by state law.

Data Sharing Agreement
Between the
Pennsylvania Department of Health and
[Name Here]

This Data Sharing Agreement ("Agreement") is entered into by and between the **Pennsylvania Department of Health** ("DOH") and the **[Name Here]** ("Recipient"). In consideration of the mutual understandings and covenants set forth herein, the parties agree as follows:

I. Purpose

a. DOH and Recipient mutually agree to enter into this Agreement to comply with the requirements of Section 514 (e) of the Privacy Rule, 45 Code of Federal Regulations ("C.F.R.") §164.514(e), issued pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as well as the act of October 27, 2014 (P.L.2911, No.191), known as the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act.

b. Upon Recipient's execution of this Agreement, DOH will provide Recipient with a Limited Data Set:

   1. That is derived from the collection of identified prescription data or system usage data from the Prescription Drug Monitoring Program (PDMP) system as set forth in the ABC-MAP act, and
   2. that contains the minimum amount of individually identifiable information reasonably necessary for the purposes, as set out in this Agreement, for which Recipient is to receive the data.

c. This Agreement addresses the conditions under which the DOH will submit, and the Recipient will use and disclose, the above-mentioned data.

II. Term

This Agreement is effective __/__/__ through __/__/__.

III. Conditions

Recipient's Permitted Uses and Disclosures:

[Example if permitted uses is defined by legislation:

Recipient is permitted to use and disclose the Limited Data Set for only the purposes as defined in Section 9 of the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act 191 of 2014.]

[Example if permitted uses is defined in a statement of work:

Recipient is permitted to use and disclose the Limited Data Set only for the purposes defined in the Statement of Work for SAP 410085405.]

IV. Prohibition on Unauthorized Use or Disclosure

a. Recipient shall neither use nor disclose the data for any purpose other than as permitted by this Agreement, as otherwise permitted in writing by Data Provider, or as Required by Law.
b. Recipient is not authorized to use or disclose the data in a manner that would violate the Privacy Rule, 45 C.F.R. Part 164, Subpart E.
c. Recipient is not authorized to use or disclose the data in a manner that would violate the act of October 27, 2014 (P.L.2911, No.191), known as the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act.
d. DOH will retain ownership of the of the original data and the Recipient shall receive a copy.
e. Recipient shall not attempt to identify de-identified information contained in the data.
f. Recipient shall adopt and use appropriate administrative, physical, and technical safeguards to preserve the integrity and confidentiality of the Limited Data Set and to prevent its use or disclosure, other than as permitted by Section 3 of this Agreement, as otherwise permitted in writing by Data Provider, or as Required by Law. These safeguards shall be consistent with the polices set forth in the security regulations [45 CFR §§ 164.308; 164.314] issued pursuant to the Health Insurance Portability and Accountability Act [42 USC §§ 1320 - 1320d-8], the Commonwealth of Pennsylvania IT Policies pertaining to Encryption Standards for Data at Rest [ITP-SEC020] and to Encryption Standards for Data in Transit [ITP-SEC031], and National Institute of Standards and Technology (NIST) Special Publication 800-63-3.
g. Recipient shall ensure that individuals accessing identifiable information from the Limited Data Set on their behalf have signed a confidentiality affidavit with DOH.

V. Data Flow

a. DOH will transmit the data securely and in a confidential manner to the Recipient as follows: through Secure File Transport (SFTP).
b. Recipient shall securely store the data, once received from DOH, on Recipient servers with appropriate administrative, physical, and technical safeguards in place per section IV of this agreement to ensure the data are accessible only to specific employees of the Recipient who need access to the data to perform the duties as permitted in Section 3 of this Agreement. Administrative, physical, and technical safeguards must be used to ensure Recipient employees only have access to the minimum amount of individually identifiable information reasonably necessary for the purposes, as set out in this Agreement, for which Recipient is to receive the data.

VI. Confidentiality

a. To the extent that DOH's data are confidential, the parties agree that the Recipient will maintain the confidentiality of information received pursuant to Pennsylvania Right to Know Law, (RTKL) 65 P.S. § 67.101 *et seq*., (Sections 102, 301, 305, 701 and 708). The Recipient, its contractors or agents, will protect the privacy and confidentiality of any individually identifiable information contained in the data consistent with the Privacy Act of 1974, and, to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 38 U.S.C. 5701(f), and other applicable laws, regulations, and policies. The Recipient may provide data access to appropriate employees, contractors and authorized users. Except as may be required in a public health emergency to protect life and health of individuals and populations, for authorized activities described, and to permit authorized users to use the information as specifically authorized by state statute, the Recipient will not attempt to identify the individuals whose records are contained in the data provided under this Agreement or link these data with other data sources for identification purposes.

b. DOH authorizes the Recipient to use or otherwise grant access to the data covered by this Agreement only as may be necessary to accomplish the purposes of this Agreement. The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement. If the Recipient wishes to use the data and information provided by DOH under this Agreement for any purpose other than those outlined in this Agreement, the Recipient shall make a written request to DOH describing the additional purposes for which it seeks to use the data. If DOH determines that the Recipient's request to use the data and information provided hereunder is acceptable, DOH shall provide the Recipient with written approval of the additional use of the data.

c. The Recipient represents further that, except as specified in this Agreement or except as DOH will authorize by written amendment, the Recipient shall not disclose, release, or otherwise grant access to the data covered by this Agreement to any third party for any purpose unless required by law. The Recipient agrees that access to the data covered by this Agreement shall be limited to those individuals necessary to achieve the purpose stated in this Agreement. Access to the DOH data shall be restricted to authorized employees,

contractors, agents, and officials who require access to perform their official duties and to authorized users. Such personnel shall be advised of: (1) the confidential nature of the information; (2) safeguards required protecting the information; and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable state and Federal laws. The Recipient agrees to limit access to, disclosure of and use of all data provided under this Agreement. The Recipient agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to the prescription data to accomplish this Agreement.

d. The Recipient shall ensure that its contractors and agents abide by the terms and conditions of this Agreement. DOH may request verification of compliance.

e. The Recipient shall adopt and use appropriate administrative, physical, and technical safeguards to preserve the integrity and confidentiality of the Limited Data Set and to prevent its use or disclosure, other than as permitted by Section III of this Agreement, as otherwise permitted in writing by DOH. The Recipient will be responsible for the observance of all conditions of use and for establishment and maintenance of appropriate administrative, technical and physical security safeguards to prevent unauthorized use and to protect the confidentiality of the data.

f. Upon termination of this Agreement, the Recipient shall return to DOH or destroy all individually identifiable information in the Recipient's possession that was created or received as a result of this Agreement by no later than 30 calendar days after termination. The Recipient shall not retain copies of the individually identifiable information unless explicitly permitted in writing by DOH or as required by law, or as otherwise permitted under this Agreement. If individually identifiable information is destroyed, the Recipient shall provide DOH with documentation or certification evidencing such destruction. Any individually identifiable information retained by the Recipient shall continue to be extended the same protections set forth in HIPAA and this Agreement for as long as it is maintained.

VII. Cost of Data Preparation

The Parties agree that no reimbursement will be sought under the terms of this agreement.

VIII. Amendments

No alteration or variation of the terms of this Agreement shall be valid unless made in writing and signed by the parties hereto. No oral understanding or agreement not incorporated herein shall be binding on any of the parties hereto.

IX. Immunity

Notwithstanding any provision of this Agreement to the contrary, the laws, regulations, rights and remedies applicable to the Commonwealth are governed solely by applicable state and

federal law. Nothing in this provision shall be construed to limit the sovereign immunity of the Commonwealth of Pennsylvania.

X. Termination

DOH or the Recipient may terminate this Agreement at any time for any reason, including failure to comply with any condition of this Agreement, upon thirty (30) days advanced written notice.

XI. Notice to Parties

If any of the above-mentioned terms and conditions are violated for any reason, the Recipient agrees to immediately notify the PDMP Office.

If data from the PDMP are used in any form of publication, including but not limited to peer-reviewed publications, reports, online publications, gray literature, etc., the following statement must be included in such publication or any release of the data:

> These data were supplied by the Prescription Drug Monitoring Program, Pennsylvania Department of Health, Harrisburg, Pennsylvania. The Pennsylvania Department of Health specifically disclaims responsibility for any analyses, interpretations, or conclusions.

A copy of any published materials or study results must be made available to the DOH upon request.

Whenever any notice, statement or other communication is required under this Agreement, it shall be sent to the following addresses, unless otherwise specifically advised:

Notices to DOH shall be sent to:
[NAME]
Prescription Drug Monitoring Program
Pennsylvania Department of Health
Room 608 Health and Welfare Building
625 Forster St
Harrisburg, PA 17120

Notices to Recipient shall be sent to:

Name: _____

Title: _____

Address: _____

IN WITNESS WHEREOF, the parties, through their authorized representatives, have properly executed this Agreement on the date of the last Commonwealth signature below.

ACKNOWLEDGED AND AGREED:

[RECIPIENT ORGANIZATION NAME]

Name: _____ Date: _____

Title: _____

COMMONWEALTH OF PENNSYLVANIA, DEPARTMENT OF HEALTH

Name: _____ Date: _____

Title: _____

West Virginia Memorandum of Understanding

This document provides general information that is not specific to any state. It is not meant as an endorsement of law or statute. It is not intended to supersede state law or substitute for advice from state or organizational legal counsel. This is an example of a Memoranda of Understanding that permits de-identified data to be shared between the PDMP and a non-state entity as permitted by state law.

Memorandum of Understanding (MOU) Data Sharing and Use Agreement
Between
West Virginia Bureau for Public Health, Office of Maternal, Child and Family Health West Virginia Violence and Injury Prevention Program
And
West Virginia Board of Pharmacy Controlled Substance Monitoring Program

The West Virginia Board of Pharmacy Controlled Substance Monitoring Program aka West Virginia's Prescription Drug Monitoring Program (WVPDMP) and the West Virginia Violence and Injury Prevention Program (WVVIPP) agree to collaborate in the project known as the Prescription Drug Overdose – Prevention for States. A description of this project is contained in Appendix A of this MOU.

A. WV VIPP agrees to the following conditions:

1. The WV VIPP's work on the Prescription Drug Overdose – Prevention for States project will be in collaboration with the West Virginia University Injury Control Research Center (WVU ICRC).
2. The WV VIPP will design and validate algorithms for identifying high- risk prescribing activity to use as a trigger for proactive reports.
3. The WV VIPP will conduct public health surveillance with PDMP data.
4. To protect confidentiality and to assure accurate use of the data, the WV PDMP shall have the opportunity to review a complete draft of any report or evaluation that uses the WV PDMP data. Copies of such documents shall be provided to the WV PDMP at least two weeks in advance of publication to allow the PDMP an opportunity to review and comment.
5. Aggregate or de-identified data provided by the WV PDMP and in WV VIPP's possess ion must be destroyed within 10 years of completion of the Prescription Drug Overdose – Prevention for States project. The WV PDMP may waive this requirement by express written agreement. Before data are destroyed, the WV PDMP must be given the opportunity to retain them. Any use of the data after completion of the Prescription Drug Overdose – Prevention for States project and prior to its destruction must be approved in writing by the PDMP.

6. No data will be published or released in any form if there is a reasonable possibility

    i. that a particular individual patient, prescriber, or dispenser can be directly or indirectly identified. Such a release is only permissible with the explicit written permission of the individual or reporting entity. De-identified data will be considered to have a reasonable possibility of indirectly identifying individuals if they include tabulations of any of the following information: Tabulations that include identifying information such as an individual's gender, age, or other identifying information when that information, either alone or in combination with other factors, including geographic area creates a risk of indirectly identifying an individual.

    ii. Rates, frequencies, lists, or other tabulations or graphical presentations that result in fewer than 20 individuals in a table cell or associated with a particular data point.

7. To avoid the risk of a particular individual or entity reporting prescription data being directly or indirectly identified from the information released:

    i. WV VIPP will not use date of birth unless converted to age in years.

    ii. WV VIPP will aggregate data before they are published to assure that an analysis does not create a risk of identifying individuals.

B. The WV PDMP agrees to provide de-identified data to the WV VIPP as follows:

1. The WV PDMP will have its information technology (IT) vendor de-identify PDMP prescription data in the following manner:

    i. Link records that belong to each patient, according to the process for linking the WV PDMP or its IT vendor currently uses.

    ii. De-identify the WV PDMP data by removing patient name, birth month and day, and street address. Insert a unique ID number which is assigned for the duration of the Prescription Drug Overdose – Prevention for States project (to identify which patient records belong to the same individual).

    iii. Leave patient gender and year of birth unencrypted for demographic analyses.

    iv. Retain patient town/city, state, and five-digit zip code of residence to enable geospatial analyses. If a zip code has so few individuals that it might pose a risk of identifying an individual, the WV VIPP will combine that zip code with neighboring zip code(s) until the combined numbers make it impossible to identify any individual.

v. Remove the prescriber DEA #. Insert a unique ID number which is assigned for the duration of the Prescription Drug Overdose – Prevention for States project so all prescriptions issued by a prescriber can be linked, but the prescriber cannot be identified.

vi. Include in each prescription record the town/city, state and zip code of each prescriber's location where his/her DEA # is assigned so geospatial analyses can be conducted by prescriber location. This can be done by cross-referencing the DEA controlled substance registration file, WV PDMP internal registration files, or other file. If a zip code has so few prescribers that it might pose a risk of identifying a prescriber, WV VIPP will combine that zip code with neighboring zip code(s) until the combined numbers make it impossible to identify any prescriber.

vii. Remove the dispenser ID. Insert a unique ID number which is assigned for the duration of the Prescription Drug Overdose – Prevention for States project so all prescriptions dispensed by each dispenser can be linked, but the dispenser cannot be identified.

viii. Include each Rx record the town/city, state and zip code of each dispenser location so geospatial analyses can be done by pharmacy location. This can be done by cross-referencing the DEA controlled substance registration file, WV PDMP internal registration files, or other file. If a zip code has so few dispensers that it might pose a risk of identifying a dispenser, WV VIPP will combine that zip code with neighboring zip code(s) until the combined numbers make it impossible to identify any dispenser.

2. Beginning with prescription data for 2015 and continuing for the term of this agreement, the WV PDMP will, or will have its IT vendor, de-identify WV PDMP prescription data on a quarterly basis using the de-identification process described above for the initial dataset. The de-identification process shall assign the same ID for the same individual patient, prescriber and dispenser as assigned in previous data submissions so the data can be tracked across quarters and years. The data updated each quarter are to include 12 months of data, i.e. the three months of the quarter and the previous 9 months, to capture any data retroactively corrected by the submitting dispenser. To enable the linking of updated quarterly data (see below) to this initial data set, the WV PDMP and/or its IT vendor will keep a secured master list of patient name, street address and birth date as well as secured master lists for prescribers and dispensers with ID numbers and zip codes. The master lists will be kept in password protected electronic files and, if also in hard copy, in a locked file cabinet. The master lists will not be shared with Prescription Drug Overdose – Prevention for States project staff.

3. If mutually agreeable to the WV VIP P and WV PDMP, limited WV PDMP datasets may be shared with other subunits of the state health department - West Virginia Bureau for Public Health.

4. The WV PDMP or its IT vendor will forward to WV VIPP each subsequent quarterly de-identified WV PDMP data file on a quarterly basis. The WV PDMP data will be sent by FedEx on a CD-ROM or a mutually agreed upon media to the WV VIPP.

Reimbursement of costs

WV VIPP agrees to provide $2,000.00 quarterly to the WV PDMP for incremental, quarterly Prescription Drug Overdose – Prevention for States datasets to reimburse the costs of de-identifying the data and transferring it to the WV VIPP, as provided above.

Period of Agreement

This agreement shall be in effect from the date of signing by both parties until August 31, 2019. The agreement may be extended by mutual agreement of both parties in writing prior to August 31, 2019.

For the West Virginia Violence and Injury Prevention Program:

_____ _____

Authorized Signature Date

For the West Virginia Prescription Drug Monitoring Program:

_____ _____

Authorized Signature Date

Appendix E: Sample Letter Sent to Provider Whose Patient Has Experienced a Non-fatal Overdose (West Virginia)

[Agency letterhead]

Dear Prescriber,

The West Virginia Board of Pharmacy is now incorporating suspected non-fatal overdose into a patient's Controlled Substance Monitoring Program (CSMP) Report. The collection of this suspected overdose data is authorized under West Virginia Code §60A-9-4.

Information related to a suspected non-fatal overdose is reported to the Board of Pharmacy by hospitals and emergency medical service providers (EMS). Details of the incident are then placed into the patient's CSMP record, usually within 5-6 weeks. While most rigorous efforts are made to ensure that the medical event was a non-fatal overdose for this individual, reporting errors may occur.

This courtesy communication is to inform you that a suspected non-fatal overdose incident has been reported for your patient: **<first name last name, date of birth>**, on **<date>**. You are recorded as having prescribed a controlled substance in the 60 days prior to the patient's suspected non-fatal overdose incident. We ask that you please review your practices regarding the prescribing of controlled substances, especially if it involves combining multiple drug types. If you are prescribing opioids, naloxone education for the patient and/or family members may be appropriate. You are also encouraged to regularly utilize the CSMP to obtain an accurate list of drugs your patients are currently receiving

Next Steps - What to Do

- If the patient requires opioid therapy, continue to prescribe opioids.
    - Discontinuing opioid prescriptions could put the patient at risk for use of illicit drugs and withdrawal.
    - Consider tapering the dose of opioid:
        - http://sempguidelines.org/wp-content/uploads/2017/04/Opioid-Tapering-Tool-Handout.pdf

  - Monitor patient closely for withdrawal symptoms, pain, and signs of substance use disorder.
  - Follow opioid prescribing guidelines: https://www.cdc.gov/drugoverdose/prescribing/guideline.html & http://sempguidelines.org/
  - For acute pain, if opioids are needed, prescribe the lowest effective dose of immediate-release opioids for the shortest duration, usually no more than 7 days.
  - Avoid co-prescribing benzodiazepines, sedatives, and multiple opioids. This can increase risk of accidental overdose.
  - Discuss the benefits and risks of opioid therapy with the patient.
- Continue to treat pain.
  - Explore non-pharmacological treatment and non-opioid pharmacology options.
- Assess patient's risk of overdose.
  - Prescribe Naloxone.
- Assess patient for possible substance use disorder.
  - Discuss referral to behavioral health services: https://www.help4wv.com/
  - Consider offering Medication Assisted Treatment (MAT).
- Check the CSMP when prescribing opioids, benzodiazepines, sedatives, and gabapentin.

West Virginia continues to lead the nation in overdose deaths. With your help West Virginia can decrease overdose deaths by continuing to treat patients with substance use disorder: http://stigmafreewv.org/

Please report any questions or concerns to CSMP Support at CSMPsupport@wv.gov.

Sincerely,

West Virginia Board of Pharmacy