COMMONWEALTH OF VIRGINIA
Meeting of the Virginia Prescription Drug Monitoring Advisory Panel

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Agenda of Meeting
January 6, 2016
10:00 AM
Board Room 4
TOPIC

Call to Order: Hughes Melton, M.D., Chairman
- Welcome and introductions
- Reading of emergency evacuation script: Ralph Orr
- Approval of Agenda
- Approval of minutes [2-6]

Public Comment:

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

Legislation and Regulation Update: Elaine Yeatts [7-17]
Comments from NOIRA: [18-24]
Review of draft language for proposed regulation: [25]

Update on Utilization of PMP Data:
Phase II: Neal Kauder, VisualResearch, Inc.
PBSS Measures: Overview [26-27]
Health and Criminal Justice Data Committee Update: Ralph Orr [28-29]
PMP Utilization rates: [30-33]

Research Requests Review Process: [34-35]

Communication activities in support of PMP:

Program Update:
- Status of Task Force Recommendations [36]
- Automated Registration Update [37-38]
- Interoperability and Integration update [39-42]
- Program Statistics [43-44]

New Business

Adjourn

DRAFT

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

Wednesday, September 30, 2015

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 10:12 a.m.
PRESIDING	S. Hughes Melton, M.D., Chair
MEMBERS PRESENT:	Randall Clouse, Office of the Attorney General Holly Morris, RPh, Crittenden's Drug, Vice Chair John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C. Brenda Clarkson, Executive Director, Virginia Association for Hospices and Palliative Care Harvey Smith, 1SG, Virginia State Police Kathrin Hobron, Virginia Department of Health (for Dr. Amy Tharp)
MEMBERS ABSENT:	Dr. Amy Tharp, Office of the Chief Medical Examiner Carola Bruflat, Family Nurse Practitioner
STAFF PRESENT:	James Rutkowski, Assistant Attorney General, Office of the Attorney General Ralph A. Orr, Program Director, Prescription Monitoring Program Carolyn McKann, Deputy Director, Prescription Monitoring Program
WELCOME AND INTRODUCTIONS	Dr. Melton welcomed everyone to the meeting of the Advisory Panel and everyone introduced themselves.
APPROVAL OF MINUTES	Mr. Clouse presented a motion to approve the minutes from the July 9, 2015 PMP Advisory Panel. The minutes were approved as presented.
PUBLIC COMMENT:	No public comments were made.
APPROVAL OF AGENDA	The agenda was approved as presented.
LEGISLATION AND REGULATION UPDATE: Ralph Orr	Mr. Orr stated that all legislative items related to the PMP are still being considered. The Notice of Intended Regulatory Action (NOIRA) which would make reporting of the NPI code to the PMP mandatory has not yet been published. Mr. Rutkowski noted that once the NOIRA is published there will be a 30-day period for public comment. Once public comment has been received and reviewed specific language can be developed and

	reviewed as a proposed regulation. The entire process from NOIRA to final regulation will take at least 18 months.
REVIEW TASK FORCE RECOMMENDATIONS: Ralph Orr	Mr. Orr referred the Panel to page 7 of the agenda packet for a copy of the Data & Monitoring Workgroup's (Workgroup) Implementation Plan Updates. With respect to mandatory requests to the Virginia PMP, the Governor's Task Force requested to have exceptions reviewed and added to the recommendation. The Workgroup looked at all exceptions from all states that had some level of mandatory requests, and all agreed that the exceptions should be very simple. The recommended exceptions include: 1) do not have to query the database for the prescribing of opiates or benzodiazepines for use in hospice or palliative care situations; 2) do not have to query the database for the prescribing of opiates or benzodiazepines for short term use post-surgery when the prescription is not re-fillable; and 3) do not have to query the database when it is not available due to some temporary technological or electrical failure or natural disaster. Mr. Orr asked the Panel whether they would like to support the Workgroup's recommendations. Ms. Morris asked how the mandatory requests would be enforced and Mr. Orr responded that it would be complaint-driven. Mr. Clouse put forward the motion to support the task force recommendation and Ms. Clarkson seconded the motion and all were in favor. With respect to unsolicited reports the Workgroup recommended that unsolicited reports on outlier prescribing and dispensing be sent to law enforcement and licensing boards. The Workgroup then revised the recommendation to grant authority to the PMP to send unsolicited reports on egregious outlier prescribing and dispensing based on criteria developed by the PMP Advisory Panel. Advisory Panel members then discussed the definition of "egregious", noting that, for example, prescribers of interest may include those who attract patients from miles and miles away even though they are difficult to get to. Mr. Orr noted that regulatory boards have a lot of tools in their toolkits to discipline licensees including requiring continuing education hours in specific topic areas, Confidential Consent Agreements, fines, summary suspensions, etc., and that this would be up to their discretion. Mr. Clouse put forth a motion to have the Advisory Panel support the Workgroup's recommendation, First Sergeant Smith seconded the motion, and all were in favor. Highlighting actions from previous recommendations of the Task Force; Mr. Orr then reviewed a recent letter to Virginia healthcare providers from Dr. Marissa Levine, the State Health Commissioner regarding the current status of Virginia relating to fatal prescription opioid overdoses and promoting the recently released prescribing guidelines toolkit from the Substance Abuse and Mental Health Services Administration (SAMHSA). Mr. Clouse noted that prescribing guidelines may help PMP staff or

	law enforcement to identify suspicious activity. Dr. Barsanti asked about prescribing guidelines, noting they should be very basic (e.g., check PMP, do a urine drug screen, proceed cautiously when the MME is greater than 100, etc.). Mr. Orr then asked the Panel to look at the Prescription Behavioral Surveillance System (PBSS) measures related to an MOU recently signed with Brandeis. Participation will allow the Virginia PMP to see 43 different measures of its data and possibly see comparison data with other states. The first report should be available in January of 2016.
UPDATE ON UTILIZATION OF DE-IDENTIFIED DATA: Neal Kauder, VisualResearch, Inc.	Neal Kauder referred the Panel to page 28 of the agenda packet, referencing the summary of the suggested research and analytics plan. Mr. Kauder noted that the information within the PMP database has an error rate of less than 1%, and with millions of records there are many ways this information can be utilized. He emphasized that he would like the Advisory Panel to tell him what parameters they would like tracked. He also emphasized that indicators should be very simple. Determining the indicators is Phase II of this data project. Phase I was purely identifying the data and compiling descriptive statistics. Mr. Kauder noted that the data is very powerful because although de-identified, each component (e.g. patient, pharmacy, prescriber, etc.) is unique and therefore, we can do predictive analytics with the data which may inform policy decisions. Mr. Kauder noted also that Key Performance Indicators (KPIs) could grow out of research questions the Panel has. Following questions about deaths in Virginia, Ms. Hobron presented an overview of death statistics that she has been working on, comparing deaths by type of drug, age, etc. Mr. Orr noted that the PMP is working on two initiatives: 1) unsolicited reports that are clinically based and 2) prescriber summary reports. He felt that the Panel should consider these initiatives when thinking about specific KPIs. Dr. Melton suggested that a subcommittee meet to discuss potential KPIs, an ex-officio subcommittee of sorts. Ms. Morris, Mr. Clouse, Dr. Barsanti and Dr. Melton all were interested in serving on the subcommittee. Dr. Melton asked Mr. Kauder about "identified" data, and Mr. Kauder stated that once we identify an issue or trend, the PMP could explore the use of active data to assist in impacting health status of Virginians with respect to prescription data.
REPORT ON THE USE OF PMP REPORTS BY THE VIRGINIA STATE POLICE DRUG DIVERSION UNIT: First Sergeant John Welch	First Sergeant Welch presented a map of Virginia and noted that there are 7 divisions in the Commonwealth with a total of 23 drug diversion agents and 3 to 4 agents in each division. He stated that he polled each division as to the biggest threat in their division and each stated that prescription pills and heroin are the greatest problem and each had many repeat offenders. Dr. Melton inquired about the overwhelming number from Northern

	Virginia and First Sergeant Welch noted that the population density is the greatest in that region accounting for the large numbers. In addition, he noted that for some of those individuals, other agencies were already investigating the particular situation. He also noted that some Commonwealth Attorneys declined to prosecute in all cases. First Sergeant Smith noted that there are different penalties ranging from a Class 1 misdemeanor to a Class VI felony with respect to possession, diversion, trafficking, etc. With respect to doctor shopping and drug diversion, Dr. Barsanti asked if there could be some sort of "alert" system within the PMP regarding his patients that would indicate suspicious activity, and Mr. Orr said that none exists at this time.
UNSOLICITED REPORTS – UPDATE AND CRITERIA DISCUSSION: Carolyn McKann	Ms. McKann reviewed the summary of unsolicited reports at various thresholds (including the threshold the PMP currently utilizes) to generate unsolicited reports and email notifications to registered and non-registered prescribers. Dr. Melton asked whether the unsolicited reports work, and Ms. McKann noted that in general, patients identified as possible doctor shoppers have decreased from about 100 per month to around 30 per month on average over the past several years, so yes, it does work. The Panel discussed the time requirements for each level and the Panel agreed that the PMP should continue to use the current level since the time required to do more notifications may not be a good use of our time. Ms. McKann noted that law enforcement receives unsolicited reports only for those individuals who meet the doctor shopping criteria and also have 10 or more prescriptions dispensed to them during a one-month period. First Sergeant Smith said that it would be beneficial to the State Police to receive a full year of prescription history for those individuals that are identified as doctor shoppers to rule out any brief acute health condition. Ms. McKann also indicated that the PMP forwards reports to State Police on individuals who may be forging prescriptions. The threshold criteria for those individuals is one prescriber and five or more pharmacies during a one month period.
PROGRM UPATE: Program Statistics, Interoperability with MD, RI; Kroger, EPIC, and Automated Registration Update: Carolyn McKann	Ms. McKann reviewed the program statistics including total requests processed, total registered users, the number of practitioner self-reports generated and data sharing with neighbor states. Ms. McKann also noted that the recent dramatic increase in requests was from incoming requests from PMP Gateway®, which is an integration solution that allows pharmacy management applications to make requests by "translating" fields so that PMPs can process the information. The PMP Gateway® has enabled Virginia's PMP to share data with Kroger pharmacies in Virginia, Ohio and West Virginia. The bulk of our increase in requests is from incoming requests from Kroger pharmacies in Ohio and West Virginia. Ms. McKann stated that the Virginia PMP began sharing data

	with Maryland the week ending July 30, 2015, and hopes to begin sharing data with Rhode Island's PMP next. The Virginia PMP has also successfully tested sharing data with EPIC, an electronic medical record platform. Ms. McKann also shared with the Advisory Panel that automated registration has begun, and that the Virginia PMP had successfully registered all licensed optometrists with valid email addresses at the time the Advisory Panel met. Ms. McKann also shared the automated registration timeline with Advisory Panel members and noted that all licensed prescribers shall be registered with the PMP by January 1, 2016, and at that time the PMP will have approximately 60,000 registered users.
NEXT MEETING	The next meeting will be held on Wednesday, January 6, 2016 from 10 a.m. to 2 p.m.
ADJOURN:	With all business concluded, the committee adjourned at 1:25 p.m.
	Dr. Samuel Melton, Chairman
	Ralph A. Orr, Director

Department of Health Professions

2016 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending sections §§ 54.1-2521, 54.1-2523 and 54.1-2525 relating to disclosure of information from the Prescription Monitoring Program and reporting requirements for dispensers.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2521, 54.1-2523 and 54.1-2525 of the *Code of Virginia* are amended and reenacted as follows:

§ 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 dispenser's 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.

§ 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.

§ 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties.

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

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

C. Prescribers may place reports requested from the program for the purpose of establishing a treatment in the medical record.

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

~~D.~~ E. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

2. That the provisions of this act amending subsection C of § **54.1-2521** of the Code of Virginia shall become effective on January 1, 2017.

Governor's Task Force on Heroin and Prescription Drug Abuse

2016 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending sections § 54.1-2522.1, relating to a requirement for prescribers to query the Prescription Monitoring Program before prescribing a benzodiazepine or an opiate.

Be it enacted by the General Assembly of Virginia:
1. That § 54.1-2522.1 of the *Code of Virginia* is amended and reenacted as follows:

§ 54.1-2522.1. Requirements of prescribers.

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

A. (Effective January 1, 2016)
Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, ~~at the time of initiating a new course of treatment to a human patient that includes~~ prior to the prescribing of benzodiazepine or an opiate ~~anticipated at the onset of treatment to last more than 90 consecutive days~~, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to ~~or as a part of execution of a treatment agreement with the patient~~ prescribing for these controlled substances, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. If the prescribing of an opiate or benzodiazepine continues for more than 90 days after the date of the initial prescription, the prescriber or prescriber's designee shall make periodic requests from the Director, no less frequently than once every 90 days until the course of treatment has ended. 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.~~

1. The opiate or benzodiazepine is prescribed to a patient currently receiving hospice or palliative care.

2. The opiate or benzodiazepine is prescribed to a patient as part of treatment for a surgical procedure and such prescription is not refillable.

3. The program is not operational or available due to temporary technological or electrical failure or natural disaster.

Governor's Task Force on Heroin and Prescription Drug Abuse

2016 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending sections § 54.1-2523.1, relating to disclosure from the Prescription Monitoring Program to law enforcement or the Department of Health Professions information on potential unusual prescribing or dispensing patterns by prescribers or dispensers.

Be it enacted by the General Assembly of Virginia:
1. That § 54.1-2523.1 of the *Code of Virginia* is amended and reenacted as follows:

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

The Director shall develop, in consultation with an advisory panel and input from the applicable licensing boards, criteria for indicators of misuse, indiscriminate prescribing and dispensing, and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse. Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523, disclose information using the criteria that indicates:

A. Potential misuse by recipients of covered substances to (i) their specific prescribers for the purpose of intervention to prevent such misuse or abuse or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

B. Potential unusual prescribing or dispensing patterns by prescribers or dispensers to (i) the Enforcement Division of the Department of Health Professions or (ii) an agent who has completed the Virginia State Police Drug Diversion School designated by the Superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department for the purpose of an investigation into possible drug diversion.

Governor's Task Force on Heroin and Prescription Drug Abuse

2016 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending sections §§ 54.1-2523 and 54.1-2912.1, requiring continuing education for certain practitioners licensed by the Board of Medicine on topics such as pain management, responsible opioid prescribing, or addiction diagnosis and management

Be it enacted by the General Assembly of Virginia:
1. That §§ 54.1-2523 and 54.1-2912.1 of the *Code of Virginia* are 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.

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 (§ 53.1-141 et seq.) of Chapter 4 of Title 53.1 or a local community-based probation officer as described in § 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.

9. Information to the Board of Medicine consisting of a list of practitioners who meet a certain threshold for prescribing covered substances for the purpose of requiring relevant continuing education. The threshold shall be determined by the Board in consultation with the Program.

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.

§ 54.1-2912.1. Continued competency and office-based anesthesia requirements.

A. The Board shall prescribe by regulation such requirements as may be necessary to ensure continued practitioner competence which may include continuing education, testing, and/or any other requirement.

B. In promulgating such regulations, the Board shall consider (i) the need to promote ethical practice, (ii) an appropriate standard of care, (iii) patient safety, (iv) application of new medical technology, (v) appropriate communication with patients, and (vi) knowledge of the changing health care system.

C. The Board shall require two hours of continuing education on topics such as pain management, responsible opioid prescribing, or addiction diagnosis and management, for certain

prescribers of controlled substances each biennium. The prescribers to whom the requirement shall apply shall be determined by the Board in consideration of prescribing data from the Prescription Monitoring Program. Prescribers so designated shall be informed of the number of continuing education hours required no later than January 1 of each odd year.

C. The Board may approve persons who provide or accredit such programs in order to accomplish the purposes of this section.

D. Pursuant to § 54.1-2400 and its authority to establish the qualifications for registration, certification or licensure that are necessary to ensure competence and integrity to engage in the regulated practice, the Board of Medicine shall promulgate regulations governing the practice of medicine related to the administration of anesthesia in physicians' offices.

VIRGINIA
REGULATORY TOWN HALL

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC76-20-10 et seq.
Regulation title(s)	Regulations Governing the Prescription Monitoring Program
Action title	Change to standards and format for reports to PMP
Date this document prepared	4/20/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The proposed regulatory action will update the required version for reporting data electronically to the Prescription Monitoring Program (PMP) and include several new data elements in the report that have been identified as useful in tracking information and providing prescriber feedback reports. The intent of the regulatory action is to make the PMP an even more useful tool in the efforts against prescription drug abuse in the Commonwealth.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific

provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The statutory authority for the Director of the Department to promulgate regulations is found in:

§ 54.1-2520. Program establishment; Director's regulatory authority.

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

Statutory authority for specifying data elements contained in and the format for the PMP report is found in:

§ 54.1-2521. Reporting requirements.

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. 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.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

Prescription drug abuse is one of the leading causes of death in the Commonwealth. The Governor's Task Force on Prescription Drug and Heroin Abuse has been studying ways to combat the problem from several perspectives, including data collection and monitoring. It is their recommendation that updating the reporting format and including additional data elements will assist prescribers and other providers in a better understanding of the standard of care for prescribing opioids and other drugs with potential for abuse. To the extent that collection of more precise data on prescribing and dispensing can address the issue of prescription drug abuse, this regulatory action is necessary to protect the health and safety of the citizens of the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

Currently, the format for reporting data to the PMP is Version 4.1 (2009) of the Electronic Reporting Standard for Prescription Monitoring Programs of the American Society of Automation in Pharmacy (ASAP). The updated Version is 4.2, so the regulation should be consistent. When a new file layout with new data elements is prescribed in regulation, the director of the program is required to notify dispensers whose transmissions must be in compliance in no less than 30 days from the date specified. To benefit dispensers and software providers who may have to adjust automated programs, the proposed regulation would change 30 days to 90 days or perhaps even longer.

Certain data elements are specified in the Code of Virginia in § 54.1-2521, which also provided that: "*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.*" To facilitate collection of meaningful data that is more useful in developing reports on prescribing of controlled substances, the Prescription Monitoring Advisory Committee has recommended that the Director of the Department consider amending section 40 to include data elements such as the National Provider Identifier which identifies the specialty area of practice, the Species Code which identified whether the prescription is written for a human or animal, the Gender Code, the Electronic Prescription Reference Number if it is an electronic prescription, and an indicator if the prescription is a partial fill. Many software applications already include the data elements under consideration because they are necessary for third-party reimbursements by Medicaid or other providers or are required elements for other state PMP's.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Data and Monitoring Workgroup of the Governor's Taskforce on Prescription Drug and Heroin Abuse has recommended that some additional data is needed for better analysis of prescribing and dispensing of controlled substances that are being abused. Specifically, the Workgroup recommended the addition of the National Provider Identifier and the Species Code as required data elements.

The Prescription Monitoring Advisory Committee has considered alternatives and has recommended updating the ASAP version for electronic reporting that most pharmacies already employ. Likewise, the additional data elements are necessary for better analysis of PMP information and for more meaningful feedback to providers about appropriate prescribing. The Committee represents a broad spectrum of interested parties, including the prescribers, Medicaid Fraud Control Unit in the Office of the Attorney General, MD's who are pain management specialists, State Police, DBHDS, the Office of the Medical Examiner, and an independent pharmacist representing small businesses.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time. The Prescription Monitoring Advisory Committee will serve as a regulatory panel for this action.

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 of dispensing as provided in the Electronic Reporting Standard for Prescription Monitoring Programs, Version 4.~~1~~2 ~~(November 2009)~~ (September 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~~ 90 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 National Provider Identifier of the prescriber;

~~2~~3. The total number of refills ordered;

~~3~~4. Whether the prescription is a new prescription or a refill;

5. Whether the prescription is a partial fill;

6. The gender code;

7. The species code;

8. The Electronic Prescription Reference Number and the Electronic Prescription Order Number if it is an electronic prescription; and

4~~9~~. The date the prescription was written by the prescriber.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Submitted via email:
ralph.orr@dhp.virginia.gov

December 16, 2015

Mr. Ralph Orr
Program Manager
Department of Health Professions
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

RE: Notice of Intended Regulatory Action: 18 VAC 76-20 Regulations Governing the Prescription Monitoring Program.

Dear Mr. Orr:

On behalf of the approximately 1,126 chain pharmacies operating in the Commonwealth of Virginia, the National Association of Chain Drug Stores (NACDS) and the Virginia Association of Chain Drug Stores (VACDS) are writing to submit comments on the Department of Health Profession's (DHP) Notice of Intended Regulatory Action regarding Section 18 of the Virginia Administrative Code 76-20: Regulations Governing the Prescription Monitoring Program (PMP). Specifically, the purpose of the proposed action is to update the required version for reporting data and add new data elements for electronic reporting to the Prescription Monitoring Program (PMP).

Over the years, prescription monitoring programs have been established throughout the country as tools to curb diversion and abuse of controlled substances prescriptions. At this time, nearly every state has implemented their own program designed to assist in the identification and prevention drug abuse and diversion at the prescriber, pharmacy, and patient levels. We support the important role that prescription monitoring programs have in helping to prevent drug abuse and diversion. In addition, chain pharmacies actively support programs that are well designed to achieve program aims in a manner that does not disrupt the provision of patient care and the legitimate practices of pharmacy and medicine, and have minimal administrative burden associated with compliance.

We also support programs that are aptly designed to accomplish the aims of the PMP without creating administrative burdens on pharmacies or impeding the delivery of pharmaceutical care. Chain pharmacy has decades-long experience with implementing and maintaining compliance with states' prescription monitoring programs across the country. Through our experience, we have found that compliance with multiple state programs is more easily achieved when there is uniformity among various state programs.

As the DHP considers updating and adding new data element requirements it is important that the data format for reporting should be limited to the data format and communications protocols for electronic reporting adopted by the American Society for Automation in Pharmacy (ASAP). As the ASAP standard has evolved over the years to include an extensive

menu of informational fields, it has come to include certain extraneous data fields that have been identified as problematic for reporting pharmacies. As chain pharmacies operate in multiple states, compliance with numerous states' reporting requirements is more feasible when data is limited to fields that are typically collected in other states programs; variations among state programs only make compliance challenging for chain pharmacies operating in multiple states. Further, collecting and reporting these informational fields would, in some cases, unnecessarily increase the number of steps involved with filling a prescription, which can negatively impact patient care. Therefore in order to promote consistency among state programs and reduce compliance burdens on dispensers, we urge the DHP to adopt the ASAP 4.2 standard, since it is used in the majority of states operating prescription monitoring programs.

We also believe that the DHP should ensure that the specific reporting requirements and various data elements that dispensers must report are limited to information that is required to be on a controlled substance prescription and/or required to process third party claims. The DHP should not require reporting of any state-specific information or extraneous "situational" fields such as a patient identification number and/or purchaser identification number. Collecting extraneous data elements requires extra data entry and collection during prescription processing that inadvertently delays the provision of health care to legitimate patients. Furthermore, collection of these data elements provides little additional actionable information while imposing great burdens on pharmacies due to the direct and indirect costs of obtaining and reporting. Also, costly software changes would be needed for pharmacy dispensing and management computer systems to accommodate the reporting of extraneous data elements.

Thank you in advance for your ongoing consideration of our comments as you make changes to the prescription drug monitoring program. We look forward to continuing to work with the DHP on this issue going forward. Please do not hesitate to contact me if we can further assist you.

Sincerely,

Jill K McCormack

Jill McCormack, Director
State Government Affairs
jmccormack@nacds.org

Appendix 1 - Annual[a] estimates of state resident population, by sex and age groups

Virginia

Age Category	Both	Male	Female	Both	Male	Female
<18	1,853,546.00	946,472.00	907,074.00	1,864,530.00	951,054.00	913,476.00
18-24	814,068.00	418,317.00	395,751.00	797,975.00	402,926.00	395,049.00
25-34	1,119,591.00	562,099.00	557,492.00	1,113,808.00	550,158.00	563,650.00
35-44	1,093,634.00	541,077.00	552,557.00	1,060,410.00	516,705.00	543,705.00
45-54	1,209,404.00	592,031.00	617,373.00	1,180,103.00	574,093.00	606,010.00
55-64	995,298.00	477,520.00	517,778.00	1,022,298.00	490,347.00	531,951.00
65 and older	1,011,063.00	438,649.00	572,414.00	1,105,381.00	484,750.00	620,631.00
Total	8,096,604.00	3,976,165.00	4,120,439.00	8,144,505.00	3,970,033.00	4,174,472.00

[a]Population estimates as of July 1 of the specified year.
The previous year's population was used when population estimates for a given year are not yet available.
Source: U.S. Department of Commerce, Economics and Statistics Administration, United States Census Bureau, Population Division. Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2013. Release Date: June, 2014. http://www.census.gov/popest/data/index.html. Accessed July 8, 2014.

Appendix 2 - Percent missing data by PDMP data element, state, quarter and year (Limit to Schedules II-V)

Virginia

PDMP Data Element	Jan-Mar 2013	Apr-Jun 2013	Jul-Sep 2013	Oct-Dec 2013	[illegible]	Jan-Mar 2015	Apr-Jun 2015	Jul-Sep 2015	[illegible]	Annual Average 2011	[illegible]	Annual Average 2013	[illegible]	Annual Average 2015
Method of payment	2.71	2.81	2.77	[illegible]		1.59	1.63	1.59		100.00		2.75		
Patient age	0.01	0.02	0.01	[illegible]		0.01	0.01	0.00		0.02		0.01		
Patient gender	26.36	26.53	26.31	[illegible]		25.09	25.09	26.43		100.00		26.33		
Patient zip code	0.03	0.05	0.08	[illegible]		0.04	0.04	0.02		0.29		0.05		
Pharmacy zip code	1.26	1.28	1.33	[illegible]		1.51	1.48	1.51		1.11		1.32		
Prescriber zip code	0.29	0.31	0.32	[illegible]		0.28	0.37	0.35		0.58		0.30		

N/A=PDMP not yet operational or data not retained
State Notes:

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

This Committee should function in a manner similar to the Technical Committee for the Offender Population Forecast, which meets multiple times a year to share information on relevant trends that might impact the correctional populations, and then produces an annual report on behalf of the Secretary of PSHS.

The Health and Criminal Justice Data Committee's format, membership, and meeting schedule should be structured according to what the Committee determines best allows it to achieve the goals of identifying important trends in criminal justice and public health related issues.

Implementation Steps:

- A Subcommittee of the Task Force's Data and Monitoring Workgroup, which included representatives from the Office of the Chief Medical Examiner, DCJS, the PMP, the Department of Forensic Science, the Virginia State Police, VDH, and Virginia Health Information, a non-governmental agency, should serve as a transitional working group that identifies agencies and analysts that should participate in the Health and Criminal Justice Data Committee or provide data to the Committee.
- The membership of the Health and Criminal Justice Data Committee should be finalized by August 1, 2015. Once formed, the Committee should select a Chair, who will serve as the point of contact for all participating agencies and as the liaison to the Offices of the Secretaries of PSHS and HHR.
- The Health and Criminal Justice Data Committee may request relevant de-identified, aggregated, locality-level data from agencies and other entities. Data should be provided to the Committee Chair electronically, on a periodic basis, as requested, and no less than quarterly. The Chair will combine the data from various agencies and share it with the Committee.
- Analysts serving on the Health and Criminal Justice Data Committee will analyze the data, identify trends or concerns, and share their preliminary findings with the Committee. The Committee should meet multiple times during the year, according to the schedule that best suits the Committee's needs.
- The Health and Criminal Justice Data Committee should provide an annual trends report to the Secretaries of PSHS and HHR. Preliminary findings of the Committee should be shared with the Secretaries independent of the annual report. A copy of the annual report should be shared with the Center for Behavioral Health and Justice. The initial report from the Committee should be submitted by January 15, 2016. Subsequent annual reports should be submitted annually by October 15.

- The Health and Criminal Justice Data Committee's initial focus should be on gathering and analyzing appropriate up-to-date data to mitigate harm from prescription drug and heroin abuse.
- The Health and Criminal Justice Data Committee will require cooperation from multiple agencies. To ensure an efficient data-sharing process, the Secretaries of PSHS and HHR should direct agencies to share, to the extent possible, up-to-date data requested by the Committee.
- To the extent possible, the Health and Criminal Justice Data Committee should monitor data-sharing improvement initiatives within the Secretaries of PSHS and HHR, and work to make any data sharing improvements developed by the Committee available to assist these initiatives.

Additional Action Required: No legislation, regulatory change or appropriation required. Coordination of Offices of HHR and PSHS

Medscape Medical News > Psychiatry

Opioid Overprescribing Not Limited to a Few Bad Apples

Megan Brooks

December 16, 2015

An analysis of national Medicare data discounts the notion that a small group of prolific prescribers operating out of corrupt "pill mills" are driving the opioid overdose epidemic in the United States.

The bulk of prescriptions for opioid painkillers are made by the broad swath of general practitioners, not by a limited group of specialists, according to a study from researchers at Stanford University School of Medicine in California.

"It's nice to see what I had always suspected was true, which is that the problem is not isolated to a few prolific prescribers. It's really a systemic problem," senior author Anna Lembke, MD, noted in an interview with *Medscape Medical News*.

"I think most of us had a sense that was true, but it's nice to have confirmatory data, especially since most media coverage has focused on a few rogue prescribers or just frankly nefarious doctors out there prescribing insane amounts of opioids in pill mills," Dr Lembke said.

The findings were published online December 14 a research letter in *JAMA Internal Medicine*.

Focus on Pill Mills Insufficient

The researchers examined Medicare prescription drug claims data from 2013 for 808,020 individual prescribers, including physicians, nurse practitioners, physician assistants, and dentists. For each prescriber National Provider Identifier number, the data identify each drug prescribed, total number of claims, and total costs. The researchers focused on schedule II opioid prescriptions containing hydrocodone, oxycodone, fentanyl, morphine, methadone, hydromorphone, oxymorphone, meperidine, codeine, opium, or levorphanol. The data represent more than 1.18 billion claims totaling nearly $81 billion.

On the basis of claims per prescriber type, it was determined that opioid prescriptions were concentrated in interventional pain management (1124.9 prescriptions, on average, per prescriber) and pain management (921.1), followed by anesthesiology (484.2) and physical medicine and rehabilitation (348.2).

From an analysis of total claims, it was determined that in 2013, most opioids were prescribed by healthcare providers in family practice (15.3 million prescriptions) and internal medicine (12.8 million), followed by nurse practitioners (4.1 million) and physician assistants (3.1 million).

The researchers say the top 10% of opioid prescribers accounted for 57% of all opioid prescriptions, similar to the prescribing pattern for all drugs for which there are Medicare data: the top 10% of all drug prescribers accounted for 63% of all drug prescriptions.

Efforts by law enforcement to shut down pill-mill prescribers are "insufficient to address the widespread overprescribing of opioids," lead author Jonathan Chen, MD, PhD, an instructor of medicine and Stanford Health Policy VA Medical Informatics Fellow, notes in a statement. "Efforts to curtail national opioid overprescribing must address a broad swath of prescribers to be effective."

Public Health Crisis

"The reason this is a public health crisis is in a large part because it's become a commonality to prescribe opioids for a lot of different things," Dr Lembke told *Medscape Medical News*.

"What was really interesting," she noted, "was the number of nurse practitioners prescribing opioids. These 'physician extenders' are really the future of medicine, so from a public health intervention point, we can't just focus on pain doctors. We've got to focus on all doctors, and even non-MDs, dentists, and nurse practitioners."

Cynthia Campbell, PhD, MPH, from Kaiser Permanente Division of Research, in Oakland, California, who was not involved in the study, agrees. "Providers on the whole healthcare team that manages patients need more education around prescribing opioids," she noted in an interview with *Medscape Medical News*. She pointed out that the US Department of Veterans Affairs (VA) has recently developed some initiatives that focus on opioid prescribing in primary care.

Dr Campbell said this new study is an "important" contribution to the literature and that the issue of prescription opioid abuse "remains a high concern."

The study was supported in part by the VA's Office of Academic Affiliations, the VA Health Services Research and Development Service, the National Institute of General Medical Sciences, and the Peter F. McManus Charitable Trust. The authors have disclosed no relevant financial relationships.

JAMA Intern Med. Published online December 14, 2015. Full text

Period: April - June 2015

Prescriptions Written	Num Practitioners	Num Prescriptions	% Population	% Presciptions	Registered Users	% Registered Users	Registered Prescriptions	% Registered Prescriptions	Queries by Group	Queries Per Perscription
1-24	13,186	106,540	47%	3%	4,353	33%	40,713	38%	6,649	6%
25-49	3,664	130,672	13%	4%	1,832	50%	65,848	50%	8,544	7%
50-99	3,699	265,268	13%	8%	2,190	59%	158,140	60%	18,732	7%
100-249	4,221	665,304	15%	20%	2,998	71%	479,681	72%	52,584	8%
250-499	1,947	680,262	7%	21%	1,601	82%	562,818	83%	45,984	7%
500-999	1,059	729,785	4%	22%	955	90%	661,739	91%	56,369	8%
1000+	451	688,880	2%	21%	420	93%	645,524	94%	94,580	14%
Total	28,227	3,266,711			14,349	51%	2,614,463	80%	283,442	9%

The following are statistics for practitioners who have a PMP login, have issued presciptions but have not issused any requests

Prescriptions Written	Num Practitioners	Num Prescriptions	% of Group	% of Population
1-24	3,559	31,333	27%	13%
25-49	1,234	43,923	34%	4%
50-99	1,298	93,297	35%	5%
100-249	1,433	226,154	34%	5%
250-499	665	230,310	34%	2%
500-999	318	214,289	30%	1%
1000+	121	182,950	27%	0%
	8,628	1,022,256	31%	31%

Orr, Ralph (DHP)

From: Peter Kreiner <pkreiner@brandeis.edu>
Sent: Friday, December 11, 2015 5:37 PM
To: Orr, Ralph (DHP); Gail Strickler
Subject: Re: Virginia 3rd quarter stats

Hi Ralph,

Here's the information I sent to ONDCP and CDC in response to a forwarded query about PDMP usage in relation to number of prescriptions.
The data are from a combination of the Prescription Behavior Surveillance System (some prescription numbers), Bureau of Justice Assistance grantee performance measures (PDMP queries), and our PDMP Training & TA Center (some prescription numbers). I was able to get data on PDMP queries by prescribers and total Schedule II - IV prescriptions, both for 2014, from 13 states: AL, CA, DE, FL, IL, IN, KY, MA, ME, OH, NC, NJ, and WV. For 8 of those states, I was also able to obtain the number of opioid prescriptions for 2014: CA, DE, FL, KY, MA, ME, OH, and WV.

Most of these states didn't have a mandatory use law in 2014. Two had a relatively strong use law, and three had somewhat weaker mandatory use laws. These laws are all fairly recent, with the earliest enacted in fall of 2011.

Here's what I found, in terms of the ratio of prescriber queries to (1) total Schedule II - IV prescriptions, and (2) Schedule II - IV opioid
prescriptions:

1. States with no mandate (8 states): queries to total prescriptions mean was .088 (standard deviation .042), range was from .037 to .149.

queries to opioid prescriptions mean was .135 (s.d. .067), range .071 to .228.

2. States with somewhat weaker mandatory use laws (3 states): queries to total prescriptions mean was .136 (s.d. .009), range .126 to .145.

queries to opioid prescriptions mean was
.272 (s.d. .001), range .271 to .273.

3. States with strongest mandatory use laws (2 states): queries to total prescriptions mean was .400 (s.d. .032), range .378 to .423.

queries to opioid prescriptions mean was .709 (s.d. .061), range .666 to .752.

Even with this limited sample, there's a lot of consistency across states within each group and the mandatory use laws are associated with much higher ratios of prescriber queries to prescriptions.

As I understand it, Virginia does not currently have a mandatory use law, so your ratio of prescriber queries to prescriptions of 8.9% is almost exactly the same as the average I found for the 8 states with no mandatory use law (8.8%).

Let me know if you want to discuss further.

Regards,
Peter

On 12/10/2015 3:37 PM, Orr, Ralph (DHP) wrote:
> Peter,
>
> If the numbers are not far off what you have seen that is great. How about I review your memo and then get back with you if I have further questions.
>
> I know time is always tight around the holidays and I don't want to infringe.
>

COMMONWEALTH OF VIRGINIA
Department of Health Professions
Prescription Monitoring Program
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
Phone: (804) 367-4566
Fax: (804) 527-4470

MEMORANDUM OF UNDERSTANDING BETWEEN THE REQUESTING ENTITY AND THE VIRGINIA PRESCRIPTION MONITORING PROGRAM FOR RESEARCH

THE FOLLOWING ITEMS MUST ACCOMPANY THE REQUEST FOR INFORMATION

1. Person/Entity Responsible for Study:

Organization:

Street Address:

City, State, Zip Code:

Area Code and Telephone Number:

Fax Number:

Please provide the CV for the individual responsible for the study.

2. Purpose/Reason for the Study and Expected Outcome:

3. Goal/s of the study and any planned deliverables (i.e. research paper, poster at a scientific meeting, etc.)

4. The target audience.

5. List of any sponsoring organization.

6. Specific time period to be covered in report:

7. Term.
The term of this MOU will be (2) years from the effective date.

8. Responsibilities of the Parties. The Virginia PMP shall provide the requesting entity with electronic data files to the requesting entity in the data file format agreed to by both parties. Each patient, prescriber and pharmacy shall be represented by a unique value, however all data shall be supplied as de-identified. (No personal identifying information such as name or address shall be provided.) The requesting entity shall provide all results, posters, written materials, etc., to the Virginia PMP for review prior to publication or dissemination. Requesting party shall not publish and/or display any results in any form prior to review and approval of Virginia PMP staff.

9. Institutional Review Board Approval

_____ Yes _____ No

Please provide a brief description of the approval process or whether you have determined that IRB approval is not necessary.

10. Please describe the security measures you will utilize during the transport, storage, access and manipulation of data.

11. Statement of agreement. I agree that I shall not permit any other person/entities to utilize the data provided to me by the Virginia PMP. I shall not publish any data whereby the identity of an individual can be determined. I shall ensure the security of this data while in use by myself as provided in the agreement. I shall provide the Virginia PMP the results of any research utilizing this data prior to dissemination of any study results. I shall destroy any and all PMP related data at the end of the period of the MOU. I shall be held accountable for any violations of these data use restrictions described herein.

Signature: Date:

I hereby attest that the requested information will not be further disclosed and will only be used for the purposes stated in the request and in accordance with the law. If data is to be re-used, a separate request must be submitted.

Signature: _____ Date: _____

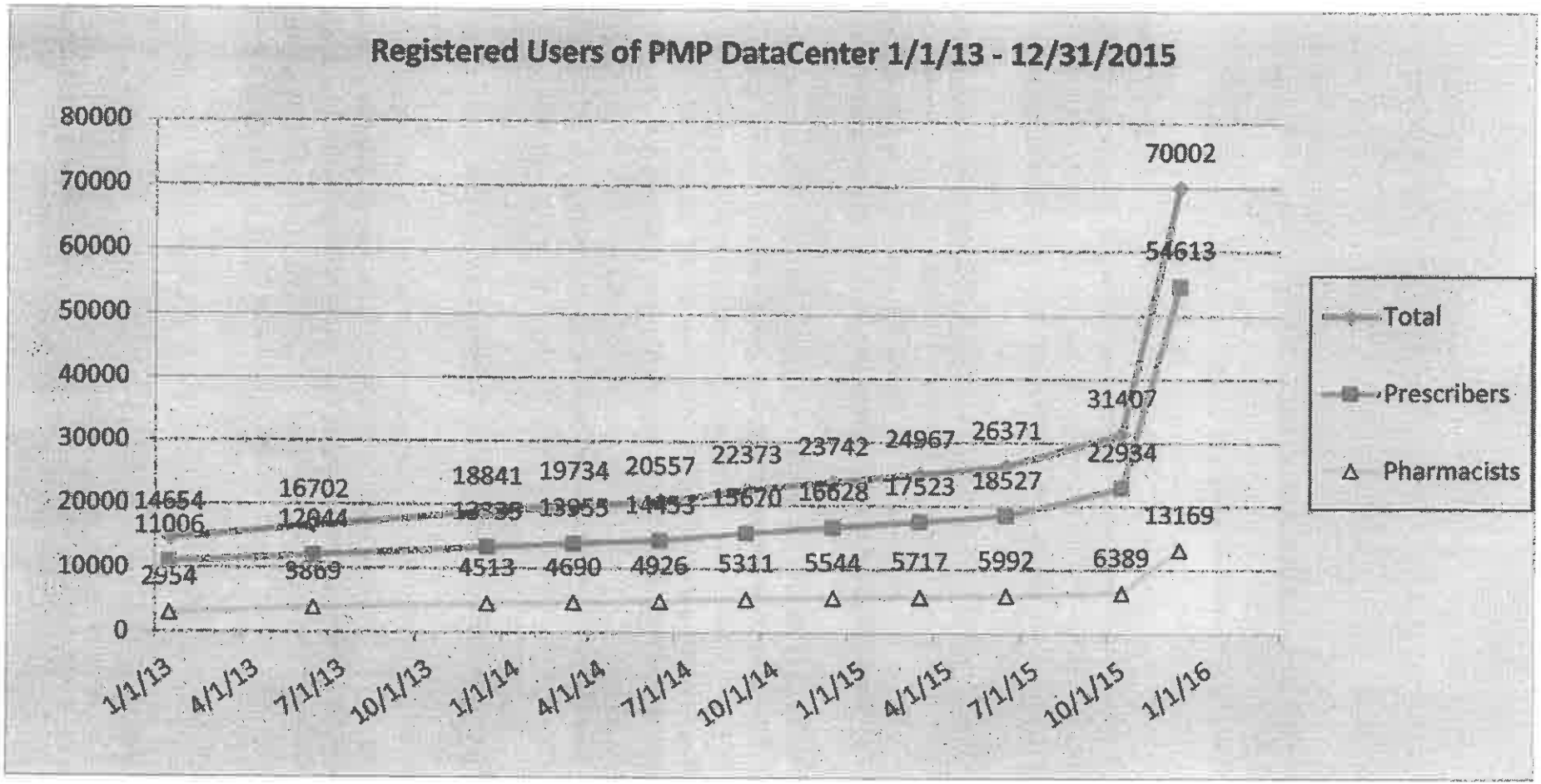
For Department Use Only

Date Received	Date of Action

Final 11-6-2015

Data and Monitoring Workgroup

1. Expand mandatory PMP registration and amend mandatory use of PMP data. (p. 7; Sec III, B)
2. Require reporting of prescriber National Provider Identifier for prescriptions for human patients and "Species Code" as a required data element. (p. 25; Sec V, K)
3. Clarify that PMP data shall not be available for use in civil proceedings. (p. 8; Sec III, C)
4. Add Morphine Equivalent Doses per Day information to PMP patient reports to provide prescribers with information as to the cumulative amount of opioid medication a patient is currently receiving in order to gauge potential risk of overdose. (p. 10; Sec III, G)
5. Develop clinically-oriented criteria for unsolicited reports to prescribers on specific patients. (p. 24; Sec V, J)
6. Develop individual prescriber feedback reports that describe actual prescribing practices. (p. 20; Sec V, E)
7. Direct applicable agencies to share data on prescription drug and heroin abuse, overdoses, drug seizures, arrest information, etc. to analyze information to mitigate harm. (p. 21; Sec V, F)
8. Create a Health and Criminal Justice Data Committee, comprised of data analysts from applicable agencies within the Secretariats of Public Safety & Homeland Security and Health & Human Resources, to study data for the purpose of better understanding the ways in which criminal justice and public health issues intersect, with the goal of improving government responses to crises, as well as identifying and responding to concerns before they become crises. (p. 21; Sec V, F)
9. Reduce the timeframe in which dispensers must report to the PMP from within 7 days of dispensing to within 24 hours of dispensing. (p. 23; Sec V, G)
10. Expand access to PMP information on a specific patient to clinical pharmacists and consulting prescribers practicing on healthcare teams treating that specific patient. (p. 23; Sec V, H)
11. Clarify that PMP reports may be placed in the medical record. (p. 24; Sec V, I)
12. Expand mandatory requests to the PMP to include the initial prescribing of an opiate or benzodiazepine and periodic reports thereafter, not to exceed 90 days, with limited exceptions. (p. 35; Sec V, FF)
13. Grant authority to the PMP, through the Director of the Department of Health Professions (DHP), to send unsolicited reports on egregious outlier prescribing and dispensing behavior to the Enforcement Division of DHP and/or to law enforcement, based on criteria developed by the PMP Advisory Panel in consultation with applicable licensing boards. (p. 36; Sec V, GG)


Registered Users of PMP DataCenter 1/1/13 - 12/31/2015
80000
70000
60000
50000
40000
30000
20000
10000
0
70002
54613
31407
22934
14654
11006
16702
12044
18841
13955
19734
14453
20557
15670
22373
16628
23742
17523
24967
18527
26371
13169
2954
3869
4513
4690
4926
5311
5544
5717
5992
6389
1/1/13
4/1/13
7/1/13
10/1/13
1/1/14
4/1/14
7/1/14
10/1/14
1/1/15
4/1/15
7/1/15
10/1/15
1/1/16
Total
Prescribers
Pharmacists

License Type	Records Received	Accounts Created	Accounts Updated	Records Rejected
TPA Optometrists	1553	1467	24	62
Physician Asst	3096	1531	1101	464
Dentists	6855	4121	1445	1289
Podiatrists	488	209	141	138
Nurse Prac (AP)	5539	2728	1825	986
Interns and Res	3023	386	87	2550
Pharmacists	13239	6605	4785	1849
Osteopaths	2840		2268	572
MDs No Email	6096			6096
MDs Group 1	9997	7353	2305	339
MDs Group2	10001	7464	2196	341
MDs Group 3	9422	7032	2061	329
TOTAL	72149	38896	18238	15015
		54%	25%	20%

Supporting Efforts to Fight Diversion and Abuse, PMP InterConnect Works in Tandem With PMP Gateway as It Automates Requests, Brings Data Into Workflow

New Deployment at Kroger Pharmacies Increases Provider Use of PMP Reports

Recognizing the importance of expanding the use of prescription monitoring program (PMP) data in pharmacists' workflow to enhance prescription drug abuse and diversion prevention efforts, NABP has been working to integrate other PMP services with NABP PMP InterConnect®. Most recently, PMP Gateway – a service that works in tandem with PMP InterConnect – has been deployed in Kroger pharmacies across Ohio. PMP Gateway, owned and operated by Appriss, Inc, works with PMP InterConnect to automate requests for a patient's PMP data, bringing it into the workflow of health care providers' electronic health information systems, including pharmacy and hospital systems. Kroger pharmacies in Ohio became the first pharmacy chain to implement use of PMP Gateway in July 2015, and Kroger subsequently deployed the service at pharmacies in Arizona, Arkansas, Kansas, Louisiana, Mississippi, Nevada, New Mexico, Virginia, and West Virginia, and has initiated pilots with pharmacies in Colorado. Kroger joins the Wisconsin Statewide Health Information Network (WISHIN) and Kettering Health Network of Ohio in becoming among the first entities to use the PMP Gateway service to make PMP data easily accessible to their health care providers. Further, because PMP Gateway works in tandem with PMP InterConnect in order to access the data, these entities have the option to access interstate PMP data, as allowed by state regulations.

New Deployment

As part of a response to the prescription drug overdose epidemic, Kroger pharmacies worked closely with the state PMPs to integrate PMP Gateway into its pharmacy dispensing software. As a result, Kroger pharmacists may now quickly access a patient's controlled substance (CS) prescription history directly in their workflow, avoiding the extra steps of having to open a web browser in order to log in and query the state's PMP. With just a click from within a patient's electronic pharmacy record, the pharmacist can review a PMP report for the patient that has been delivered seamlessly into the workflow. Behind the scenes, PMP Gateway accesses PMP InterConnect to transmit a request for PMP data and returns that data to Kroger where it is presented to the Kroger pharmacist.

"The clinical utility of this feature is highly valued by our pharmacists and its efficient accessibility means controlled substance histories can be reviewed in seconds, not minutes," said Bill Shinton, director of pharmacy operations for Kroger. "Our PMP usage has climbed by an order of magnitude and we achieved 1,000,000 CS report reviews within the first two months of our rollout – truly a win for our patients and pharmacists alike."

Ohio to Support Additional Integration Projects

On October 26, 2015, Ohio Governor John Kasich announced that the state will support additional projects by investing up to $1.5 million a year to automate Ohio Automated Rx Reporting System (OARRS) data into electronic medical records and pharmacy dispensing systems. Funding will cover the initial costs of integration and the maintenance of connections between such systems, reports the Board in the November 2015 *State of Ohio Board of Pharmacy Newsletter.* Information for Ohio pharmacies and other health care institutions is available on the OARRS website *(www.pharmacy.ohio.gov/integration).*

Past Implementations

PMP Gateway was deployed in WISHIN in September 2014, providing authorized health care providers with access to WISHIN the ability to quickly access PMP data from the Wisconsin Prescription Drug Monitoring Program. Kettering Health Network in Ohio launched use of PMP Gateway in April 2015, allowing its authorized health care providers the ability to access Ohio PMP data from within the hospital's electronic health records workflow.

Use of NAR$_X$CHECK and Interstate Data Can Further Impact

To further assist health care providers in the process of reviewing patient PMP reports, Kroger has also added the NAR$_X$CHECK service. NAR$_X$CHECK, also owned and operated by Appriss, Inc, is a software tool that generates risk-based scores reflecting a patient's CS history. First developed to assist emergency department physicians in making the most appropriate treatment decisions for patients, the NAR$_X$CHECK service analyzes PMP data and provides a report on narcotic, sedative, and stimulant usage including a three-digit, risk-based NAR$_X$CHECK Score that indicates to a physician or pharmacist whether there is a low, moderate, or high probability that a patient could be abusing a drug.

In addition to the option of adding the NAR$_X$CHECK service, because PMP Gateway is integrated with PMP InterConnect, Kroger also has access to interstate data if permitted by the rules of those states participating in PMP InterConnect. This access

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Automated PMP Requests

(continued from page 215)

allows for a more complete patient CS history report to be delivered into the health care providers' workflow, supporting dispensing decisions.

Third Parties Require State's Permission to Access Data

NABP has executed memorandums of understanding (MOUs) with 31 PMPs to participate in PMP InterConnect. In executing these agreements, state PMPs have entrusted NABP with ensuring the security of encrypted data that pass through PMP InterConnect. In addition, NABP has put in place the requisite control, safeguards, and governance to ensure that PMPs remain in complete control of their data and with whom they share their data. PMP InterConnect participants are accountable to one another and have responsibilities that they must uphold as part of executing the MOU with the Association.

These responsibilities and security measures also extend to any agreements executed with non-PMP entities, such as Kettering Health Network, Kroger pharmacies, and WISHIN. All agreements must clearly define the responsibilities of the third party, as well as clear ownership, liability, and legal structure to ensure secure and legal access to, and usage of PMP data.

Importantly, no third-party entity will be able to access a state's data through PMP Gateway without that state's permission. As an example, Kroger pharmacies worked closely with the State of Ohio Board of Pharmacy in its initial implementation of PMP Gateway. This partnership allowed the Board the opportunity to approve Kroger's use of OARRS data. Ohio Board Executive Director Steven W. Schierholt, Esq, stated that the integration project "allows busy pharmacists the ability to quickly review patient data within their workflow to prevent the abuse and misuse of controlled substance medications." Kroger subsequently partnered with boards of pharmacy and/or PMP administrators in the states of Arizona, Arkansas, Colorado, Kansas, Louisiana, Mississippi, Nevada, New Mexico, Virginia, and West Virginia to obtain the needed authorizations to deploy PMP Gateway at its pharmacies in those states.

Boards of pharmacy, PMPs, and other relevant agencies in additional states may be called upon to review requests for permission to access PMP data as more third-party entities seek to deploy PMP Gateway in their electronic health records systems and/or dispensing software.

More information about PMP InterConnect is available in the Programs section of the NABP website. Questions about PMP Gateway or PMP InterConnect may be directed to Government Affairs and Member Relations by sending an email to Government Affairs@nabp.net.

PMP InterConnect

(continued from page 217)

funding support, the software that supports the data exchanges between all PMP InterConnect participants also received some enhancements in 2015. Appriss, Inc, NABP's technology provider for PMP InterConnect, has worked closely with the Association and participating state PMPs to roll out the new software version – application programming interface (API) Version 4.

As requested by state participants, to meet user needs the updated software now includes new, expanded role-based permissions, including the option to select physician, dentist, nurse practitioner, optometrist, etc, from the list of health care provider roles. These new categories allow for state PMPs to share data with more states, including states with more stringent laws on prescribing authority. In addition, new response codes give PMP users more specific details about the status of their PMP request. In October 2015, some states transitioned to the new API Version 4. Additional states will soon be transitioning to the software.

Fact and Fiction

Launched in 2011, PMP InterConnect was designed by NABP to facilitate interoperability and interstate data sharing between state PMPs by providing a secure communications exchange platform for participating states. The system does not house any data and ensures that each state's data access rules are enforced. To further clarify PMP InterConnect's goal and mission and the overall function and administration of the program, NABP created a new guidance document, "NABP PMP InterConnect: Sorting Facts From Fiction," that is currently available in the Programs section under PMP InterConnect on the NABP website at *www.nabp.net*. NABP hopes this new document clarifies many misconceptions about the program that have prevented some states from adopting the standards and infrastructure that the already connected 30 states have embraced. The document clarifies misconceptions such as funding, security, technical architecture, and program governance.

States that have further questions about PMP InterConnect may contact the NABP Member Relations and Government Affairs department at GovernmentAffairs@nabp.net or by calling 847/391-4406. More information about PMP InterConnect, including the most up-to-date participation information, is also available in the Programs section of the NABP website at *www.nabp.net*.

PMP InterConnect Participation, Use Reaches Record Growth in 2015; Program Progresses Toward Goal of National Interoperability

Participation and use of NABP PMP InterConnect® to support secure interstate data sharing between state prescription monitoring programs (PMPs) has grown significantly in 2015. Over the past year alone, three state PMPs connected to PMP InterConnect, bringing the total number of participating states that are now securely sharing prescription drug data through the information platform up to 30.

2015 Participation Overview

Currently, the following state PMPs are connected to PMP InterConnect: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin.

PMP InterConnect is expected to see continued growth moving into 2016 as one state has executed a memorandum of understanding (MOU) to participate, and another six states/jurisdictions are currently reviewing MOUs.

In addition, several other state PMPs not connected to the program have shown interest in reviewing an MOU. These state PMPs were invited to attend the July 15-16, 2015 NABP PMP InterConnect Steering Committee meeting for an overview of the program and to see how the participating 30 states have adopted and implemented its use to combat prescription drug abuse. For a full breakdown of PMP InterConnect participation in 2015, see the timeline below.

The number of interstate prescription drug data requests has also grown significantly in 2015. For example, in the early stages of the program in 2011 only a few thousand interstate transactions were supported each month. In 2015, however, the program began processing up to 1 million interstate requests per month.

Also in 2015, in recognizing the program's growth and achievements over the years to effectively support secure interstate data sharing between the state PMPs, NABP approved funding to support participation in PMP InterConnect at no cost to the state PMPs through June 2018.

Software Enhancements

In addition to the record-breaking participation growth and additional

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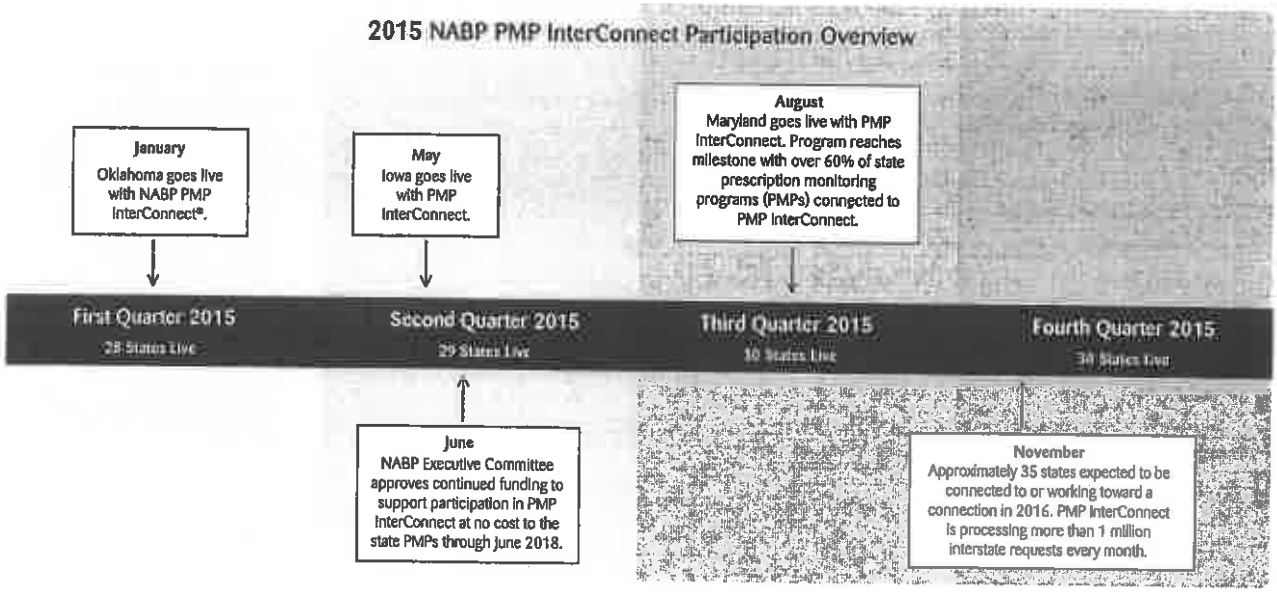

The above timeline represents the growth of the NABP PMP InterConnect® program's participation throughout 2015. For a complete overview of PMP InterConnect participation, see the NABP PMP InterConnect map (PDF) in the programs section of the NABP website at *www.nabp.net.*

Automated PMP Requests
(continued from page 215)

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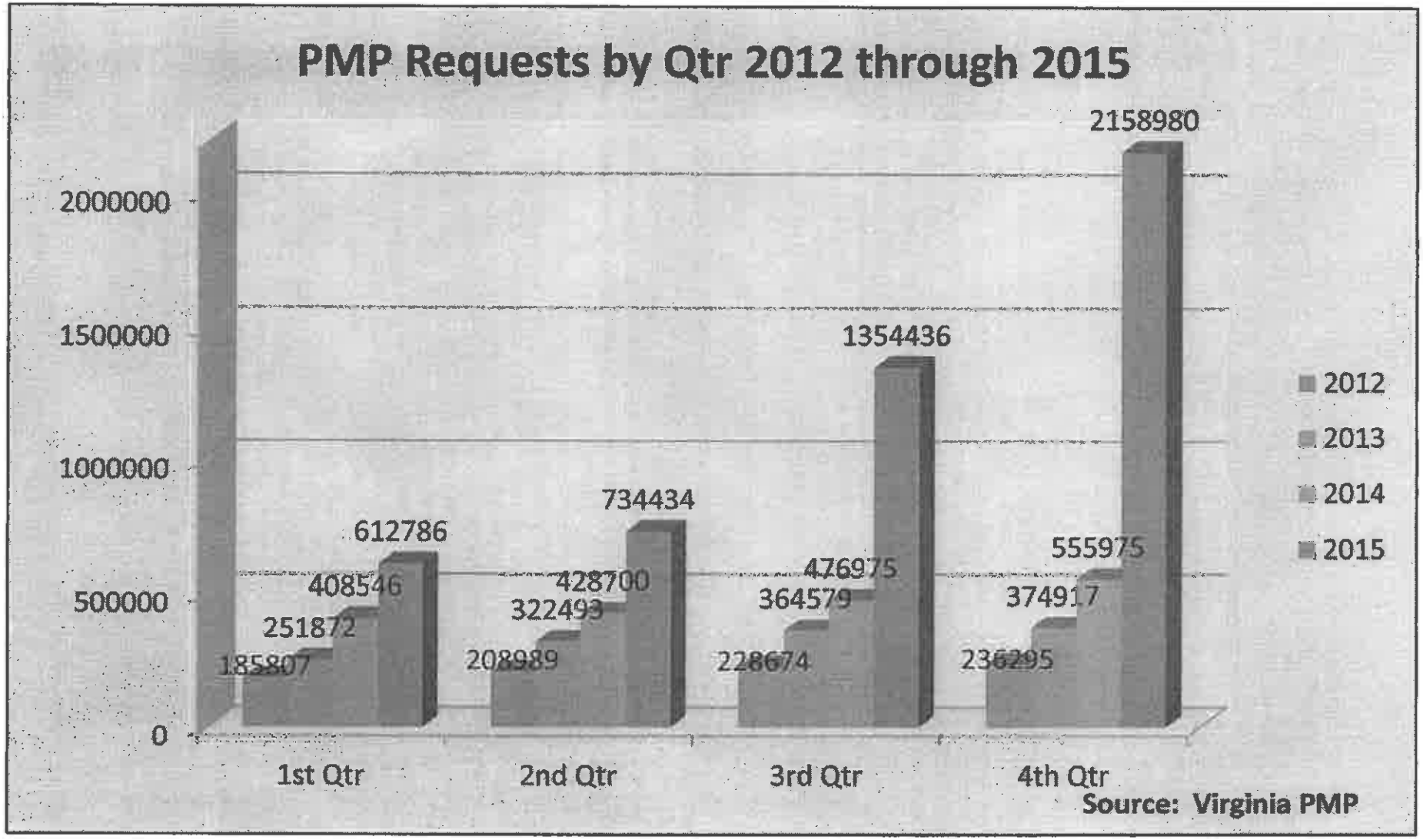
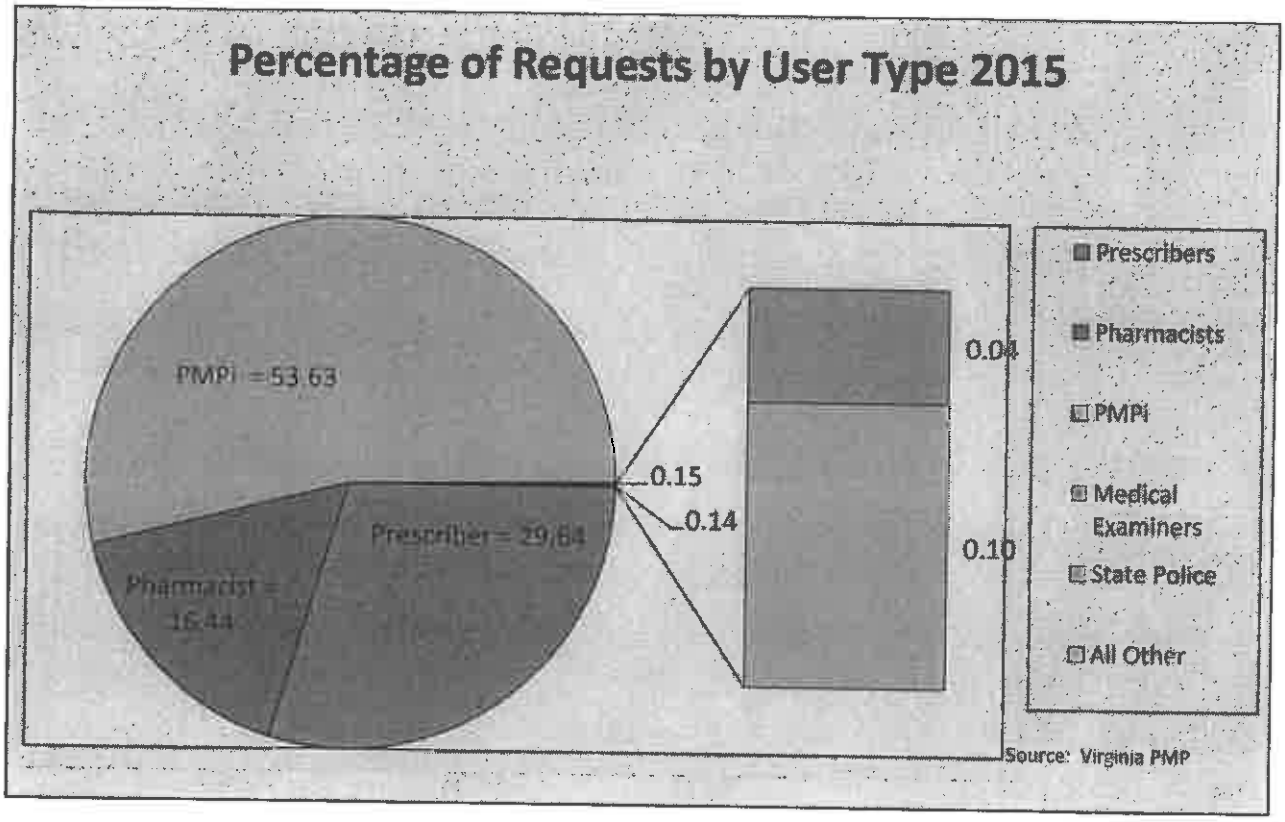

PMP Requests by Qtr 2012 through 2015
2000000
1500000
1000000
500000
0
185807
251872
408546
612786
208989
322493
428700
734434
228674
364579
476975
1354436
236295
374917
555975
2158980
1st Qtr
2nd Qtr
3rd Qtr
4th Qtr
2012
2013
2014
2015
Source: Virginia PMP



	Total Requests by User Type 2014 and 2014		
	2014	Direction	2015
DHP	1,115	↓	1,000
State Police DDU	2,434	↓	1,834
Prescribers	1,105,551	↑	1,440,871
Recipients	36	↓	34
Medical Examiners	7,361	↓	7,235
Health Practitioners' Monitoring Program	1,321	↓	1,149
DEA	568	↑	645
Pharmacists	456,519	↑	799,098
Medicaid Fraud Control Unit	23	↑	65
PMPi	293,002	↑	2,606,515
US Atty	1	No change	1
Local Law Enforcement	1,918	↓	1,821
FBI	347	↑	368
TOTAL	1,870,196	↑	4,860,636