Government of the District of Columbia
Department of Health

Prescription Drug Monitoring Program: Advisory Committee Meeting

899 NORTH CAPITOL ST. NE – 2ND FLR.
WASHINGTON, DC 20002

January 16, 2018

10:00am- 12:00 pm

OPEN SESSION AGENDA

CALL TO ORDER:

PRESIDING:

COMMITTEE MEMBERSHIP/ATTENDANCE:

ADVISORY COMMITTEE MEMBERS:		
	DR. JACQUELINE WATSON, DOH CHIEF OF STAFF	
	MR. FRANK MYERS, BOARD OF MEDICINE EXECUTIVE DIRECTOR	
	DR. SHAUNA WHITE, BOARD OF PHARMACY EXECUTIVE DIRECTOR	
	DR. NATALIE KIRILICHIN, EMERGENCY MEDICINE PHYSICIAN	
	CAPT. GEORGE CALDWELL, METROPOLITAN POLICE DEPARTMENT	
	MS. JESSICA DONALDSON, CERTIFIED PHARMACY TECHNICIAN	
	MR. GLENN HARRIS, CONSUMER MEMBER	
STAFF:	MS. ALYCE OSBORNE, PUBLIC HEALTH ANALYST	
	MS.TADESSA HARPER-NICHOLS, PROGRAM SPECIALIST	
LEGAL STAFF:	MS. CARLA WILLIAMS, ASSISTANT GENERAL COUNSEL	
VISITORS:		

Open Session Agenda

Quorum:

Introduction:		
1201-O-01	**Welcome and PDMP Overview**	
1201-O-02	**PDMP Advisory Committee Introductions**	
1201-O-03	**PDMP Advisory Committee Appointee duties and commitment** (a) PDMP Municipal Regulations, § 10316.1 – 10316.8 (b) Proposed quarterly meetings in Year 1	
1201-O-04	**Program Update & PDMP Legislation Review** (a) Pharmaceutical Control Division PDMP presentation	
1102-O-05	**Administrative Discussion**	
Matters for Committee Consideration	(a) Gabapentin as a drug of concern (b) Naloxone dispensation data collection in the PDMP (c) Requiring Mandatory Registration or Mandatory Query	
Comments from the Public		
Motion to Adjourn the Open Session	Madam Chair, I move that the Committee close the Open Public session portion of the meeting. (Roll Call Vote)	

This concludes the Public Open Session of the meeting.

Open Session Meeting Adjourned at __:__

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District of Columbia

Prescription Drug Monitoring Program

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What is a Prescription Drug Monitoring Program?

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- PDMPs are electronic databases used to monitor prescription trends within a jurisdiction by reporting the dispensation of targeted controlled drugs.
- Information is collected from dispensers to monitor controlled substance dispensations
- Prescriber's and dispensers are encouraged to use PDMP data to make informed patient care decisions
- This information may be used to monitor matters of substance abuse, fraud or diversion
- PMP AWARxE (developed by Appriss) is the software vendor for the DC PDMP

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DC PDMP Timeline

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Events	Dates
Stakeholder Meeting to review Draft Legislation	February 2012
Legislation Introduced in City Council	September 2012
Committee on Health Hearing	July 2013
Legislation Passed	February 2014
Draft regulations Ready	Fall 2014
Stakeholder Meeting on Draft Regulations	November 2014
Regulation Effective	December 11th 2015
90 Day Notice Sent[5]	May 15th 2016
Program Registration	July 1st 2016
Reporting Begins	August 15th 2016
Database Access Launched	October 19th 2016
PDMP Project Transitioned to Program	November 30, 2016

PDMP Overview

Covered Substance[1]

- All drug products containing Cyclobenzaprine or Butalbital
- All controlled substances included in schedules II, III, IV and V

Administer

- The direct application of a controlled substance, whether by injection, inhalation , inhalation, ingestion, or any other means, to the body of a patient or research subject by a practitioner (or in the practitioner's presence, by the practitioner's authorized agent) or the patient or research subject at the direction of and in the presence of the practitioner

Dispense

- To distribute a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery

Reporting Period

- The 24 hour time period immediately following the dispensing of a covered substance

Data Collection

Prescriber Information

- Prescriber's DEA number, NPI number or other mutually acceptable identification number[9]
- Full name
- Date prescription was issued

Dispenser Information

- Dispenser's DEA number, NPI number or other mutually acceptable identification number
- Facility
- Address
- Telephone number
- Date prescription was dispensed

Medication Processing Information

- Prescription number
- Prescription type (new or refill)
- Number of refill being dispensed(if applicable)
- NDC code of the drug dispensed
- Quantity dispensed
- Day's supply dispensed
- Number of refills ordered

Patient Information

- Full name
- Address
- Telephone number
- Date of Birth
- Gender
- Payment Method

Reporting Exceptions/Exclusions

- A DC licensed methadone treatment program or substance abuse treatment pharmacy or facility
- A DC licensed pharmacy that dispenses controlled substances (schedules II-V, cyclobenzaprine; and butalbital) for inpatient hospital are or nursing home patients only
- A pharmacy or facility that dispensing covered substances to inpatients in hospices
- A pharmacy or a facility that never possesses or dispenses controlled substance (schedules IIV), or cyclobenzaprine and butalbital
- A dispensing facility that is experiencing a hardship created by a natural disaster or other emergency beyond the control of the licensee
- An ongoing controlled research project or clinical trial approved by a regionally accredited institution of higher education or under the supervision of a governmental agency

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Government of the District of Columbia
Department of Health
Health Regulation and Licensing Administration
Pharmaceutical Control Division
Prescription Drug Monitoring Program

DC PDMP DATA SUBMITTER WAIVER FORM

I request an exemption from reporting to the District of Columbia Prescription Drug Monitoring Program (DC PDMP).

I certify that: (CHECK ONE ONLY)

☐ I represent a DC licensed methadone treatment program or substance abuse treatment pharmacy or facility and therefore am exempt from reporting data, as defined in District of Columbia regulation 10301.5(b).

☐ I represent a DC licensed hospital pharmacy that distributes controlled substances (schedules II-V, cyclobenzaprine; and butalbital), as defined in District of Columbia regulation 10301.5(c), for inpatient hospital care only.

☐ I represent a pharmacy or facility that dispensing covered substances to inpatients in hospices licensed or certified by the Department, as defined in District of Columbia regulation 10301.5(d)

☐ I represent a pharmacy or a facility that never possesses or dispenses controlled substance (schedules II-V), or cyclobenzaprine and butalbital, as defined in District of Columbia regulation 10302.1(a)(b) prescriptions and request a permanent zero report, as defined in District of Columbia regulation 10304.

☐ I represent a dispensing facility that is experiencing a hardship created by a natural disaster or other emergency beyond the control of the licensee, as defined in District of Columbia regulation 10305.2(a). Please provide description in a separate document:

☐ I represent an ongoing controlled research project or clinical trial approved by a regionally accredited institution of higher education or under the supervision of a governmental agency, as defined in District of Columbia regulation 10305.2(b). Please attach a description of the research project.

Comments: _____

(Please limit to 60 characters, including spaces)

I further certify that if this pharmacy or facility begins to dispense controlled substance (schedules II-V), cyclobenzaprine, or butalbital prescriptions that qualify for reporting under the provisions of District of Columbia regulation 10302.1(a)(b), I will immediately notify the DC PDMP and will commence reporting immediately.

Government of the District of Columbia
Department of Health
Health Regulation and Licensing Administration
Pharmaceutical Control Division
Prescription Drug Monitoring Program

Facility Name	DC License Number
Facility Street Address	DC Controlled Substance Number
City, State, Zip	DEA Number
Representative Name (Printed)	Phone Number
Title	Email address
Signature	Date

Requests and questions should be submitted to the DC PDMP via email or fax. Upon receipt of a complete Waiver, the Program may take up to thirty (30) business days to process and respond.

E-mail: doh.pdmp@dc.gov Fax: 877-862-4252

The Program may grant exemptions and waivers on a case-by-case basis, which shall be subject to the terms and conditions stated the waiver, limited to a specified time period, and subject to being vacated. Licensees must reapply to renew waivers Denial by the Program of a request for a waiver shall be deemed a final Department action. A dispenser whose request for a waiver is denied m seek review of the final Department action in the Superior Court of the District of Columbia within twenty (20) days after receipt o the notice. The review shall be an on the record review of the decision, and not a de novo review.

For Government Use Only

Date Received (mm/dd/yy)	☐ Approved ☐ Denied	Term (mm/dd/yy)	Expiration Date (mm/dd/yy)	Director or Designee Signature	Date of action (mm/dd/yy)

Reason for denial: _____

(Please limit to 60 characters, including spaces)

899 North Capitol St., NE, 2nd Floor, Washington, DC 20002 (855) 932-4767 (phone), 877-862-4252 (fax)
Website: http://doh.dc.gov/pdmp; email: doh.pdmp@dc.gov
Rev.6.1.2016

Zero Reporting

- Zero report forms must be completed when covered substances are not dispensed during the reporting period
- Due 24 hours after last report
- Permanent zero status may be requested if covered substances will not be dispensed for a prolonged period of time
- Permanent zero reports are null upon dispensation of a covered substance

PDMP Users

Prescribers

Dispensers

Delegates

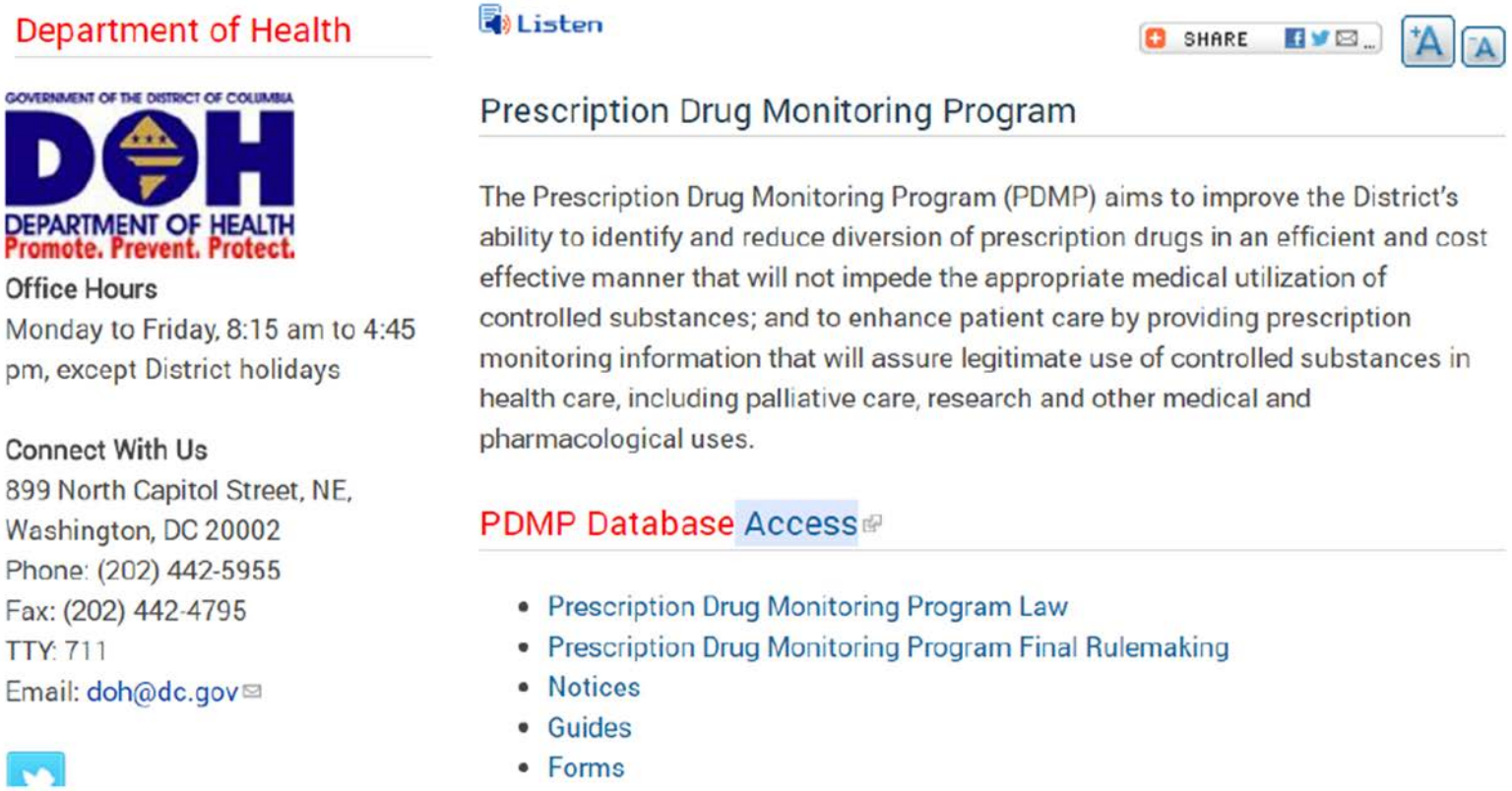
Authorized Agents

Patients

Policymakers

Researchers

Registration



Department of Health

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Office Hours
Monday to Friday, 8:15 am to 4:45 pm, except District holidays

Connect With Us
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Washington, DC 20002
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Fax: (202) 442-4795
TTY: 711
Email: doh@dc.gov

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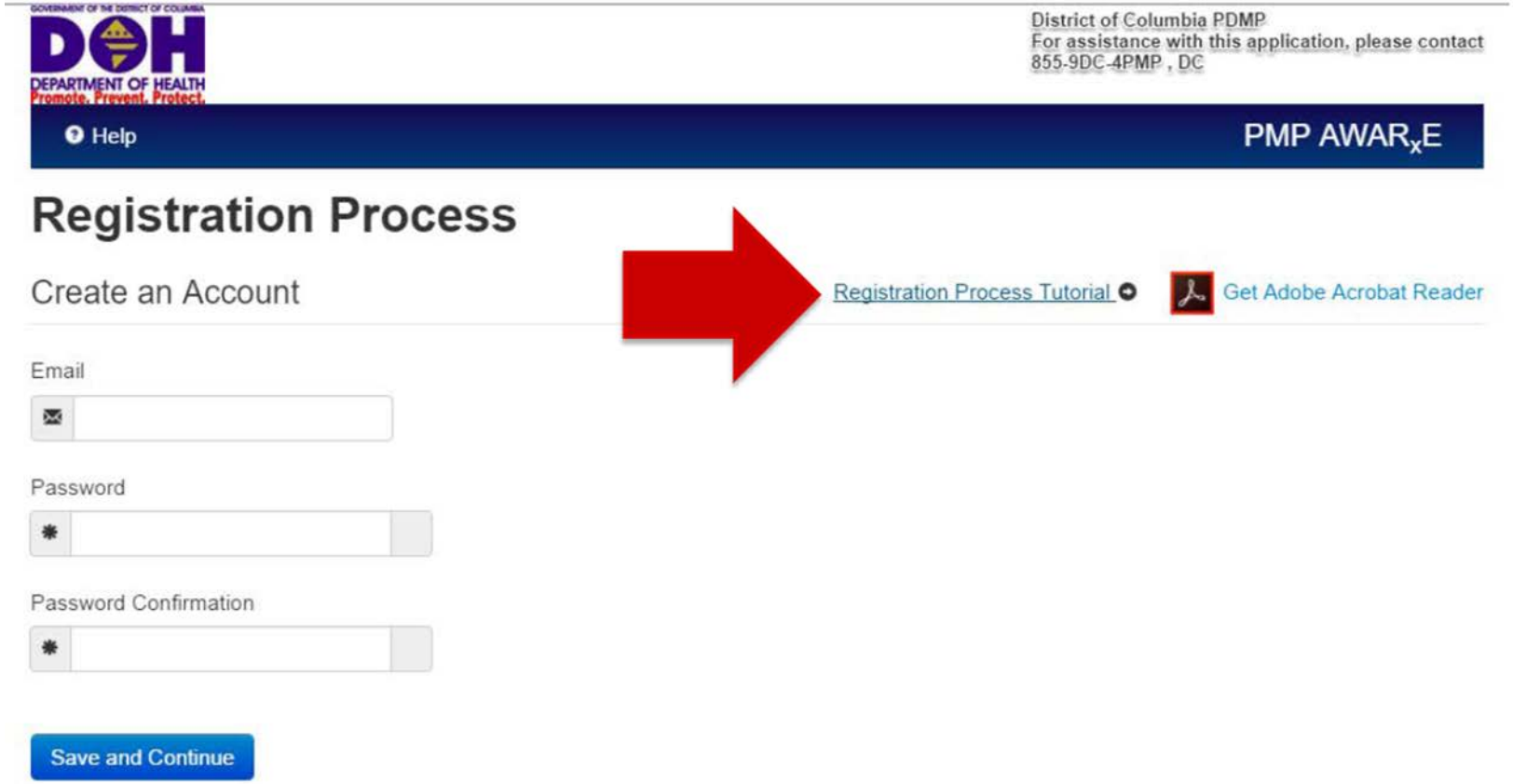
Prescription Drug Monitoring Program

The Prescription Drug Monitoring Program (PDMP) aims to improve the District's ability to identify and reduce diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of controlled substances; and to enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in health care, including palliative care, research and other medical and pharmacological uses.

PDMP Database Access

- Prescription Drug Monitoring Program Law
- Prescription Drug Monitoring Program Final Rulemaking
- Notices
- Guides
- Forms

Registration



Approved Users

User Role	User Count	% Distribution
Physician (MD, DO)	601	45.29%
Pharmacist	324	24.42%
Nurse Practitioner / Clinical Nurse Specialist	148	11.15%
Pharmacist in Charge	82	6.18%
Physician Assistant	79	5.95%
Dentist	30	2.26%
VA Prescriber	13	0.98%
Veterinarian	13	0.98%
Podiatrist (DPM)	8	0.60%
Admin	7	0.53%
Pharmacy Technician	5	0.38%
Medicaid Fraud Units	3	0.23%
Midwife with Prescriptive Authority	3	0.23%
Board of Medicine Investigator	2	0.15%
State Police	2	0.15%
Board of Pharmacy Investigator	1	0.08%
DEA	1	0.08%
Medical Examiner/Coroner	1	0.08%
Optometrist	1	0.08%
Prescriber without DEA	1	0.08%
State Medicaid Program	1	0.08%

Total Approved Users-1,327

As of 1/5/2017

Dispenser Role

- Dispensers are required to report all covered substances dispensed unless exempt
- May access database to analyze patient history of covered substance
- If a correction to the information is needed it must be corrected by the dispenser within 72 hours
- Must give notice at their facility stating that patient information will be sent to the PDMP
- Dispenser can discuss concerns with the prescriber and patient

Prescriber Role

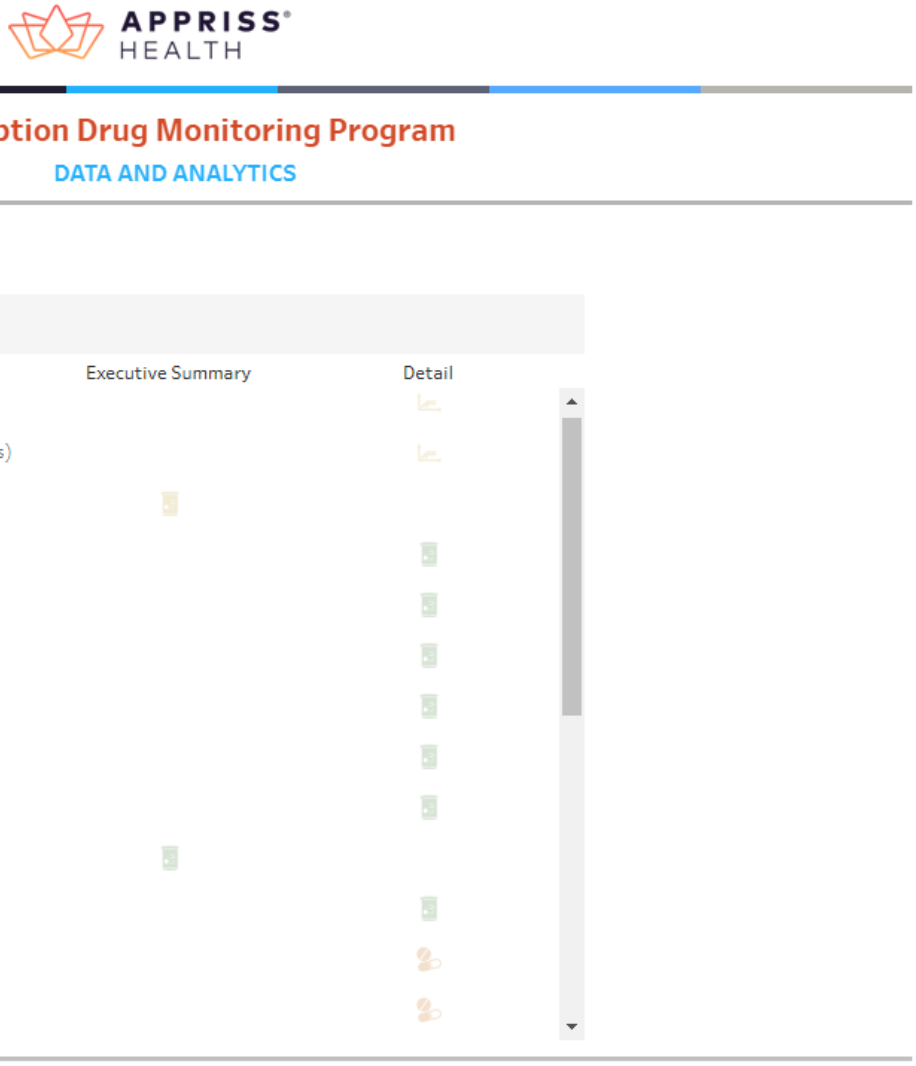
- Support avoidance of prescribing duplicate or inappropriate therapies that enable diversion
- Detection of patients at risk of drug abuse
- Prescriber's have access to self-reports illustrating their prescribing activity
- Must provide notice at their practice stating the use of the PDMP
- Any covered substance being dispensed including one's dispensed at their practice must be reported

Interconnect

DC PDMP is currently connected with the following states through PDMP Interconnect:

- ✓ Massachusetts
- ✓ West Virginia
- ✓ Connecticut
- ✓ Rhode Island
- ✓ New York
- ✓ Virginia
- ✓ Maryland
- ✓ Pennsylvania
- ✓ South Carolina
- ✓ Minnesota

Analytics


APPRISS HEALTH
Prescription Drug Monitoring Program
DATA AND ANALYTICS
Domain:
(All)
Click the symbol to begin Analysis:
Executive Summary
Detail
Universe
Do your own Analysis (All Years)
Do your own Analysis (Most Recent Two Years)
PDMP Analytics Gateway
Prescriptions
By Demographic Environment - County
By Drug Schedule
By Payment Types
By Prescriber County, Zip
By Refill Types
By Schedule, Demographic Environment
By Year
By Year, Month
Drugs
Buprenorphine Activity by County
Buprenorphine Activity by Prescriber County

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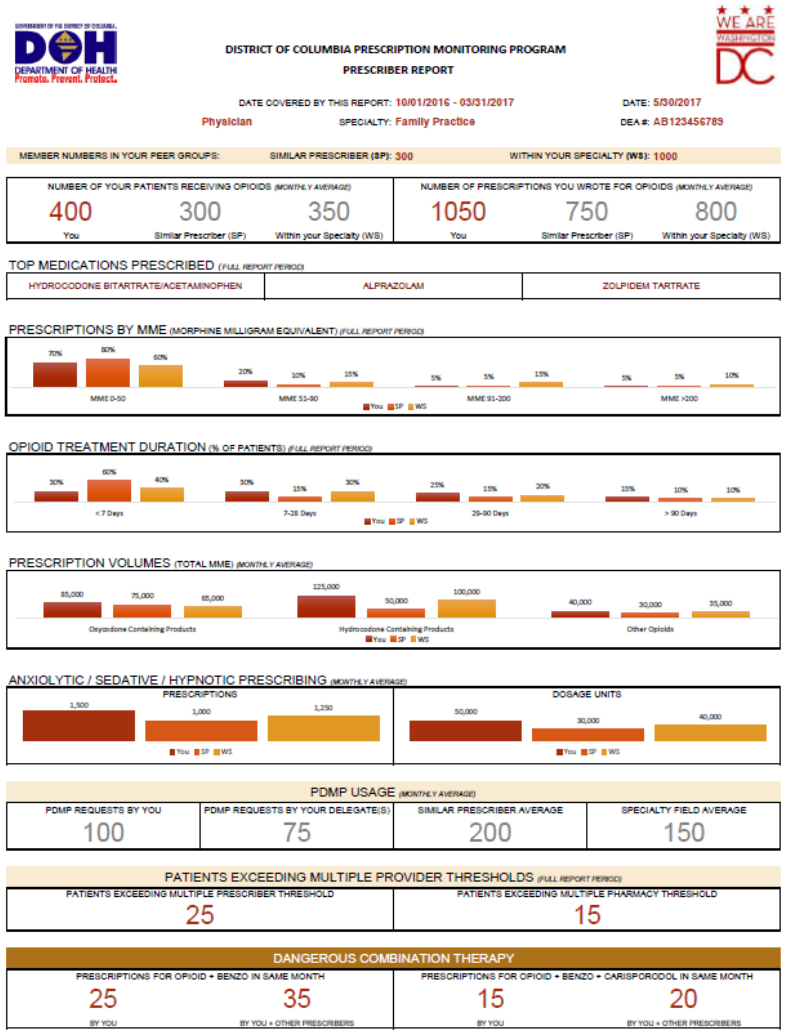
Forthcoming PDMP Enhancements and Regulatory Changes

Prescriber Report Cards



DISTRICT OF COLUMBIA PRESCRIPTION MONITORING PROGRAM
PRESCRIBER REPORT

DATE COVERED BY THIS REPORT: 10/01/2016 - 03/31/2017
DATE: 5/30/2017
Physician
SPECIALTY: Family Practice
DEA #: AB123456789

MEMBER NUMBERS IN YOUR PEER GROUPS: SIMILAR PRESCRIBER (SP): 300 WITHIN YOUR SPECIALTY (WS): 1000

NUMBER OF YOUR PATIENTS RECEIVING OPIOIDS (MONTHLY AVERAGE)			NUMBER OF PRESCRIPTIONS YOU WROTE FOR OPIOIDS (MONTHLY AVERAGE)		
400	300	350	1050	750	800
You	Similar Prescriber (SP)	Within your Specialty (WS)	You	Similar Prescriber (SP)	Within your Specialty (WS)

TOP MEDICATIONS PRESCRIBED (FULL REPORT PERIOD)

HYDROCODONE BITARTRATE/ACETAMINOPHEN	ALPRAZOLAM	ZOLPIDEM TARTRATE

PRESCRIPTIONS BY MME (MORPHINE MILLIGRAM EQUIVALENT) (FULL REPORT PERIOD)

OPIOID TREATMENT DURATION (% OF PATIENTS) (FULL REPORT PERIOD)

PRESCRIPTION VOLUMES (TOTAL MME) (MONTHLY AVERAGE)

ANXIOLYTIC / SEDATIVE / HYPNOTIC PRESCRIBING (MONTHLY AVERAGE)

PDMP USAGE (MONTHLY AVERAGE)

PDMP REQUESTS BY YOU	PDMP REQUESTS BY YOUR DELEGATE(S)	SIMILAR PRESCRIBER AVERAGE	SPECIALTY FIELD AVERAGE
100	75	200	150

PATIENTS EXCEEDING MULTIPLE PROVIDER THRESHOLDS (FULL REPORT PERIOD)

PATIENTS EXCEEDING MULTIPLE PRESCRIBER THRESHOLD	PATIENTS EXCEEDING MULTIPLE PHARMACY THRESHOLD
25	15

DANGEROUS COMBINATION THERAPY

PRESCRIPTIONS FOR OPIOID + BENZO IN SAME MONTH		PRESCRIPTIONS FOR OPIOID + BENZO + CARISPOROCOL IN SAME MONTH	
25	35	15	20
BY YOU	BY YOU + OTHER PRESCRIBERS	BY YOU	BY YOU + OTHER PRESCRIBERS

Mandates

States that Require Mandatory Enrollment/Query by Prescribers and Dispensers

Mandatory Enrollment of Prescribers and Dispensers	
Prescribers and Dispensers	25
Prescribers Only	8
Dispensers Only	4
No Mandatory Enrollment	15

Mandatory Query by Prescribers and Dispensers	
Prescribers and Dispensers	14
Prescribers Only	26
No Mandatory Query-	12

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Mandatory Enrollment

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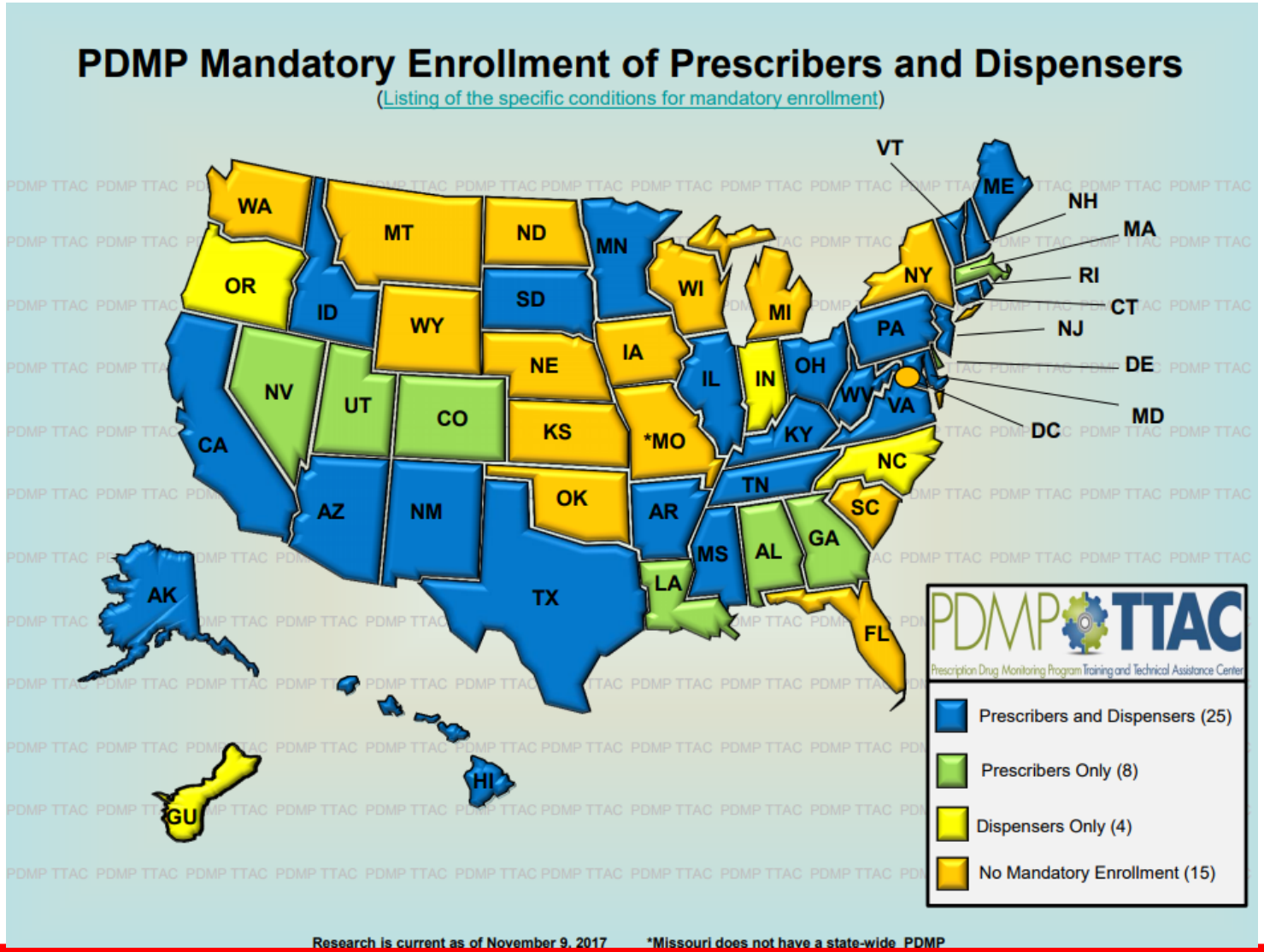

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Mandatory Query

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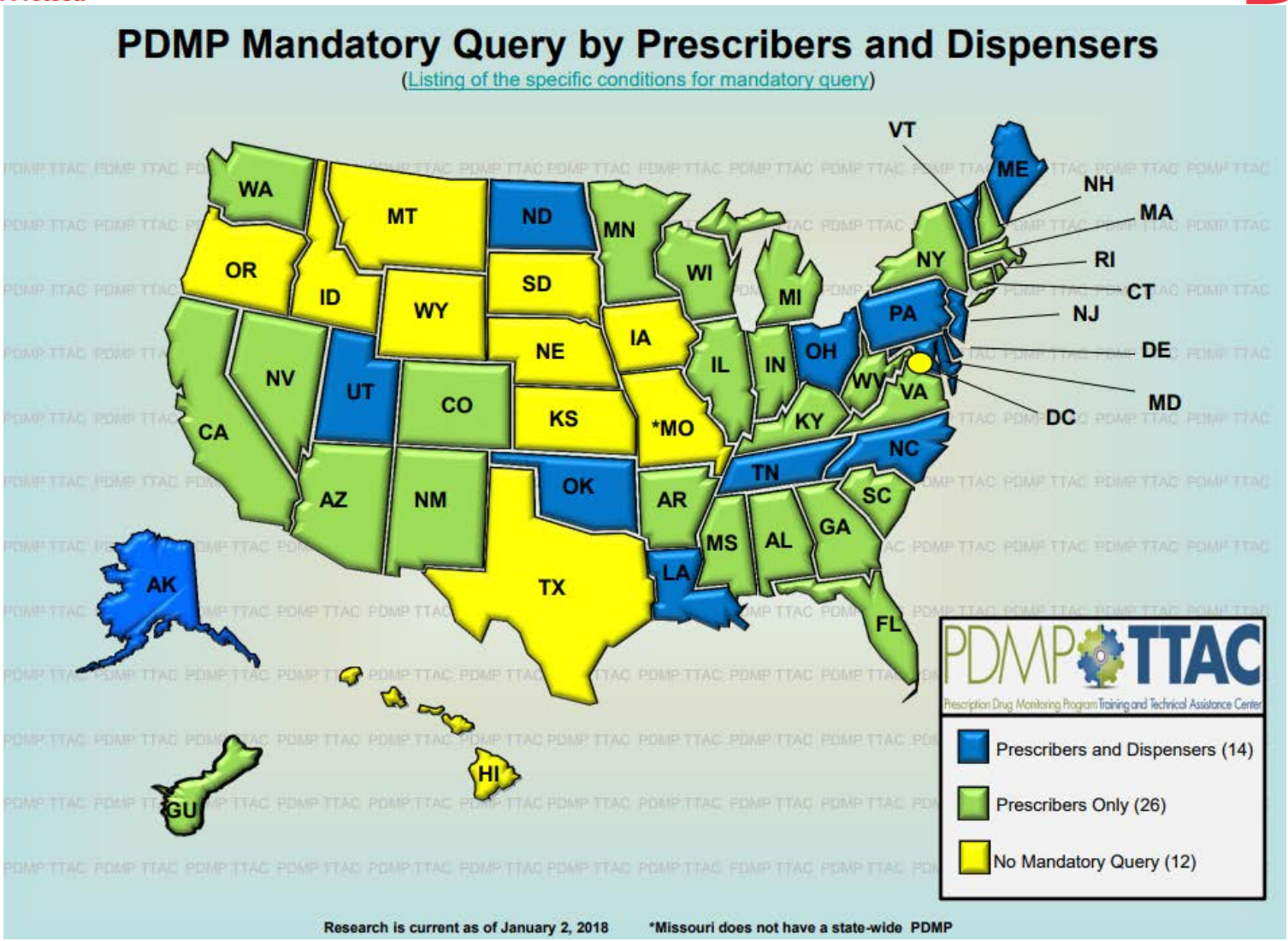

Gabapentin Reporting

States that require Gabapentin reporting into the PDMP -

- Illinois
- Kentucky
- Massachusetts
- Nebraska
- North Dakota
- Ohio
- Virginia
- West Virginia
- Wyoming

DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS

FOR

THE PRESCRIPTION DRUG MONITORING PROGRAM

CHAPTER 103 PRESCRIPTION DRUG MONITORING PROGRAM

Secs.

10300 GENERAL PROVISIONS

10300.1 The Prescription Drug Monitoring Program (Program) shall employ information technology necessary for dispensers to report the prescription monitoring data set forth in § 10301.4 to the Program.

10300.2 A prescriber or dispenser:

(a) Is not required or obligated to access or use the prescription monitoring data available under the Program; and

(b) When acting in good faith, is not subject to liability or disciplinary action arising solely from:

(1) Requesting or receiving, or failing to request or receive, prescription monitoring data from the Program; or

(2) Acting, or failing to act, on the basis of prescription monitoring data provided by the Program.

10300.3 The Program shall retain prescription monitoring data for at least three (3) years from the date of receipt.

10301 PRESCRIPTION MONITORING DATA REPORTING REQUIREMENTS

10301.1 Each dispenser of a covered substance shall submit the prescription monitoring data required in § 10301.4, in the form and manner required by § 10303, to the Program within twenty-four (24) hours after a covered substance is dispensed for each covered substance dispensed. For purposes of complying with this chapter, dispensing shall not include merely placing the covered substance prescription into a bin for pickup by the ultimate user or his or her agent.

10301.2 For purposes of complying with § 10301.1 of this chapter, the Program shall provide dispensers at least ninety (90) days written notice of the date that reporting shall begin.

10301.3 Any dispenser located outside the geographical boundaries of the District that is licensed or registered by the District, shall submit the prescription monitoring data set forth in § 10301.4 to the Program within twenty-four (24) hours after the covered substance is dispensed to an ultimate user who resides in the District. The submission shall be in the form and manner required under § 10303.

10301.4 Upon dispensing a covered substance, the dispenser of the covered substance shall report the following prescription monitoring data to the Program:

(a) Patient full name;

(b) Patient address;

(c) Patient telephone number;

(d) Patient date of birth;

(e) Patient gender;

(f) Dispenser DEA number, NPI number, or other mutually acceptable identification number;

(g) Dispenser name;

(h) Dispenser address;

(i) Dispenser telephone number;

(j) Prescriber DEA number, NPI number, or other mutually acceptable identification number;

(k) Prescriber’s full name;

(l) Date prescription was issued by prescriber;

(m) Date prescription was dispensed;

(n) Prescription number;

(o) Prescription type is new or is a refill;

(p) Number of refill being dispensed, if applicable;

(q) NDC code for the drug dispensed;

(r) Quantity dispensed;

(s) Days' supply dispensed;

(t) Number of refills ordered;

(u) Source of payment for the prescription;

(v) Any elements required as a condition of eligibility for a federal grant as outlined in the PDMP Instruction Manual; and

(w) Any other information that may be requested by the Director in furtherance of the Program.

10301.5 The reporting requirements of this chapter shall not apply to the dispensing of covered substances when the dispensing is limited to the following:

(a) Administering covered substances;

(b) Dispensing covered substances within an appropriately licensed narcotic maintenance program, such as a methadone treatment program or substance abuse treatment program;

(c) Dispensing covered substances to inpatients in hospitals or nursing facilities licensed by the Department or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the District; or

(d) Dispensing covered substances to inpatients in hospices licensed or certified by the Department.

10301.6 The failure of any person subject to the reporting requirements of this chapter to report the dispensing of a covered substance, unless otherwise exempted under this chapter, or the willful failure to transmit accurate information shall constitute

grounds for:

(a) The revocation, suspension, or denial of a District controlled substances registration;

(b) Disciplinary action by the relevant health occupations board pursuant to Section 514(c) of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1205.14(c)); and

(c) The imposition of civil fines pursuant to Section 104 of Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985 (D.C. Law 6-42; D.C. Official Code § 2-1801.04).

10301.7 Each dispenser shall ensure that information reported to the Prescription Drug Monitoring Program is correct and shall submit corrections when necessary.

10302 COVERED SUBSTANCES

10302.1 Covered substances are controlled substances, as defined in this rulemaking, and the following drugs of concern:

(a) All drug products containing Cyclobenzaprine; and

(b) All drug products containing Butalbital.

10303 STANDARDS AND FORMAT FOR REPORTING

10303.1 The required prescription monitoring data subject to reporting pursuant to §§ 10301 and 10302 shall be transmitted electronically to the Program:

(a) Within twenty-four (24) hours of dispensing;

(b) In the format provided in the Electronic Reporting Standard for Prescription Monitoring Programs of the American Society for Automation in Pharmacy (ASAP), Version 4.2 (November 2011) or later; and;

(c) Shall be consecutive and include any covered substances dispensed after the last date and time reporting information was submitted.

10303.2 The Program shall make available a PDMP Instruction Manual that sets forth information about the required file layout format and acceptable media transmission for submitting the required reporting information.

10303.3 Prescription monitoring data subject to reporting pursuant to §§ 10301 and 10302 shall be transmitted to the Program in the required file layout format through the media transmission set forth in the PDMP Instruction Manual. Dispensers shall begin transmitting the required data on the date specified by the Program, which shall be no less than ninety (90) days after receiving notice from the Program.

10303.4 An alternative means of reporting may be approved by the Program based upon a written request for an exception if good cause is shown.

10303.5 Prescription monitoring data that is not accepted by the Program due to errors or omissions shall be corrected by the dispenser and resubmitted to the Program within twenty-four (24) hours after the dispenser receives notice of the errors or omissions.

10303.6 If a dispenser cannot submit the required prescription monitoring data electronic report due to a mechanical, electrical, or other technical failure, the dispenser shall:

(a) Notify the Program within twenty-four (24) hours of discovery of the technical failure;

(b) Describe in detail the specific circumstances preventing the dispenser from submitting the required report and include any available documentation; and

(c) Submit a report for each covered substance dispensed during the period of technical failure as soon as possible, but no later than three (3) business days following reestablishment of the means of electronic reporting.

10304 ZERO REPORTING

10304.1 A dispenser that dispenses no covered substances within a twenty-four (24) hour reporting period shall submit a report documenting that zero covered substances were dispensed during that twenty-four (24) hour reporting period.

10304.2 The Program may, upon written attestation that a dispenser possesses no covered substances for dispensing, allow a dispenser to submit a permanent zero report. If at any time the dispenser begins dispensing covered substances, the permanent zero report shall no longer be valid and the dispenser shall start reporting at least every twenty-four (24) hours as required.

10304.3 Dispensers that only dispense covered substances in circumstances not required to be reported, as set forth in § 10301.5, shall file a written attestation with the Program that they are exempt from reporting.

10305 CRITERIA FOR GRANTING WAIVERS OF THE REPORTING REQUIREMENTS

10305.1 The Program may grant a temporary waiver of all or some of the reporting requirements to a dispenser who files a request in writing or electronically on a form provided by the Program and who meets the criteria for waiver set forth in § 10305.2.

10305.2 The criteria for a waiver of the reporting requirements shall include a history of compliance with laws and regulations by the dispensers regularly practicing at that location and may include, but is not limited to:

(a) Substantial hardship created by a natural disaster or other emergency beyond the control of the dispenser; or

(b) Dispensing in a controlled research project approved by a regionally accredited institution of higher education or under the supervision of a governmental agency.

10305.3 The Program may grant waivers on a case-by-case basis, which shall be subject to the terms and conditions stated in the waiver, limited to a specified time period, and subject to being vacated.

10305.4 Denial by the Program of a request for a waiver shall be deemed a final Department action.

10305.5 A dispenser whose request for a waiver is denied may seek review of the final Department action in the Superior Court of the District of Columbia within twenty (20) days after receipt of the notice. The review shall be an on the record review of the decision, and not a *de novo* review.

10306 PRESCRIBER AND DISPENSER ACCESS TO PRESCRIPTION MONITORING DATA

10306.1 Prescribers, dispensers, and their delegates shall register with the Program in order to access or otherwise request disclosure of prescription monitoring data.

10306.2 Prescribers, dispensers, and their delegates who have successfully registered with the Program may access or otherwise request information on an existing or new patient for the purpose of:

(a) Establishing a prescription history to make informed treatment or dispensing decisions;

(b) The medical care or treatment of the patient about whom prescription monitoring data is being requested; or

(c) Performing due diligence and exercising professional judgment when presented with a prescription to dispense a covered substance for use by the patient about whom prescription monitoring data is being requested.

10306.3 Upon request from a prescriber, the Director may provide a report containing prescription monitoring data on all covered substances dispensed pursuant to the prescriber's own prescriptions or by the prescriber, provided that the request is submitted on a form or in a manner approved by the Program.

10306.4 As part of the registration process, a prescriber or dispenser shall attest:

(a) That the prescription monitoring data received from the Program shall not be further disclosed by the prescriber or dispenser except as allowed by law; and

(b) That the prescription data shall only be used for the purposes stated in the request and in accordance with the law.

10306.5 The Program shall:

(a) Establish procedures to authenticate that the prescriber or dispenser is licensed in good standing, and eligible to access the prescription monitoring data; and

(b) Authorize a prescriber or dispenser to access or otherwise request disclosure of prescription monitoring data electronically.

10306.6 If the authorization issued to a registrant is compromised in any manner that may allow another individual to access prescription monitoring data for unauthorized purposes, the registrant shall notify the Program within twenty-four (24) hours after discovery.

10306.7 A prescriber or dispenser authorized to access prescription monitoring data may delegate his or her authority to access the data to up to two (2) health care professionals who are:

(a) Licensed, registered, or certified by a health occupations board; and

(b) Employed at the same location and under the direct supervision of the prescriber or dispenser.

10306.8 Each delegate shall submit a separate application for registration, which shall include the individual’s license, registration, or certification number, and a copy of another form of government issued identification.

10306.9 The supervising prescriber or dispenser, and the delegate, shall sign the delegate registration application, attesting that the delegate is an employee of the same facility, under the direct supervision of the requesting prescriber or dispenser, and that any requests made of the Program will be for use by the supervising prescriber or dispenser.

10306.10 A delegate registration shall expire on June 30th of each even-numbered year, or at any time the delegate leaves, if the delegating prescriber or dispenser removes the authorization, or if the individual otherwise becomes ineligible to receive information from the Program, whichever occurs first. The delegating prescriber or dispenser shall notify the Program in writing within twenty-four hours (24) of any change.

10306.11 The delegating prescriber or dispenser is responsible for ensuring that the delegate is knowledgeable of the laws related to confidentiality of Program information, and shall immediately notify the Program of any known unauthorized use of Program information by a delegate.

10306.12 A prescriber or dispenser who delegates his or her authority to request disclosure of or otherwise access prescription monitoring data to a health care professional shall:

(a) Make reasonable efforts, including regularly reviewing and auditing any available logs of system access and use, to ensure the authorized health care professional is requesting disclosure of, redisclosing, or otherwise accessing prescription monitoring data in clear compliance with the law and this chapter, and all other State and federal laws and regulations governing the security and confidentiality of protected health information and personal medical records;

(b) Immediately notify the Program, as well as the licensing entity responsible for licensing, certifying, or registering the authorized health care professional, if the prescriber or dispenser believes that the confidentiality of prescription monitoring data or the security of the Program has been compromised by an authorized health care professional; and

(c) Notify the Program within twenty-four (24) hours of any requested change in the registration status of an authorized health care professional, including if that authorized health care professional is no longer employed by or practicing under the authority of the prescriber or dispenser.

10307 MANDATORY DISCLOSURE OF PRESCRIPTION MONITORING INFORMATION FOR LAW ENFORCEMENT AND REGULATORY PURPOSES

10307.1 To request disclosure of prescription monitoring data for law enforcement or regulatory purposes, an individual shall be registered with the Program as an authorized agent entitled to receive reports.

10307.2 A request for registration as an authorized agent shall be accompanied by:

(a) An attestation from the applicant's employer confirming the identity of the applicant and the applicant's eligibility to receive the reports; and

(b) An attestation from the applicant that the prescription data will not be further disclosed and will be used only for the purposes stated in the request and in accordance with the law.

10307.3 A registration as an authorized agent shall expire on June 30th of each even-numbered year or at any time the agent leaves, or otherwise becomes ineligible to receive information from the Program.

10307.4 An authorized agent shall only request disclosure of information related to a specific criminal investigation or as authorized under § 10307.5. Requests shall be made in a format designated by the Program and shall contain:

(a) An agency case number or other identifier sufficient to identify an existing *bona fide* individual investigation;

(b) A specified time period to be covered in the report;

(c) The specific patient, prescriber, or dispenser for whom the report is to be made; and

(d) The name, title, and original signature of the official under whose authority the request is made.

10307.5 After receiving a request for access or information in accordance with this section, the Program shall disclose to the requestor information relevant to:

(a) A specific investigation of a specific patient, dispenser, or prescriber to an agent designated by the Chief of the Metropolitan Police Department to conduct drug diversion investigations;

(b) An investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health occupations board or the Department;

(c) A disciplinary proceeding before a health occupations board or in any subsequent hearing, trial, or appeal of an action or board order to designated employees of the Department;

(d) The proceedings of any grand jury or additional grand jury that has been properly impaneled; or

(e) A specific investigation of a specific dispenser or prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.

10308 DISCRETIONARY DISCLOSURE OF INFORMATION

10308.1 The Director may, at the Director's discretion, disclose prescription monitoring data in the Program's possession as permitted by the Act to certain persons, provided the request is made in the format designated in § 10303 and the PDMP Instruction Manual and meets the requirements of this chapter.

10308.2 The Director may disclose personal dispensing information concerning a patient who is over the age of eighteen (18) years to that patient, provided the request is accompanied by a copy of a valid photo identification issued by a government agency of any jurisdiction in the United States verifying that the recipient is over the age of eighteen (18) and includes a notarized signature of the requesting party. If the patient is under the age of eighteen (18), the information may be disclosed to the parent or legal guardian of the patient, provided the disclosure is not otherwise prohibited by District or federal law.

10308.3 The Director may disclose information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting, or denying licenses, certificates, or registrations to practice a health profession when the regulatory authority licenses the dispenser or prescriber, or the dispenser or prescriber is seeking licensure by the regulatory authority making the request, provided the request is related to an allegation of a possible controlled substance violation and is accompanied by an agency case number or other identifier sufficient to confirm an existing *bona fide* individual investigation.

10308.4 The Director may disclose to designated employees of the Department of Health Care Finance, or to the Medicaid Fraud Control Unit of the Office of the Inspector General, as appropriate, the following:

(a) Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the District Medicaid program, DC Health Care Alliance, or any other public health care program;

(b) Information relating to an investigation concerning a specific patient who is currently eligible for and receiving, or who has been eligible for and has received, medical assistance services; or

(c) Other information relevant to the Medicaid Fraud Control Unit of the Office of the Inspector General related to a specific prescriber, dispenser, or patient.

10308.5 Requests for information made pursuant to § 10308.4 of this chapter shall be made in a format designated by the Program and shall contain:

(a) An agency case number or other identifier sufficient to identify an existing *bona fide* individual investigation;

(b) A specified time period to be covered in the report;

(c) The identification of the specific patient, prescriber, or dispenser for whom the report is to be made; and

(d) The name, title, and original signature of the official under whose authority the request is made.

10308.6 The Director may disclose information relevant to the determination of the cause of death of a specific patient to the designated employees of the Office of the Chief Medical Examiner, provided that the request is made in a format designated by the Program and signed by the Chief Medical Examiner.

10308.7 To request prescription monitoring data from the Program pursuant to this section, authorized employees shall register with the Program.

10308.8 A request for registration as an authorized agent shall be accompanied by:

(a) An attestation from the applicant's employer confirming the identity of the applicant and the applicant’s eligibility to receive the reports; and

(b) An attestation from the applicant that the prescription monitoring data will not be further disclosed and will only be used for the purposes stated in the request and in accordance with law.

10308.9 A registration as an authorized agent issued pursuant to this subchapter shall expire on June 30th of each even-numbered year or at any time the agent leaves, or otherwise becomes ineligible to receive information from the Program. The employer shall notify the Program, in writing, within twenty-four (24) hours when an agent leaves his or her current employment or otherwise becomes ineligible to receive information from the Program.

10308.10 The Director may disclose information for bona fide research or education purposes to qualified personnel in response to requests determined by the Program to be consistent with institutional review board protocols and human subjects research protections, provided that:

(a) Data elements that would reasonably identify a specific patient, prescriber, or dispenser shall be deleted or redacted from the prescription monitoring data prior to disclosure;

(b) The request is made in a format designated by the Program and is signed by the Chief Researcher or Principal educator. The request shall be accompanied by the requestor's credentials, and a written proposal or abstract explaining the purpose and scope of the research, analysis, education, or study plan with sufficient detail to enable the Program to determine the validity of the request and abilities of the requestor; and

(c) The release of information to the requestor shall only be made pursuant to a signed agreement between the qualified personnel of the requestor and the Director to ensure compliance with the Act.

10308.11 With the exception of personal dispensing information provided to a patient or the parents or legal guardian of a patient, all requests for disclosure of prescription monitoring data shall by accompanied by an attestation that the prescription data will not be further disclosed and shall only be used for the purposes stated in the request and in accordance with the law.

10309 INTEROPERABILITY WITH OTHER STATE PRESCRIPTION DRUG MONITORING PROGRAMS

10309.1 Upon request, the Program may disclose prescription monitoring data to another state's prescription drug monitoring program provided that the request:

(a) Is submitted on a form or in a manner approved by the Program;

(b) Is under the authority of the authorized administrator of that state's program; and

(c) Assures that prescription monitoring data will only be used or redisclosed in accordance with District law.

10309.2 The Program may develop and implement interoperability to facilitate the automated exchange of prescription monitoring data provided that a written agreement has been established with the other state's program, or third party, and provided that the information technology employed will:

(a) Only disclose prescription monitoring data in a manner consistent with District laws and regulations; and

(b) Operate in accordance with State and federal laws and regulations governing the security and confidentiality of protected health information and personal medical records.

10310 NOTICE OF REQUESTS FOR INFORMATION

10310.1 Any prescriber or dispenser who intends to request information from the Program about a patient or prospective patient shall provide notice to the patient that a request may be made to obtain information on all covered substances dispensed to that patient. The notice may be provided by use of a conspicuous sign in an area that will be easily viewed and read by the patient.

10310.2 In lieu of posting a sign, the prescriber or dispenser may provide notice in written material provided to the patient, or may obtain written consent from the patient.

10311 CONFIDENTIALITY

10311.1 All prescription monitoring data collected, maintained, or submitted pursuant to this Program is confidential, privileged, not subject to discovery, subpoena, or other means of legal compulsion in civil litigation, and is not a public record.

10311.2 The Program shall ensure that confidential or privileged patient information is kept confidential and that records or information protected by a privilege between a health care provider and a patient, or otherwise required by law to be held confidential, is filed in a manner that, except as otherwise provided by law or regulation, does not disclose the identity of the person protected.

10311.3 The Program shall periodically conduct an audit review of prescription monitoring data and disclosure requests to ensure compliance with this chapter and the Act.

10312 REQUESTS TO PROGRAM TO CORRECT PRESCRIPTION MONITORING DATA

10312.1 If a patient, a patient's authorized representative, or a prescriber believes that prescription monitoring data relating to the patient's or prescriber’s prescription history is incorrect, the patient, authorized representative, or prescriber may notify the dispenser and request correction.

10312.2 Upon receiving notice from a patient, a patient’s authorized representative, or prescriber that prescription monitoring data specific to a patient's prescription history or a prescriber’s prescribing history is incorrect, the dispenser shall:

(a) Correct the information, if appropriate, within seventy-two (72) hours, including reversing information for any prescription that was not dispensed, if applicable; and

(b) Provide a corrected prescription history report to the patient or the patient's authorized representative, if requested to do so.

10313-10315 [RESERVED]

10316 THE PDMP ADVISORY COMMITTEE

10316.1 The PDMP Advisory Committee ("Committee") shall consist of seven (7) members, three (3) of which shall be *ex officio* members. The Director of the Department of Health ("Director") shall appoint the remaining four (4) members, who may be from the public or private sectors, who may serve without residency restrictions, and who shall represent multiple disciplines and stakeholders in the area of prescription drug abuse. Membership of the Committee shall be as follows:

(a) The Director, or his or her subordinate designee, who shall serve as chairperson;

(b) The Executive Director for the Board of Medicine or his or her subordinate designee;

(c) The Executive Director for the Board of Pharmacy or his or her subordinate designee; and

(d) Four (4) members who shall represent multiple disciplines and stakeholders in the area of prescription drug abuse, and include representation from the medical and pharmacy practices, the Metropolitan Police Department, and a consumer member.

10316.2 All actions of the Committee shall be taken pursuant to a vote of a majority of the members of the Committee. A majority of the appointed members shall constitute a quorum.

10316.3 The chairperson shall only vote in cases of a tie among Committee members.

10316.4 Each appointed member of the Committee shall serve at the pleasure of the Director. Public members of the Committee shall serve a maximum term of nine (9) years from the date of appointment.

10316.5 Members of the Committee shall not be compensated for time expended in performing Committee duties.

10316.6 The Committee shall convene at least two (2) times per year to advise the Director:

(a) On the implementation and evaluation of the Program;

(b) On the establishment of criteria for indicators of possible misuse or abuse of covered substances;

(c) On standardization of the methodology that should be used for analysis and interpretation of prescription monitoring data;

(d) In determining the most efficient and effective manner in which to disclose the findings to proactively inform prescribers regarding the indications of possible abuse or misuse of covered substances;

(e) On identifying drugs of concern that demonstrate a potential for abuse and that should be monitored; and

(f) Regarding the design and implementation of educational courses for:

(1) Persons who are authorized to access the prescription monitoring information;

(2) Persons who are authorized to access the prescription monitoring information, but who have violated the laws or breached professional standards involving the prescribing, dispensing, or use of any controlled substances or drugs monitored by the Program;

(3) Prescribers on prescribing practices, pharmacology, and identifying, treating, and referring patients addicted to or abusing controlled substances or drugs monitored by the Program; and

(4) The public about the use, diversion and abuse of, addiction to, and treatment for the addiction to controlled substances or drugs monitored by the Program.

10316.7 The Committee shall keep minutes of all its meetings.

10316.8 Pursuant to Section 2(b) of the Open Meetings Act, effective March 31, 2011 (D.C. Law 18-350; D.C. Official Code § 2-575(b)), and for the purposes set forth therein, the Committee may also meet in closed session.

10399 DEFINITIONS:

10399.1 The following terms shall have the meanings ascribed:

Act – the Prescription Drug Monitoring Program Act of 2013, effective February 22, 2014 (D.C. Law 20-66; D.C. Official Code §§ 48-853.01 *et seq.*).

Administer – the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner (or, in the practitioner's presence, by the practitioner's authorized agent); or

(b) The patient or research subject at the direction of and in the presence of the practitioner.

Controlled substance – a drug, substance, or immediate precursor, as set forth in Schedules I through V of Subchapter 2 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981(D.C. Law 4-29; D.C. Official Code §§ 48-901 *et seq*.)

Covered substance – all controlled substances included in Schedules II, III, IV, and V as set forth in Subchapter 2 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code §§ 48-901 *et seq*.), Schedules II through V of the Federal Controlled Substances Act (21 U.S.C. § 812), and any other drug as specified by rulemaking, that is required to be reported to the Program pursuant to the Act.

DEA – the United States Drug Enforcement Administration.

Department – the District of Columbia Department of Health.

Director – the Director of the District of Columbia Department of Health.

Dispense – to distribute a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

Dispenser – a practitioner who dispenses a covered substance to the ultimate user, or his or her agent, but shall not include:

(a) A licensed hospital or institutional facility pharmacy that distributes covered substances for the purpose of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility;

(b) A practitioner or other authorized person who administers a covered substance;

(c) A wholesale distributor of a covered substance; or

(d) A clinical researcher providing a covered substance to research subjects as part of a research study approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protections programs.

District – the District of Columbia.

Drug –

(a) Any substance recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium or other official drug compendium or any supplement to any of them;

(b) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;

(c) Any chemical substance, other than food, intended to affect the structure or any function of the body of man or other animal; and

(d) Any substance intended for use as a component of any items specified in subparagraph (a), (b), or (c) of this paragraph, but does not include medical devices or their components, parts, or accessories.

Drugs of concern – a drug that is not a controlled substance, but which is nevertheless identified by the Director or the PDMP Advisory Committee as a drug with the potential for abuse.

Health occupations board – a board that, pursuant to Section 408 of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1204.08), licenses and regulates health professionals with the authority to prescribe or dispense covered substances.

Interoperability – with respect to a District of Columbia or state prescription drug monitoring program, the ability of that program to share electronically reported prescription information with another state, district, or territory of the United States' prescription drug monitoring program or

a third party, approved by the Director, which operates interstate prescription drug monitoring exchanges.

Patient – the person or animal who is the ultimate user of a controlled substance or other drug required to be submitted under the Act for whom a lawful prescription is issued or for whom a controlled substance or such other drug is lawfully dispensed.

Practitioner –

(a) A physician, dentist, advanced practice registered nurse, veterinarian, scientific investigator, or other person who is licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in the District of Columbia; or

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of its professional practice or research in the District of Columbia.

Prescriber – a practitioner or other authorized person who prescribes a controlled substance or other covered substance in the course of his or her professional practice.

Prescription drug monitoring program – a program that collects, manages, analyzes, and provides information regarding covered substances or other drugs required under the Act or a program established by a similar act in another state, district or territory of the United States.

PDMP Advisory Committee – the multi-discipline committee established pursuant to Section 3 of the Act, which functions under the Department to advise the Director on the implementation and evaluation of the District's prescription drug monitoring program.

PDMP Instruction Manual – the manual maintained by the Director that provides detailed instructions for registering with, reporting to, and requesting information from the Program.

Program or PDMP – the prescription drug monitoring program established by the Act.

Reporting period – the twenty-four (24) hour time period immediately following the dispensing of a covered substance.

Stakeholder – a person, group, or organization that could be affected by the Program's actions, objectives, and policies.

Ultimate user – a person who lawfully possesses a controlled substance for that person's own use or for the use of a member of that person's household or for administering to an animal owned by him or her or by a member of that person's household.

Zero report – an electronic data submission reflecting no dispensing activity for a given period.