DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health ("Department"), pursuant to the Prescription Drug Monitoring Program Act of 2013, effective February 22, 2014 (D.C. Law 20-66; 61 DCR 7, published January 3, 2014; D.C. Official Code § 48-853.01)(the Act), Mayor's Order _____, dated _____, hereby gives notice of his intent to take final rulemaking action to adopt the following new chapter 103 (Prescription Drug Monitoring Program) of Title 17 (Business, Occupations and Professions) of the District of Columbia Municipal Regulations (DCMR), entitled "Prescription Drug Monitoring Program," in not less than thirty (30) days from the date of publication of this notice in the D.C. Register. The adoption of Chapter 103, which had until now been reserved, is necessary to implement the Act, which will help improve the District's ability to identify and reduce the diversion of prescription drugs, and enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in health care.

Chapter 103 (Prescription Drug Monitoring Program) of Title 17 (Business Occupations and Professions) is added as follows:

CHAPTER 103 PRESCRIPTION DRUG MONITORING PROGRAM

Secs.

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10300 GENERAL PROVISIONS

10300.1 The Prescription Drug Monitoring Program (Program) shall make available the information technology necessary for dispensers to report the prescription monitoring data set forth in § 10301.3 of this chapter 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 3 years from the date of receipt.

10301 PRESCRIPTION MONITORING DATA REPORTING REQUIREMENTS

10301.1 Beginning _____, 2016, each dispenser of a covered substance shall submit the prescription monitoring data required in § 10301.3 of this chapter, in the form and manner provided by the Director, to the Program within 24 hours after the 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 Any dispenser located outside the physical boundaries of the District, but that is licensed or registered by the District, shall submit the prescription monitoring data set forth in § 10301.3, in the form and manner required by the Director, to the Program within 24 hours after the covered substance is dispensed for each covered substance dispensed to an ultimate user who resides within the District.

10301.3 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 date of birth;
(d) Patient gender;
(e) Dispenser DEA number or other mutually acceptable identification number;
(f) Dispenser name;
(g) Dispenser address;
(h) Dispenser telephone number;
(i) Prescriber DEA number or other mutually acceptable identification number;

(j) Prescriber's full name
(k) Date prescription was issued by prescriber;
(l) Date prescription was dispensed;
(m) Prescription number;
(n) Prescription type is new or is a refill;
(o) Number of refill being dispensed if applicable
(p) NDC code for the drug dispensed;
(q) Quantity dispensed;
(r) Days' supply dispensed;
(s) Number of refills ordered;
(t) Source of payment for the prescription; and
(u) Any elements required as a condition of eligibility for a federal grant as outlined in the PDMP Instruction Manual.

10301.4 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;

(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 by the Department.

10301.5 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 § 3-1205.14(c); and

(c) The imposition of civil fines pursuant to § 2-1801.04.

10301.6 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 The covered substances required to be reported to the Prescription Drug Monitoring Program shall include both the statutory requirement of all Schedule II through V controlled substances, as defined, and the drugs of concern set forth in § 10302.2 of this chapter.

10302.2 Pursuant to Section 2 of the Act, the dispensing of any of the following drugs of concern shall be reported to the Prescription Drug Monitoring Program:

(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 shall be transmitted electronically to the Program or its agent:

(a) Within 24 hours of dispensing;

(b) In the format provided in the Electronic Reporting Standard for Prescription Monitoring Programs, no earlier than Version 4.2 (November 2011) of the American Society of Automation in Pharmacy (ASAP); and

(c) Shall be consecutive and inclusive of any dispensing of covered substances from the last date and time reporting information was submitted.

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

10303.3 The required prescription monitoring data 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 30 days after receiving notice from the Program.

10303.4 Under extraordinary circumstances, an alternative means of reporting may be approved by the Program based upon a written request for an exception.

10303.5 Prescription monitoring data that is not accepted by the vendor due to a substantial number of errors or omissions shall be corrected and resubmitted to the Program by the dispenser within 24 hours after the dispenser receives notice that the submitted data had an unacceptable number of errors or problems.

10303.6 In the event that 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, by a communications method approved by the Program, within 24 hours of discovery of the technical failure;

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

(c) Submit a report for each covered substance dispensed during the period of technical failure as soon as possible, but no later than 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 reporting period, shall submit a report documenting that zero covered substances were dispensed during that 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 such 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 24 hours as required.

10304.3 Dispensers that only dispense covered substances in circumstances not required to be reported, as set forth in § 10304 of this chapter, 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 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.

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 A prescriber, dispenser, or delegate, shall register with the Program or its vendor, in a manner specified by the Program, in order to access or otherwise request disclosure of prescription monitoring data.

10306.2 Prescribers, dispensers, delegates who have successfully registered with the Program or its vendor, may directly access or otherwise request information on a specific patient or prospective 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 monitored prescription drug for use by the patient about whom prescription monitoring data is being requested.

10306.3 Upon request from a prescriber or dispenser, the Director may provide a report containing prescription monitoring data on all monitored prescription drugs dispensed pursuant to the prescriber's 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 or its vendor 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 directly access or otherwise request disclosure of prescription monitoring data electronically.

10306.6 If the authorization issued to a registrant is compromised, the registrant shall notify the Program or its agent, by a method approved by 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 facility and under the direct supervision of the prescriber or dispenser.

10306.8 A separate form shall be submitted for each delegate, and shall include the individual's license, registration, or certification number, and a copy of another form of government issued identification.

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

10306.10 A delegate registration issued pursuant to this subchapter shall expire on June 30 of each even-numbered year, or at any such time as the agent leaves or alters his or her current employment, or if the delegating prescriber or dispenser removes the authorization, or 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 such 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 every reasonable effort, 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 or its agent, by a method approved by 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) Immediately notify the Program or its agent, by a method approved by the Program, 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 access or 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 only used for the purposes stated in the request and in accordance with the law.

10307.3 A registration as an authorized agent issued pursuant to this subchapter shall expire on June 30th of each even-numbered year or at any such time as the agent leaves or alters his or her current employment or otherwise becomes ineligible to receive information from the Program.

10307.4 An authorized agent shall only access or request disclosure of information related to a specific investigation as authorized. Queries or 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 which the report is to be made; and

(d) Bears 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 or of a specific 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 specific 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 to certain persons, provided the request is made in the format designated by the Program in the PDMP Instruction Manual and meets the requirements of this subchapter.

10308.2 The Director may disclose personal dispensing information concerning a patient who is over the age of 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 18 and includes a notarized signature of the requesting party. If the patient is under the age of 18, the information may be disclosed to the parent or legal guardian of the patient, provided such 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 to 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 relating to a specific patient who is currently eligible for and receiving, or who has been eligible for and has received medical assistance services;

(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 which 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 be signed by the Chief Medical Examiner.

10308.7 In order to request prescription monitoring data from the Program pursuant to this section, authorized employees shall register with the Program, as applicable.

10308.7 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 shall only be used for the purposes stated in the request and in accordance with law.

10308.8 A registration as an authorized agent issued pursuant to this subchapter shall expire on June 30th of each even-numbered year or at any such time as the agent leaves or alters his current employment or otherwise becomes ineligible to receive information from the program. The employer shall notify the Program within twenty-hour (24) hours when an agent leaves or alters his current employment or otherwise becomes ineligible to receive information from the program.

10308.9 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, and is accompanied by the requestor's credentials, 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.

10308.10 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 the 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 such patient that such a request may be made to obtain information on all covered substances dispensed

to that patient. Such 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 such 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, maintain, 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 be 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, be filed in a manner that, except as otherwise provided bylaw or the regulations, 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 patient's prescriber believes that prescription monitoring data relating to the patient's prescription history is incorrect, the patient, authorized representative, or prescriber may request that the Program correct the data provided that the request:

(a) Is submitted to the Program in writing and on a form or in a manner approved by the Department; and

(b) Includes documentation, which may include but not be limited to, a copy of the original prescription and a signed, notarized statement from the prescriber or dispenser that demonstrates which of the specific data elements reported to the Program are incorrect.

10312.2 Upon receiving notice from the Program that prescription monitoring data specific to a patient's prescription history is incorrect, the dispenser shall:

(a) Correct the information, including reversing information for any prescription that was not dispensed, if applicable, and

(b) Issue a corrected prescription history report to the patient or the patient's authorized representative.

10313-10315 RESERVED

10316 THE PDMP ADVISORY COMMITTEE

10316.1 The PDMP Advisory Committee ("Committee") shall consist of at least seven (7) members. The Director shall appoint the members and the chairperson of the Committee. The composition of the Committee shall include: ex officio, the Program Director of the Prescription Drug Monitoring Program, the Executive Director for the Board of Medicine, and the Executive Director for the Board of Pharmacy, or their subordinate designees. The other four (4) members shall represent multiple disciplines and stakeholders in the area of prescription drug abuse, and include representation from the medical and pharmacy practices and a consumer member. The Director may select the members from the public or private sector without residency restrictions.

10316.2 The Director of the Department of Health ("Director"), or his or her subordinate designee, shall act as the chair of the Committee.

10316.3 All actions of the Committee shall be taken pursuant to a vote of a majority of the members of the Committee. For purposes of determining the existence of a quorum, a quorum shall be deemed to mean a majority of the appointed members.

10316.4 The chairperson shall only vote in cases of a tie among Committee members.

10316.5 Each member of the Committee shall serve at the pleasure of the Mayor or of the Director. Public members of the Committee shall serve a maximum term of nine (9) years from the date of appointment.

10316.6 Members of the Committee shall not be compensated for time expended in the performance of his or her Committee duties.

10316.7 The Committee shall convene at least two (2) times per year to assist the Director:

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

(b) To establish the criteria for indicators of possible misuse of covered substances;

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

(c) To determine 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;

(d) To identify drugs of concerns that demonstrate a potential for abuse and that should be monitored; and

(e) With 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 prescription monitoring program;

(3) Prescribers on prescribing practices, pharmacology, and the identification, treatment, and referral of a patient addicted to or abusing controlled substances or drugs monitored by the prescription monitoring 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 prescription monitoring program.

10316.8 The Committee shall keep minutes of all its meetings.

10316.9 Pursuant to D.C. Official Code § 2-575(b), and for the purposes set forth therein, the Committee may also meet in closed session.

Section 10399.1 is added as follows:

The following terms with the ascribed meanings are added as follows:

Act- the Prescription Drug Monitoring Program Act of 2013, effective February 22, 2014 (D.C. Law 20-66; 61 DCR 7, published January 3, 2014; D.C. Official Code § 48-853.01.

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 (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 defined in Subchapter 2 of the District of Columbia Uniform Controlled Substances Act (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 are required to be reported to the Prescription Drug Monitoring 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 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, that 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 to be submitted 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, that functions under the Department to assist in the implementation and evaluation of the District's prescription drug monitoring program.

PDMP Instruction Manual - the manual maintained by the Director publicly available on the website 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- is the Twenty-four 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.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the *D.C. Register*, to Phillip Husband, General Counsel, Department of Health, Office of the General Counsel, 899 North Capitol Street, N.E., 5th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 8:00 a.m. and 4:00 p.m. at the address listed above, or by contacting Angli Black, Administrative Assistant, at Angli.Black@dc.gov, (202) 442-5977.