Prescription Drug and Heroin Abuse Taskforce
Data/Monitoring Workgroup Meeting Agenda
July 28, 2015, 10:00 A.M.-2:00 P.M.
Perimeter Center Conference Center
Board Room 4
Henrico, Virginia

Welcome and Introductions: Dr. Carol Forster and Katya Herndon

Review Minutes from *April 29, 2015 meeting*

Review of Task Force Action on Workgroup Recommendations

Discussion:

Discuss outstanding recommendation adopted by Task Force at May 2015 meeting: expand mandatory PMP requests to include the initial prescribing of an opiate or benzodiazepine and periodic reports thereafter, not to exceed 90 days, with limited exemptions

Discuss outstanding recommendation deferred by Task Force at May 2015 meeting: authorize "unsolicited" reports on outlier prescribing and dispensing to be sent to law enforcement and licensing boards

Governor's Task Force on Prescription Drug and Heroin Abuse

Data and Monitoring Workgroup

Meeting Seven, Minutes (DRAFT)

April 29, 2015

Members/Staff Present:
Co-Chair: Carol Forster, M.D., Mid-Atlantic Permanente Medical Group
Co-Chair: Katya Herndon, Chief Deputy Director, Department of Forensic Science
Staff: Ralph Orr, Director, Virginia Prescription Monitoring Program
Baron Blakley, Research Analyst, Department of Criminal Justice Services
Enrique Cancel, Group Supervisor, DEA Diversion Richmond Office (representing Greg Cherundolo)
Timothy Coyne, Public Defender
Delegate Charniele Herring, Virginia House of Delegates
Brian Hieatt, Sherriff, Tazewell County
Rosie Hobron, MPH, Statewide Forensic Epidemiologist, VDH-OCME
Major Rick Jenkins, Deputy Director, BCI, Virginia State Police
Rusty Maney, RPh, Richmond District Pharmacy Supervisor, Walgreens
Marty Mooradian, Impacted Family Member
Lisa Miller, DVM
David Trump, M.D., Chief Deputy Commissioner, Virginia Department of Health (representing Dr. Marissa Levine)

Members Absent:
Greg Cherundolo, ASAC, Richmond DEA-US DOJ
Marissa Levine, M.D., State Health Commissioner,
David Sarrett, DMD, MS, Dean, VCU School of Dentistry
Amanda Wahnich, MPH, Enhanced Surveillance Analyst, VDH
Deborah Waite, Ops Manager, Virginia Health Information
Anne Zehner, MPH, Epidemiologist, VDH

Meeting Agenda
Welcome and Introductions
Review Minutes from April 14, 2015 meeting

Discussion:

- Discuss possible recommendation to support placement of PMP report in the medical or prescription record of the patient
- Discuss outstanding item from December 2014 Task Force meeting: *"expand mandatory requests to include acute treatment"*
- Discuss area of concern from December 2014 Task Force Meeting: *"Send "Unsolicited" reports indicating indiscriminate prescribing or dispensing (i.e. geographic distribution)"*
- Discuss implementation plan for recommendations:

Workgroup mission: To advance solutions to share and integrate data among relevant licensing boards, state and local agencies, law enforcement, courts, health care providers and organizations, and

programs such as the PMP, in order to clarify and address public safety and public health concerns, understand emerging trends, and utilize data-driven decision-making to mitigate harm.

Welcome and Introductions

The meeting was called to order at 10:10 a.m.

Review of Minutes from April 14, 2015 Meeting

Ms. Herndon asked Workgroup members if there were any suggested changes to or comments about the draft minutes from the previous meeting, which had been distributed. Being none, the minutes were approved as presented.

Discuss possible recommendation to support placement of PMP report in the medical or prescription record of the patient

Mr. Orr reminded the members that this topic had been brought up at the last meeting as a possible recommendation for the Workgroup to consider. Mr. Orr pointed out that, on page 9 of the agenda packet, there is information that Ohio now makes it clear that prescribers may place reports in the medical record. Mr. Orr indicated that, although the Virginia PMP previously has advised that PMP reports may be placed in the medical record, existing statutory language creates uncertainty and the information is not generally kept in the record. There is precedent for legislation being drafted to clarify existing PMP statutory language. For instance, because healthcare providers did not feel that there was clear authority allowing a healthcare provider to discuss PMP report information to another healthcare provider providing treatment to that patient, legislation was passed to clarify that this type of communication is authorized. Mr. Orr explained that the Workgroup could recommend either a legislative or a regulatory change to clarify that placing the PMP report in the medical record is an acceptable practice to back up notes or comments made based on review of the report. The Workgroup approved a motion to recommend legislative action to amend §54.1-2525 to specify that reports received from the PMP may be placed in the medical record of the patient.

Discuss outstanding item from December 2014 Task Force meeting: *"expand mandatory requests to include acute treatment"*

The Workgroup continued the discussion on this topic from the last meeting. Mr. Orr advised that, beginning April 1, 2015, Ohio prescribers must request, assess, and document receipt of a history report from the Ohio PMP for every patient before initially prescribing an opioid analgesic or benzodiazepine. Further, the prescriber must request periodic updates at intervals not exceeding 90 days if the prescription is for more than 90 days (pages 8-9 of Agenda Packet). Ohio is just one of 24 states with some form of mandatory use requirement for their PMPs (page 18 of Agenda Packet).

A March 25, 2015 Issue Brief from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS), which was distributed as part of the meeting materials and discussed by the Workgroup, referenced data showing a positive impact of laws mandating the use of PMPs.

Ms. Hobron pointed out that, in 2013, drug/poison deaths outpaced gun and motor vehicle deaths for the first time (page 11 of Agenda Packet). She also noted that, while the data is not yet complete, it appears that 2014 drug/poison death totals will be higher than 2013.

Mr. Orr pointed out that the current mandatory use language does not cover prescribers working in emergency departments, urgent care centers or dental practices, or any type of prescribing of an opiate for acute pain. There is data that shows that general practitioners, family medicine, and Doctors of Osteopathy were the top prescribers of opioid analgesics in 2012 followed by internal medicine, dentistry, and orthopedic surgery (page 12 of Agenda Packet). Many of these prescribers are likely prescribing to treat acute pain and not chronic pain.

Mr. Orr discussed information showing the percentage of prescribers as registered users with those prescribers at the highest level of prescribing most likely to be registered and those at the lowest level least likely to be registered (page 16 of Agenda Packet). This also applies to the query rate. As a group, those registered prescribers prescribing more than 1000 requests in the quarter queried at a rate of 12.74% while those who prescribed the least queried at a rate of 6.46%. Further review of this data found that, of the 397 registered prescribers writing 1000 or more controlled substance prescriptions in the reviewed quarter, 116 made no requests to the PMP (page 17 of Agenda packet). Mr Orr explained that a preliminary review of the same information for the prescribers in the 500-999 prescribing range showed that 435 of 1075 registered users made no requests.

The Workgroup discussed language used in other state statutes, such as Ohio and New York, which provide exceptions to mandatory use of the PMP. Dr. Forster proposed that some of the exceptions to making requests from the other states be recommended, such as when the PMP is not available, when the prescription period is very short (e.g., 48 -72 hours), and when a drug is prescribed to treat acute pain following surgery. Mr. Orr noted that there are some current exceptions in Virginia, including treatment of pain for patients on dialysis or patients receiving cancer treatment.

The Workgroup approved a motion to recommend legislative action to amend §54.1-2522.1 to expand mandatory requests to include the initial prescribing of an opiate or benzodiazepine and periodic reports thereafter, not to exceed 90 days and to include exceptions from mandatory requesting as described above.

Discuss area of concern from December 2014 Task Force Meeting: *"Send "Unsolicited" reports indicating indiscriminate prescribing or dispensing (i.e. geographic distribution)"*

Mr. Orr explained that 31 states currently have authority to send unsolicited reports to law enforcement, and 30 states have authority to send unsolicited reports to regulatory entities (page 28 of Agenda Packet). The group discussed several current state initiatives (pages 19-27 of Agenda Packet) that include Prescriber Report Cards (AZ), letters to top prescribers and reports to licensing boards (TN), reports to investigators on possible at-risk prescribers (KY), reports to licensing boards and law enforcement (TX), proactive reporting on risky prescribing and dispensing (NJ), and identifying and contacting at-risk prescribers (NY). Mr. Orr explained that the PMP currently has no authority to provide any information that may indicate indiscriminate prescribing or dispensing to licensing boards or to law enforcement. This includes information where the program may identify a prescriber in another state that is writing numerous prescriptions for Virginia or out-of-state residents that get filled in Virginia pharmacies. It could also be a case where a pharmacy is filling a majority of prescriptions for controlled substances written by prescribers located in another state or hundreds of miles away and the patients do not live in the local area. Dr. Forster recommended that, if such unsolicited reports were to be provided, there should be some notification made to the prescriber or dispenser that provides an opportunity to change prescribing or dispensing behavior prior to the information being given to a licensing board or to law enforcement. Mr. Orr pointed out that the PMP is not a regulatory entity nor does it have any investigative authority so it may be improper to place the PMP in the position of arbiter instead of its current role of providing information to authorized users based on criteria and existing authority.

Mr. Orr explained that the PMP only has current authority to send unsolicited reports on patients meeting or exceeding certain criteria to their specific prescribers (generally exhibiting doctor shopping behavior) and to law enforcement (doctor shopping behavior or forgeries).

The Workgroup approved a motion to recommend legislative action to amend §54.1-2523.1 to authorize Unsolicited Reports on outlier prescribing and dispensing. The PMP will provide notice to prescribers or dispensers when their prescribing or dispensing records meet certain criteria. The Workgroup discussed what entity should set the specified criteria for these unsolicited reports. Mr. Orr noted that, under the Code, the Director of DHP currently has the authority, in consultation with an

advisory panel, to develop criteria for unsolicited reports on specific patients. The Workgroup discussed the fact that the relevant licensing boards (e.g., Board of Medicine, Board of Pharmacy, and Board of Dentistry) may have an interest in providing input on the criteria. Notice will include information regarding the specified criteria and advise that if outlier prescribing or dispensing continues for a certain period of time, information may be forwarded for investigation to law enforcement and/or the appropriate licensing board.

Discuss implementation plan for recommendations

The Workgroup reviewed the updated Task Force Timetable calling for a draft implementation plan based on Workgroup recommendations to be sent for review by May 22, 2015. The Task Force will review Workgroup recommendations at the May 12 meeting and will review and finalize the Implementation Plan at the June 16 meeting. Workgroups may still meet during the summer to review new information, refine recommendations, or make new recommendations based on new information. Mr. Orr displayed the template that may be used for the May 12 meeting and went through the various slides, adding information as discussed during the meeting.

The meeting adjourned at 2:00 p.m.

DATA & MONITORING WORKGROUP RECOMMENDATIONS

Accepted by Task Force and Completed During 2015 General Assembly Session

COMPLETED RECOMMONDATION 1: Implemented through passage of HB1841 (Delegate Herring).
Requires all prescribers and pharmacists to be registered with the PMP (provisions effective January 1, 2016) and requires prescribers to request info from the PMP before prescribing benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 days (eliminates treatment agreement requirement).

COMPLETED RECOMMONDATION 2: Implemented through passage of HB1810 (Delegate Herring).
Clarifies that records in possession of the PMP shall not be available for civil subpoena, disclosed, discoverable or compelled to be produced in a civil proceeding, or admissible as evidence in a civil proceeding for any reason.

Accepted by Task Force and Included in 6/16/15 Implementation Plan

RECOMMENDATION 1:
Reduce the timeframe in which dispensers must report to the PMP from within 7 days of dispensing to within 24 hours of dispensing.

- Daily reporting provides prescribers and dispensers access to more timely information. Data from the PMP for the first six months of 2014 showed the following:
  - 4,537 individuals received prescriptions from two or more prescribers within a 24-hour period (an average of 25 individuals per day);
  - 43,708 individuals received prescriptions from two or more prescribers within 7 days (an average of 243 individuals per day).
- As of January 1, 2016, 21 states will have implemented a requirement for reporting to their prescription monitoring programs within 24 hours of dispensing.
- There are currently three bills being considered in Congress to authorize grant funding for prescription monitoring programs that will make reporting within 24 hours an eligibility requirement or a preference element for receiving grant funding.
- This recommendation has also been adopted by the PMP Advisory Panel.

Implementation Steps:

- This recommendation should be implemented through legislation that amends Code §54.1-2521 and has a delayed effective date of January 1, 2017.
- Once the legislation passes:
  - Dispensers will need to update their systems and processes to ensure reporting occurs within the new 24-hour time period by the legislation's effective date. Recommendation is for a delayed effective date of January 1, 2017, to provide dispensers time to make the necessary changes to their systems.
  - The PMP will disseminate information regarding the new reporting timeframe to all PMP registered users and other interested entities (e.g., Virginia Pharmacists Association, application vendors).

- The PMP will update its reporting manual to reflect this change upon approval of the legislation.

RECOMMENDATION 2:

Adds the Morphine Equivalent Doses per Day (MEDD) Score to PMP patient reports to provide prescribers and dispensers with information as to the cumulative amount of opioid medication a patient is currently receiving in order to gauge potential risk of overdose.

Implementation completed. MEDD scores were added to the PMP effective June 2, 2015. PMP notified all registered users of this change.

RECOMMENDATION 3:

Develop clinically oriented criteria for the PMP to send unsolicited reports to prescribers on specific patients.

- Code § 54.1-2523.1 permits the PMP to send unsolicited reports to prescribers when PMP data indicates "potential misuse . . . of covered substances" by patients. The Director of the Department of Health Professionals is required to develop the criteria for these reports in consultation with the PMP Advisory Panel.
  - Currently, the unsolicited reports sent to prescribers on specific patients address doctor shopping behavior.
- Examples of clinically oriented criteria for these reports include patients who have MEDD scores over a specified level, who are on concomitant therapy of opioids and benzodiazepines, or who meet other criteria that may indicate increased risk for abuse and/or overdose.

Implementation Steps:

- The PMP Advisory Panel had preliminary discussions about possible criteria at its meeting held earlier this month. Further discussions will occur at the September PMP Advisory Panel meeting. Recommendations will be made to the Director of the Department of Health Professions for specified clinically oriented criteria.
- Once criteria is adopted, the PMP will explore various options to implement this reporting, including doing it in-house, making changes to its PMP application and contracting with an entity to develop the reports.
- The PMP will disseminate information to all PMP registered users and interested entities about any clinically oriented criteria adopted for these unsolicited reports.

Additional Action: No legislation or regulatory change required. Appropriations language may be necessary to authorize the PMP to expend funds to make enhancements to the PMP software application or utilize contracted services (PMP is a non-general fund entity).

RECOMMENDATION 4:

Enable the PMP to determine in what specialty the prescriber is practicing by requiring the reporting of (i) the prescriber National Provider Identifier (NPI) for prescriptions for human patients; and (ii) the species code.

- Capturing the NPI and species code will assist the PMP in sending individual prescriber feedback reports based on specialty.

Implementation Steps:

- The reporting of the NPI and species code as required data elements to the PMP will be added through amendments to the Regulations Governing the Prescription Monitoring Program (18 VAC 76-20-10 et seq.). PMP anticipates filing its NOIRA in the near future.
- The PMP will disseminate information about this new requirement to all PMP registered users and interested entities prior to the regulation's effective date.
- The PMP will update its PMP reporting manual to reflect these changes prior to the regulation's effective date.

Additional Action: Appropriations language may be necessary to authorize the PMP to expend its funds to make enhancements to the PMP software application to add NPI and species code or utilize contracted services (PMP is a non-general fund entity).

RECOMMENDATION 5:

Develop individual prescriber feedback reports that describe actual prescribing practices.

- Code § 54.1-2523 permits the PMP to send reports to prescribers on "[i]nformation relating to prescriptions for covered substances issued by [the] prescriber, which have been dispensed and reported to the [PMP]."
- Examples of initial prescriber feedback reports include advising each prescriber the number of patients the prescriber has who are receiving opioid prescriptions, who are on concomitant therapy, who are receiving a specified level of MEDD or who meet other indicators.
- A future goal for this recommendation is to provide individual prescriber feedback reports that compare the prescribing practices of a prescriber with his peers in the same specialty (e.g., cardiologist to cardiologist). The amendments to the Regulations Governing the Prescription Monitoring Program being implemented through Recommendation 4 (i.e., adding the NPI and species code to the PMP) are required before individual prescriber feedback reports by specialty can be implemented.
- In the interim, the PMP will be developing prescriber feedback reports that are <u>not</u> tied to specialty, but would report information to prescribers such as the number of patients the prescriber has with an MEDD score over 120 or some other specified number.

Implementation Steps:

- The PMP will explore various options to implement the initial prescriber feedback reports, including in-house resources, expanding capabilities of the PMP application, and contracting for services.
- The PMP Advisory Panel had preliminary discussions about these reports at its meeting held earlier this month. Further discussions will occur at the September PMP Advisory Panel meeting. The Director of Health Professionals, in consultation with the PMP Advisory Panel, will recommend the information to be included in these prescriber feedback reports.
- The PMP will disseminate information about the individual prescriber feedback reports to all PMP registered users and interested entities prior to their implementation.
- Once the Regulations Governing the Prescription Monitoring Program are amended to require reporting of the NPI and species code, the PMP will develop individual provider feedback reports based on the prescriber's specialty.

Additional Action: Appropriations language may be necessary to authorize the PMP to expend its funds to implement this recommendation to make enhancements to the PMP software application or utilize contracted services (PMP is a non-general fund entity).

RECOMMENDATION 6:

Create a Health and Criminal Justice Data Committee, comprised of data analysts from applicable agencies within the Secretariats of Public Safety & Homeland Security and Health & Human Resources, to study data for the purpose of better understanding the ways in which criminal justice and public health issues intersect, with the goal of improving government responses to crises, as well as identifying and responding to concerns before they become crises.

- This Committee should function in a manner similar to the Technical Committee for the Offender Population Forecast, which meets multiple times a year to share information on relevant trends that might impact the correctional populations, and then produces an annual report on behalf of the SPSHS.
- The Health and Criminal Justice Data Committee's format, membership, and meeting schedule should be structured according to what the Committee determines best allows it to achieve the goals of identifying important trends in criminal justice and public health related issues.

Implementation Steps:

- The Workgroup's Data Sets Subcommittee should serve as a transitional working group that identifies agencies and analysts that should participate in or provide data to the Health and Criminal Justice Data Committee.
- The membership of the Health and Criminal Justice Data Committee should be finalized by August 1, 2015. Once formed, the Committee should select a Chair, who will serve as the point of contact for all participating agencies and as the liaison to the Offices of the SPSHS and SHHR.
- The Health and Criminal Justice Data Committee may request relevant de-identified, aggregated, locality-level data from agencies and other entities. Data should be provided to the Committee Chair electronically, on a periodic basis.
- Analysts serving on the Health and Criminal Justice Data Committee will analyze the data, identifying trends of concerns, and sharing their findings with the Committee. The Committee should meet multiple times during the year, according to the schedule that best suits the Committee's needs.
- The Health and Criminal Justice Data Committee should provide an annual trends report to the SPSHS and SHHR. A copy of the report should be shared with the Center for Behavioral Health and Justice. The initial report from the Committee should be submitted by January 15, 2016. Subsequent reports should be submitted annually by October 15.
- The Committee's initial focus should be on gathering and analyzing appropriate information to mitigate harm from prescription drug and heroin abuse.
- The Committee will require cooperation from multiple agencies. To ensure an efficient data-sharing process, the Secretaries of PSHS and HHR should direct agencies to share, to the extent possible, the data requested by the Committee.
- To the extent possible, the Committee should monitor data-sharing improvement initiatives within the Secretaries of PSHS and HHR, and work to make any data sharing improvements developed by the Committee available to assist these initiatives.

RECOMMENDATION 7:

Expand access to PMP information on a specific patient to clinical pharmacists and consulting prescribers practicing on healthcare teams treating that specific patient.

- Currently, the authority for access to PMP information is strictly limited to the prescribing and dispensing functions of prescribers and pharmacists, and it does not reflect the common practice in healthcare where "team care" is utilized.
- This suggested change aims to improve patient outcomes by making PMP information available to all appropriate healthcare providers.
- This recommendation has also been adopted by the PMP Advisory Panel.

Implementation Plan:

- Legislation to amend Subsection C of Code § 54.1-2523 is required to implement this recommendation.
- The PMP will disseminate information about this change to all PMP registered users and interested entities prior to the legislation's effective date.

RECOMMENDATION 8:

Clarify that PMP reports may be placed in the medical record.

- Although the Virginia PMP has previously advised that PMP reports may be placed in the medical record, existing statutory language creates uncertainty, and the information is not generally kept in the medical record.

Implementation Steps:

- Legislation to amend Code § 54.1-2525 is necessary to implement this recommendation. Section addresses unlawful disclosure of PMP information.
- The PMP will disseminate information advising that PMP reports may be placed in medical records to all PMP registered users and interested entities prior to the legislation's effective date.

Recommendation Accepted by Task Force on 5/12/15 with Request for Additional Detail from Workgroup Regarding Implementation

RECOMMENDATION: Expand mandatory requests to the PMP to include the initial prescribing of an opiate or benzodiazepine with required periodic requests thereafter. There will be limited exceptions to this new mandatory PMP check requirement.

- In particular, the Task Force would like information on what exceptions should be included.

Recommendation Deferred by Task Force on 5/12/15 to Allow Workgroup Additional Time to Work Out the Details

RECOMMENDATION: Authorize the PMP to provide unsolicited reports on prescribers and dispensers to law enforcement and licensing boards.

- In particular, the Task Force would like to know who will develop the criteria for these unsolicited reports.

Discussion: Mandatory Requests

CURRENT LANGUAGE:

§ 54.1-2522.1. Requirements of prescribers.

A. (Effective until January 1, 2016) Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions upon filing an application for licensure or renewal of licensure, if the prescriber is not already registered.

A. (Effective January 1, 2016)

Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

2014, cc. 93, 178; 2015, c. 517.

MODEL LANGUAGE:
(Taken from National Alliance for Model State Drug Laws Model Prescription Monitoring Program (PMP) Act)
SECTION 11. REQUIREMENT TO QUERY THE PRESCRIPTION MONITORING PROGRAM.
A prescriber or prescriber's designee shall query the prescription monitoring program prior to initially prescribing or personally dispensing a controlled substance to a patient. If the patient's course of treatment continues for more than ninety (90) days after the date of the initial prescription, the prescriber or prescriber's designee shall make periodic requests for prescription monitoring program

information, no less frequently than [once every 3/6/9 months or annually] until the course of treatment has ended.
This requirement shall not apply if one of the following conditions is met:
(a) The controlled substance is prescribed or dispensed to a patient currently receiving hospice care.
(b) The controlled substance is prescribed or dispensed to a patient as part of a treatment for a surgical procedure that has or will occur in a licensed health care facility and such prescription is non-refillable.
(c) The quantity of the controlled substance prescribed or dispensed does not exceed an amount which is adequate for a single seven-day treatment period and does not allow a refill and no subsequent prescriptions are written or dispensed within a fifteen (15) day time period.
(d) The controlled substance is directly administered to the patient by the prescriber or other person authorized to administer a controlled substance.
(e) If it is not possible to query the prescription monitoring program in a timely manner due to an emergency situation.
(f) The program is not operational due to temporary technological or electrical failure or natural disaster.

SAMPLE EXISTING STATE LANGUAGE:
KY
Administrative regulations may exempt:
Exemptions (Board of Medical Licensure): The following practitioners are exempt from these requirements:
1. Licensee administering substance or anesthesia immediately prior to or during surgery;
2. Licensee administering controlled substance necessary to treat in emergency situation:
- At the scene of an emergency
- In licensed ground or air ambulance, or
- In ED or ICU of licensed hospital
3. Licensed pharmacist or Board of Pharmacy licensee dispensing drugs to licensed pharmacy;
4. Licensee prescribing/dispensing for hospice patient in scope of hospice program or inpatient unit. Hospice program shall maintain plan of care in accordance with federal regulations
5. Optometrist prescribing Schedule III, IV or V substance
6. Licensee prescribing 3-day supply of Schedule III substance following oral surgery by dentist.

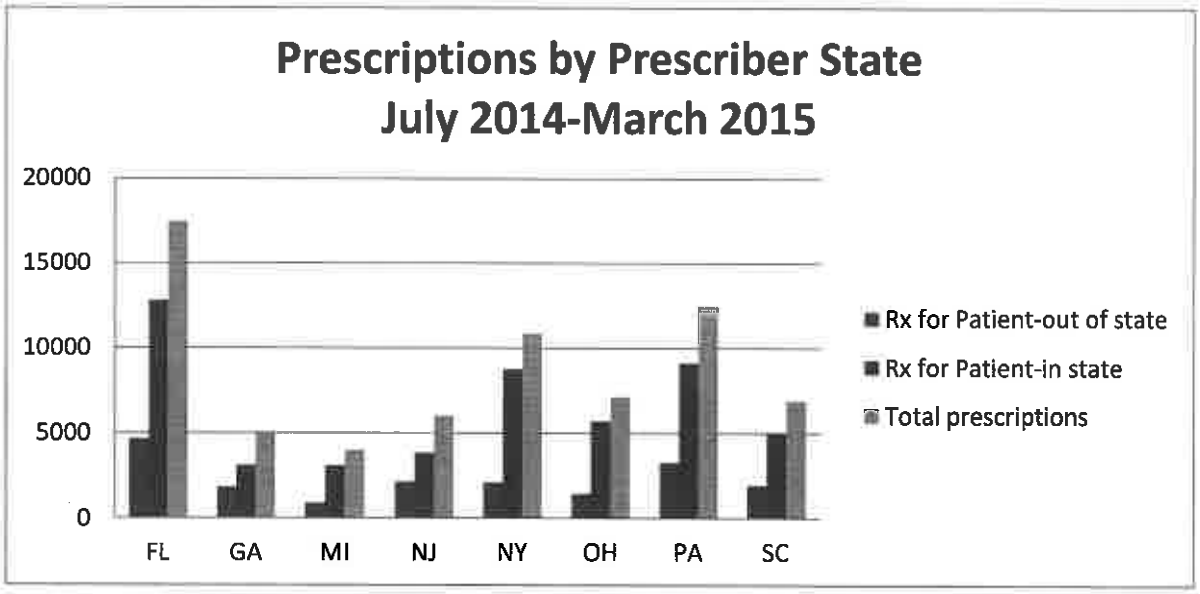
OH (from FAQ on OARRS website)
Q5) As a prescriber, under what circumstances am I required to request, assess and document receipt of a patient's OARRS prescription history report? UPDATED
Beginning April 1, 2015, Ohio law establishes several new requirements for Ohio prescribers related to the Ohio Automated Rx Reporting System (OARRS):

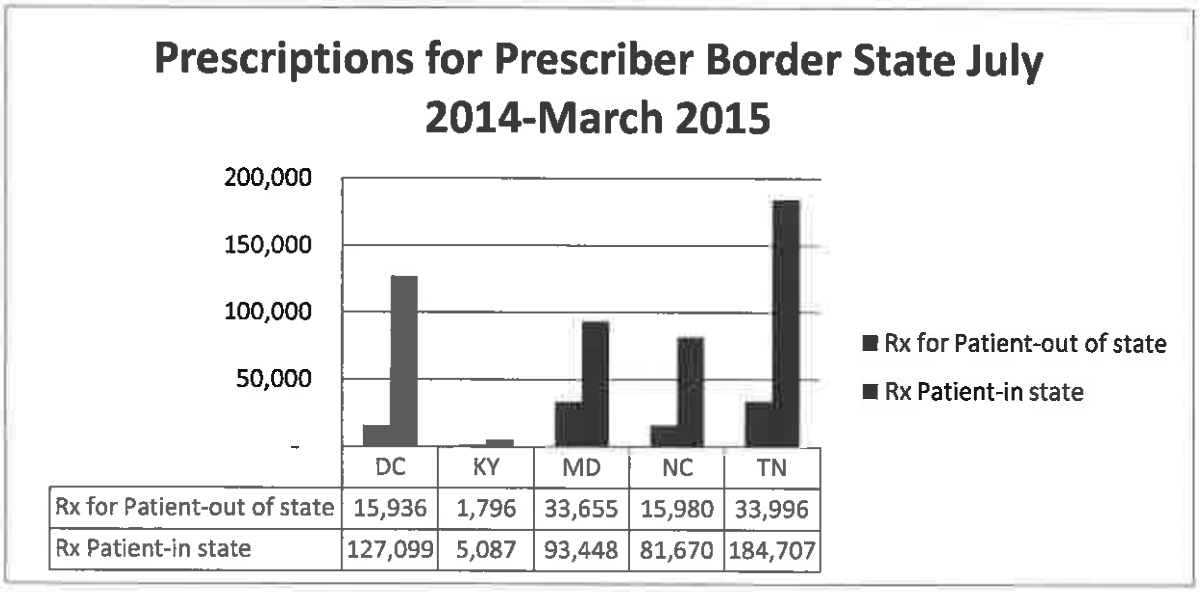
- Before initially prescribing or personally furnishing an opioid analgesic or a benzodiazepine to a patient, the prescriber must request patient information from OARRS that covers at least the previous 12 months.

- The prescriber must also make periodic requests for patient information from OARRS if the course of treatment continues for more than 90 days. *The requests must be made at intervals not exceeding ninety days, determined according to the date the initial request was made.*
- Under the circumstances described above, the prescriber is required to assess the OARRS information and document in the patient record that a patient prescription history report was received and assessed.
- *Please note: A recent change in Ohio law no longer requires an optometrist holding a therapeutic pharmaceutical agents certificate to query OARRS in the situations listed above. However, an optometrist holding a therapeutic pharmaceutical agents certificate must comply with rule 4725-16-04 of the Administrative Code regarding when to access information in OARRS.*
- **Q6) Are there any exceptions to the law?**
- Yes. Exceptions to mandatory checks prior to prescribing an opioid analgesic or benzodiazepine include the following scenarios:
- The drug is prescribed or personally furnished to a hospice patient or to any other patient who has been diagnosed as terminally ill (advanced practice registered nurses, physician assistants, and physicians but not dentists and optometrists);
- The drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days (all prescribers except optometrists);
- The drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer (advanced practice registered nurses, physician assistants, and physicians but not dentists and optometrists);
- The drug is prescribed or personally furnished for administration in a hospital, nursing home, or residential care facility (advanced practice registered nurses, physician assistants, and physicians but not dentists and optometrists);
- The drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery (physicians only); and
- The OARRS report is not available (all prescribers).

NOTES:

Discussion: "Unsolicited" reports on outlier prescribing and dispensing to be sent to law enforcement and licensing boards





	DC	KY	MD	NC	TN
Rx for Patient-out of state	15,936	1,796	33,655	15,980	33,996
Rx Patient-in state	127,099	5,087	93,448	81,670	184,707

CURRENT LANGUAGE:

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

The Director shall develop, in consultation with an advisory panel, criteria for indicators of misuse and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse. Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523, disclose information using the criteria that indicates potential misuse by recipients of covered substances to (i) their specific prescribers for the purpose of intervention to prevent such misuse or abuse or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of the

Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

(2005, cc. 637, 678; 2012, cc. 21, 71; 2013, c. 739.)

MODEL LANGUAGE:
(Taken from National Alliance for Model State Drug Laws Model Prescription Monitoring Program (PMP) Act)
SECTION 8. ACCESS TO AND USE OF PRESCRIPTION MONITORING INFORMATION; CONFIDENTIALITY.
(a) Prescription monitoring information submitted to the [designated state agency or entity] shall be confidential, is not subject to public or open records laws, and is not subject to disclosure or use except as provided in this Section. Further, prescription monitoring information is not available for civil subpoena, nor shall such records be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding where a prescriber or dispenser is not a named party.
(b) The [designated state agency or entity] shall maintain procedures to protect the privacy and confidentiality of patients and to ensure that information collected, recorded, transmitted, and maintained pursuant to this Act is not obtained, disclosed, or used except as provided in this Section.
(c) The [designated state agency or entity] shall implement technological improvements to facilitate secure access to the PMP through electronic health information systems as expeditiously as possible.
(d) The [designated state agency or entity] shall review the prescription monitoring information. If the review identifies information that satisfies criteria established by the [designated state agency or entity] in consultation with the Advisory Committee:

(i) for referring information about a patient to a prescriber or dispenser, the [designated state agency or entity] shall provide the relevant information to the appropriate prescribers and dispensers.

(ii) for referring information to a law enforcement agency or a professional licensing or certification agency or board, the [designated state agency or entity] shall provide the relevant information to the appropriate agency or board for further inquiry and action, as deemed appropriate by that agency or board.

SAMPLE EXISTING STATE LANGUAGE:
West Virginia §60A-9-5
(b) The Board of Pharmacy shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on

specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the prescribers or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable prescriber or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

From Brandeis University PDMP Center of Excellence: Guidance on PDMP Best Practices
Options for Unsolicited Reporting 2014
www.pdmpexcellence.org

Unsolicited reporting on medical providers
Unsolicited reporting is applicable concerning medical providers who, whether intentionally or not, may be engaging in risky or illegal prescribing or dispensing. The CDC recommends that PDMPs focus on "prescribers who clearly deviate from accepted medical practice in terms of prescription painkiller dosage, numbers of prescriptions for controlled substances, and proportion of doctor shoppers among their patients."23 Alerts concerning questionable activity by providers may be appropriately addressed to licensing boards, peer review committees, third-party payers, Medicare and state Medicaid, and other bodies charged with monitoring medical practitioners. When analysis of PDMP data identifies probable criminal activity, such as prescribing and/or dispensing by pill mills, referral to law enforcement agencies is appropriate.
Indicators of possible problematic *prescribing* detectable in PDMP data might include, for example, opioid prescriptions and/or doses in excess of accepted norms for the type of practice (e.g., a dentist routinely prescribing and renewing a month's supply of 80 mg oxycodone); primarily prescribing combinations of drugs known to be "drug cocktails" (e.g., the combination of hydrocodone or oxycodone, alprazolam, and carisoprodol); having many patients in a practice that meet criteria for doctor shopping; and prescribing for many out-of-state or geographically distant patients. Data on deaths, overdoses, and other adverse health outcomes associated with prescription drug abuse among a prescriber's patients would also be relevant. Signs of possible problematic *dispensing* by pharmacists and physicians include high proportions of cash payments for prescriptions dispensed, especially for prescriptions

that duplicate those covered by Medicaid, filling what are obviously forged prescriptions, and filling duplicate or excessive prescriptions without seeking confirmation from prescribers. Reliable criteria in PDMP and other data of questionable activity by providers need further research and validation. As PDMPs review provider prescription records that might trigger unsolicited reports, they should consider possible legitimate reasons for what might appear to be problematic prescribing or dispensing, such as pain management specialists practicing in a hospital based pain clinic. *Even after such review, it is important to note that unsolicited reports on providers are only preliminary, possible indicators of a problem. Determining whether a problem exists and any further investigation is appropriate is a matter for further consideration by the body receiving the report (e.g., licensing board, peer review committee, or law enforcement agency). Such investigations can involve coordination among some or all of those bodies charged with maintaining good medical practice and ensuring public safety.*

Reports on providers to licensing boards

Even if possible problematic prescribing or dispensing does not reach a level or type meriting law enforcement investigation, it may nevertheless be appropriate for reporting to medical and pharmacy licensing boards. Here are two instances of such reporting:

Kentucky. As part of its recent legislative mandate for proactive use of PDMP data, Kentucky's PDMP—the Kentucky All Schedule Prescription Electronic Reporting system (KASPER)—conducts unsolicited reporting on prescribers in coordination with the Drug Enforcement and Professional Practices branch of the Office of the Inspector General (OIG). Reporting is based upon criteria established by the Governor's KASPER Advisory Council, which is composed of representatives from Kentucky licensing boards, professional associations, law enforcement, and other key stakeholders. Prescription history reports on the top prescribers of the most commonly abused and diverted controlled substances are sent to OIG investigators, who evaluate the reports to see if further investigation of potentially inappropriate or illegal prescribing is warranted. Initial prescriber reviews were conducted based on KASPER Advisory Council criteria specifying the top two percent of prescribers issuing prescriptions for oxycodone, hydrocodone, oxymorphone, methadone, alprazolam, and the drug "cocktail" (see "Unsolicited reporting on medical providers" above). The OIG investigators are registered pharmacists and certified peace officers in Kentucky who review the provider's prescribing history, the type of practice, prior record of disciplinary action, and several other factors. If the review indicates a substantial likelihood of problematic prescribing, the information is forwarded to the appropriate licensing board for further review. A second set of prescriber reviews is underway based upon revised criteria provided by the KASPER Advisory Council after evaluating the results of the initial reviews. If a report forwarded to a licensing board results in a prescriber investigation, the licensing board notifies authorized personnel in the OIG, Attorney General's office, and Kentucky State Police Drug Enforcement/Special Investigations unit. Such notifications assist in case coordination and de-confliction (such as identifying when an investigation of the same provider is underway by a sister agency). Since unsolicited reporting began in July 2012, KASPER reports have triggered over 80 licensing board investigations of prescribers. These have resulted in retirements, agreed orders setting out sanctions and terms to be imposed upon the prescriber, and controlled substance license revocations, with the result that some problematic prescribers have modified their practices or have been removed from the system. Without proactive analysis of KASPER data and reporting to boards, these prescribers would likely have gone undetected.

New Jersey. The New Jersey statute enabling the PDMP, which started in September 2011, permits unsolicited reporting of medical providers to law enforcement. Quarterly analyses are conducted to look for concerning patterns of prescribing and dispensing, such as identifying the state's top prescribers and pharmacies for controlled substances commonly encountered in cases of illegal prescribing. Database searches are conducted using drug therapeutic codes and dosage types (e.g., 30

mg Roxicodone) and payment type. If suspicious departures from normal prescribing practice are detected, the appropriate law enforcement agency (or licensing board, depending on the level and type of activity) is contacted. Recent analyses related to possible diversion have focused on top prescribers of oxycodone where payments for prescriptions are made in cash. The PDMP also runs ad hoc analyses to further explore patterns identified in quarterly reviews or investigate developments reported to the PDMP by other agencies. For example, law enforcement agencies may report that promethazine with codeine syrup is turning up on the street, so analyses are run for promethazine. The PDMP hopes to add more regular analyses using preset criteria as resources permit.

From Brandeis University PDMP Center of Excellence: Guidance on PDMP Best Practices
Interventions with Possible At-Risk Providers:
Tennessee: Letters to top prescribers and reports to licensing boards. In 2013, the Tennessee legislature adopted a requirement that, using the PDMP, the Tennessee Department of Health (TDH) identify and notify at least annually the top fifty prescribers in the past calendar year. The notification letters include information about the practitioner's level of prescribing and ask the prescribers or their medical supervisors to justify the amounts prescribed as medically necessary, on pain of disciplinary action for non-compliance. Letters are not sent if the prescriber is a subject of an active investigation. TDH then determines, in consultation with medical experts on appropriate prescribing, whether the prescriber's explanation is justified, taking into account factors such as medical specialty and ages of patients. If the explanation leaves concerns about over-prescribing unaddressed, the prescriber or medical supervisor is given 15 days to produce additional supporting evidence that the level of prescribing is medically warranted. If concerns about excess prescribing still remain, TDH may contact the relevant licensing board for its review of the case, which may trigger an investigation should inappropriate prescribing seem likely. As of this report no data were available on numbers of prescribers contacted thus far or other outcomes of the letter initiative. In addition to the letter initiative, the Tennessee PDMP currently provides data to licensing board investigators on the most frequent prescribers, both for numbers of prescriptions and total dosage units of certain controlled substances. The PDMP is in the process of incorporating refinements to these criteria, such as data on how a provider's prescribing compares to norms for a particular specialty (e.g., general medicine or orthopedics) and how practices vary in the types and dosages of prescribed controlled substances.

NOTES: