PDMP TTAC

Prescription Drug Monitoring Program Training and Technical Assistance Center

Technical Assistance Guide for PDMP Administrators

Standardizing a Process for PDMP Data Requests by Researchers

February 2019

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Prepared for

Bureau of Justice Assistance

BJA
Bureau of Justice Assistance
U.S. Department of Justice

This project was supported by Grant No. 2014-PM-BX-K001 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and the Office of Sex Offender Sentencing, Monitoring, Apprehending, Registering, and Tracking (SMART). Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice.

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1. Introduction/Purpose

The misuse and abuse of prescription drugs, particularly opioids, continue to contribute in epidemic proportions to fatal and nonfatal overdoses across the country. Prescription Drug Monitoring Program (PDMP) data have long been recognized as a valuable source of information to help address prescription drug misuse, diversion, fraud, and overdoses. Some PDMP administrators have utilized the information to enhance public health and public safety interventions, conduct epidemiological analyses, and study the impact of PDMP policies and practices. However, the use of PDMP information for research and evaluation purposes by academic researchers has been limited. As states and local communities implement initiatives to address prescription drug abuse, misuse, and overdoses, requests for PDMP data by researchers are expected to rise.

Currently, 43 of 52 PDMPs have legal authority to release PDMP data for research and evaluation purposes.[1] Only four states (Colorado, Indiana, Maine, and Massachusetts) have institutionalized a standard format for researchers to request de-identified PDMP data (provided in the appendix). This technical assistance guide is intended for PDMP administrators interested in developing a standard procedure or process in which nongovernment researchers may request certain PDMP data for public health surveillance, research, and evaluation. The TTAC conducted a review of existing data request forms, protocols, and data use agreements (DUAs) from various state agencies, ranging from states' PDMPs to departments of health, public safety, and justice. The following sections describe three areas of information administrators should consider in the process of providing PDMP data for research purposes: (1) initial data request, (2) data use agreement, and (3) Institutional Review Board (IRB) certification. Administrators should determine the type and level of detailed information they or their review committee members need for the process of approving/denying access to PDMP data, since there is duplicate information in each category.

2. Initial Data Request

The general purpose of this initial step should be to assess the validity and feasibility of the data request. For example, is the data requestor planning to conduct a bone fide research study, and are the requested data available for release? The following table contains a list of information commonly found in the initial request phase for many publicly available and restricted data. Colorado, Maine, and Massachusetts developed a standard form for researchers requesting de-identified PDMP data (see Appendices A, C, and D).

Information to Be Obtained	Notes/Explanations
Point-of-contact information	Includes principal investigator name, contact information, institutional affiliation
General description of study	Study's goals, objectives, aims
General description of how data will be used for proposed study	Explanation of why PDMP data are needed

[1] For list of states, please visit http://www.pdmpassist.org/pdf/Data_Use_Res_Epi_Educ.pdf.

Information to Be Obtained	Notes/Explanations
Data elements	PDMP should consider providing a list of available data fields
Data time periods requested	The start and end dates of records requested
Plan for data storage/protection	Usually covered also in the DUA and IRB
Plan for data confidentiality	Usually covered also in DUA and IRB
Project start and end dates	Study start and end dates
Plan for data destruction	What will be done with the data at end of study?
List of people who will have access to the data	Typical to include their roles/qualifications
Option for prior publication review	Typical for most state agencies
Study sponsor/funder	Financial source, if any
IRB approval/exemption certification	Does the study require an IRB review?
Data use agreement (DUA)	Typically obtained after the requestor receives approval

3. Data Use Agreement (DUA)

DUAs are typically required after the contingent approval of the data request. They serve as a legal binding contract between the PDMP office and the researcher or the researcher's academic institution. Therefore, some of the information obtained during the initial data request is typically also included in the DUA. The following table contains common terms and conditions expected of the researcher for use of publicly available data sources from state agencies. An example of a DUA is provided by the Maine PDMP (see Appendix C).

Common Terms/Conditions	Notes
Assurance of data integrity, security, and confidentiality	Includes data storage and security plan
Non-transfer of data for other projects/purposes	Statement specifying that the data provided will be used only for the approved study
Protection of potential identification of individuals	Includes specifications on public reporting of potentially identifying information and small-cell suppression
Data destruction plan	Specification on what will be done with the provided data file at completion of project within a time frame (e.g., seven years in case of audit)
Option/requirement to review prior to publication	
IRB certification of approval or exemption	

Additional Terms/Conditions	Notes
Protocol for data security	
Notification of data security breach	Specifies a privacy officer or specific staff member
State agency/department retains ownership of data	
Notification of change in key project staff	
Cost for data preparation	Some state agencies charge researchers for the cost of data preparation

4. Institutional Review Board (IRB)

Most state agencies require certification of an IRB approval or exemption of the study prior to the release of their data, even when the data are considered secondary or archival. The primary purpose of an IRB is to protect the rights of human subjects participating in research; however, they also serve to ensure that researchers are compliant with the ethical and regulatory standards for conducting research. Most IRBs require detailed information beyond the study's purpose, methodology for analyses, and protocols for data security and confidentiality. For example, IRBs within an academic institution typically require researchers to provide the study's methodology including the analytic plan. They also require researchers to receive periodic training on human subjects' protection and obtain certificates of confidentiality. PDMP administrators may wish to request a copy of the requestors' IRB protocol as one method to ensure the protection of the data, if an IRB is required. The following table contains common types of information required as an IRB study protocol.

Common Information Required by IRBs	Notes
Study goals	Includes the expected benefits
Principal investigator's qualifications	
Other research personnel and qualifications	
Literature review related to study	Includes why the study is needed
Study design	Includes methodology/analytic plan
Plan for individuals' privacy	Includes how individuals within data will be kept confidential or anonymous
Plan for data storage	Includes who will have direct access to data, how long it will be kept, and when and how it will be destroyed
Plan for findings dissemination	
Project timeline	
Data use agreement	Typically required before an IRB provides certification of approval or exemption
Training and certification of human subjects' confidentiality	Academic institutions require certain researchers to obtain certification

Appendix A—Colorado Department of Regulatory Agencies PDMP Data Request Form

PDMP Researcher Data Request Form

Please provide the information requested below. (Print or Type) Use full name not initials. (* indicates a required field)		
*Name of Researcher		*Researcher's Organization
*Street Address		
*City	*State	*Zip Code
*Phone Number		*Email Address
***General Description of Research Project (attach additional pages as needed) (discuss the reason why you are requesting data and what you will use it for):**		
***Description of the Data Needed (attach additional pages as needed) (provide a description of the data you are interested in receiving and what format you need the data provided in, see checklist):**		
*Signature		*Date
Procedure: Once completed, this form should be sent to the following address. DORA Division of Professions and Occupations Colorado State Board of Pharmacy Prescription Drug Monitoring Program 1560 Broadway, Suite 1350 Denver, CO 80202		

For Department Use Only			
Date Received	☐ Approved ☐ Disapproved	Director or Designee Signature	Date of Board Review
Notes:			

COLORADO PRESCRIPTION DRUG MONITORING PROGRAM DE-IDENTIFIED DATA AGREEMENT FOR RESEARCH / EDUCATION REQUEST CHECKLIST

☐**Complete the attached researcher data request form**. Return the completed request form and all supporting documentation (including this checklist) to the Colorado State Board of Pharmacy, Prescription Drug Monitoring Program.

☐**Submit documentation** demonstrating how the research project meets the requirements listed in **CRS 12-42.5-404(5)** and **Rule 23.00.10(b) and (i)**.

CRS 12-42.5-404(5)
The Board, pursuant to a written agreement that ensures compliance with this part 4, may provide data to qualified personnel of a public or private entity for the purpose of bona fide research or education so long as the data does not identify a recipient of a practitioner who prescribed, or a prescription drug outlet that dispensed a prescription drug.

Rule 23.00.10 b

"Bona fide research or education" means research conducted by qualified entities whose recognized primary purpose is scientific inquiry; the results of which would likely contribute to the basic knowledge of prescribing practitioners, dispensing pharmacists, or entities for the purpose of curtailing substance abuse of consumers. The Board shall determine in its discretion on a case-by-case basis whether an individual or entity seeking access to the PDMP pursuant to CRS 12-42.5-404(5) constitutes "bona fide research or education' conducted by qualified personnel for purposes of satisfying the statutory limitations therein.

Rule 23.00.10 i

"Qualified personnel" means persons who are appropriately trained to collect and analyze data for the purpose of conducting bona fide research or education.

☐**Submit documentation which describes the date and location data requested**. Utilize check boxes to define the de-identified data requested. Only check the boxes for data applicable to the request.

Dispensing pharmacy location ☐	Prescribing Practitioner location ☐	Patient location ☐
By county ☐	By county ☐	By county ☐
By 3 digit zip code ☐	By 3 digit zip code ☐	By 3 digit zip code ☐
By city ☐ _____	By city ☐ _____	By city ☐ _____

Prescription written time frame ☐ (Date the prescribing healthcare practitioner wrote the controlled substance prescription)	Prescription dispensed time frame ☐ (Date the dispensing pharmacy dispensed the controlled substance prescription)
From: To:	From: To:

☐ **As applicable, submit a written description of controlled substance prescription drugs requested.** Examples include: all controlled substance drugs, defined by DEA Schedule; specific drugs, including hydrocodone, oxycodone, alprazolam, etc.; specific strengths (i.e. 30 mg, 5 mg, etc.). Also describe how drug data should be reflected on the report, such as by label or generic name, or by DEA Schedule or NDC number.

☐ **As applicable, submit written documentation describing whether information regarding payment source is requested.** Payment types collected by the Colorado PDMP include: Private Pay, Medicaid, Medicare, Commercial Insurance, Military Installations and VA, Worker's Comp, Indian Nations, and Other.

☐ **Submit examples demonstrating requested format of completed report.** Submit an example of requested format for the completed report, so that every attempt may be made to ensure the data resulting from the de-identified data agreement is as similar in format as possible to the format requested by the research entity.

NOTE: The Colorado State Board of Pharmacy ("Board") must review and approve every request for a de-identified data agreement for PDMP data to be utilized for the purposes of research or education. The Board meets every other month. Staff for the Board recommends that researchers obtain Board approval for an agreement for de-identified PDMP data *prior* to the research organization soliciting and receiving funds for the research.

Appendix B—Indiana Board of Pharmacy Prescription Monitoring Program (INSPECT)

Release of De-Identified INSPECT Data

Policy

The Indiana Board of Pharmacy (Board) may release de-identified data[1] for research or educational purposes in accordance with the requirements set forth herein.

Applicable Laws

IC 35-48-7-11.1 Confidentiality

…

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled public records.

Protocol for Release of De-Identified Data

Researcher must apply for the release of the de-identified data by (a) submitting a protocol and institutional review board (IRB) application and approval for Board review and, if deemed necessary by the Board, (b) making a personal appearance in front of the INSPECT Subcommittee.[2] The Board will place the application on its meeting agenda.

Board will review protocol and grant or deny the application to release the de-identified data based on the following factors:

1. The reason for the study and anticipated outcome (e.g. publication, presentation at scientific meeting, etc.);
2. Data fields and time frame requested;
3. Agreement that use of the data is limited to the protocol terms;
4. Agreement that the data cannot be transferred/shared with anyone outside the specific research project for which it is approved;
5. Agreement that research results will be reported to the INSPECT Subcommittee and approved by the Subcommittee prior to publication;
6. Agreement that the Indiana Board of Pharmacy and INSPECT may use the results for Board related purposes (e.g. reports to legislature); and
7. Any other information the Board deems necessary to render a decision on the application.

[1] De-identified data is defined below under the heading "INSPECT De-identified Data Defined".
[2] The institutional review board (IRB) must be registered with the Office for Human Research Protections (OHRP).

If data is to be re-used, another protocol and IRB approval is required. INSPECT staff will track all approved protocols and retain a copy of all data released pursuant to protocol. For good cause shown, the Board reserves the right to waive these policy requirements.

INSPECT De-identified Data Defined

Specific fields a de-identified data file will contain: (Based off SHOPPER.rpt)

**INSPECT will not perform any type of sorting or analysis, only the data dump.*

1. Zip Code
2. Date Rx Written
3. Date Filled
4. Quantity
5. Days Supply
6. Drug Information
7. Dispensing Pharmacy
8. Payment Type

INSPECT will NOT provide:

- DEA Numbers
- Patient address
- Patient names
- Customer ID Numbers
- A report on a "specific" product or single drugs, e.g. Oxycontin, Hydrocodone.

INSPECT may provide customized data:

- By Schedule – All schedule IIs, schedule II & III together, etc.
- By Drug Type – Pain Releiver, Sedative, Stimulant or Tranquilizer families
- ANY BJA/Governor Metric

Appendix C—MAINE Substance Abuse and Mental Health Services

Data Use Proposal

Use this proposal form to request pre-approval to use data housed by the Maine Office of Substance Abuse and Mental Health Services (SAMHS), Department of Health and Human Services. This form allows for researchers to gain contingency approval of using SAMHS data for the purpose of Institutional Review Board (IRB) applications.

Principal Investigator	
When is the research project slated to begin and end?	
Data Set Requested	Prescription Monitoring Program Data
Years of Data Requested	Click here to enter a date. to Click here to enter a date.
List Variables Requested	
Project Goals and Objectives	
Summary of Research Project Purpose	
How will this research advance the field of substance abuse prevention, intervention, treatment, and/or recovery?	
Will you also use data from other States?	
Who will have access to the data?	
How will the data be stored and secured?	

For questions on this form please contact:
Anne Rogers, M.Ed., ABD, CHES
Data and Research Manager
Substance Abuse and Mental Health Services
Data, Quality Management, & Resource Development
207-287-4706
Anne.Rogers@maine.gov

MAINE Substance Abuse and Mental Health Services
Maine Department of Health and Human Services

Agreement Regarding Client Confidentiality
For Business Associates and Researchers

The Substance Abuse and Mental Health Services, Maine Department of Health and Human Services (SAMHS) is providing **choose data source** data to Name of Organization/Individual (the entity) for the purpose of specific research or for the purpose of providing contracted services to SAMHS. The data provided or collected is likely to include patient/client identifiable information regarding alcohol or drug use or treatment or other protected health information.

Definition of PHI for *both* HIPAA and Substance Abuse purposes. For the purposes of this agreement "protected health information" (PHI) will refer to both personal identifying information regarding alcohol or drug abuse or treatment protected by 42 U.S.C. §§ 290dd-3 and 290ee-3 and regulations at 42 CFR Part 2 and protected health information defined under HIPAA, 42 U.S.C. §§ 1320d(6). PHI includes information on individuals where SAMHS has removed identifying information, but there is a reasonable possibility that a person may be indirectly identified by narrowing the data set.

The entity will use the data for the purpose of the following research or contracted services: describe the research, purpose of the data request.

The entity agrees as follows.

1. Requester:
    a. Researchers, by signing this agreement, confirm that they are qualified to do the research and have a research protocol under which the terms of this agreement will be maintained. To obtain PHI the research will provide a satisfactory evidence to SAMHS D&R that an Institutional Review Board (IRB), formed and maintained in accordance with the U.S. Department of Health and Human Services Code of Federal Regulations for Protection of Human Subjects (45 CFR 46, revised March 8, 1983), have reviewed the protocol and determined that the rights and welfare of the subjects of the research will be adequately protected and that the risks of disclosing patient identifying information are outweighed by the benefits of the research. Even if such a statement is provided, researchers may not disclose PHI except back to SAMHS.
    b. Business Associates, by signing this agreement, confirm that they have the qualifications and security protocols in place to protect the data and information as outlined below. And that the signator has a current business relationship with SAMHS to use the data as identified above.
2. The recipient/entity acknowledges it will receive PHI and agrees to fully comply with the regulations set out at 42 C.F.R. Part 2 and comply with the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. §§ 1320d (1) – (8), and its implementing regulations. Any ambiguity in this agreement must be interpreted to comply with HIPAA and 42 CFR Part 2. If there is a conflict, whichever law or regulation that provides the individual with the best privacy protection will apply.
3. The entity must not disclose PHI, except back to SAMHS, unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. Consent forms must comply with both HIPAA and with 42 CFR Part 2.

4. The recipient/entity will not publish or release data in any form if there is a reasonable possibility that a particular patient/client can be directly or indirectly identified from the information released. Data will be considered to have a reasonable possibility of indirectly identifying individuals if it includes:
    a. Tabulations that include identifying information such as race, gender, income, ethnicity, age, health conditions, use of a methadone clinic, pregnancy or other identifying information when that information, either alone or in combination with other factors, including geographic area, creates a risk of indirectly identifying the individual.
    b. Rates, frequencies or other tabulations or combined factors that result in fewer than 6 individuals in a cell, or fewer than 20 individuals in a set, such as a specific agencies data.

    To reduce the risk of indirectly identifying individuals, the entity:
    c. Will not use date of birth unless converted to age in years
    d. Will not use date of admission for treatment or date of prevention program or event unless converted to week, month or year.
    e. Will aggregate data before it is published to assure that it does not create a risk of identifying individuals.
5. PHI may be used only as needed to carry out the research or contracted services described above.
6. PHI in any media format will be stored in a secure manner, allowing access only as needed by those within the entity's organization who need access in order to perform the research or contracted services. The entity must have written procedures to maintain the security of PHI.
7. The recipient/entity must make available in a timely manner to SAMHS its internal practices, books, records and procedures relating to the use, disclosure and security of PHI received from or collected for SAMHS.
8. The recipient/entity must:
    - Mitigate, to the extent practicable, any harmful effect that is known to the entity of a use or disclosure of PHI in violation of this agreement, and
    - Report to SAMHS any use or disclosure of PHI of which the entity becomes aware that is not permitted under the law or this agreement.
9. The recipient/entity must keep a record of all releases of PHI in accordance with 45 CFR § 164.528, whether or not the release conforms with the law. Records of releases relating to an individual must be promptly provided to the individual as directed by SAMHS pursuant to 45 CFR § 164.524.
10. Some circumstances may meet one of the very limited exceptions to confidentiality in 42 CFR Part 2. Under such circumstances, PHI may not be disclosed except by written agreement from SAMHS. The entity will resist in any judicial or administrative proceedings any efforts to obtain access to personal identifying information regarding substance abuse or treatment. Any such efforts will be reported immediately to SAMHS. This paragraph does not apply with respect to the disclosure of information about a person within the criminal justice system where participation in a drug or alcohol program is a condition of the disposition of a criminal proceeding against the patient, provided that disclosure is only made to those who need to know within the criminal justice system, the patient has consented in writing, and there is full compliance with 42 C.F.R. § 2.35.
11. All PHI obtained in the course of research or providing contracted services must be destroyed when the entity has completed the research. PHI may not be disclosed in any report whether or not related to the research or the contracted services.
12. This Agreement shall be effective from the time the Business Associate or Researcher receives or collects PHI until the time it has destroyed all PHI related to the research or contracted services or returned it, without retaining a copy in any media format, to SAMHS.

13. Upon the SAMHS's knowledge of a material breach by the Business Associate or researcher, SAMHS shall either, at its sole discretion:
    (a) Provide the Business Associate or researcher an opportunity to cure the breach or end the violation within a time frame and upon such conditions as established by SAMHS; or
    (b) Immediately terminate this Agreement in the event the Business Associate or researcher has breached a material term of this Agreement. In the case of termination, all PHI in the Business Associate's or Researcher's possession, or in the possession of their agents or subcontractors related to the contract or research shall be either destroyed or returned to SAMHS, at SAMHS direction, with no copy in any media format remaining with the Business Associate or Researcher.
14. The Business Associate or Researcher agrees to ensure that any agent, including a subcontractor to whom it provides or entrusts PHI as defined in this Agreement, will agree in writing to the same restrictions and conditions governing PHI set out in the Agreement which apply to the Business Associate or researcher.

_____
Print Name

_____ _____
Signature Date

Appendix D—Massachusetts Department of Public Health Prescription Monitoring Program Data Request Form

The Commissioner or designee may provide de-identified data to a public or private entity for statistical research or educational purposes. M.G.L. c. 94C, §24A

Prescription Monitoring Program (PMP) Deidentified Data Request Form Submission Guidelines

(Patients seeking their own controlled substance prescription history need to submit this in writing or via email at the following: BHCSQ, 99 Chauncy Street, Boston MA 02111 or email to: mapmp.dph@MassMail.State.MA.US)

- All sections must be completed unless otherwise indicated. Incomplete Data Request Forms will not be processed.
- All completed Data Request Forms must be signed, and scanned and submitted electronically to: mapmp.dph@state.ma.us or submitted by mail to the address noted above (email transmission is recommended).
- For more information on the Massachusetts Prescription Monitoring please visit: www.mass.gov/dph/dcp/pmp

Section 1. Data Requester's Primary Contact information

Organization Name: [ ]

First Name: [ ] **Last Name:** [ ]

Suffix: [ ]

Degrees (if applicable): [ ]

Credentials (if applicable):
Drug Enforcement Administration (DEA#) : [ ]
Professional License #: [ ]
Board of Pharmacy #: [ ]
National Provider Information (NPI#): [ ]

Business Address: Data requests must include street address; applications with PO Box address will not be processed.

Facility Name & Department: [ ]

Street: [ ] **City:** [ ] **State:** [ ] **Zip:** [ ]

Mailing Address (Check here if the same as Business Address, if not please enter below): [ ]

Street: [ ] **City:** [ ] **State:** [ ] **Zip:** [ ]

Business Telephone No. : [ ]

Requester's Email Address: [ ]

September 12, 2016, Version 1

Section 2. Data Request **Information**

Purpose of Request: Check One ("X")	
☐	Research
☐	Grant
☐	Evaluation
☐	Industry

The purpose of this section is to provide a description of the project and the intended use of the requested data.

1. Briefly describe your organization and your current role.

2. Provide brief description of the data request.

3. Please place an X next to Massachusetts and/or all applicable Massachusetts Counties from which you are requesting data.

State/County	Check County to Request Data
Massachusetts	☐
Barnstable	☐
Berkshire	☐
Bristol	☐
Dukes	☐
Franklin	☐
Hampden	☐
Hampshire	☐
Middlesex	☐
Nantucket	☐
Norfolk	☐
Plymouth	☐
Suffolk	☐
Worcester	☐

4. Please describe the type of data you are requesting (i.e. Year, Drug Schedule).
(County and state level data are categorized by age group, drug type, schedule, gender, and year.)

5. Does the data request require Institutional Review Board (IRB) approval? (Y/N) [ ] If yes, please attach the IRB approval.

6. Is this data request used to inform a grant and/or grant application? (Y/N) [ ] If yes, please attach the specifications of the grant.

7. Do you intend to publish the findings from this data request? (Y/N) [ ] If yes, please see the publishing restrictions below.

8. Have you submitted previous PMP data requests? (Y/N) [ ] If yes, please provide the dates and project/research titles of all previous PMP data requests.

9. How will the data be used to inform your research?

Note: To satisfy this description, you may attach additional pages. If this form does not meet your needs, please contact the Office of Prescription Monitoring and Drug Control Program for additional information.

Section 3. Data Request Form Submission

By signing this form, the requester agrees to the following:

1. You are not permitted to publish any articles that reference this data without authorized approval from the MA Department of Public Health (MDPH).
2. MDPH shall reserve the right to deny PMP data requests.

Print Name _____

Affiliation and Title: _____

_____

Signature Date

Department of Public Health Use Only

Date Request Received:

Data Request Number (assigned by program):

Date Request Completed:

Check ("X") for Status of Request	Status
☐	Data Request Approved
☐	Data Request Rejected
☐	Need more information