COUNCIL OF THE DISTRICT OF COLUMBIA
COMMITTEE ON HEALTH
COMMITTEE REPORT
1350 Pennsylvania Avenue, NW, 20004

TO: All Councilmembers

FROM: Councilmember Yvette M. Alexander, Chairperson, Committee on Health

DATE: September 26, 2013

SUBJECT: Report on Bill 20-127 the "Prescription Drug Monitoring Program Act of 2013"

The Committee on Health, to which Bill 20-127 was referred, reports favorably thereon and recommends approval by the Council.

CONTENTS

I. Background and Need 1
II. Legislative Chronology 4
III. Position of the Executive 4
IV. Comments of Advisory Neighborhood Commissions 5
V. List of Witnesses 5
VI. Impact on Existing Law 5
VII. Fiscal Impact 5
VIII. Section-by-Section Analysis 5
IX. Committee Action 8
X. Attachments 8

I. BACKGROUND & NEED

The stated purpose of Bill 20-127 it 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.

A Prescription Drug Monitoring Program (PDMP) is an electronic database which collects specific data and monitors the dispensing of covered substances in the District of Columbia. Bill 20-127 applies to Schedule II, III, IV and V controlled substances, as defined in §§48-902.06 – 48-902.12 of the D.C. Uniform Controlled Substances Act. This bill requires

each dispenser of a covered substance to report, within twenty-four hours, specific information on the prescription, as required by the Department of Health ("DOH" or "Department"). A 'dispenser' is a practitioner who dispenses a covered substance to the ultimate user or his or her agent. This bill would also apply to dispensers located outside of the District, but who are licensed or registered by the city. A dispenser does not include (1) a licensed hospital or institutional facility that distributes for the purpose of inpatient care, (2) a practitioner or other authorized person who administers such a substance, (3) a wholesale distributor or (4) a clinical researcher who provides covered substances to research subjects as part of a research study.

This bill also authorizes the Director to enter into written agreements with other PDMP programs for the purpose of interoperability and the mutual exchange of information among PDMPs, and also requires DOH to establish a multi-vendor advisory committee, which will assist the Department in implementation and evaluation of the PDMP. Within the Department of Health, the Pharmaceutical Control Division is delegated the authority to register controlled substances and registrations. The Pharmaceutical Control Division currently licenses every facility or person who manufactures, distributes, dispenses, or conducts research with any controlled substance in the District of Columbia.

Prescription drug abuse has become a nationwide problem. The Centers for Disease Control and Prevention have classified prescription drug abuse as an epidemic. The National Survey on Drug Use and Health (NSDUH) show that nearly one-third of people aged 12 and over who used drugs for the first time began by using a prescription drug non-medically.[1] Individuals tend to erroneously believe that if drugs are prescribed by health professionals, they are safer than illegal drugs or "street drugs". While these drugs are necessary for individuals who are in a great amount of pain, and are manufactured under guidelines needed for human consumption, they have the potential to cause great harm, and even death, to individuals who misuse them. Unfortunately, some of these drugs are highly addictive, increasing potential misuse for those who are able to obtain them. This leads to several different issues, one of which includes "doctor shopping". Typical doctor shopping involves an individual going to several different doctors, and consequently, several different pharmacies, to obtain access to many drugs at once. Without a way to communicate to one another, doctors and pharmacies are left in the dark as to what kind of prescriptions a patient has recently received as well as the frequency in which they have been receiving them. This lack of communication amongst the health professionals' network makes it easy for individuals to obtain and abuse prescription drugs.

[1] http://www.whitehouse.gov/ondcp/prescription-drug-abuse

This bill applies to Schedule II, III, IV and V controlled substances. Some examples of these drugs are as follows:

SCHEDULE	EXAMPLES
Schedule II	Morphine; hydrocodone; oxycodone
Schedule III	Anabolic steroids; Tylenol with codeine
Schedule IV	Xanax; Valium
Schedule V	Robitussion AC; Lyrica[2]

District of Columbia doctors and pharmacists have limited resources when it comes to tracking the use of controlled substances on a citywide scale, and frequently rely on each other to prevent diversion. When a pharmacist suspects that a patient may be abusing drugs, they have several options: they can contact the medical office to verify the prescription, contact the individual's insurance to attempt to identify past medical history, or call nearby pharmacies to determine if an individual has exhibited any signs of drug diversion behavior at that location. Ultimately, the pharmacist has the power to deny a request to fill a prescription, but the current options leave too much room for error. Bill 20-127 fills in these holes by creating effortless communication between providers. By allowing dispensers of covered controlled substances access to the PDMP database, dispensers will have all of the resources necessary to feel confidant when dispensing a potentially dangerous controlled substance.

A hearing on Bill 20-127 took place on July 12, 2013. Several witnesses testified at the hearing or submitted testimony to become a part of the written record. One issue was the inclusion of Schedule V controlled substances in the PDMP reporting requirements. Witnesses with this issue explained that many Schedule V substances contain limited quantities or no narcotics, and have a low potential for abuse, and that including them in the mandatory reporting requirements will have a bias effect on a doctor's decision to prescribe these medications, despite the fact that the prescribing doctor is not required to check the PDMP database prior to prescribing a substance. Typically, it will be the pharmacist, and not the physician, who will be required to check and report to the PDMP database. Only eighteen of the forty-nine states with PDMP programs have exempted Schedule V drugs from reporting requirements.

Additionally, the American Insurance Association explained their desire to require a database inquiry by every prescriber in every instance. While the bill does give prescribers access to the PDMP database, it does not require them to do so. Several witnesses expressed their concerns for requiring prescribers to be forced to check the database prior to prescribing. They

[2] http://www.justice.gov/dea/druginfo/ds.shtml

feared that it would result in doctors being overly hesitant to give prescriptions to medicines that have legitimate pain relieving benefits.

II. LEGISLATIVE CHRONOLOGY

February 7, 2013	Bill 20-127, the "Prescription Drug Monitoring Act of 2013" is introduced by Chairman Phil Mendelson at the request of the Mayor.
February 19, 2013	Bill 20-127 is referred to the Committee on Health.
February 15, 2013	Notice of Intent to Act on Bill 20-127 is published in the *D.C. Register*.
June 14, 2013	Notice of Public Hearing is published in the *D.C. Register*.
July 12, 2013	The Committee on Health held a Public Hearing on Bill 20-127.
September 24, 2013	The Committee on Health meets to mark-up and vote on the report and committee print of Bill 20-127.

III. POSITION OF THE EXECUTIVE

Dr. Saul Levin, Interim Director for the Department of Health, was the Executive Witness. Dr. Levin supported this bill and saw it as a positive initiative to protect patient safety with regard to prescription drug abuse among residents of the District of Columbia. He explained that the non-medical use of prescription drugs is a widespread and serious problem and that PDMPs ability to collect and review prescription data from pharmacies would greatly assist the District in combating drug diversion.

Dr. Levin also noted that of the forty-six states with operational prescription drug monitoring programs, thirty-one include the authority to monitor Schedule V substances. He explained that according to the Prescription Drug Monitoring Program Center for Excellence, the established best practice guideline is to collect data from Schedules II through V, as drugs in all schedules have abuse potential. He emphasized that the Department feels strongly that all schedules of controlled substances should be included in data collection. Dr. Levin also noted that excluding Schedule V drugs could result in the loss of federal grant money, as Schedule II through V substances are considered the minimum required standards. He concluded that a stakeholder meeting was convened between the Department of Health, the DC Health Professions Boards, the DC Pharmacy Association, the DC Medical Society, the DC Nursing Association, community pharmacies, the Metropolitan Police Department, DC Health Care Finance, and several other agencies regarding Bill 20-127.

IV. COMMENTS OF ADVISORY NEIGHBORHOOD COMMISSIONS

The Committee received no testimony or comments from Advisory Neighborhood Commissions.

V. LIST OF WITNESSES

Dr. Catherine May	Public Witness
Bonita Pennino	American Cancer Society Cancer Action Network
Eric Goldberg	American Insurance Association
Daphne Bernard, PharmD	Chair, Board of Pharmacy
Janice Orlowski, MD	Chair, Board of Medicine
Saul Levin, MD, MPA	Interim Director, Department of Health

VI. IMPACT ON EXISTING LAW

Bill 20-127 would impact existing law by adding a new section to the D.C. Official Code, which would provide for the existence of the prescription drug monitoring program.

VII. FISCAL IMPACT

The attached September 25, 2013 fiscal impact statement from the Chief Financial Officer states that funds are sufficient in the proposed FY 2014 through FY 2017 budget and financial plan to implement the bill.

VIII. SECTION BY SECTION ANALYSIS

Section 1: States the short title of Bill 20-127.

Section 2: Definitions.

Section 3: Establishes the PDMP program and the Director's regulatory authority.

(a) Explains that the PMDP shall reside with the Department of Health and that it shall

(1) Maintain the electronic system

(2) Provide dispensers with electronic filing sheets
(3) Verify credentials and authorize use of those using the system

(b) The Director of DOH shall issue rules necessary to implement the program
(c) Permits the Director to contract with another District agency or vendor in order to maintain the PDMP
(d) Requires Director to establish an advisory committee to assist with implementation of the PDMP

Section 4: Reporting requirements and exceptions

(a) Requires dispensers to submit information to PDMP with 24-hours of covered substance being dispensed, unless otherwise required
(b) Failure to report or willful failure to submit accurate information shall constitute grounds for revocation, suspension, or denial of DC controlled substances registry
(c) Information required to be reported
(d) Formatting requirements
(e) Exemptions from reporting requirements:
(1) Administering covered substances
(2) Licensed narcotic maintenance programs
(3) Dispensing to inpatients in hospitals or nursing facilities
(4) Inpatients in hospices
(5) As otherwise determined by Department regulations

Section 5: Authority to Access Database

(a) Any authorized prescriber or dispenser can access the PDMP, along with two health care delegates who are licensed and employed at the same facility

Section 6: Confidentiality of data; disclosure of information; discretionary authority of the Director

(a) All data, records, and reports shall be confidential and exempt from disclosure.
(b) Director can only disclose information from PDMP when:
(1) Information is relevant to specific investigation of patient as designated by Chief of Police for drug diversion investigation
(2) Information is relevant to misconduct of licensed health occupations board member or Department
(3) Information relevant to grand jury proceeding that has been properly impaneled
(4) Information relevant to specific investigation conducted by the U.S. Drug Enforcement Administration
(c) In accordance with District and federal law, the Director may release information;

(1) Information of patient over 18, or information to parent of patient under 18;
(2) Information on a specific patient to a prescriber for the purpose of establishing treatment history when that patient is under the care of that prescriber;
(3) Information on a specific patient to a dispenser for the purpose of establishing prescription history to assist the dispenser in determining the validity of a prescription;
(4) Information relevant to an investigation or proceeding of a specific dispenser/prescriber seeking licensure
(5) Information relevant to a dispenser/prescriber participating in the District Medicaid Program, DC Health Care Alliance, or any other public health program
(6) Information relevant to cause of death
(7) Information for the purpose of bona fide research or education

(d) Confidential information shall not be made available for discovery or court subpoena or introduced into evidence in any medical malpractice suit

Section 7: Interoperability; Information exchange with other prescription drug monitoring

(a) Director may enter into written agreements with other PDMPs for the purpose of mutual exchange of information

Section 8: Criteria for indicators of misuse; Director's authority to disclose information; intervention

(a) Director may establish through rulemaking:
(1) Criteria for indicators of misuse
(2) A method for the analysis of data collected by the PDMP to determine misuse

Section 9: Immunity from liability

(a) Director and employees of the Department shall not be liable for civil damages for inaccurate information
(b) In the absence of gross negligence or willful misconduct, prescribers or dispensers shall not be liable for inaccurate information

Section 10: Unlawful disclosure of information and acts; disciplinary action authorized; penalties

(a) It is unlawful for anyone with access to this information to disclose this information, unless otherwise provided for by this Act.
(b) It is unlawful for anyone who receives information in the PMDP to redisclose this information, unless otherwise provided for by this Act.

(c) Nothing in this Act prohibits a prescriber/dispenser from redisclosing information obtain the PDMP to another prescriber/dispenser who covers the same patient.

Section 11: Adopts the Fiscal Impact Statement.

Section 12: States the Act will take effect following Mayoral approval and Congressional review.

IX. COMMITTEE ACTION

On Thursday, September 26, 2013, the Committee on Health met to consider Bill 20-127, the "Prescription Drug Monitoring Act of 2013". The meeting was called to order at 2:20 p.m., and Bill 20-127 was the only item on the agenda. After ascertaining a quorum, Councilmember Alexander opened up the floor for discussion. Councilmember Grosso thanked the committee for moving on this bill, which would align it with a majority of states in the country. He continued by explaining that one day he would like to see doctors be able to query the database for their names, as a way for them to determine whether their prescription pads had ever been stolen, which would be another way for them to prevent drug diversion. Councilmember Grosso concluded by saying that he liked that doctors were able to check the database prior to giving out prescriptions, but didn't think they should be required to do so. Chairperson Alexander moved the print and report separately, with leave for staff to make technical and editorial changes. The vote on the print and report was unanimous (Chairperson Alexander and Councilmembers Bonds, Grosso, Orange voting "aye." Councilmember Catania was absent). The meeting adjourned at 2:25 p.m.

X. ATTACHMENTS

1. Bill 20-127 as introduced.
2. Copies of Written Testimony.
3. Fiscal Impact Statement.
4. Legal Sufficiency Memorandum.
5. Committee Print of Bill 20-127.

COUNCIL OF THE DISTRICT OF COLUMBIA
1350 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Memorandum

To: Members of the Council

From: Nyasha Smith, Secretary to the Council

Date: February 12, 2013

Subject: Referral of Proposed Legislation

Notice is given that the attached proposed legislation was introduced in the Office of the Secretary on Thursday, February 07, 2013. Copies are available in Room 10, the Legislative Services Division.

TITLE: "Prescription Drug Monitoring Program Act of 2013", B20-0127

INTRODUCED BY: Chairman Mendelson at the request of the Mayor

The Chairman is referring this legislation to the Committee on Health.

Attachment

cc: General Counsel
Budget Director
Legislative Services

VINCENT C. GRAY
MAYOR

FEB 7 2013

The Honorable Phil Mendelson
Chairman, Council of the District of Columbia
1350 Pennsylvania Avenue, N.W., Suite 504
Washington, D.C. 20004

Dear Chairman Mendelson:

Enclosed for consideration and enactment by the Council, is the "Prescription Drug Monitoring Program Act of 2013."

If enacted, the "Prescription Drug Monitoring Program Act of 2013" will 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 will enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in healthcare, including palliative care, research and other medical and pharmacological uses.

This legislation will bring the District of Columbia in line with the vast majority of the country. At present, only the District of Columbia, Missouri, and New Hampshire have not passed legislation to enact a prescription drug monitoring program. Having a prescription drug monitoring program will allow the District to promote the appropriate use of controlled substances for legitimate medical purposes while deterring the misuse, abuse, and diversion of controlled substances.

I urge the Council to take prompt and favorable action on the enclosed legislation.

Sincerely,

Vincent C. Gray

Vincent C. Gray

Chairman Phil Mendelson
at the request of the Mayor

A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

Chairman Phil Mendelson, at the request of the Mayor, introduced the following bill, which was referred to the Committee on _____.

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.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, that this act may be cited as the "Prescription Drug Monitoring Program Act of 2012".

Sec. 2. Definitions.

For the purposes of this act, the term:

(1) "Administer" means 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.

ATTACHMENT ONE

(2) "Controlled substance" means 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.*).

(3) "Covered substance" means 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.), 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 this chapter.

(4) "Department" means the District of Columbia Department of Health.

(5) "Director" means the Director of the District of Columbia Department of Health.

(6) "Dispense" means 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.

(7) "Dispenser" means a practitioner who dispenses a covered substance to the ultimate user, or his or her agent, but does not include:

(A) A licensed hospital or institutional facility pharmacy that distributes such 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 such a substance;

(C) A wholesale distributor of a Schedule II, III, IV and/or V controlled substance or other covered substance; or

(D) A clinical researcher providing a Schedule II, III, IV and/or V controlled substance or other 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.

(8) "District" means the District of Columbia.

(9) "Drug" means:

"(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.

(10) "Health occupations board" means a board that, 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), licenses and

regulates health professionals with the authority to prescribe or dispense covered substances.

(11) "Interoperability" means, 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.

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

(13) "Practitioner" means:

(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.

(14) "Prescriber" means a practitioner or other authorized person who prescribes a controlled substance or other covered substance in the course of his or her professional practice.

(15) "Prescription drug monitoring program" means a program that collects, manages, analyzes, and provides information regarding Schedule II, III, IV and V controlled substances or other drug required to be submitted under this Act or program established by a similar act in another state, district or territory of the United States.

(16) "Ultimate user" means a person who lawfully possesses a drug 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.

Sec. 3. Program establishment; Director's regulatory authority.

(a) There is established a Prescription Drug Monitoring Program ("Program") within the Department of Health. The Program shall:

(1) Establish, maintain, and administer an electronic system to monitor the dispensing of covered substances;

(2) Provide dispensers with a basic file layout to enable electronic transmission of the information required under the Act; and

(3) Establish and maintain a process for verifying the credentials and authorizing the use of prescription information by those individuals and agencies listed in subsections (b) and (c) of section 6 of the Act.

(b) The Director, in accordance with subchapter 1 of Chapter 5 of Title 2 shall issue rules, including the establishment of criteria for granting waivers to the reporting

requirements set forth in this Act, as are necessary to implement the Prescription Drug Monitoring Program.

(c) The Director may contract with another District agency or a private vender as may be necessary for the implementation and maintenance of the Prescription Drug Monitoring Program. Any such contractor shall be bound to comply with the provisions regarding confidentiality of data in this Act and shall be subject to the penalties specified in this Act.

(d) The Director shall also establish a multi-discipline advisory committee, which shall function under the Department to assist in the implementation and evaluation of the Prescription Drug Monitoring Program.

Sec. 4. Reporting requirements; exceptions.

(a) Each dispenser shall submit to the Program the required reporting information for each prescription dispensed for a covered substance within twenty-four (24) hours after the covered substance is dispensed, unless otherwise established by the Director through rulemaking, but this does not include merely placing the covered substance prescription into a bin for pickup by the ultimate user or his or her agent. Any dispenser located outside the boundaries of the District of Columbia, that is licensed or registered by the District of Columbia, shall submit the required reporting information to the Program for each prescription dispensed for a covered substance to an ultimate user who resides within the District of Columbia within twenty-four (24) hours after the date that the covered substance is dispensed, unless otherwise established by the Director through rulemaking.

(b) The failure of any person subject to the reporting requirements of this Act to report the dispensing of a covered substance, unless otherwise exempted under this Act, or the willful failure to transmit accurate information shall constitute grounds for the revocation, suspension, or denial of a District of Columbia controlled substances registration; 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 the imposition of civil fines pursuant to section 104 of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985 (D.C. Law 6-42, D.C. Official Code § 2-1801.01 *et seq.*).

(c) Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information to the Program:

(1) Patient name;

(2) Patient address;

(3) Patient date of birth;

(4) Patient gender;

(5) Dispenser identification number;

(6) Prescriber identification number;

(7) Date prescription was issued by prescriber;

(8) Date prescription was dispensed;

(9) Prescription number;

(10) Prescription type, whether the prescription is new or is a refill;

(11) NDC code for the drug dispensed;

(12) Quantity dispensed;

(13) Number of days' supply dispensed;

(14) Number of refills ordered;

(15) Source of payment for the prescription; and

(16) Any other required information as specified in the regulations promulgated by the Director to implement this Act, or as required in order for the Prescription Drug Monitoring Program to be eligible to receive federal funds.

(d) Each dispenser shall transmit the required reporting information in accordance with the manner, format, standards, and schedules established by the Director through rulemaking.

(e) The reporting requirements of this Act shall not apply to the dispensing of covered substances when the dispensing is limited to the following:

(1) Administering covered substances;

(2) Dispensing covered substances within an appropriately licensed narcotic maintenance program;

(3) 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;

(4) Dispensing covered substances to inpatients in hospices licensed by the Department; or

(5) Dispensing covered substances as otherwise provided in the Department's regulations.

Sec. 5. Authority to Access Database.

(a) Any prescriber or dispenser authorized to access the information in the possession of the Program pursuant to this Act may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to up to two health care professionals who are:

(1) Licensed, registered, or certified by a health occupations regulatory board under the Department; and

(2) Employed at the same facility and under the direct supervision of the Prescriber or dispenser.

Sec. 6. Confidentiality of data; disclosure of information; discretionary authority of the Director.

(a) All data, records, and reports relating to the prescribing and dispensing of covered substances to patients and any abstracts from such data, records, and reports that are in the possession of the Prescription Drug Monitoring Program pursuant to this Act and any materials relating to the operation or safety of the program shall be confidential and shall be exempt from disclosure based on requests made pursuant to District of Columbia Freedom of Information Act (D.C. Official Code § 2-531 *et seq.*). Information obtained pursuant to the Prescription Drug Monitoring Program may only be disclosed as provided in this Act.

(b) Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable District and federal laws and regulations, the Director shall disclose the following:

(1) Information relevant to 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;

(2) Information relevant to 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; information relevant to 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;

(3) Information relevant to the proceedings of any grand jury or additional grand jury that has been properly impaneled in accordance with D.C. Official Code § 11-1916; and

(4) Information relevant to 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.

(c) In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his or her discretion, disclose:

(1) Information in the possession of the Program concerning a patient who is over the age of 18 to that patient, or to the parent or legal guardian of a child aged 18 years or under, unless otherwise prohibited by District or federal law;

(2) Information on a specific patient to a prescriber, as defined in this Act, for the purpose of establishing the treatment history of the specific patient when such patient is either under care and treatment by the prescriber or the prescriber is initiating

treatment of such patient. The request shall be made and the information shall be provided in the manner specified by the Director through rulemaking, and notice shall be given to patients that such information may be requested by a prescriber from the Prescription Drug Monitoring Program.

(3) Information on a specific patient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription when the patient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. The request shall be made and the information shall be provided in the manner specified by the Director through rulemaking, and notice shall be given to patients that such information may be requested by a dispenser from the Prescription Drug Monitoring Program.

(4) 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 such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority;

(5) 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; or 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 to the Medicaid Fraud Control Unit of the Office of the Inspector General, or to designated employees of the Department of Health Care Finance, as appropriate;

(6) 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; and

(7) Information for the purpose of bona fide research or education to qualified personnel, however:

(A) Data elements that would reasonably identify a specific patient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure; and

(B) Release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this Act.

(d) Confidential information that has been received, maintained, or developed by any health occupations board or disclosed by the health occupations board pursuant to this Act shall not be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this section shall not be construed to inhibit any investigation or prosecution conducted pursuant to this Act.

Sec. 7. Interoperability; Information exchange with other prescription drug monitoring programs.

(a) The Director is authorized to enter into written agreements with other prescription drug monitoring programs, or a third party, approved by the Director, that operates an interstate prescription drug monitoring exchange, for the purpose of interoperability and the mutual exchange of information among prescription drug

monitoring programs, and describing the terms and conditions for the sharing of prescription information under this section.

(b) The Director may provide prescription monitoring information pursuant to such agreements, which shall only use the information for the purposes allowed by this Act.

(c) The Director may request and receive prescription drug monitoring information from other states' prescription drug monitoring programs and may use such information under the provisions of this Act.

Sec. 8. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

(a) The Director may establish through rulemaking:

(1) Criteria for indicators of misuse; and

(2) A method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse.

(b) Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to this Act, disclose information using the criteria that indicates potential misuse by recipients of the covered substances to their specific prescribers for the purpose of intervention to prevent such misuse.

Sec. 9. Immunity from liability.

(a) The Director and the employees of the Department shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Program pursuant to this Act.

(b) The Director and the employees of the Department shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with this Act and the Department's regulations.

(c) In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this Act shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

Sec. 10. Unlawful disclosure of information and acts; disciplinary action authorized; penalties.

(a) It shall be unlawful for any person having access to the confidential information in possession of the Prescription Monitoring Program or any data or reports produced by the program to disclose such confidential information except as provided in this Act. Any such person who discloses this confidential information in violation of the provisions of this Act shall be guilty of a Class 1 misdemeanor upon conviction.

(b) It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any such person who discloses confidential information in violation of this Act shall be guilty of a Class 1 misdemeanor upon conviction.

(c) Nothing in this section shall prohibit a person who prescribes or dispenses a covered substance required to be reported to the program from redisclosing information obtained from the Program to another prescriber or dispenser who has prescribed or dispensed a covered substance to the same patient.

(d) Unauthorized use or disclosure of confidential information received from the Program shall also be grounds for disciplinary action by the relevant health occupations board.

Sec. 11. The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act of 1973, as amended, approved December 24, 1973, (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 12. This Act shall take effect one (1) year following approval by the Mayor (or in the event of veto by the mayor, action by the Council to override the veto), a 30-day period of Congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act of 1973, as amended, approved December 24, 1973, (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.

Council of the District of Columbia
Committee on Health
Notice of Public Hearing
1350 Pennsylvania Ave., N.W., Washington, D.C. 20004 **DRAFT**

COUNCILMEMBER YVETTE M. ALEXANDER, CHAIRPERSON
COMMITTEE ON HEALTH ANNOUNCES A PUBLIC HEARING

on

B20-127, the "Prescription Drug Monitoring Act of 2013"

and

PR20-280, the "Health Services Planning Program Regulations Approval Resolution of 2013"

Friday, July 12, 2013
11:00 a.m., Room 120, John A. Wilson Building
1350 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

B20-127, the "Prescription Drug Monitoring Act of 2013"

1. Dr. Catherine May — Public Witness

Executive Witnesses

1. TBD — TBD

PR20-280, the "Health Services Planning Regulations Approval Resolution of 2013"

1. Susan Walker — Public Witness
2. Valencia Muhammed — Public Witness
3. John Kamya — Public Witness

Executive Witnesses

1. TBD — TBD