FINAL/APPROVED

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

Tuesday, February 1, 2011

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	Kenneth Walker, M.D., Chair
MEMBERS PRESENT:	Randall Clouse, Office of the Attorney General, Medicaid Fraud Unit, Vice Chair Brenda Mitchell, President, Virginia Association for Hospices Holly Morris, RPh, Crittenden's Drug Harvey Smith, 1SG, Virginia State Police Dr. Anna Noller, Representing Dr. Amy Tharp, Office of the Chief Medical Examiner
MEMBERS ABSENT:	John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C. Carola Bruflat, Family Nurse Practitioner Mellie Randall, Department of Behavioral Health and Developmental Services
STAFF PRESENT:	Arne Owens, Chief Deputy Director, Department of Health Professions Elaine Yeatts, Senior Policy Analyst Ralph A. Orr, Program Director, Prescription Monitoring Program Carolyn McKann, Deputy Director, Prescription Monitoring Program
WELCOME AND INTRODUCTIONS	Dr. Walker welcomed everyone to meeting of the Advisory Panel.
PUBLIC COMMENT:	No public comments were made.
APPROVAL OF AGENDA	The agenda was approved as presented.
APPROVAL OF MINUTES	The Panel reviewed draft minutes for the September 21, 2010 meeting. The minutes were approved as presented.
GENERAL ASSEMBLY LEGISLATIVE UPDATE: ELAINE YEATTS	Elaine Yeatts presented a handout containing bills of interest to the Prescription Monitoring Program. These bills are listed on the following pages followed by a brief description of each and/or its impact on the Virginia Prescription Monitoring Program (PMP).

HB 1434 (Patron-Garrett): *Marijuana, synthetic; penalties for possession, intent to sell, distribute, etc.*
This is the first of approximately 15 similar bills introduced this session. HB1434 appears to be the bill that will go through the House. The DEA has an emergency schedule action regarding the passage of such legislation. The final language should be such that if chemicals used to manufacture synthetic marijuana are altered, that the resulting legislation will also apply to those.
HB1762 (Patron-Crockett-Stark): *Schedule I; adds 5-methoxy-N,N-dimeythltryptamine to list.*
This Virginia bill provides convergence with the DEA schedule.
HB 2252 (Patron-Nutter): *Prescription Monitoring Program; report required for certain prescriptions.* This bill was tabled in the House. This would have required prescribers to request a PMP report on patients under certain circumstances including the belief that the patient is seeking controlled substances for that other than medical treatment.
HB2255 (Patron-Nutter): *Disclosure of health records; health care providers who dispense controlled substances.* As of 2/1/2011 passed in the House. This bill would allow a prescriber or pharmacist to re-disclose health information obtained from a Prescription Monitoring Program report to another health care provider as it relates to the patient's treatment.
HB2256 (Patron-Nutter): *Schedule II drugs; identification required in filling prescriptions.* Specifies that certain duties imposed upon a pharmacist in the delivery of Schedule II drugs may be undertaken by an agent of the pharmacist and modifies requirements for identification of persons picking up a prescription if the individual is not the patient for whom the drug is prescribed.
HB878 (Patron-Reynolds): *Pseudoephedrine; prohibited from being sold without a prescription.* This bill never made it out of committee. Would have required that pseudoephedrine be dispensed only with a prescription as a Schedule III controlled substance.
SB1029 (Patron-Puckett): *Disclosure of health records; health care providers who dispense controlled substances.* This bill is identical to **HB2255** described above.
SB1095 (Patron-Hanger): *Schedule II, etc., controlled substances; prescriber to request information about patient.* Stricken. Would have required prescribers to query the PMP for any patient for whom they are prescribing a Schedule II, III or IV controlled substance.
SB1096 (Patron-Hanger): *Pharmacies; shall have access to Prescription Monitoring Program.* The actual language of this bill has changed by virtue of amendment. The intent of the language was changed to mean that each pharmacy shall have the ability to query the PMP, primarily through internet access. The Board of Pharmacy may develop regulations in response to the passage of this bill.

SB 1150 (Patron-Quayle): *Schedule II drugs; identification required in filling prescriptions.* This bill is identical to **HB2256** described above.

RECOMMENDATIONS RELATED TO PROGRAM REGULATIONS—NEXT STEPS: ELAINE YEATTS

Ms. Yeatts reviewed next steps regarding the recommended changes to the PMP regulations. Ms. Yeatts recommended proceeding with the fast track process which would allow the program to skip two of the three full steps of the Administrative Process Act. The program may meet the requirements of the fast track process because the intent of the regulatory changes is to allow the PMP to be eligible for federal grant funding. Ms. Yeatts also noted that there is language in the Code that allows the DHP Director to add non-clinical data elements without the regulatory process.

Mr. Ralph Orr reviewed the NASPER (National All Schedules Electronic Reporting Act) requirements as well as recommended changes to current regulations. NASPER has introduced many minimum eligibility requirements which the PMP currently does not meet and which are necessary to be eligible for federal grant funding. One requirement in order to qualify for a NASPER grant is the PMP's reporting requirement of ASAP (American Society of Automation in Pharmacy) 4.1 (November 2009) or higher. NASPER also requires reporting within seven days of dispensing. The PMP requires semi-monthly reporting only. The PMP estimates that approximately 50% of Virginia pharmacies report weekly, and therefore the PMP does not consider this to be an undue burden on program participants (dispensers).

Mr. Orr explained that the current 95 version of ASAP is outdated. The new standard is much more powerful, should make programming for data reporting easier. The ASAP 4.1 standard also makes the error correction process simpler and "Zero reports" may be submitted on behalf of dispensers through the pharmacy software as it would recognize no data for that time frame.

Pharmacy software vendors would need to upgrade their applications to meet the ASAP 4.1 standards. If a vendor does not already have the latest ASAP standard, the cost for members of ASAP is approximately $175.00. For non-members, the cost is approximately $650.00.

Mr. Orr then discussed the data elements recommended to be added to the regulations, the first element being the method of payment. The second element would be each pharmacy's Drug Enforcement Administration (DEA) number. Currently, the PMP utilizes each pharmacy's NCPDP # as our unique identifier, and utilizing each pharmacy's DEA number instead would allow us to be in sync with other states as well as providing cost savings to the program as the DEA registration database may be obtained for free for state PMPs. The third element would be the total number of refills ordered; the fourth element would be whether the prescription is a new prescription or a refill.

Elements 3 and 4 would provide extra clarity in reporting. The fifth element would be the date the prescription was written. This would allow users to identify if there was a significant gap between the time the prescription was written and the date it was filled. The last element would be the estimated number of days the prescription should last. To emphasize, most of these elements are required for the PMP to qualify for federal funding, and Ms. Yeatts suggested that the Panel recommend these changes to the Director.

Mr. Orr noted that we also recommend striking some language in the Code, 18VAC76-20-60, because the language does not accurately reflect the way we currently do business. The information is collected for each registered user, and is used in the login procedure; not in the submit request process. The following changes are recommended:

B.2. The prescriber for the purpose of establishing a treatment history for a patient or prospective patient, provided the request is accompanied by ~~the prescriber's registration number with the United States Drug Enforcement Administration (DEA)~~ and attestation that the prescriber is in compliance with patient notice requirements of 18 VAC76-20-70.

B.5. A dispenser for the purpose of establishing a prescription history for a specific person to assist in determining the validity of a prescription, provided the request is accompanied by ~~the dispenser's license number issued by the relevant licensing authority and~~ an attestation that the dispenser is in compliance with the patient notice requirements of 18 VAC 76-20-70.

Mr. Randall Clouse made a motion to accept the changes and Ms. Brenda Mitchell upheld the recommendation. Ms. Holly Morris mentioned that she was somewhat concerned about the burden of weekly reporting to some pharmacies. Ms. Morris noted that obtaining funding is very important; however, it would be helpful to see capabilities that would allow pharmacies to automate the reporting of data to the program.

Mr. Orr noted that the Federal grants generally cannot be used for operational expenses and that for the near future, due to low interest rates; we are probably going to have to rely on Federal funding for any improvements to the program. NASPER by way of the minimum eligibility requirements is encouraging all the programs across the country to act and appear similar, in order to simplify things for health care entities utilizing them.

The motion passed unanimously.

DRUG DEATH STATISTICS—OFFICE OF THE CHIEF MEDICAL EXAMINER: DR. ANNA NOLLER

Dr. Anna Noller, State Forensic Epidemiologist for the Office of the Chief Medical Examiner, presented an overview of drug deaths statistics for 2009 and 2010. Dr. Noller emphasized that currently there are approximately 250 death investigations still awaiting completion for 2010 data, the majority of which are awaiting toxicology results. Drug deaths increased every year from 1999 through 2008. There was a slight decrease in deaths from 2008 to 2009. Dr. Noller anticipates that, pending results

from the outstanding data, there may also be a slight decrease in 2010.

The committee then discussed the prevalence of alcohol, and Dr. Noller noted that alcohol, for public health reasons, is not included in the "mixed" category, because it may skew the results to some degree. Dr. Noller noted that drug deaths for persons in their 20's and 30's are overwhelmingly male; however, females are beginning to catch up with males. Mr. Orr asked Dr. Noller how Virginia's statistics compared with national data, but she is not aware how they compare in terms of the prevalence of female deaths increasing. She has noted that because of the awareness of prescription drug abuse in the western part of the state, illegal drug use is increasing in western Virginia. 1SG Smith stated the he has been seeing a decrease in crystal meth labs and a corresponding increase in already manufactured Mexican crystal meth. Dr. Noller noted that for greater than a decade, the western region has consistently been the greatest number of drug deaths per capita. Virginia's overall average is 8.7 deaths per 100,000.

Dr. Noller included the rates of deaths due to motor vehicle accidents by county as a comparison to rates of death due to drug overdose. She noted that she determines the cause of death due to drug overdose by blood toxicology only.

Dr. Noller introduced her FHMO [fee-moh] table listing all deaths due to Fentanyl, hydrocodone, methadone and oxycodone. She indicated that one or more of these drugs is present in nearly 50% of all drug deaths. 1SG Smith noted that he is seeing an increase in diversion of fentanyl in patch form.

Mr. Orr inquired, and Dr. Noller responded that blood toxicology cannot tell you whether a drug is the short or long-acting variety. Dr. Noller also noted that there are low death rates for amphetamines including Adderall and Ritalin.

Preliminary results from 2010 show that drug deaths for the 35-44 age group are higher for female, not male which would be a first for that age group.

1SG Smith added that the next National Take-Back Day is scheduled for April 30, 2011.

ARNE OWENS: DEPARTMENT OF HEALTH PROFESSIONS REPORT

Arne Owens noted that much of the Director's and Deputy Director's time has been spent recently with legislative matters of the General Assembly. He indicated that the agency's five bills are moving forward through the process.

Mr. Owens also noted that due to budget constraints, we continue to seek opportunities to operate more efficiently.

The Health Practitioners' Monitoring Program (HPMP) contract with Virginia Commonwealth University Health Systems is currently in the process of being re-negotiated. This will result in a five-year contract. This program provides monitoring of impaired health professionals who are being followed according to Orders entered by the Department of Health Professions due to complaints brought forward by a multitude of sources.

Mr. Owens stated that Dr. Cane and Mr. Owens continue to serve as Senior Advisors to the Virginia Health Reform Initiative (VHRI), and are focusing on healthcare workforce capacity reform. Virginia is continuing to implement changes resulting from the Federal health law. Dr. Bill Hazel, Secretary of Health and Human Resources is the Chairman of the Advisory Council for VHRI. The Advisory Council consists of six task forces from all different sectors. Work will continue on the VHRI throughout 2011, and Virginia will continue its course in compliance with Federal law.

Mr. Owens also stated that the Healthcare Workforce Data Center (HWDC) has received additional funding from the Department of Health. The HWDC has sent out several surveys to all professions as a part of each licensure renewal process. The data gathered from these surveys will be a significant resource. The Virginia Health Workforce Development Authority, whose mission is to identify, educate, recruit and retain health professionals in the state of Virginia for the overall health of all Virginians, will continue to review work force issues in Virginia. The Department of Health will also collaborate with the Department of Health Professions to look at work force issues in Virginia, identify solutions and make recommendations. Currently DHP is looking at capacity issues including projected shortages.

PROGRAM UPDATE: RALPH ORR

Mr. Orr noted that the "Report on the Collection of Data and Information about Utilization of the Prescription Monitoring Program pursuant to SJR 73 and SJR 75 (2010) (State Document NO. 13)" did not result in any proposals during this legislative session as a result of recommendations considered in the report. The Advisory Panel did not have any comments regarding the report.

Mr. Orr discussed the issue of interoperability with other states. Both the Institute for Justice Information Systems (IJIS) and the National Association of Boards of Pharmacy (NABP) have independently been working on a nationwide solution to the issue of interoperability among states. IJIS is a non-profit organization dedicated to support services for information exchange and technology initiatives. NABP is a professional organization that supports the state boards of pharmacy in creating uniform regulations to protect the public health. Mr. Orr has been working with both IJIS and the Council on State Governments (CSG) to address the issue of interoperability. The CSG is a region-based forum that fosters the exchange of ideas to help state officials shape public policy. NABP is working on developing a data sharing model for PMP interoperability and plans to begin a pilot in June of 2011. They intend to have the project fully operational by September 30, 2011. NABP indicates that each PMP would have an agreement with NABP, and that participation in the project would be at no or little cost to states. The PMIX project, also a data sharing project established

to allow PMP programs to communicate, is currently located at the Ohio Board of Pharmacy. Ohio's and Kentucky's PMP programs are preparing to do pilot testing with live data on this system.

PROGRAM STATISTICS

Mr. Orr reviewed the program's statistics for 2010. Mr. Orr stated that the program now averages 10,000 requests per week, receiving approximately 500 each Saturday and approximately 400 each Sunday. Nearly 25% of the request totals are processed in the evenings and on weekends. Mr. Orr stated that we now have greater than 9,000 registered users. Dr. Walker inquired about the total number of potential registered users. Mr. Orr indicated that in early 2010, we mailed 39,000 informational brochures to all licensed prescribers and pharmacists in Virginia, and we now have nearly 25% of that total registered.
Mr. Orr noted that the number of registered delegates is extremely low; we have less than 300 delegates in total.
Mr. Orr reported that the prescribers who prescribe the greatest number of controlled substances are also the ones most likely to register to use the program. In addition, the majority of requests are submitted by prescribers, and the percent of requests by user type appear to be largely consistent across the states.

PMP SURVEY

Mr. Orr again mentioned the "Report on the Collection of Data and Information about Utilization of the Prescription Monitoring Program pursuant to SJR 73 and SJR 75 (2010)." This report was pursuant to Senate Joint Resolutions 73 and 75 passed during the 2010 session. The resolutions requested specific data by month as well as any recommendations for changes to the PMP for the 2011 General Assembly. The resolutions contained a question specifically requesting information about the impact of the PMP program. To that end, a survey was developed and sent to selected prescribers that had received unsolicited reports from the PMP in 2010. Responses were anonymous. The survey was initially sent on January 6, 2011. The closing date was originally set at January 21, 2011, but was extended to January 28, 2011 since the response rate by the twenty-first was merely 26% of those receiving the survey. A reminder email was sent with a link to the survey instrument and the survey was closed on January 28, 2011. The response rate increased to 47% as a result of the extension. Approximately 11,800 emails were sent during the course of the initial survey, and only 61 of those were returned with invalid addresses.

REVIEW NEW CONCEPT FOR PROVIDING UNSOLICITED REPORTS

Ms. Carolyn McKann reviewed the current and the new process for providing unsolicited reports. Ms. McKann stated that currently a threshold report in run by month to identify patients at risk, and reports accompanied by cover letters are sent to all prescribers on each patient's report, regardless of whether they are registered on non-registered. The registered users also receive an email and instructions on how to view their report.

The new process will not provide for any mailed reports. Non-registered users will receive a letter stating the name of the patient in question, the purpose of the PMP, and instructions how to register on-line to become a registered user. Registered users will no longer receive a mailed report and cover letter. Those registered will receive only an email, a link to recover the PMP report, and directions on how to view the report. This will increase the efficiency of this process since most reports will not require postage, and the PMP reports will only be viewed by those for whom they are intended. Currently, a small percentage of reports are returned, having been mailed to an old or inaccurate address.

NEXT MEETING The next meeting will be held on a date yet to be determined in June, 2011.

ADJOURN: With all business concluded, the committee adjourned at 1:17 p.m.

Kenneth Walker, M.D., Chairman

Ralph A. Orr, Program Manager