

COMMONWEALTH OF VIRGINIA Meeting of the Virginia Prescription Drug

Monitoring Advisory Panel

Perimeter Center, 9960 Mayland Drive, Second Floor Henrico, Virginia 23233

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Agenda of Meeting March 30, 2015 1:00 PM **Board Room 3**

Call to Order: Randall Clouse, Chairman

- Welcome and introductions
- Reading of emergency evacuation script: Ralph Orr
- Approval of Agenda
- Approval of Minutes | 6

Public Comment:

Department of Health Professions Report: David E. Brown, D. C.

Governor's Task Force on Prescription Drug and Heroin Abuse Report: David E. Brown, D. C.

2015 legislation and DHP Regulations Update: Elaine Yeatts

M-17

Expand access to PMP for clinical pharmacists and prescribers participating on healthcare teams: \ Ralph Orr

Review reporting requirements to PMP to include frequency of reporting, Species Code, and 19-25 others: Ralph Orr

Utilization of PMP data: Analysis of information held by PMP-Ralph Orr

26-27

Guidance related to research requests for PMP data: Ralph Orr

28-43

Program Update: Carolyn McKann

Program Statistics 44-4

PMP Interoperability and Integration—Status 50

Morphine Milligram Equivalent Dose—Update 51-53

Unsolicited Reports—Update 54
Outreach Activities 55-57

Next Meeting

Adjourn

DRAFT/UNAPPROVED

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS VIRGINIA PRESCRIPTION MONITORING PROGRAM MINUTES OF ADVISORY PANEL

Monday, November 10, 2014

9960 Mayland Drive, Suite 300 Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of the advisory panel of the Prescription Monitoring		
	Program was called to order at 1:10 p.m.		
	p.m.		
PRESIDING	Randall Clouse, Chair		
MEMBERS PRESENT:	Holly Morris, RPh, Crittenden's Drug, Vice Chair		
	Carola Bruflat, Family Nurse Practitioner		
	Dr. Kathrin Hobron, Representing Dr. Amy Tharp, Office of the		
	Chief Medical Examiner		
	Mellie Randall, Representative, Department of Behavioral		
	Health and Developmental Services		
	John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C.		
	Harvey Smith, 1SG, Virginia State Police		
MEMBERG ADGESTO	S. Hughes Melton, M.D., Mountain Valley Health		
MEMBERS ABSENT:	Brenda Clarkson, Executive Director, Virginia Association for		
GUESTS PRESENT:	Hospices and Palliative Care		
STAFF PRESENT:	William Gormley, M.D. Chief Medical Examiner		
STAFF PRESENT:	David E. Brown, D.C., Director, Department of Health		
	Professions (DHP)		
	Jaime Hoyle, Chief Deputy Director, Department of Health Professions		
	James Rutkowski, Assistant Attorney General, Office of the Attorney General		
	Elaine Yeatts, Senior Policy Analyst		
	Ralph A. Orr, Program Director, Prescription Monitoring		
	Program		
	Caroline Juran, RPh, Executive Director, Virginia Board of		
	Pharmacy Pharmacy		
WELCOME AND	Mr. Clouse welcomed everyone to the meeting of the advisory		
INTRODUCTIONS	panel.		
PUBLIC COMMENT:	No public comments were made.		
APPROVAL OF	The agenda was approved as presented.		
AGENDA			
ELECTION OF	Holly Morris nominated Randall Clouse and Mr. Clouse was		
CHAIRMAN AND VICE-	subsequently unanimously elected Chairman of the Advisory		
CHAIRMAN	Committee for the upcoming term. Mr. Randall Clouse		

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	nominated Holly Morris and Ms. Morris was subsequently	
	unanimously elected as Vice-Chairman for the upcoming term.	
David E. Brown, D.C.: DEPARTMENT OF HEALTH PROFESSIONS REPORT Report on Governor's Task Force on Prescription Drug and Heroin Abuse	Dr. Brown welcomed the Panel and thanked them for taking time from their schedules to do this important work. Dr. Brown explained that last year Virginia participated in a Policy	
PROGRAM UPDATE:	Ralph Orr	
Unsolicited Reports Morphine Milligrom	Mr. Orr gave a report on the current status of unsolicited reports performed by the PMP. The PMP currently has authority to send unsolicited reports on recipients meeting or exceeding certain criteria to prescribers of those recipients and to law enforcement. The criterion that is currently used is based on the number of prescribers and dispensers that a recipient uses in a certain time period. Statistics on these reports and broader indicators were discussed. It was suggested that the criteria needs to move towards more clinical impact issues such as a morphine equivalent dose over a certain amount per day, or prescribing of an opioid when a patient is receiving other controlled substances that may affect the use of the opioid. Information was presented on a project being done in Arizona where a "prescribing history" report is being sent to prescribers of controlled substances. (pages 7-9 in agenda packet) Mr. Orr pointed out that to do something similar in Virginia we would need to require the reporting of the prescriber's National Provider Identification number (NPI) which has a specialty code attached to it. Dr. Melton and Dr. Barsanti felt this type of information may be helpful to practitioners if presented as information to assist the prescriber but to be cautious about applying labels to prescribing behavior.	
Morphine Milligram Equivalent Dose	Mr. Orr presented information to the Panel regarding Morphine Milligram Equivalent Dose (MMED), pointing out that according to information from FDA that a substantial increase in	

overdose risk exists for patients receiving over 100 MMED per day. The MMED is computed by taking the strength of each opioid dispensed, multiplying that number by the multiplier (page 11 of agenda packet) for that drug, multiplying that number by the quantity dispensed and then dividing that result by the days supply. This provides the MMED for that specific dispensed drug. A review of several guidelines from several organizations followed as well as a discussion of guidelines developed by the State Medical Board of Ohio that relate to MMED information being placed on that State's PMP reports. Mr. Orr showed the Panel the MMED calculator posted on the Ohio PMP website and discussed the placement of the MMED score on the Ohio PMP report. The MMED score only reflects the narcotic prescriptions dispensed to the patient, it does not address other controlled substances the patient has received. Another type of clinical tool that is available is called NARxCHECK. This product provides a risk score for narcotics, sedatives, and stimulants based on an algorithm developed from a large data set and then compared to the patient's PMP report. (Pages 19-20 of agenda packet). Mr. Orr stated that placing an MMED score on the PMP report is a service that can be added to the PMP application while the NARxCHECK feature is something that would be added to a user's application and not under the control of the PMP. The Panel's consensus was that providing the MMED on the PMP report would be very beneficial and should be added. However, education and guidelines supporting this information needs to be developed and made available to users prior to implementation.

PMP Outreach Efforts: Presentations

Mr. Orr provided a synopsis of program education activities over the past 2 years (pages 21-23 of the agenda packet). Dr. Melton was thanked for his participation in many of these training events. Presentations for healthcare providers represent the bulk of education activities and have changed over the years to be clinically applicable to actual scenarios a prescriber may see in his or her practice and to address how to read and understand the information contained in a PMP report. PMP staff also provides training on the PMP to law enforcement, regulatory investigators, and other interested parties.

PMP and Social Media YouTube and Twitter

Realizing the need to make more PMP information available on the internet the PMP has produced two YouTube videos to assist healthcare practitioners in registering for the PMP and to provide basic information about the program. The PMP has recently initiated a Twitter account which is showing some promise in providing information about prescription drug abuse to a much wider audience. Mr. Orr introduced Daniel Chait, an intern from VCU, who is assisting the program with improving its presence on Twitter and with the development of messages for upcoming projects such as the mandatory registration of prescribers which

becomes effective in July 2015. Information and samples of YouTube and Twitter activity was discussed as well as a brief overview of a press release from June 2014 and a listing of recent articles about the PMP. Dr. Melton suggested adding trending topics to the Twitter account.

Utilization of Data

Mr. Orr discussed the need for use of PMP data beyond the traditional use of an authorized user making a request and receiving information back. There is a need to detect changes in prescribing and dispensing patterns, to assist in developing policy solutions to prescription drug abuse and drug overdoses, and to provide data for resource allocation decisions. The PMP has the authority to provide de-identified data for research and education purposes but until recently mechanisms to develop this type of data was not available. The PMP has recently signed an MOU with the Department of Criminal Justice Services to provide de-identified data that can then be compared to their existing data sets to develop a more accurate picture of drug supply patterns in the Commonwealth. The PMP is working on an MOU with Brandeis University under a CDC/FDA/BJA grant to provide data sets to Brandeis, which will apply 43 measures and provide a report on these measures on a quarterly basis. The Department of Health (VDH) has approached the PMP with a desire to develop an MOU to obtain these de-identified data sets in order to compare to data sets held by VDH including drug death data and overdose data from emergency rooms among others. Early results from these collaborations should be available by June 2015.

Drug Death Data

Dr. Kathrin Hobron, Office of the Chief Medical Examiner: Dr. Hobron gave a presentation on Fatal Prescription Drug Overdoses in Virginia, 2007-2013 (Pages 33-43 of the agenda packet). In 2013 there were 912 drug deaths exceeding both the number of motor vehicle fatalities and firearm related deaths. Of these deaths, 634 were attributed solely to prescription drugs and 468 of those were attributed specifically to prescription opioid overdoses. The age groups with the highest number of prescription opioid overdoses were males aged 25-24, and females aged 45-54.

PMP Interoperability and Integration

Mr. Orr gave an update of interoperability with other states stating that the PMP is now connected with 17 other states and is working to connect with several more as there are now 26 states that have implemented the National Association of Boards of Pharmacy (NABP) PMPInterConnect®. This includes the 3 border states of Kentucky, Tennessee, and West Virginia. Requests from users in other states made up approximately 15% of all requests in the 2nd quarter of 2014. Integration into healthcare practitioner workflow is the next means to improve access of PMP information to healthcare

	practitioners. Mr. Orr has been participating on an Office of National Coordinator, Standards and Integration Framework project to develop a mechanism that will allow electronic health records (EHR), e-prescribing applications, and pharmacy applications to have PMP data integrated into their applications. This is difficult because these entities all use different standards to do the functions related to their specific application. NABP and its technology partner, Appriss are developing a translation service, called Gateway to facilitate the sharing of PMP data across applications. The project is currently in its pilot implementation phase and Virginia is likely to be participating with a pharmacy application vendor as well as a major EHR vendor.	
Discussion of 2013-2014 Legislation	Elaine Yeatts, Policy Analyst, Department of Health Professions: Ms. Yeatts gave a report on legislation passed in 2013 and 2014 affecting the PMP (Pages 48-49 of the agenda packet). Panel members expressed concern over the wording requiring mandatory requests being made only if a prescription was being initiated for chronic use and the prescriber and patient have entered into a treatment agreement. Ms. Yeatts explained that there was a bill that would have changed the reporting requirement from within 7 days of dispensing to within 3 days of dispensing. The bill (SB 638) was not moved from Committee but the Chair of Senate Education and Health requested a report on this topic detailing information on other state reporting requirements. This report has been submitted to the Committee. Ms. Yeatts stated that the majority of states require reporting within 7 days of dispensing but the movement is definitely towards daily reporting. Panel members felt this was an issue to be further explored with possible benefits from timelier reporting but did not want such a requirement to impact negatively on dispensers. Information on the naloxone pilot was also provided where lay rescuers may obtain and then use this medication to reverse an opioid overdose. Panel was supportive of expanding the pilot from its current coverage area.	
Program Statistics	Mr. Orr briefly discussed current program statistics (Pages 50-60 of the agenda packet) pointing out that the PMP expects to process approximately 1.9 million requests this year and add 5000 new users.	
NEW BUSINESS	 Mr. Orr discussed possible enhancement recommendations that may be considered by the Governor's Task Force on Prescription Drug and Heroin Abuse. These included: 1. Require daily reporting of dispensed prescriptions to PMP—Panel consensus was to explore this issue 2. Automated mandatory registration for pharmacists (this was a recommendation from the strategy developed in 	

ADJOURN:	The next meeting will be held on a date yet to be determined in March 2015. With all business concluded, the committee adjourned at 4:00 p.m. Randall Clouse, Chairman
NEXT MEETING	 2013 through the NGA policy Academy)—Panel consensus was yes and to review existing code language for mandatory requests for possible update and clarification 3. Add NPI of prescriber as a required data element—Panel consensus was yes as a means to support "peer comparison" reports for prescribers 4. Initiate "peer comparison" reports for prescribers—Panel consensus was yes but the emphasis was that this should focus on education and informing prescribers 5. Authorize PMP to report information indicating indiscriminate prescribing or dispensing to appropriate licensing board—Panel consensus was to explore with details needed for a review process and criteria setting. 6. Provide authority for prescriber and pharmacist access to PMP data that is not tied directly to a prescribing or dispensing function—Panel consensus was a definite yes to support the continuing evolution of a team approach to health care

Report of the 2015 General Assembly

Prescription Drug Monitoring Advisory Panel

HB 1445 Cannabidiol oil and THC-A oil; possession of marijuana.

Chief patron: Albo

Summary as passed:

Possession or distribution of marijuana for medical purposes; epilepsy. Provides an affirmative defense in a prosecution for the possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil possessed pursuant to a valid written certification issued by a practitioner of medicine or osteopathy licensed by the Board of Medicine for purposes of treating or alleviating a patient's symptoms of intractable epilepsy. The bill provides that a practitioner shall not be prosecuted for distribution of marijuana under the circumstances outlined in the bill. The bill contains an emergency clause. This bill is identical to SB 1235.

EMERGENCY

02/26/15 Senate: Signed by President

02/26/15 House: Enrolled Bill communicated to Governor on 2/26/15

02/26/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

02/26/15 Governor: Approved by Governor-Chapter 7 (effective 2/26/15)

02/26/15 Governor: Acts of Assembly Chapter text (CHAP0007)

HB 1458 Naloxone or other opioid antagonist; pharmacist may dispense in cases of opiate overdose.

Chief patron: O'Bannon

Summary as passed:

Naloxone; administration in cases of opiate overdose. Provides that a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, that a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose, and that firefighters and law-enforcement officers who have completed a training program may possess and administer naloxone. The bill also provides that a person who in good faith prescribes, dispenses, or administers naloxone or other opioid antagonist used for overdose reversal in an emergency to an individual who is believed to be experiencing or about to experience a life-threatening opioid overdose shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if acting in accordance with the provisions of § 54.1-3408 or in his role as a member of an emergency medical services agency. This bill is identical to SB 1186.

03/06/15 House: Signed by Speaker 03/07/15 Senate: Signed by President

03/10/15 House: Enrolled Bill communicated to Governor on 3/10/15

03/10/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015 03/12/15 House: Bill text as passed House and Senate reprinted (HB1458ER)

HB 1564 Schedule I drugs; adding several substances to list.

Chief patron: Garrett

Summary as introduced:

Schedule I drugs. Adds N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB), and 3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA) to Schedule I of the Drug Control Act, in accordance with the action of the Board of Pharmacy adding these substances to Schedule I pursuant to § 54.1-3443. This bill is identical to SB 1380.

02/19/15 House: Signed by Speaker 02/20/15 Senate: Signed by President

02/23/15 House: Enrolled Bill communicated to Governor on 2/23/15

02/23/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

02/25/15 House: Impact statement from VCSC (HB1564ER)

HB 1736 Wholesale distributors; notice to Board of Pharmacy when ceasing distribution of certain drugs.

Chief patron: Hodges

Summary as passed House:

Wholesale distributors; notice to Board of Pharmacy when ceasing distribution to a dispenser due to suspicious ordering. Requires a wholesale distributor or nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances to notify the Board of Pharmacy within five days of the cessation. The bill defines "suspicious orders of controlled substances," provides that a wholesale distributor or nonresident wholesale distributor shall be immune from civil liability for notifying the Board of Pharmacy unless such notice was given in bad faith or with malicious intent, and prohibits the Board of Pharmacy from imposing any disciplinary or enforcement action against a licensee or permit holder solely on the basis of such notice received from a wholesale distributor or nonresident wholesale distributor.

02/27/15 House: Impact statement from VDH (HB1736ER)

02/27/15 House: Enrolled Bill communicated to Governor on 2/27/15

02/27/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/17/15 Governor: Approved by Governor-Chapter 299 (effective 7/1/15)

03/17/15 Governor: Acts of Assembly Chapter text (CHAP0299)

HB 1737 Outsourcing facilities; new regulatory framework created for permitting.



Chief patron: Hodges

Summary as introduced:

Outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration. Creates a new regulatory framework for permitting of outsourcing facilities that compound drugs and are located within the Commonwealth and for registering nonresident outsourcing facilities in the Commonwealth.

02/27/15 House: Enrolled Bill communicated to Governor on 2/27/15

02/27/15 House: Impact statement from VDH (HB1737ER)

02/27/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/17/15 Governor: Approved by Governor-Chapter 300 (effective 7/1/15)

03/17/15 Governor: Acts of Assembly Chapter text (CHAP0300)

HB 1738 Hospices; notice to dispenser of patient's death within 48 hours.

Chief patron: Hodges

Summary as passed House:

Hospices; notice of patient's death to dispenser. Requires every hospice licensed by the Department of Health or exempt from licensure pursuant to § 32.1-162.2 with a hospice patient residing at home at the time of death to notify every pharmacy that has dispensed partial quantities of a Schedule II controlled substance for a patient with a medical diagnosis documenting a terminal illness, as authorized by federal law, within 48 hours of the patient's death.

02/26/15 House: Signed by Speaker 02/26/15 Senate: Signed by President

02/27/15 House: Enrolled Bill communicated to Governor on 2/27/15

02/27/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/02/15 House: Impact statement from VDH (HB1738ER)

HB 1750 Investigational drugs; expanded access.

Chief patron: Ransone

Summary as passed:

Expanded access to investigational drugs, biological products, and devices. Provides that a manufacturer of an investigational drug, biological product, or device may make such drug, product, or device available to a person who has a terminal condition when (i) the person has, in consultation with his treating physician, considered all other treatment options currently approved by the U.S. Food and Drug Administration and the treating physician has determined that no reasonable opportunity exists for him to participate in an ongoing clinical trial; (ii) the potential benefits of use of the investigational drug, biological product, or device to treat his terminal condition are greater than the potential risks; (iii) the person has received a recommendation from his treating physician for use of such drug, product, or device for treatment of his terminal condition; and (iv) the person has provided written informed consent. The bill provides that a manufacturer that provides such drug, product, or device may provide the drug,

product, or device free of charge or may require the person to pay costs associated with its manufacture and provides that health insurance providers may, but are not required to, provide coverage for costs associated with use of such drug, product, or device. For a health care provider who recommends an investigational drug, biological product, or device and for a manufacturer, distributor, administrator, health care provider, sponsor, or physician who manufactures, supplies, distributes, administers. prescribes, or recommends such drug, product, or device, the bill provides immunity from civil liability and provides that no claim or cause of action shall exist in any state court for claims of property, personal injury, or death caused by, arising out of, or relating to the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescription, recommendation, administration, efficacy, or use of such drug, product, or device to a person who meets eligibility under the law. The bill provides that no health care provider who recommends, prescribes, administers, distributes, or supplies an investigational drug, biological product, or device shall be deemed to have engaged in unprofessional conduct or shall be adversely affected in any decision relating to licensure on such grounds and provides that nothing shall require any person to violate or act in contravention of any federal or state law as such law relates to the prescribing, dispensing, administration, or use of an investigational drug, biological product, or device. This bill is identical to SB 732.

03/06/15 House: Impact statement from VDH (HB1750ER)

03/06/15 House: Signed by Speaker 03/07/15 Senate: Signed by President

03/10/15 House: Enrolled Bill communicated to Governor on 3/10/15

03/10/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

HB 1810 Prescription Monitoring Program; civil subpoenas.

Chief patron: Herring

Summary as passed:

Prescription Monitoring Program; subpoenas. Provides that records in possession of the Prescription Monitoring Program shall not be 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 for any reason.

03/06/15 House: Signed by Speaker 03/07/15 Senate: Signed by President

03/10/15 House: Enrolled Bill communicated to Governor on 3/10/15

03/10/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/23/15 Governor: Approved by Governor-Chapter 507 (effective 7/1/15)

HB 1839 Controlled substances; scheduling.

Chief patron: Robinson

Summary as introduced:

Scheduling of certain controlled substances. Removes hydrocodone combination products from Schedule III and classifies alfaxalone, suvorexant, and tramadol as Schedule IV controlled substances.

02/27/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/02/15 House: Impact statement from VDH (HB1839ER)

03/02/15 House: Impact statement from VCSC (HB1839ER)

03/17/15 Governor: Approved by Governor-Chapter 303 (effective 7/1/15)

03/17/15 Governor: Acts of Assembly Chapter text (CHAP0303)

HB 1841 Prescription Monitoring Program; requirements for dispensers.

Chief patron: Herring

Summary as passed House:

Prescription Monitoring Program; requirements for dispensers. Requires the Department of Health Professions to register every dispenser licensed by the Board of Pharmacy with the Prescription Monitoring Program and eliminates the requirement that such registration occur upon filing of an application for licensure or renewal of a license. The bill also limits the requirement that a prescriber who prescribes benzodiazepine or an opiate request information from the Director of the Department of Health Professions to determine what other covered substances are currently prescribed to a patient in cases in which the course of treatment is anticipated at the onset of treatment to last more than 90 days. The provisions of the bill relating to registration of dispensers become effective on January 1, 2016.

02/26/15 Senate: Signed by President

02/27/15 House: Enrolled Bill communicated to Governor on 2/27/15

02/27/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/02/15 House: Impact statement from VDH (HB1841ER)

03/23/15 Governor: Approved by Governor-Chapter 517 (effective 1/1/16 see bill)

HB 2063 Telemedicine services; provision of health care services.

Chief patron: Kilgore

Summary as passed House:

Telemedicine services; prescriptions. Amends the definition of telemedicine services to encompass the use of electronic technology or media, including interactive audio or video, for the purpose of diagnosing or treating a patient or consulting with other health care providers regarding a patient's diagnosis or treatment. The measure also provides that for the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when certain conditions are met. This bill is identical to SB 1227.

02/20/15 Senate: Signed by President

02/23/15 House: Enrolled Bill communicated to Governor on 2/23/15

02/23/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/16/15 Governor: Approved by Governor-Chapter 115 (effective 7/1/15)

03/16/15 Governor: Acts of Assembly Chapter text (CHAP0115)

HB 2192 Practitioners of the healing arts; prohibits dispensing controlled substances unless licensed.

Chief patron: Garrett

Summary as passed House:

Board of Pharmacy; practitioners dispensing controlled substances. Prohibits a practitioner of the healing arts from dispensing controlled substances unless licensed by the Board of Pharmacy to sell controlled substances. The bill requires facilities from which practitioners of the healing arts dispense controlled substances to obtain a permit from the Board but exempts facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances from fees associated with obtaining and renewing such permit. The bill also requires the Board of Pharmacy to promulgate regulations to implement the provisions of this act within 280 days of its enactment.

02/20/15 Senate: Signed by President

02/23/15 House: Enrolled Bill communicated to Governor on 2/23/15

02/23/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/16/15 Governor: Approved by Governor-Chapter 117 (effective 7/1/15)

03/16/15 Governor: Acts of Assembly Chapter text (CHAP0117)

SB 817 Prescription Monitoring Program; disclosure of information.

Chief patron: Howell

Summary as passed Senate:

Prescription Monitoring Program; disclosure of information. Requires the Director of the Department of Health Professions to disclose information from the Prescription Monitoring Program relevant to a specific investigation, supervision, or monitoring of a specific recipient for purposes of the administration of criminal justice to a probation or parole officer or local community-based probation officer who has completed the Virginia State Police Drug Diversion School designated by the Director of the Department of Corrections or his designee.

02/20/15 Senate: Signed by President

02/23/15 Senate: Enrolled Bill Communicated to Governor on 2/23/15

02/23/15 Governor: Governor's Action Deadline Midnight, Sunday, March 29, 2015

03/16/15 Governor: Approved by Governor-Chapter 118 (effective 7/1/15)

03/16/15 Governor: Acts of Assembly Chapter text (CHAP0118)

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

2 An Act to amend and reenact § 54.1-2523 of the Code of Virginia, relating to Prescription Monitoring Program; subpoenas.

Approved

[H 1810]

-1pp101

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2523 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Records in possession of the Prescription Monitoring Program shall not be 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 for any reason. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in

compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to 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 to conduct drug diversion investigations pursuant to § 54.1-3405.

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 regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency 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 discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription 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 Virginia Medicaid program or information relevant to an investigation relating to a specific recipient 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 Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.
- 6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.
- 7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, 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 subdivision.
- 8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Program, to that prescriber.
- D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.
- E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.
- F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, 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 subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

VIRGINIA ACTS OF ASSEMBLY --- CHAPTER

An Act to amend and reenact § 54.1-2522.1, as it shall become effective, of the Code of Virginia and to 2 amend the Code of Virginia by adding a section numbered 54.1-2522.2, relating to the Prescription 3 Monitoring Program; requirements for dispensers.

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[H 1841]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2522.1, as it shall become effective, of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-2522.2 as follows:

§ 54.1-2522.1. (Effective July 1, 2015) Requirements of prescribers.

A. 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.

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 and for which a treatment agreement is entered into, 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.

§ 54.1-2522.2. Requirements for dispensers.

The Department shall register every dispenser licensed by the Board of Pharmacy pursuant to Article 3 (§ 54.1-3310 et seq.) of Chapter 33 with the Prescription Monitoring Program.

2. That the provisions of this act amending subsection A of § 54.1-2522.1 of the Code of Virginia and adding a section numbered 54.1-2522.2 shall become effective on January 1, 2016.

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 118

An Act to amend and reenact § 54.1-2523 of the Code of Virginia, relating to Prescription Monitoring Program; disclosure of information.

[S 817]

Approved March 16, 2015

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2523 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in

compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to 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 to conduct drug diversion investigations pursuant to § 54.1-3405.

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 regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of

4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.

5. Information relevant to a specific investigation, supervision, or monitoring of a specific recipient for purposes of the administration of criminal justice pursuant to Chapter 1 (§ 9.1-100 et seq.) of Title 9.1 to a probation or parole officer as described in Article 2 (\S 53.1-141 et seq.) of Chapter 4 of Title 53.1 or a local community-based probation officer as described in \S 9.1-176.1 who has completed the Virginia State Police Drug Diversion School designated by the Director of the Department of Corrections or his designee.

C. In accordance with the Department's regulations and applicable federal law and regulations, the

Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be

requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription 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 Virginia Medicaid program or information relevant to an investigation relating to a specific recipient 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 Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.

6. Information relevant to determination of the cause of death of a specific recipient to the designated

employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, 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 subdivision.

8. Information relating to prescriptions for covered substances issued by a specific prescriber, which

have been dispensed and reported to the Program, to that prescriber.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the

divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, 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 subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

IMPLEMENTATION PLAN:

AUTOMATED REGISTRATION OF PRESCRIBERS AND PHARMACISTS FOR USE OF THE PRESCRIPTION MONITORING PROGRAM

1. Purpose: HB1841 passed by the 2015 General Assembly becomes effective July 1, 2015 and requires the Department of Health Professions (DHP) to register prescribers and pharmacist for the Prescription Monitoring Program (PMP) by January 1, 2016. This bill removes the barrier to registration caused by the need of a separate registration for the PMP by using information already collected and maintained as part of the licensing process.

2. Registration Process:

- a. DHP IT staff will create a process to create a "batch file" of selected license types from the licensing system to be registered with the PMP (see timetable below). Additionally, newly approved and/or renewed licenses for prescribers and pharmacists will be added to this batch file on either a daily or weekly basis.
- b. The PMP application will receive this batch file via a web service application and process the registration for those licensees that are not currently registered with the PMP. If there is not enough information to process the registration, a pending file will be created for manual follow-up by PMP staff. **NOTE**: a valid email address is a requirement of the PMP application.
- c. Once the system creates a new registration, an email with the username and a temporary password is sent to the licensee. The licensee upon logging into the PMP will be sent to their "User Profile" to setup security questions and to provide other information such as a DEA number, NPI number, and work phone number and Fax.

3. Timetable: (Subject to Change)

a. Optometrists—smallest group
b. Physician Assistants
c. Nurse Practitioners
d. Pharmacists
e. Dentists

July

August
August
September (see

e. Dentists September (separate from reporting requirements to reduce confusion)

f. Doctors of Osteopathy
g. Podiatrist
September

h. MDs—largest group October, November, December (by alphabetic group)

i. Renewal or approval of licensure July, then ongoing

NOTE: License groups may be registered sooner based on project success with registrations. (Dependent an amount of manual intervention required by PMP staff)

ISMP. Acute Care ISMPMedication Safety Alert !

> No unlabeled containers—continued from page 1

tragic story was featured in our short documentary film, Beyond Blame (www.ismp.org/sc?id=440), which describes how medication errors affect practitioners and patients alike. One of the film's stand-out scenes features the anesthesiologist present during the event saying, "Now I will bet any dollar that I have, that this has happened before, multiple times, same type of scenario, and I'll bet it's going to happen again." Well, he was right! Since then, ISMP and others have repeatedly published cases of mix-ups between unlabeled solutions or medications on the sterile field, including but not limited to the following examples:

- A woman was injected with hydrogen peroxide instead of lidocaine 1% for local anesthesia when both were on the sterile field in unlabeled cups. The patient suffered no adverse reaction (<u>www.ismp.org/sc?id=443</u>).
- A man was injected with lidocaine 2% instead of contrast media during angiography; both were on the sterile field in unlabeled syringes. He suffered a grand mal seizure but recovered (<u>www.ismp.org/sc?id=443</u>).
- A caustic germicidal solution (pH of 13) was mistakenly applied to the genitals of a 37-year-old male patient instead of vinegar during surgical removal of genital warts, causing severe burns (<u>www.ismp.org/sc?id=443</u>).
- A patient's face was injected with ethyl alcohol instead of lidocaine prior to a surgical procedure. Both of the clear solutions were in unlabeled basins. The patient suffered partial facial paralysis (<u>www.ismp.org/sc?id=445</u>).
- A patient had an injection site infiltrated with contrast media from an unlabeled basin instead of lidocaine for local anesthesia prior to angiography. Local tissue damage resulted (www.ismp.org/sc?id=443).
- A 60-year-old woman undergoing coil placement via cerebral angiography to repair a brain aneurysm was accidentally injected with the skin prep solution, chlorhexidine, instead of contrast media. Both clear solutions were on the sterile field in unlabeled basins. Severe chemical injury to the injection site in the patient's groin led to leg amputation, which resulted in a stroke, organ failure, and death (www.ismp.org/sc?id=444).
- A patient under general anesthesia had his knee injected with EPINEPHrine found in an unlabeled syringe on an OR prep table, which was mistaken for bupivacaine. The patient experienced a heart attack, pulmonary edema, and died (www.ismp.org/sc?id=441).

High-profile cases like these and the national attention given to unlabeled medication and solution containers by The Joint Commission, the Centers for Medicare & Medicaid Services, the US Food and Drug Administration, ISMP, and others suggest that most healthcare professionals have basic knowledge of the risks associated with unlabeled containers. Thus, repetition of this error suggests that healthcare providers have lost the perception of risk associated with unlabeled products, mistakenly believe the risk is insignificant or justified, or have forgotten to implement effective prevention strategies in all procedural areas. First, normalcy bias may cause some to falsely believe that an error would never happen to them. This leads to the mistaken belief that labeling is not always necessary or the rationalization of faulty strategies. These faulty strategies may include identifying products by where they continued on page 3—No unlabeled containers >

> SAFETY briefs cont'd from page 1

Propylene glycol is a clear, colorless, odorless, and tasteless product used as a stabilizer, thickener, and texturizer. The above product contains 103.6 g/100 mL of propylene glycol. The infant received 600,000 units of vitamin D2 equivalent to 75 mL of solution or 77.7 g of propylene glycol. According to the World Health Organization, this far exceeds the maximum tolerable amount of 25 mg/kg/day (or 227.5 mg for the baby in this event). In fact, the baby was exposed to 340 times the maximum amount, which led to acute renal failure. The infant's serum creatinine rose from 0.22 mg/dL to 3 mg/dL. Fortunately, the child survived. Renal toxicity has occurred in neonates who were given HIV medications such as KALETRA (lopinavir/ritonavir) oral solution, which also uses propylene glycol as a carrier given the lack of better alternatives for solubility of this drug (www.ismp.org/sc?id=442).

As a dietary supplement, vitamins are regulated by the US Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN). FDA, which received this error report, should require manufacturers to state the propylene glycol ingredient more prominently on the label, including the amount in the container. Since all liquid vitamin D2 products have propylene glycol, consider preparing an approximate dose for stoss therapy from vitamin D2 liquid filled capsules that do not contain propylene glycol. Computer systems should warn staff about excessive propylene glycol and the potential for renal toxicity with pediatric patients.

State drug tracking database helps prevent an error. Many states have been working to reduce prescription drug abuse, overdose, and misuse by enacting legislation to set up scheduled drug electronic tracking programs. Doctors and pharmacists can access the program database to prevent an individual from going from doctor to doctor to obtain controlled drugs. A report we received recently shows how these systems can also protect patients

continued on page 3-SAFETY briefs >

against medication errors.

> No unlabeled containers—continued from page 2

are placed on the sterile field and overreliance on immediate use before the container leaves one's hands. Or, unlabeled containers may be considered "someone else's problem," a phenomenon similar to bystander apathy that causes people to ignore a problem because they believe it is not relevant to them, unlikely to happen, something they can't fix, or someone else's responsibility to fix. Additionally, some may believe they have implemented the perfect labeling procedures only to find partial compliance because the task is tedious, error-prone, or impractical without system changes.

Results from the **2011 ISMP Medication Safety Self Assessment for Hospitals** (N=1,310 hospitals) showed that 1% of participating hospitals **never** labeled containers of solutions or medications on the sterile field; 24% labeled containers **inconsistently**; and only 73% reported **full compliance** with this important safety practice. Compliance may not be significantly better today, 3 years later.

SAFE PRACTICE RECOMMENDATIONS: Will the next victim be in your hospital? Or, will you improve your labeling practices? While you may not have experienced a serious sentinel event despite poor labeling practices, you shouldn't wait until a patient is harmed in your facility to take action. Consider the following:

Provide labels. Make labeling easy by purchasing sterile markers, blank labels, and preprinted labels prepared by the facility or a commercial vendor that can be opened onto the sterile field during all procedures in all areas and used effectively on syringes, basins, bowls, and cups. To minimize staff time, prepare surgical packs ahead of time with sterile markers, blank labels, and preprinted labels for all anticipated medications and solutions that will be needed for the case.

Require labels. In **all** patient care areas, require labels on **all** medications, medication containers (e.g., syringes, medicine cups, basins), and other solutions on (and off) the sterile field, even if there is only one medication or solution involved. Also require labels on all solutions, chemicals, and reagents (e.g., formalin, saline, Lugol's solution, radiocontrast media) that are used in perioperative and procedural units, or in other units where procedures might be performed.

Differentiate look-alike names and products. If drug or solution names are similar, use tall man lettering on the labels to differentiate them, or highlight/circle the distinguishing information on the label. When possible, purchase skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or other solutions.

Label one at a time. Individually verify each medication and complete its preparation for administration, delivery to the sterile field, and labeling on the field at the time of preparation, **before** another medication is prepared.

Confirm medications and labels. Before preparing a medication or solution listed on a physician's preference list, verify with the physician that it will be required for the procedure and needed on the sterile field. When preparing the medication or solutions for the procedure, require the scrub person, the circulating nurse, or a second practitioner involved in the procedure to concurrently verify all medications/solutions visually and verbally by reading the product name, strength, and dosage from the labels. (If there is no scrub person, the circulating nurse or other nurse should verify the medication/solution with the licensed professional performing the procedure.) During the procedure, when passing a medication to the licensed professional percontinued on page 4—No unlabeled containers >

> **SAFETY** briefs cont'd from page 2

A patient admitted during the night through the emergency department (ED) had a home medication list that included a DURAGESIC (fentaNYL) 100 mcg patch, which was circled to be continued on admission, Upon checking the state prescription database to verify that the patient was receiving 100 mcg regularly, the pharmacist noticed that the patient hadn't filled a prescription for the patches in the past 4 months. After confirming with the ED nurse that the patient was not currently wearing a patch, the pharmacist did not feel comfortable dispensing the pain medication when it hadn't been used in months, meaning the patient was essentially opioid naïve by then. The pharmacist entered a note to "clarify home med," and the hospitalist discontinued the order for the patch. Of note, the patient went to surgery the next day and the home medication list was printed. Unfortunately, the pharmacist and hospitalist who knew the fentaNYL patch was not a recent home medication did not delete or clarify the entry on the home medication list. The surgeon circled Duragesic patch on the home medication list to continue its use. The same pharmacist happened to receive the postoperative orders and, again, did not dispense the patch. The Duragesic patch was not continued upon discharge.

This is a great illustration of the safety potential in reviewing a state scheduled drug database when a new patient is admitted with a controlled substance prescription. This enabled the pharmacist to detect a potentially dangerous medication error.

Where did this come from? A hospital reported several occurrences in which medications not purchased or provided by the pharmacy made their way into the hospital supply, including on pharmacy shelves and in automated dispensing cabinets (ADCs). Recent examples include lidocaine ampuls that came from an IV line insertion kit and a heparin flush syringe brought in from home by a patient's family. Likewise, doctors sometimes bring unauthorized medications into the hospital to use for a patient.

continued on page 4—SAFETY briefs >

DRAFT Legislative proposal for 2016 General Assembly

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

- B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:
- 1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to 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 to conduct drug diversion investigations pursuant to § 54.1-3405.
- 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 regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).
- 3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.
- 4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency 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 discretion, disclose:
- 1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.
- 2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the when a prescriber is consulting on or initiating treatment of such a specific recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.
- 3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices or to a pharmacist for the purpose of providing clinical consultation on the care and treatment of the recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription 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 Virginia Medicaid program or information relevant to an investigation relating to a specific recipient 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 Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.
- 6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

- 7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, 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 subdivision.
- 8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Program, to that prescriber.
- D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.
- E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.
- F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, 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 subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

DRAFT Legislation Proposal for 2016 General Assembly

§ 54.1-2521. Reporting requirements.

- A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.
- B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:
- 1. The recipient's name and address.
- 2. The recipient's date of birth.
- 3. The covered substance that was dispensed to the recipient.
- 4. The quantity of the covered substance that was dispensed.
- 5. The date of the dispensing.
- 6. The prescriber's identifier number.
- 7. The dispenser's identifier number.
- 8. The method of payment for the prescription.
- 9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.
- 10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.
- C. Data shall be transmitted to the Department or its agent within 24 hours or the next business day whichever comes later.
- C.D The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

DRAFT Regulation Proposal

18VAC76-20-40. Standards for the manner and format of reports and a schedule for reporting.

- A. Data shall be transmitted to the department or its agent within seven days 24 hours or the next business day whichever comes later of dispensing as provided in the Electronic Reporting Standard for Prescription Monitoring Programs, Version 4.1 (November 2009) Version 4.2 (2011) of the American Society of Automation in Pharmacy (ASAP), which are hereby incorporated by reference into this chapter.
- B. Data shall be transmitted in a file layout provided by the department and shall be transmitted by a media acceptable to the vendor contracted by the director for the program. Such transmission shall begin on a date specified by the director, no less than 30 days from notification by the director to dispensers required to report.
- C. Under extraordinary circumstances, an alternative means of reporting may be approved by the director.
- D. Data not accepted by the vendor due to a substantial number of errors or omissions shall be corrected and resubmitted to the vendor within five business days of receiving notification that the submitted data had an unacceptable number of errors or problems.
- E. Required data elements shall include those listed in subsection B of § 54.1-2521 of the Code of Virginia and the following:
- 1. The Drug Enforcement Administration (DEA) registration number of the dispenser;
- 2. The total number of refills ordered;
- 3. Whether the prescription is a new prescription or a refill; and
- 4. The date the prescription was written by the prescriber.
- 5. The National Provider Identifier of the prescriber when prescribing for human patients.
- 6. The Species Code of the recipient of the prescription.
- 7. The Electronic Prescription Reference Number, if applicable.
- 8. Partial Fill Indicator
- 9. Gender Code of Patient

Ratio of VSP Division Rate to Statewide Rate 2013 Prescription Opioid Measures

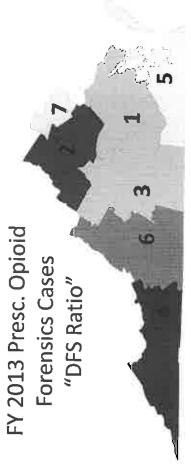


www.dcjs.virginia.gov

CY 2013 Drug/Poison Deaths, Top 4 Presc. Opioids "OCME Ratio"

July 2013 Recipients of **Opioid Prescriptions** "PMP Ratio"

- highest rate across all three measures (2- Division 4 (Southwest VA) had the 3 times the statewide rate)
- highest PMP rate, its OCME and DFS rates Although Division 3 had the second were no higher than the state's
- Division 6 had the second highest OCME rate, and third highest PMP and DFS



APPENDIX 3

 $\mathbf{5}$ Preliminary analysis. Not for distribution, citation, or attribution.

De-identified PMP Data Preliminary Findings

Sources of Opioid Prescriptions Filled in Virginia Pharmacies



www.dcjs.virginia.gov

months of 2010 & locations, first six Change in # of opioid presc. from various

100.0%

%0.06

80.0%

70.0%

• VA up 5%

%0.09

50.0%

Originating From Each Location Proportion of Va. Opioid Prescriptions

- TN up 22%
- NC down 37%
- MD down 14%

40.0%

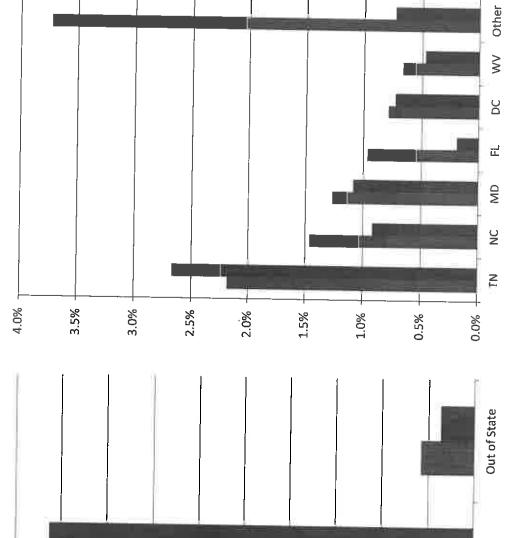
30.0%

20.0%

10.0%

%0.0

- FL down 80%
- WV down 29% DC down 8%
- All other down



■ Jan-Jun 2014 Jan-Jun 2010

Preliminary analysis. Not for distribution, citation, or attribution.



COMMONWEALTH OF VIRGINIA

Department of Health Professions Prescription Monitoring Program

9960 Mayland Drive, Suite 300 Richmond, VA 23233-1463

Phone: (804) 367-4566 Fax: (804) 527-4470)

REQUEST FOR DISCLOSURE OF INFORMATION FROM PRESCRIPTION MONITORING PROGRAM FOR RESEARCH

Please provide the information re	equested below. (Print or Type) Use full name not initials
Person Responsible for Study:	
Organization:	
Street Address:	
City, State, Zip Code:	
Area Code and Telephone Number	
Fax Number:	
Specific time period to be covered	d in report:
THE FOLLOWING	TEMS MUST ACCOMPANY THE REQUEST FOR INFORMATION
The purpose/goal of study: Specific data elements requested: (Note: Personal Information such The target audience: Sponsoring Organizations: CV for person responsible for stud	as name and address will not be released.)
I hereby attest that the requested stated in the request and in accordance	d information will not be further disclosed and will only be used for the purposes dance with the law.
Signature:	Date:
	For Department Use Only
Date Received	Date of Action



OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614/466-4143

E-MAIL: exec@bop.ohio.gov

FAX: 614/752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750

URL: http://www.pharmacy.ohio.gov

March 26, 2015

Contact Name Company Name Address CSZ

Dear Contact:

Thank you for your interest in obtaining information from the Ohio Automated Rx Reporting System (OARRS) for the purpose of research and education. Please use this information packet as a guide for submitting a formal request for de-identified research data from OARRS. Doing so will ensure that your request complies with all state and federal laws, rules and regulations as well as the policies set forth by the Ohio State Board of Pharmacy.

In order to request OARRS data for the purpose of research and education, you must submit a written request for the information in the form of a Memorandum of Understanding (MOU). The MOU must be accompanied by written approval from and Institutional Review Board (IRB). The MOU (see attachment "Sample Memorandum of Understanding) must include the following:

- The reason for the study and anticipated outcome (i.e., publication, presentation at scientific meeting, etc.)
- Data File Format. See section, "Data File Format" of attachment "Sample Memorandum of Understanding".
 This is the standard format for research data provided by OARRS. Deviations from this file format will require compensation to the Board at a rate of \$100 per hour.
- Time period requested
- Agreement that use of the data is limited to the protocol terms. If data is to be re-used, a separate request
 must be made.
- A date of expiration not greater than two (2) years from the date the MOU is signed
- Agreement that the data cannot be transferred/shared with anyone outside the specific research project for which it is approved
- Agreement that the research project or any resulting publications, documents or presentations may not use the name, seal or logo of the Ohio State Board of Pharmacy, Ohio Automated Rx Reporting System or the State of Ohio without prior written authorization by the Ohio State Board of Pharmacy. Such authorization will only be provided upon review of the final product to be published or presented.

Thank you,

Chad Garner
Director of OARRS, Ohio State Board of Pharmacy

MEMORANDUM OF UNDERSTANDING BETWEEN COMPANY NAME AND THE OHIO STATE BOARD OF PHARMACY

COMPANY NAME (Company) and the Ohio State Board of Pharmacy (OSBP) enter into this Memorandum of Understanding (MOU) concerning the *Project Title* project effective March 26, 2015.

1. Background and Purpose

State the background and purpose of the project here.

2. Project Goals

State all goals and deliverables (i.e. publication, presentation at scientific meeting, etc.) here.

3. Term

The term of this MOU will begin on the Effective Data and continue for two (2) years, expiring thereafter. This MOU may be terminated by either party on fourteen (14) days prior written notice.

4. Responsibilities of the Parties

The OSBP shall provide Company with electronic data files relevant to this research effort as described in subsequent section "Data File Format" and shall deliver it in the method described in subsequent section "Method of Delivery". OSBP shall de-identify the data so that no individual or business may be identified. Each patient, prescriber, and pharmacy will be described by a unique value that is consistent throughout the dataset.

Company will share the research results related to OSBP data with the OSBP.

5. Data File Format

Data shall be provided by OSBP to Company in the format of a text file. Data fields shall be separated by a single pipe (|) character. Individual prescription records shall be separated by carriage return and line feed. The first row will contain column headers. The data will be separated into separate files by standard calendar quarter. The following fields will be included in the data set:

1. DateFilled

Type: Date (MM/dd/yyyy)

Desc: The date the prescription was filled by the pharmacist

2. RxNumber

Type: VarChar

Desc: The prescription number assigned by the pharmacy

3. RefillCode

Type: Integer

Desc: The refill number. 0=new

4. Quantity

Type: Float

Desc: The "amount" of drug dispensed. This field should be combined with the form and the strength (found in the Redbook table) in order to accurately determine the milligram quantity of drug dispensed.

5. DaysSupply

Type: Float

Desc: The number of days the prescription should last if taken per prescriber's orders

6. NDC

Type: VarChar

Desc: National Drug Code

6.1 DRUG

Type: VarChar

Desc: The name of the drug, followed by the strength and form of the drug (e.g.

Dextroamphetamine 30mg TER)

7. DateWritten

Type: Date (MM/dd/yyyy)

Desc: The date the prescription was written by the prescriber

8. NumofRefillsAuth

Type: Integer

Desc: The number of times the prescriber has authorized the pharmacy to refill the prescription

9. PaymentType

Type: Integer

Desc: The primary method of payment for the prescription: 1 - Private Pay (Cash), 2 - Medicaid, 3 - Medicare, 4 - Commercial PBM Insurance, 5 - Major Medical, 6 - Worker's Compensation

10. PharmacyHash

Type: STRING

Desc: Unique identification for the pharmacy

11. PharmacyZip

Type: String

Desc: First three digits of the pharmacy's zip code

12. PharmacyBACCode

Type: String

Desc: Business Activity Code - See table below

13. PharmacyBACSubCode

Type: String

Desc: Business Activity SubCode - See table below

14. PrescriberHash

Type: STRING

Desc: Unique identification for the prescriber

15. PrescriberZip

Type: String

Desc: First three digits of the prescriber's zip code

16. PrescriberBACCode

Type: String

Desc: Business Activity Code - See table below

17. PrescriberBACSubCode

Type: String

Desc: Business Activity SubCode - See table below

18. PatientGroupIDHash

Type: STRING

Desc: Identifier of a patient

19. PatientAge

Type: Integer

Desc: Age of the patient at the time of dispensing

20. PatientSex

Type: Integer

Desc: 1-Male; 2-Female

21. PatientZip

Type: String

Desc: First three digits of patient's zip code

BAC	Sub Code	Description
A	0 Sub Code	Description
	_	RETAIL PHARMACY
A	1	CENTRAL FILL PHARMACY
Α	3	CHAIN PHARMACY
A	44	AUTOMATED DISPENSING SYSTEM
В	0	HOSPITAL/CLINIC
С	0	PRACTITIONER
С	1	PRACTITIONER-DW/30
С	2	PRACTITIONER-MILITARY
С	3	MLP-MILITARY
С	4	PRACTITIONER-DW/100
D	0	TEACHING INSTITUTION
Ε	0	MANUFACTURER
E	1	MANUFACTURER (C I,II BULK)
F	0	DISTRIBUTOR
G	0	RESEARCHER
G	1	CANINE HANDLER
Н	0	ANALYTICAL LAB
J	0	IMPORTER
J	1	IMPORTER (C I,II)
K	0	EXPORTER
L	0	REVERSE DISTRIBUTOR
M	1	MLP-AMBULANCE SERVICE
М	2	MLP-ANIMAL SHELTER
М	3	MLP-DR OF ORIENTAL MEDICINE

м	4	MLP-DOS
M	5	MLP-EUTHANASIA TECHNICIAN
M	6	MLP-HOMEOPATHIC PHYSICIAN
M	7	MLP-MEDICAL PSYCHOLOGIST
M	8	MLP-NATUROPATHIC PHYSICIAN
M	9	MLP-NURSING HOME
M	Α	MLP-NURSE PRACTIONER
M	В	MLP-OPTOMETRIST
M	С	MLP-PHYSICIAN ASSISTANT
M	D	MLP-REGISTERED PHARMACIST
N	0	MAINTENANCE
Р	0	DETOXIFICATION
R	0	MAINTENANCE & DETOX
S	0	COMPOUNDER/MAINTENANCE
Т	0	COMPOUNDER/DETOXIFICATION
U	0	COMPOUNDER/MAINT & DETOX

6. Time Period

Data files provided by the OSBP shall include prescriptions dispensed between January 1, 2008 and the current date. Subsequent data files will be provided by the OSBP to Company upon written request, but not more frequent than every six (6) months.

7. Method of Delivery

The OSBP shall deliver the data files on recordable DVD media by United States Postal Mail to the following address:

Mr. John Doe Attn: Your Company Your Street Address City, State, Zip

8. Warranty

All information provided under the terms of this MOU is provided "AS IS". The OSBP makes no warranty, express or implied, as to the accuracy, capability, efficiency, merchantability, fitness for a particular purpose, of functioning of the product. In no event will the OSBP be liable for any general, consequential, indirect, incidental, exemplary or special damages, even if either party has been advised of the possibility of such damages.

9. Indemnification

Both parties enter into this MOU on the condition that each indemnifies and holds harmless each other, its Directors, Trustees, officers, agents and employees, from any and all liability or damages, whatever the cause, to each other or third parties, including attorney's fees, court costs, and other related costs and expenses, arising out of (1) the efforts performed pursuant to this MOU and/or (2) any third party allegations that information provided by one party to the other infringes any rights in copyright, trade secret, or patent.

10. Proprietary and Confidential Information

Proprietary and Confidential information shall include, but not be limited to, products, processes, analyses, technologies, source codes, innovative concepts and ideas, product development plans, customer information

information whose dissemination is restricted through a prior agreement and other valuable information marked by the owner as proprietary and confidential.

Proprietary and Confidential information does not include information which:

- Was already known or independently developed by the recipient;
- Is already available or becomes available to the public by no fault of the recipient;
- Was received by a third party who was free to disclose it.

Each team member of either party who is involved with the work address by this MOU shall be informed of his/her obligations of confidentiality.

All information (including Proprietary and Confidential Information) obtained by either party shall be returned to it, or destroyed, promptly upon request, together will all copies made thereof by the receiving party.

11. Representation

Company shall refrain from using the name, acronym, seal or logo of the Ohio State Board of Pharmacy, Ohio Automated Rx Reporting System or State of Ohio in any public communication, both written and verbal, with the public regarding the planning, implementation or final product of the project governed by this MOU, except as permitted in writing by the Ohio State Board of Pharmacy. Such permission may be requested in writing, to the Ohio State Board of Pharmacy.

12. Ownership

Each party acknowledges that the items noted in Section 2 and Section 4 of this MOU and any Proprietary and Confidential Information provided by the other party shall remain the sole and exclusive property of the providing party which holds the title to and all proprietary rights, including copyright and trade secret rights, in such information. The parties shall share joint ownership of any intellectual property which may be developed in the course of activities under this MOU. De-identified information provided by OSBP is not a public record and may not be transferred or shared with any party not involved in the project governed by this MOU. Use of the data provided by OSBP to Company may be used solely for the purpose of reaching the goals noted in Section 2. Any other use of the data shall require a separate MOU.

13. Entire Agreement

The MOU constitutes the entire agreement between the parties with respect to the subject matter contained herin. This MOU supersedes all prior understands and agreements between the parties with respect to the subject matter contained herin. This MOU and the rights and obligations herunder may not be modified, amended, or waived, whether in whole or in part, except by a writing signed by authorized representatives of both parties.

14. Independent Entities

Nothing in this MOU shall create any partnership or joint venture between the parties and neither party shall have the authority to bind the other with respect to any third party.

15. Disputes

Any unresolved dispute, controversy, or claim between the Parties arising under this MOU, including the breach, termination or validity thereof, shall be finally settled by arbitration, conducted on a confidential basis, under the then current commercial arbitration rules of the American Arbitration Association.

16. Applicable Law

This MOU shall be governed by the laws of the State of Ohio.



17. Notices

All notices pertaining to or required by this MOU shall be in writing and shall be signed by an authorized representative and shall be deliver by hand or sent by mail addressed as follows:

If Company Name:

Mr. John Doe Attn: Your Company Your Street Address City, State, Zip

If the Ohio State Board of Pharmacy:

OARRS Contact
Ohio Automated Rx Reporting System
Ohio State Board of Pharmacy
77 South High Street Room 1702
Columbus, OH 43215

effective as of	lum of Understanding with the intent that it be
Ohio State Board of Pharmacy	Company Name
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:



New Mexico Regulation and Licensing Department BOARDS AND COMMISSIONS DIVISION

Board of Pharmacy

5200 Oakland Avenue, NE * Suite A * Albuquerque, New Mexico 87113 (505) 222-9830 * Fax (505) 222-9845 * (800) 565-9102 www.rld.state.nm.us/boards/pharmacy.aspx

REQUEST FOR DATA FROM THE NEW MEXICO PRESCRIPTION MONITORING PROGRAM (PMP) FOR APPROVED RESEARCH PURPOSE(S)

In order to address your request for data from the New Mexico PMP, please note the following process and provide the required information.

Your request for data must be reviewed and approved by the following:

- 1. The New Mexico PMP Director
- 2. The New Mexico Board of Pharmacy at next scheduled meeting
- 3. The New Mexico Department of Health

All entities must feel comfortable that the information will be used in accordance with appropriate research study goals, that necessary secure data transport, storage, access and disposal measures will be utilized and that the results will be reported back to the state prior to dissemination if requested.

All data will be supplied as de-identified.

Please supply the below information:

Your Name and Contact Info					
Your Institution:					
PI for Study:					
IRB Approval?	Yes	O No	Explain:		



New Mexico Regulation and Licensing Department BOARDS AND COMMISSIONS DIVISION Board of Pharmacy 5200 Oakland Avenue, NE = Suire A = Albuquerque, New Mexico 87113 (505) 222-9830 = Fax (505) 222-9845 = (800) 565-9102 www.rld.statc.nm.us/boards/pharmacy.aspx

Purpose of Study:	
Protocol (what uses will be made of the data? How will it be reported?)	
What data do you seek? (be as specific as possible)	_
	_
If you desire sub-state data, please provide a justification.	
7. See See See See See See See See See Se	
What time period do you desire?	
What is your preferred format in which to receive the data?	



New Mexico Regulation and Licensing Department BOARDS AND COMMISSIONS DIVISION

Board of Pharmacy

5200 Oakland Avenue, NE = Suite A = Albuquerque, New Mexico 87113 (505) 222-9830 = Fax (505) 222-9845 = (800) 565-9102 www.rld.state.nm.us/boards/pharmacy.aspx

г	Describe the security measures you will employ regarding data transport, storage, access and disposal
	If New Mexico specific data is to be presented as part of the study, do you agree that the New Mexico- specific results will be reported back to the state for review and approval prior to dissemination?
(Yes No Explain:
	Additional Notes:
Ē	The state of the s

You may also attach any supporting information regarding your research study. Please submit all materials via email to Carl Flansbaum, PMP Director at Carl.Flansbaum@state.nm.us.



Arizona State Board of Pharmacy
Controlled Substances Prescription Monitoring Program
P.O. Box 18520
Phoenix, Arizona 85005-8520
602-771-2744 Fax 602-771-2748
https://pharmacypmp.az.gov

By using these data you agree to comply with the following data use restrictions.

Arizona Revised Statute 36-2604(D) allows Controlled Substances Prescription Monitoring Program (CSPMP) information to be shared for statistical or research purposes. Any other disclosure of CSPMP information to an unauthorized person is strictly prohibited. Any effort to determine the identity of a reported case in this dataset is a felony under ARS § 36-2610(D). ARS § 36-2604 describes allowed use of CSPMP information. The Arizona State Board of Pharmacy (ASBP) CSPMP does all it can to assure that the identity of data subjects cannot be disclosed. All direct identifiers including name, address, phone number, and DOB, as well as any characteristics that might lead to identification, are omitted from the dataset. Users shall not attempt to identify individuals from any computer file nor shall they link with a computer file containing patient identifiers. Any published results MUST be presented in a manner which ensures that individual patient identifiers are not included in reports or manuscripts. Any intentional identification or disclosure of a person or establishment violates the assurances of confidentiality given to the providers of the information.

Therefore, users must agree to these provisions:

- You will not use nor permit others to use the data in any way other than for statistical reporting and analysis
 purposes as summarized in the attached summary.
- You will not present/publish data in which an individual is identified. Small cell sizes should span large areas, groupings, or time frames that make identification of an individual highly unlikely.
- You will not attempt to link nor permit others to link the data with individually identified records in other ASBP or non-ASBP datasets.
- You will not attempt to learn the identity of any person whose data is contained in the supplied file(s).
- If the identity of any person is discovered inadvertently, then the following action should be taken:
 - o no use will be made of this knowledge
 - ASBP/CSPMP will be notified of the incident
 - o you will not share the discovered identity with others
- You will not release nor permit others to release the data in full or in part to any person except with the written approval of ASBP/CSPMP.
- If accessing the data from a centralized location on a time-sharing computer system or LAN, you will not share your logon name and password with any other individuals. You will also not allow any other individuals to use your computer account after you have logged on with your logon name and password.
- The source of information should be cited in all publications in the following format: "Source: Arizona State Board of Pharmacy, CSPMP, YYYY-YYYY". ("YYYY" = 4-digit years of the date of dispensing).
- Share any results/papers/findings from analysis of these data with ASBP/CSPMP before findings are presented outside the requesting organization.
 - Publication in a peer-reviewed journal may only occur after:
 - ASBP/CSPMP reviews the work to be submitted
- Be held accountable for any violation of these data use restrictions.
- Data will be returned to ASBP/CSPMP or confirmed to be destroyed at the conclusion of the project by the anticipated termination date indicated below or ASBP/CSPMP will be contacted to extend the date.

I understand and agree to comply with the above stated restrictions in my use of these data and associated documentation.

Printed Name and Signature	Date
Anticipated termination date:	Contact phone number: Email address:





DIVISION OF POLICY AND COMMUNICATIONS • P.O. BOX 2120, RICHMOND, VA 23218-2120

May 2, 2013

Contact:

Charles B. Pyle, Director of Communications (804) 371-2420 Julie C. Grimes, Communications Manager (804) 225-2775

VDOE & the Virginia Longitudinal Data System: Improving Student Outcomes & Protecting Privacy

The Virginia Longitudinal Data System (VLDS) provides state policy makers, authorized researchers and citizens with access to educational and workforce training data from multiple sources while protecting the privacy of Virginia students.

VLDS supports critical reporting on the quality of public education — such as accurate graduation and dropout rates for high schools and school divisions — while providing information that can help policy makers improve programs that prepare and connect Virginians with employment opportunities.

Data are provided by the Virginia Department of Education (VDOE), the State Council of Higher Education for Virginia (SCHEV), the Virginia Community College System (VCCS) and the Virginia Employment Commission (VEC).

The development of VLDS was funded through a Longitudinal Data Systems Grant awarded to Virginia under the American Recovery and Reinvestment Act of 2009. The federal grant allowed the commonwealth to build on VDOE's state-funded Educational Information Management System and put additional high quality data into the hands of teachers, administrators, researchers, policymakers and the public — while safeguarding the privacy of students and adults.

VLDS does not create a central database. Data are maintained separately in the databases of each participating state agency and are merged on demand in what is known as a federated longitudinal data system that protects the privacy of individuals. No agency or researcher can match the data back to an identifiable student or individual.

Does VLDS provide personally identifiable information to the federal government?

No. VLDS does not provide student-level data to the US Department of Education (USED) or any other federal agency. The commonwealth is not participating in any project to create a national or multistate database of personally identifiable student information.

As required by various federal laws, VDOE does, however, report aggregate school- and division-level information to USED. This information includes enrollment data, the percentage of students eligible for free and reduced-price meals, the percentage of students meeting state proficiency standards and other school- and division-level reports that do not include personally identifiable information.

How does VLDS protect the privacy of Virginia students and their families?

VLDS uses a double-de-identification process developed in partnership with Virginia Tech that prevents the release of personally identifiable information, such as a student name, date of birth or state-testing identifier.

Identifiable data — such as names and birth dates — are replaced by randomly generated identifiers by each agency prior to being merged and matched by VLDS. During the merger, the agency-assigned identifiers are replaced by new VLDS-generated random identifiers. The algorithms used to generate the identifiers expire and are automatically destroyed after each inquiry, providing for unique encryption for every VLDS data merge.

Is VLDS part of the Common Core State Standards Initiative?

No. The Virginia Board of Education did not adopt the Common Core State Standards. Instruction and accountability in the commonwealth's public schools are based on the Virginia Standards of Learning.

Will recent changes in FERPA force VDOE to share personally identifiable information?

No. While the December 2, 2011, revisions to Family Educational Rights and Privacy Act (FERPA) regulations broaden the circumstances under which the sharing of personally identifiable information with researchers is allowable under federal law, FERPA does not require states to share it.

VDOE has not changed its policies that protect personally identifiable information from disclosure and has no plans to do so.

Under what conditions may researchers access data through VLDS?

All research supported by VLDS must be approved by the state agencies providing the data. Research is subject to the terms of required legal agreements prohibiting the disclosure of personally identifiable information and must be aligned with these state-identified research questions:

- How can Virginia improve high school graduation rates while increasing students' preparation for college and careers?
- How can Virginia improve the preparation, recruitment, and retention of Virginia's education personnel, including their meaningful and ongoing professional development, especially in teacher shortage areas and in hard-to-staff schools?
- How can Virginia improve state workforce-training programs?
- How can Virginia do a better job preparing young people and adults for employment opportunities and match the needs of job seekers with those of employers?

The participating state agencies guide and oversee the work of researchers to ensure accuracy and privacy.

Does VLDS allow researchers to access data about the physical characteristics, homes and personal beliefs of students and their families?

No. Information that school divisions may collect for a legitimate local purpose — such as improving the efficiency of pupil transportation — is not collected by VDOE and therefore not available through VLDS.

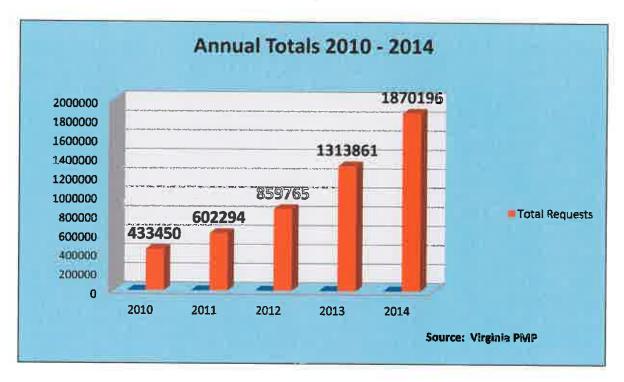
VDOE collects only the data it is required to collect under state and federal laws and regulations. The department does not collect information about students' religious beliefs, voting preferences of parents, family income, health, extracurricular activities or GIS positions of homes and school bus stops.

Where can I find more information about how VLDS supports efforts to improve educational outcomes and the training programs that prepare and connect Virginians with employment opportunities?

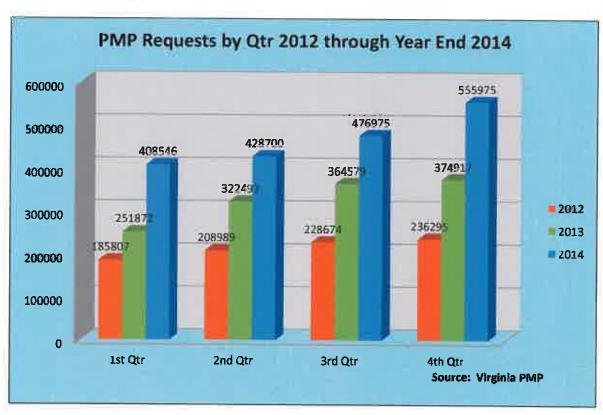
More information about VLDS — including an informative video — is available on the VDOE website at this address: http://www.doe.virginia.gov/info_management/longitudinal_data_system/index.shtml.

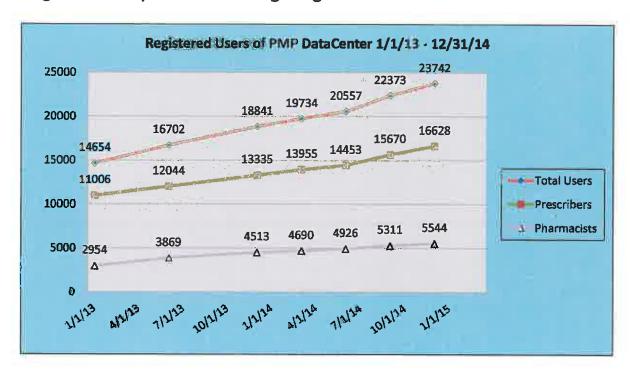
PMP De-identified Data Fields

Recipient	Prescriber	Dispenser	Prescription	Drug
Information	Information	Information	Information	Information
De-identified ID	De-identified ID	De-identified ID	De-identified	NDC
			Rx Number	Number
Year of Birth	Prescriber 5-digit Zip	Dispenser 5-digit Zip	Date Dispensed	Drug Name
Recipient 5-digit			Date Written	Drug
Zip				Strength
Recipient State			Days Supply	Drug Form
			Quantity	
			Number of	
			Refills	
			Refill Number	
			Payment	
			Method	

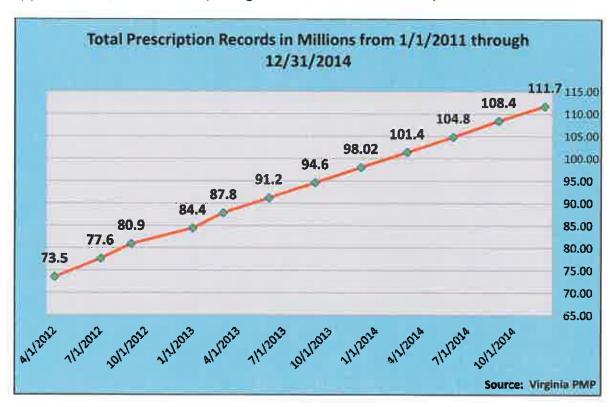


In 2013, the Virginia Prescription Monitoring Program (PMP) processed over 1.3 million requests; in 2014, the program processed over 1.8 million requests. The graph below shows the growth in processed requests by quarter.

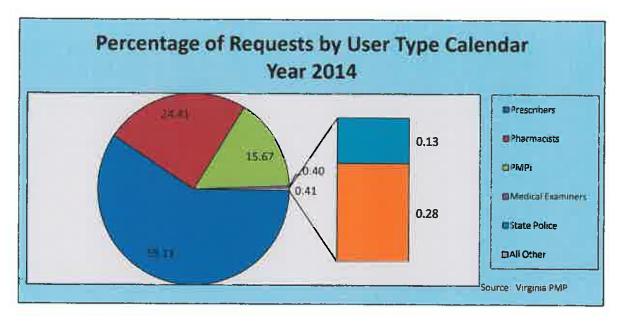




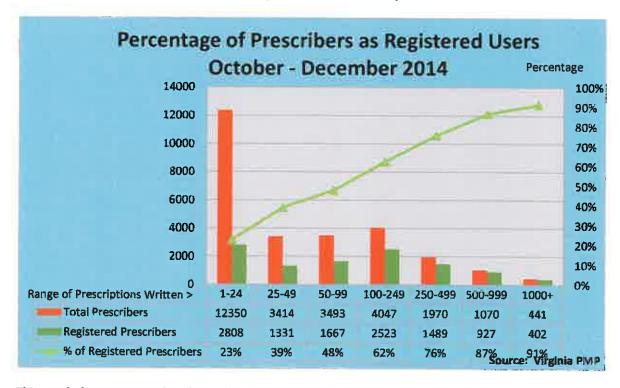
By year-end 2014, the PMP had 23,742 registered users and had enrolled 4,901 users.



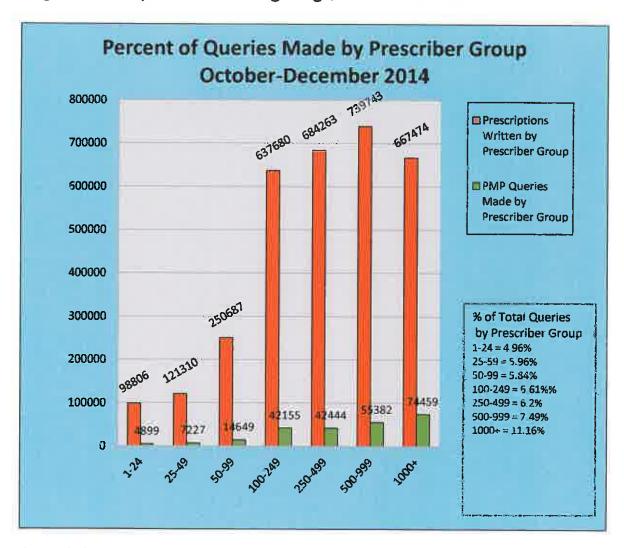
By year-end 2014, the Virginia PMP had nearly 112 million prescription records in its database.



The percentage of requests by user type continues to change based on the user mix. As more pharmacists register, their use has increased (up from 22.99% at the end of June to 24.41% at year's end). Likewise, as Virginia becomes interoperable with additional state PMP programs, the number of requests from this category (PMPi) has also increased (up from 14.84% in June to 15.67% at the end of December). Previous to 2013, prescriber requests were consistently 90% or more of the total.



This graph demonstrates that those who most frequently prescribe controlled substances are most likely to be registered users of the Virginia PMP.



This graph shows the relationship between the number of prescriptions written by each prescriber group and the number of PMP queries on individual patients made by each prescriber group.



COMMONWEALTH of VIRGINIA

Office of the Governor

William A. Hazel, Jr., MD Secretary of Health and Human Resources

January 30, 2015

Dear Prescriber:

In 2013 more Virginians died from overdose than died in auto accidents: 468 people died in Virginia from a prescription opiate overdose, and another 213 died from heroin. Since 2000, deaths from prescription drug overdoses in Virginia have more than doubled, and deaths from heroin overdoses have doubled in just the past two years.

On September 26, 2014, Governor McAuliffe established the Task Force on Prescription Drug and Heroin Abuse to combat this problem. This group, co-chaired by Secretary of Public Safety and Homeland Security Brian Moran and myself, is tasked with recommending short-term and long-term measures that can tackle prescription drug and heroin abuse and addiction, using best practices and evidence-based strategies.

The Governor and this Task Force are committed to reversing these dangerous trends, but to do so we need your help. Most people who abuse heroin begin with the illicit use of prescription drugs, and all too often properly prescribed prescription drugs end up being abused. That is why we are asking you to:

- 1. Continue to use the Prescription Monitoring Program (PMP). By checking the prescription history of patients before initiating a course of scheduled drugs, you have contributed in an almost 75% decrease in doctor shopping (i.e., patients using 5 or more prescribers and 5 or more pharmacies) since 2012. If you are not yet registered to use the PMP, here is a link.
- 2. Stay up-to-date with best practices in pain management, addiction, and opiate prescribing. Quality continuing education is available from numerous sources, such as professional associations and employer-sponsored CME. On-line courses are available, such as these from the National Institute on Drug Abuse (NIDA) and the Federation of State Medical Boards (FSMB). Also, the National Institute on Drug Abuse has a variety of Opioid Prescribing Resources.
- 3. <u>Discuss safe storage and proper disposal of controlled substances with your patients</u>. In one survey teens cited ease of obtaining drugs from home medicine cabinets as their top reason for using them. Encourage your patients to purchase a lockbox, and dispose of unused medications at take-back days or the nearest drop-off center (search here or call the DEA at 1-800-882-9539 to find a center).

PMP Prescriber January 30, 2015 Page Two

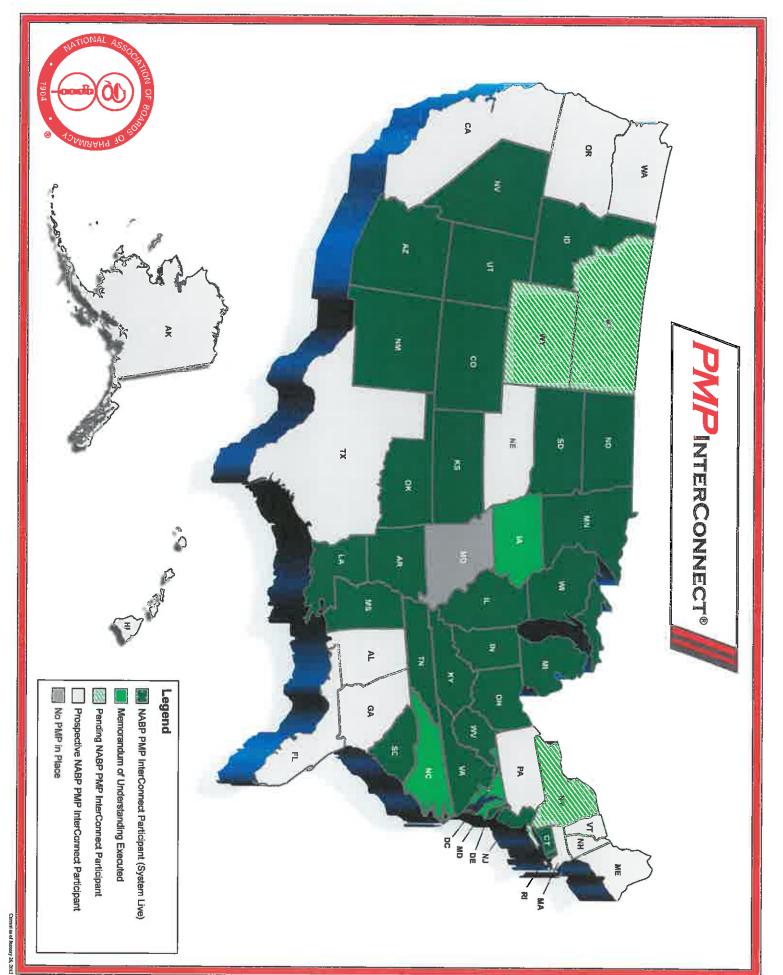
4. <u>Be mindful of the quantity of your opiate prescriptions.</u> Let's keep extra medications out of the medicine cabinet in the first place.

In addition, the Board of Medicine has adopted guidance document #85-24, on the Use of Opiate Analgesics in the Treatment of Chronic Pain, which you may find helpful.

Together we can stem the tide of prescription drug abuse. Thank you for your help.

Sincerely,

William A. Hazel, Jr., M.D.





TENNESSEE CONTROLLED SUBSTANCE MONITORING PROGRAM: BOARD OF PHARMACY - DEPARTMENT OF HEALTH

665 MAINSTREAM DRIVE **NASHVILLE, TENNESSEE 37243**

Phone:(615) 253-1305 Email:CSMD.admin@tn.gov Fax:(615) 253-8782

Patient RX History Report

Search Criteria: Page: 1 of 5 Date: 02-25-2014

Disclaimer: Information contained in the report results from the search criteria entered and incorporated by the user and from the data entered by the dispenser. Any clinical notifications incorporated into this report are the result of information submitted by the dispenser. Therefore, the Tennessee Department of Health and the Board of Pharmacy do not express or imply any warranty regarding the accuracy, adequacy, completeness, reliability, or usefulness of the data provided. Additionally, neither the Tennessee Department of Health nor the Board of Pharmacy make recommendations, or give any legal advice, to the user as to actions, if any, that might be required as a result of viewing the report or the information contained in the report.

Pt ID Patients that match search criteria Name Address

Active Cumulative Morphine Equivalent **See explanation provided at the end of the report**

40

Prescriptions

Fill Date	Product, Str, Form	Quantity D	Quantity Days Pt ID	Prescriber	Written Rx#	Rx#	Daily MED¹ Active² N/R Pham	Active ²	S S	Pharm	Pav
01/29/2014	01/29/2014 APAP/HYDROCODONE BITARTRATE, 325 MG-10 MG, TAB	120.00	30 6417	SCH ST22 NP	01/29/2014 04091015	04091015	40.00	40.00 Y	z	N FH10	2
01/29/2014	ALPRAZOLAM, 1 MG, TAB	30 00	10 6417	SCH STZZ NP	01/29/2014	4 04091016	(#)	Z	z	FH	9
12/30/2013	APAP/HYDROCODONE BITARTRATE, 325 MG-10 MG, TAB	120.00	30 6417	SCH ST22 NP	12/30/2013 04090765	04090765	40.00	z	z	FH1	04
12/30/2013	ALPRAZOLAM, 1 MG, TAB	30.00	30 6417	SCH ST22 NP	12/30/2013	04090766	ı	Z	z	FH	01
11/26/2013	APAP/HYDROCODONE BITARTRATE, 325 MG-10 MG, TAB	120.00	30 6417	SCH ST22 NP	11/26/2013	04090513	40.00	z	z	FH	2
11/26/2013	ALPRAZOLAM, 1 MG, TAB	30.00	30 6417	SCH ST22 NP	11/26/2013	04090514	18	z	z	H	01
10/09/2013	HYDROCODONE BITARTRATE AND ACETAMIN, 500 MG-10 MG,	120.00	30 6417	SCH ST22	10/09/2013 04090128	04090128	40.00	z	z	H	24



TENNESSEE CONTROLLED SUBSTANCE MONITORING PROGRAM: BOARD OF PHARMACY - DEPARTMENT OF HEALTH

665 MAINSTREAM DRIVE NASHVILLE, TENNESSEE 37243

Phone:(615) 253-1305 Email:CSMD.admin@tn.gov Fax:(615) 253-8782

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Hydromorphone	Hydrocodone	Fentanyl	Codeine	Buprenorphine	Drug
4	1	7.2	0.15	10	Morphine Equivalent Multiplier

Oxycodone

ζη ---

Methadone Morphine

Drug

Morphine Equivalent Multiplier

	04091015	RX#	US Departn	T	
	04091015 APAP/HYDROCODONE BITARTRATE, 325 MG-10 MG, TAB	Drug	US Department of Health and Human Services, Center for Disease Control	Hydromorphone 4	Hydrocodone 1
	10 MG	Strength	se Control		
	×				
	_	Multiplier		Tramadol	Oxymorphone
	×			1	пе
Active C	120.00	Quantity			
umulative	-1-				
Active Cumulative Morphine Equivalent	30	Days		0.1	ယ
ulvalent	H			ş	
40.00	40.00	Daily MED			

Subject Line: Virginia's Prescription Monitoring Program to add MEDD score to Patient Reports

Dear PMP Registered User,

Resource Links:

National Guideline Clearinghouse-- Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid therapy: http://www.guideline.gov/content.aspx?id=23792

CDC common elements in guidelines for prescribing opioids for chronic pain: http://www.cdc.gov/homeandrecreationalsafety/pdf/Common_Elements in Guidelines for Prescribing_Opioids-a.pdf

Presentation—Clinical Guidelines for Opioid Analgesic Prescribing: http://www.nascsa.org/Conference2014/Presentations/jones.pdf

MEDD Calculators:

https://www.ohiopmp.gov/portal/MED Calculator.aspx

http://agencymeddirectors.wa.gov/mobile.html

http://www.nyc.gov/html/doh/html/mental/MME.html

Please note that this score only calculates a score for opioids dispensed to a patient. It does not reflect any information on the use of any other type of controlled substance such as benzodiazepines, stimulants, or sedatives.

Additionally, if a patient does not have an active prescription for an opiate no score will be visible on the report.

Virginia PMP Summary of Unsolicited Reports 10/2014 through 2/2015

The statistics for each month from October of 2014 through February of 2015 with respect to suspected doctor shopping is summarized in the Table 1 below:

Table 1. Summary o	f Unsolicited Reports:	Individuals Suspected	d of Doctor Shopping
	Total Patients	Total Email	Total Letters Sent
	Identified	Notifications Sent	
October 2014	9	62	25
November 2014	14	45	28
December 2014	17	69	36
January 2015	49	244	110
February 2015	31	109	89
TOTAL	120	529	288

The statistics for each month from October of 2014 through December 2014 with respect to individuals suspected of doctor shopping whose reports were referred to the Virginia State Police Drug Diversion Unit for further review is summarized in Table 2 below:

Table 2. Individuals Suspected of Docto	r Shopping Sent to VSP DDU for Review
	Total Individuals Referred
October 2014	9
November 2014	3
December 2014	8
TOTAL	20

The statistics for each month from October 2014 through December of 2014 with respect to suspected forgery is summarized in Table 3 below:

Table 3. Summary	of Unsolicited Reports: Individ	luals Suspected of Forgery
	Total Patient s Identified	Total Referred to State Police
October 2014	6	1
November 2014	7	3
December 2014	4	0
TOTAL	17	4

Outreach Efforts: Virginia Prescription Monitoring Program November 13, 2014 through March 27, 2015

November 2014

- Carolyn McKann attended the Tuesday, November 18, 2014 meeting of the Rural Substance Abuse Awareness Coalition (RSAAC) of Goochland and Powhatan counties. The mission of RSAAC is to develop an alcohol and drug free community through collaborative planning, community action and policy advocacy. Participants discussed possible state funding of a school drug and alcohol survey, the development of a new non-profit focusing on opioid abuse prevention called I.W.I.N.S. (www.iwishineverstarted.org) as well as the success of October's Red Ribbon Week at Goochland Middle School.
- Ralph Orr participated in a state conference call on <u>November 20, 2014</u> for the National Governor's Association (NGA) Policy Academy on Reducing Prescription Drug Abuse. Virginia participated in the first NGA Policy Academy on this topic during 2012-2013 and created a strategy that became the impetus for Governor McAuliffe to issue Executive Order 29 to establish a Task Force on Prescription Drug and Heroin Abuse. Mr. Orr presented information on how the initial workgroup was structured, legislation that was passed in 2014 as a result of strategy recommendations, and how the strategy resulted in the Task Force being convened.

January 2015

- Ralph Orr attended the second meeting of DBHDS' Handle with C.A.R.E. Initiative on <u>January 30</u>, 2015. The agenda for the 2nd meeting included 3 presentations:
 - 1. Virginia's Substance Exposed Infant (SEI) Legislation
 - 2. Policies and procedures that guide CPS SEI investigations and responses
 - 3. SBIRT (Screening, Brief Intervention and Referral for Treatment)

March 2015

- Ralph Orr gave a presentation on the PMP to the Substance Exposed Pregnancies Interagency Workgroup on Friday, <u>March 13, 2015</u>.
- Ralph Orr met with Debbie Condrey, Chief Information Officer, VDH and representatives from ConnectVirginia on <u>March17, 2015</u> to discuss integration of PMP data with the health information exchange.
- Carolyn McKann attended the Tuesday, <u>March 24, 2015</u> meeting of the Rural Substance Abuse Awareness Coalition (RSAAC) of Goochland and Powhatan counties. Participants discussed 1) substance abuse risk factor poll results, 2) agency activities involving substance prevention and suicide prevention and 3)

substance abuse surveys including the Pride Questionnaire, parent surveys and community member surveys. The Pride Questionnaire will be administered in the fall to the local school systems, but we do not yet know whether the survey is opt-in or opt-out.

Future Endeavors:

May 2015

- Ralph Orr will give a presentation on the PMP to third year medical students at the Carilion School of Medicine.
- DHP Investigator Training during the agency-wide education meeting.

Sept 2015

• Ralph Orr will give a presentation on the PMP to the Drug Courts Association.

October 2015

 Ralph Orr will give a presentation on the PMP at the Drug Diversion School presented by the Virginia State Police and the National Association of Drug Diversion Investigators (NADDI). Summary of Exemptions from Reporting to the Virginia Prescription Monitoring Program (PMP)

As a registered user of the Virginia Prescription Monitoring Program, a prescriber may wonder why some controlled substances are not on the PMP report. The reason for this may be that the reporting of that prescription/dispensing may be exempt from reporting requirements. Therefore, it is important to be aware when making a medical treatment decision that not all of the medications dispensed to the patient are on the PMP report but there are other tools such as urine drug screens available to assist in making treatment decisions.

There are several exemptions provided in law that may cause covered substances not to be reported. Some exemptions involve programs provided by pharmaceutical companies. When a prescriber gives a patient a manufacturers' sample of a covered substance, the sample is not required to be reported. Likewise, providing a patient a covered substance offered by a pharmaceutical manufacturer as part of an indigent patient program is also not reportable to the program. However, it should be noted that these programs are usually limited to Schedule VI drugs, which are not covered substances.

Other exemptions are based on the location where care is being provided. For instance, dispensing to a patient in a bona fide medical emergency is exempt. However, prescriptions written and presented to a patient in the ER and filled elsewhere *are* reportable to the PMP. Similarly, administration of a covered substance in a physician's or dentist's office, for example, is also not reportable. Dispensing (administering) a controlled substance to a patient who is an inpatient in either a hospital, hospice or nursing home is also not reportable to the PMP. This exemption does not apply to dispensing to patients residing in Assisted Living Facilities.

One of the more important exemptions to the reporting requirement is the dispensing of covered substances within a licensed narcotic maintenance treatment program, also known as a substance abuse treatment program, or OTP. This exemption is based on a federal regulation, 42 CFR Part 2, in order to protect the identity of individuals in a substance abuse treatment program.

When veterinarians dispense controlled substances to animals in the usual course of their practice, this is not reportable to the PMP. However, a licensed pharmacy dispensing controlled substances to animals *must* report these prescriptions to the PMP.

Hopefully the scenarios described here will help prescribers to interpret the PMP report and raise awareness that the exemptions to reporting may impact a medical treatment decision involving the prescribing of controlled substances.