

DRAFT

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

Wednesday, January 6, 2016

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

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| CALL TO ORDER: | A meeting of the advisory panel of the Prescription Monitoring Program was called to order at 10:23 a.m. |
| PRESIDING | S. Hughes Melton, M.D., Chair |
| MEMBERS PRESENT: | John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C. Carola Bruflat, Family Nurse Practitioner Randall Clouse, Office of the Attorney General Dr. Amy Tharp, Office of the Chief Medical Examiner Brenda Clarkson, Executive Director, Virginia Association for Hospices and Palliative Care Holly Morris, RPh, Crittenden's Drug, Vice Chair Harvey Smith, 1SG, Virginia State Police |
| MEMBERS ABSENT: | Mellie Randall, Representative, Department of Behavioral Health and Developmental Services |
| STAFF PRESENT: | David E. Brown, D.C., Director, Department of Health Professions (DHP) Lisa Hahn, Deputy Director, Department of Health Professions (DHP) James Rutkowski, Assistant Attorney General, Office of the Attorney General Elaine Yeatts, Senior Policy Analyst 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 all members and staff introduced themselves. |
| APPROVAL OF AGENDA | The agenda was approved as presented. |
| APPROVAL OF MINUTES (p. 2 – 6 agenda packet) | Dr. Melton accepted a motion to approve the minutes from the September 30, 2015 minutes of the PMP Advisory Panel and all were in favor. The minutes were approved as presented. |
| PUBLIC COMMENT: | No public comments were made. |
| David E. Brown, D.C.: DEPARTMENT OF | Dr. Brown welcomed the Panel and thanked them for taking time from their schedules. Dr. Brown introduced Lisa Hahn as the |

**HEALTH
PROFESSIONS REPORT**

**Elaine Yeatts:
2015 LEGISLATION
AND REGULATION
UPDATE (p. 7 – p 25
agenda packet):**

new Chief Deputy Director of DHP. Ms. Hahn will continue serve as the Executive Director of 3 Boards: Funeral Directors and Embalmers, Long-Term Care Administrators and Physical Therapy until after the end of the 2016 General Assembly Session. Ms. Hahn has previously been employed with the Department of Criminal Justice Services and began her civil service as a police officer in the City of Richmond. She has a master's in public administration from Virginia Commonwealth University.

Ms. Yeatts provided an overview of legislation related to the Prescription Monitoring Program which will be presented during this session.

The first piece of legislation Ms. Yeatts presented is one for which DHP requested introduction and was accepted as part of the Governor's legislative package. The legislation amends Chapter 25 of the Code of Virginia and does three things. First, the legislation provides for a reporting requirement for PMP data within 24 hours of dispensing. Second, the legislation will allow prescribers and pharmacists that are consulted on behalf of a patient's care (but do not provide direct care) to query the PMP. Third, the legislation provides language which clarifies that PMP reports may be kept in the medical record.

Ms. Yeatts also discussed 3 bills which resulted from recommendations from the Governor's Task Force on Prescription Drug and Heroin Abuse. The first bill strikes the language with respect to mandatory queries of the database referencing that treatment "last more than 90 consecutive days" and states the prescriber must query "prior to prescribing a benzodiazepine or an opiate". The proposed legislation also strikes the language referencing a "list of benzodiazepines and opiates" that has a "low potential for abuse by human patients". There are three exceptions to the query mandate including the prescribing of opiates or benzodiazepines for either hospice/palliative care or for a surgical procedure, or program unavailability due to technical failure. Dr. Brown suggested a 3-year sunset on the bill to insure an evaluation of the impact of the legislation.

Ms. Yeatts discussed the second piece of legislation resulting from the task force recommendations, which would allow PMP staff authority to disclose certain PMP information related to possible indiscriminate prescribing or dispensing to the appropriate Board for investigation.

Ms. Yeatts presented the third piece of legislation which would require CME for prescribers licensed by the Board of Medicine if they meet a certain threshold for prescribing. The Board of Medicine would determine that threshold and would notify those

**COMMENTS FROM
NOIRA: Elaine Yeatts
Review of draft language
for proposed legislation (p
24 – p. 25 agenda packet).**

licensees that they require CME. Dr. Barsanti noted that there is a risk that some licensees will decide not to prescribe simply to avoid the CME. Ms. Yeatts noted that there are already many hours of CME required anyway, and this is not necessarily burdensome. Panel members discussed that the BOP recently began requiring 2.0 hours of CE on prescribing and addiction for their licensees.

Ralph Orr reviewed a not yet filed bill, which would require that the Director give access to health care plan employees. This would be a departure from the PMP's current approach for access by healthcare providers because it would allow access to those not providing care to a specific patient. Dr. Melton noted that the proposed amendment would allow the health care plan to "fill in the missing pieces" with respect to the enrollee, noting that the health care plan's main focus is to steer these patients to specific case management services. The second proposed amendment is very different because it allows health plan employees to have access to information to identify overprescribing. Ms. Morris stated that she has concerns about the proposed legislation because it will allow individuals who are not clinicians or pharmacists or trained investigators access to the PMP. Ms. Yeatts suggested the committee submit comments about this bill. Panel members want to know how many other states have laws in place similar to this. Dr. Barsanti noted that if the prescriber looks at the PMP, and the dispenser looks at the PMP, why do we need a third party who is less qualified to look at the PMP? It was noted that if passed, the upcoming mandate (mandatory requests) may address any oversight (with respect to knowledge of prior dispensing history) in prescribing and dispensing.

Ms. Yeatts noted that the Virginia PMP received a comment from the National Association Chain Drug Stores (NACDS) with respect to the Notice of Intended Regulatory Action (NOIRA) regarding the regulations governing the PMP, expressing concern if pharmacies would be required to submit additional specialized data elements not already gathered for processing prescriptions and claims. Proposed new data elements include reporting of the following elements: NPI, whether the Rx is a partial fill, gender code, species code and the Electronic prescription reference and order number. Ms. Yeatts noted that the Director would be proposing the change to the regulation and asked the PMP Advisory Panel to consider the proposed language. Dr. Melton accepted a motion that the proposed language be recommended and the committee approved it as presented. Ms. Yeatts explained the regulatory process; that once proposed regulations are published in the Virginia Register, there is a 60-day comment period, after which the bill goes back to the Director, comments reviewed and final language submitted. The process is long, and

UPDATE ON UTILIZATION OF PMP DATA: Phase II: Neal Kauder, VisualResearch, Inc.

the proposed regulation will probably not take effect until 2017.

Neal Kauder reported what Visual Research had accomplished since the last meeting. He noted that they have reviewed data based on zip code data and have established a new database that his group is very comfortable with. Mr. Kauder inquired of the panel members how important the MME is—should his team focus on looking at opioids only? Dr. Melton noted that combining benzodiazepines with opioids does increase the overdose rate. Dr. Barsanti further noted that it would be difficult to come up with a meaningful score when looking at other types of drugs (such as muscle relaxants) in combination with opiates. The panel agreed that to begin looking at the data, we should begin with a simple measure and look at only opiates. Dr. Tharp noted that the dosing is not as important as the simple knowledge that the patient is using benzodiazepines in combination with opiates. Mr. Kauder said that when looking at a measure, it is easy to understand as a rate divisible by 100.

Mr. Kauder stated that we can look at opiate prescribing by planning district or health district, for example. Mr. Orr noted that the under 18 age group in Virginia is 1.85 M out of the total population of 8.2 M. The panel agreed that we should look at the population over age 18. The panel agreed that the rate (1/1000 or 1 per 100,000, etc.) could be determined at a later date.

Mr. Kauder also inquired about the MME score. Does the panel want to know all those individuals with a score >80? >100? >120? Dr. Barsanti asked what the denominator is. The panel agreed we should be looking at individuals with MME score of 100 as the threshold and the denominator being those prescribed opiates in the database.

Mr. Kauder noted that we can look at many different measures. Where are the most prescriptions? Who writes the highest doses? Who queries the database? Where are prescriptions most likely written? How far are patients travelling for prescriptions? The panel discussed that zip codes for out of state for pharmacies represent mail order pharmacies shipping to Virginia residents. Mr. Kauder noted that he would look into the travel issue..

PBSS MEASURES: OVERVIEW (p. 26 and p. 27 agenda packet): Ralph Orr

Ralph Orr discussed PBSS measures. Mr. Orr noted that the Virginia PMP has an MOU with Brandeis University to obtain these measures from PMP de-identified data. The Virginia PMP recently received its first quarterly report of data from PBSS. Mr. Orr noted that there are some missing data elements and explained that when a data element is missing from greater than 25% of the prescriptions in the database, that particular measure is not calculated. When the PMP can require the reporting of the gender of a patient that will resolve the biggest hurdle to reviewing and receiving outcomes for all PBSS measures. Mr. Orr shared a report that indicated that 30% of those prescribed LA opiates in our database were opiate naïve (defined

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| <p>HEALTH AND CRIMINAL JUSTICE DATA COMMITTEE UPDATE (p. 28 and p. 29 agenda packet): Ralph Orr</p> <p>PMP UTILIZATION RATES (p. 31 – p. 33 agenda packet): Ralph Orr</p> | <p>as having received no opiates for the previous 60 days) and received a mean daily dose of over 100 MED (Morphine Equivalent Dose).</p> <p>Mr. Orr explained that this committee was created as a result of a recommendation approved by the Governor’s Task Force on Prescription Drug and Heroin Abuse. It has met twice to discuss the availability of data from disparate agencies and will continue to explore this data and how it can be used to identify trends and inform policy and resource allocation decisions</p> <p>Mr. Orr shared a Medscape article that reported that Family Practice and Internal Medicine physicians actually prescribe the majority of prescription opiates; which implies that focusing efforts on high prescribers (or pill mills) will not impact sufficiently on solving the problems of prescription drug abuse.</p> <p>Mr. Orr presented information showing the number and percentage of those users who prescribe and the number and percentage of users who query. Mr. Orr then showed an email from Peter Kreiner of Brandeis University who reviewed Virginia’s PMP data. The data compared query rates in Virginia to those states that do not have mandatory use laws. The take-home lesson is that Virginia compares to states with no mandatory use mandates. The confusion regarding our mandatory use law will be alleviated if the proposed legislative language is passed. Dr. Melton suggested that DHP should focus education and other efforts on the prescribers who write between 100 and 500 prescriptions per quarter because they write so many prescriptions and query so infrequently.</p> |
| <p>RESEARCH REQUESTS REVIEW PROCESS (p. 34 and p. 35 agenda packet): Carolyn McKann and Ralph Orr</p> | <p>Ms. McKann reviewed the research request form and the panel discussed charging a cost for providing the data. Discussion then centered on whether the research would fall under a FOIA request. Mr. Clouse indicated that the committee could approve our own cost schedule for the research requests. Ms. Bruflat indicated that (they) never provide research data to anyone who cannot demonstrate IRB approval. The committee members agreed that the form should indicate the applicant must attach a copy of an IRB approval. The committee asked that staff investigate what our options are in terms of costs associated with the research requests, and perhaps develop our own fee schedule.</p> |
| <p>COMMUNICATION ACTIVITIES IN SUPPORT OF PMP: Matt Treacy and Diane Powers</p> | <p>Matt Treacy discussed initiatives for 2016 with respect to PMP communications materials. Mr. Treacy indicated that materials would be developed for two different audiences: 1) practitioners and 2) the general public. Mr. Treacy also noted that the materials would be digitally-based; however, print copies would be available for each publication. Their intent is to use interactive web pages with links, to include a whole suite of electronic tools.</p> |

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| <p>STATUS OF TASK FORCE RECOMMENDATIONS UPDATE (p36 agenda packet): Ralph Orr</p> <p>AUTOMATED REGISTRATION UPDATE (p. 37 and p. 38 agenda packet): Ralph Orr</p> <p>INTEROPERABILITY AND INTEGRATION UPDATE (p. 39 – p. 42 agenda packet): Carolyn McKann</p> | <p>The publications will include: 1) a PMP brochure; 2) a one-page overview and 3) a video tutorial presented by Mr. Orr. Plans are also to update the website, removing any reference to registration since registration is now mandatory upon licensure. The planned overview will include “how to use the PMP” as well as “why we should use the PMP”. Any or all of these documents may be included on the Governor’s task force website.</p> <p>Mr. Orr gave a brief overview of the status of the 13 recommendations from the Data-Monitoring Workgroup. Several of the recommendations have already been completed and there is or has been action taken to implement all remaining recommendations.</p> <p>Mr. Orr noted that the automated registration process, once underway, was very successful. The total number of registered users increased from 23,741 on January 1 of 2015 to 70,002 on January 1 of 2016. Mr. Orr noted that among those individuals who could not be automatically registered, the majority of those did not have email addresses, and an email has been sent to their email address of record within the emergency response system to encourage them to either provide a valid email address to the PMP or to register. Approximately 78% of those whose records were rejected for the automated registration had no email address. The PMP will continue to work on mechanisms to ensure 100% registration of authorized licensees.</p> <p>Carolyn McKann indicated that interoperability had a great impact on the increase in program requests in 2015. On December 17, 2015 the Virginia PMP added New Jersey and Rhode Island as data sharing states, bringing the total to 19 states. Ms. McKann also noted that 35 states now have Memorandums of Understanding (MOUs) with NABP’s PMPi. Ms. McKann noted that our neighboring state, North Carolina, has executed an MOU but does not yet have the software capability to share data with us. Ms. McKann also noted that NABP’s PMPi project processes nearly 1 million requests from the participating states each month, and Virginia processes nearly half a million requests each month through the Gateway service, which allows pharmacy and hospital systems to piggyback on the PMPi service. The Gateway requests processed by Virginia are primarily incoming requests from Kroger pharmacies in Ohio, West Virginia and Virginia.</p> <p>Ms. McKann briefly explained that Kroger pharmacies log into the pharmacy system and immediately have access to PMP information without a second login ID. In addition, Kroger receives what is called a NARxCHECK report, which provides a relative risk score for the following three groups of controlled substances: opiates, stimulants and sedatives.</p> |
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| <p>PROGRAM STATISTICS (p. 43 and p. 44 agenda packet): Carolyn McKann</p> | <p>Ms. McKann reviewed selected program statistics, including a pie chart showing that the PMPi portion of the Virginia PMP is greater than half of all requests. She also noted that the PMPi requests are primarily from prescribers and pharmacists. Ms. McKann then showed a comparison of request types from year end 2014 and year end 2015, demonstrating the extreme growth in the program in 2015 from interoperability, and the relative stability in requests by many of the investigative user types.</p> |
| <p>NEXT MEETING</p> | <p>The next meeting will be held on March 2, 2016.</p> |
| <p>ADJOURN:</p> | <p>With all business concluded, the committee adjourned at 1:50 p.m.</p> |
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| | <p style="text-align: right;">_____ S. Hughes Melton, M.D., Chairman</p> |
| | <p style="text-align: right;">_____ Ralph A. Orr, Director</p> |