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

Tuesday, July 10, 2012 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 10:08 a.m.

PRESIDING Kenneth Walker, M.D., Chair

MEMBERS PRESENT: Carola Bruflat, Family Nurse Practitioner

Brenda Clarkson, Executive Director, Virginia Association for

Hospices and Palliative Care

Randall Clouse, Office of the Attorney General, Medicaid Fraud

Unit, Vice Chair

Holly Morris, RPh, Crittenden's Drug

Dr. Anna Noller, Representing Dr. Amy Tharp, Office of the

Chief Medical Examiner

Mellie Randall, Representative, Department of Behavioral

Health and Developmental Services

MEMBERS ABSENT: John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C.

Harvey Smith, 1SG, Virginia State Police

S. Hughes Melton, M.D., Mountain Valley Health

GUESTS PRESENT: Kim Barnes, HIT Project Coordinator, Office of Information

Management and Health IT, Virginia Department of Health Brenda Mitchell, Virginia Association for Hospices and

Palliative Care

STAFF PRESENT: Dianne Reynolds-Cane, M.D., Director, Department of Health

Professions (DHP)

Arne Owens, Chief Deputy Director, Department of Health

Professions

Howard Casway, Senior Assistant Attorney General, Office of

the Attorney General

Elaine Yeatts, Senior Policy Analyst

Diane Powers, Director of Communications, Department of

Health Professions

Ralph A. Orr, Program Director, Prescription Monitoring

Program

Carolyn McKann, Deputy Director, Prescription Monitoring

Program

WELCOME AND Dr. Walker welcomed everyone to the meeting of the advisory

INTRODUCTIONS 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 June 14, 2011 meeting. The minutes were approved as presented.

ELECTION OF CHAIRMAN AND VICE-CHAIRMAN Dr. Anna Noller nominated Randall Clouse and Mr. Clouse was subsequently elected Chairman of the Advisory Committee for the upcoming term; all were in favor, none opposed. Mr. Randall Clouse nominated Holly Morris and Ms. Morris was subsequently elected as Vice-Chairman for the upcoming term; all were in favor, none opposed.

DIANNE REYNOLDS-CANE, M.D.: DEPARTMENT OF HEALTH PROFESSIONS REPORT Dr. Cane welcomed the advisory panel members and opened discussion by noting that the Department of Health Professions is already developing proposed legislation for next year's General Assembly session. Dr. Cane also mentioned that the Department has developed new policies regarding video teleconferencing (VTC) to assist staff in providing training, communicating with the public and other possible uses.

The Virginia Health Reform Initiative, chaired by Dr. Hazel, Secretary of Health and Human Resources, is currently reviewing the Affordable Care Act Supreme Court decision and is developing steps to implement Federal health reform in Virginia.

Dr. Cane also mentioned the Virginia Healthcare Workforce Authority, which is evaluating the current and future healthcare workforce in Virginia.

Dr. Cane informed the panel members that Substance Abuse Free Environment, Inc. (SAFE) of Chesterfield County is holding a medication take-back day on Saturday, July 14, 2012 from 10:00 a.m. to 2:00 p.m. at the Bon Secours St. Francis Watkins Center, near the intersection of Midlothian Turnpike and Route 288. Lastly, Dr. Cane thanked Dr. Walker for his service and noted that he will be sorely missed, as he has been on the PMP Advisory Panel since the program's inception in September of 2003. Ms. Brenda Mitchell of Virginia Association for Hospices and Palliative Care has also been a long time member of the panel serving from December 1, 2005 through December 30, 2012. Plaques commemorating the services of Dr. Walker and Ms. Mitchell were presented by Mr. Orr.

A question was presented for Dr. Cane, and Dr. Cane referred the question to Ms. Diane Powers since it related to the use of video teleconferencing. Ms. Powers indicated that we are currently in "Phase I" to bring VTC on-line. The Department has made a capital investment in polycom, which will allow for example, a

guest speaker to use their own laptop to present a PowerPoint presentation to a group at a distant location. Ms. Powers added that if Mr. Orr received inquiries from Federal court, the polycom could be utilized to communicate to the audience. The Department anticipates that the polycom will be used frequently by DHP investigators, as many of them work in the field. The question was posed about using polycom for Board meetings, but Ms. Elaine Yeatts noted that the regulations require a quorum present at a certain location in order for the meeting to be validated; it addition, the public must be "noticed" as to the time and location of the Board meetings in order to provide an opportunity for public comment. Lastly, Ms. Powers indicated that she had recently visited Virginia Commonwealth University's School of Allied Health to see how they leveraged the teleconferencing equipment that they own. The equipment will result in cost savings due to reduced travel expenses and well as travel time

KIM BARNES: STATEWIDE HEALTH INFORMATION EXCHANGE Kim Barnes, HIT Project Coordinator, Office of Information Management and Health IT, spoke about ConnectVirginia, the Commonwealth's Health Information Exchange. Ms. Barnes noted that Holly Morris serves as a member on the ConnectVirginia Governance Board. Ms. Barnes stated that in 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed as a part of the federal stimulus package and that money has been set aside for each state and territory to become interoperable with a larger nationwide health information exchange. Money was allocated based on a demographic formula which led to Virginia being granted \$3 M to be spent over a 4-year period. The Virginia Department of Health (VDH) issued an RFP intending to award the contract to an existing nonprofit organization. The contract was awarded to the Community Health Alliance to provide the statewide health information exchange. Ms. Barnes further explained that Virginia is an opt-in state; individuals must agree to allow their health data to be queried by authorized users of ConnectVirginia. The data can be extracted for permitted purposes only as dictated by HIPAA. Individual practitioners can only obtain data if they are a part of a larger system, known as "nodes". The HIE (ConnectVirginia) is basically a record locator service. Data extracted in each exchange may include lab results, x-rays, e-prescribing, etc. INOVA Health Systems will be the first "node" to utilize ConnectVirginia and they are expected to be able to access the system live as of September 2012. The second node to come online will be the state agencies node. The goal of the Health Information Exchange is to be nationwide. The Commonwealth has asked Community Health Alliance to utilize secure messaging (also known as DIRECT messaging), which is even more secure than encryption. Secure messaging is also point-to-point; one would need to know the

address of the individual seeking data. Ms. Barnes did indicate there will be fees associated with this service and that funds provided to initiate the service are not sustainable. Users will allow for an administrator and 2 delegates, which is similar to the PMP program prior to this year's legislation enabling an unlimited number of delegates for PMP access. Ms. Barnes indicated that hub users will initially be charged an \$80.00 fee to connect to ConnectVirginia. Ms. Barnes also estimated that the annual cost to run ConnectVirginia will be approximately \$2M. Ms. Barnes was asked which state agencies would be "nodes" for ConnectVirginia, and she responded that Medicaid and Behavioral Health will undoubtedly be nodes on ConnectVirginia. Further, Medicaid recipients would also be required to opt-in. Mr. Clouse mentioned that it should be considered that the opt-in should not be required for Medicaid recipients. Mr. Orr noted that the ONC/SAMHSA workgroup on Information Usability and Presentation did not recommend that patients be able to "opt-out" of having PMP information restricted because of use of an HIE.

Dr. Cane asked whether ConnectVirginia could be utilized for investigative purposes by employees of DHP in the Enforcement unit. Dr. Cane further noted that the ability to obtain health information for investigative purposes would be an invaluable tool, and posed the question whether DHP could be one of the state agencies which have access to this data.

RALPH ORR: ONC/SAMHSA/MITRE WORKGROUPS— ENHANCING ACCESS TO PDMPS Mr. Orr discussed his participation with the Office of National Coordinator (ONC)/Substance Abuse and Mental Health Services Administration (SAMHSA) project entitled "Enhancing Access to PDMPs". This project involved 94 people from 53 organizations and will produce a report with detailed recommendations to increase the use and effectiveness of PMPs by leveraging health information technology. Mr. Orr served as Chair of Workgroup 2—Information Usability and Presentation and participated in Workgroup 4—Law & Policy. The report outlining the recommendations of the workgroups has not yet been published but Mr. Orr gave a report based on a presentation given in June at the annual meeting of PMPs. Mr. Orr summarized what members of the workgroups identified as impediments to the use of PDMPs. These included low usage, limitations on authorized users, workflow issues, low technical maturity and lack of business agreements. Workgroup members concluded that in order for the programs to leverage value, the users need real-time access to data and those programs should move toward timelier reporting of data. Currently one state requires having prescription data loaded within five (5) minutes of dispensing. Members also noted that integration with electronic health records (EHR) and pharmacy systems would greatly increase the value of the information. The state of Ohio is piloting a "patient at-risk filter" called Narxchek which would

indicate each patient's low/medium/high risk for abuse or diversion as it relates to possible prescribing of controlled substances. Workgroup participants noted that it would be of great value to develop a standard set of prescription data to be presented on a report to support prescribers' clinical decisionmaking. Mr. Orr also mentioned that low technical maturity of state PDMPs has prevented the adoption of a specific data exchange standard. The overall concept is to migrate from a human-centric process over to a machine-centric process which will allow the development of reportable technical, clinical and legal results. There are currently four pilots, which will be completed by September, involving the emergency department, the ambulatory setting, the emergency department linked to a health information exchange and the pharmacy. The pharmacy pilot is threshold driven and prompts the query of a PDMP given that the patient has met certain threshold parameters. Mr. Orr noted that Indiana's PMP is now linked into their state's Health Information Exchange as part of one of these pilots.

PROGRAM UPDATE: PMP

Mr. Orr reported that a REMS (Risk Evaluation Mitigation System) was released yesterday for long-acting/sustained release opioid products by the FDA. This REMS contains a requirement that each manufacturer is responsible for development of educational materials for patients and an educational curriculum for prescribers and dispensers about the product. However, there is nothing that requires anyone to take the educational curriculum developed.

Mr. Orr noted that 43 states now have operational PMPs, including Florida. Maryland intends to incorporate PMP totally into the HIE of their state. At this time there is not a good timetable for their PMP to become active.

Missouri and Washington, D.C. do not have pending or authorizing legislation for a prescription monitoring program. Mr. Orr displayed informational maps developed by the National Alliance for Model State Drug Laws (NAMSDL) which demonstrate several states are now requiring prescribers and pharmacists to either register for their PMP and/or requiring them to access the PMP in certain circumstances.

INTEROPERABILITY— STATUS

Mr. Orr reported that Virginia is currently interoperable with Ohio, Indiana, Connecticut, Michigan, South Carolina, North Dakota, Arizona and Kansas programs. Virginia PMP users have made over 5455 requests in 2012 and out-of-state users have made 35279 requests. Mr. Orr pointed out that 10% of all requests have had an interoperability component in 2012. This is remarkable given that there is not currently a border state active in the system at this time.

Mr. Orr explained that West Virginia and Kentucky could be active shortly and that is hopeful that our other border states will also sign on to PMPi before fall.

DISCUSSION OF LEGISLATION

Mr. Orr reviewed legislation passed by the 2012 General Assembly. Effective July 1, 2012, pharmacies are required to add the method of payment to the prescription uploads. The Virginia PMP has also expanded access to all federal law enforcement agencies with authority to conduct drug diversion investigations, this primarily being the FBI. Additionally, prescribers may now have an unlimited number of licensed delegates rather than being limited to only two. Lastly, the Virginia PMP now has the authority to send unsolicited reports related to recipients to authorized agents of the State Police for investigation into possible diversion.

PROGRAM STATISTICS

Dr. Anna Noller provided some background information with respect to death rates from drug poisonings in Virginia. While official statistics for 2011 are not complete, Dr. Noller noted that deaths from illicit drugs appear to have increased and deaths from prescription drugs have remained fairly level when compared to 2010 data.

Ms. Carolyn McKann reviewed the program statistics for utilization of the program through June 30, 2012. The program continues to receive increasing numbers of requests for patientspecific prescription history. The second quarter showed the highest number of requests for information in one three-month period since the inception of the program. Ms. McKann noted that the program anticipates processing greater than 800,000 requests during 2012. The program continues to add approximately one million prescription records each month and approximately 50 or so new registered users each week. Currently there are over 77 million records in the PMP database. Ms. McKann explained the slides depicting the percentage of prescribers as registered users of the PMP. The slides show that in one year's time the percentage of registered prescribers at the highest level of prescribing increased almost 14 percentage points from 75.1% to 88.9%.

UPDATE: UNSOLICITED REPORTS Ms. McKann showed a summary of patients meeting certain thresholds for January, February and March of 2012. Ms. McKann noted that during each month there are a considerable number of patients who appear again on the threshold report during the following month. A threshold report which may be indicative of prescription forgery was also reviewed. Again, there were many repeat patients from a previous month on each month's report. Mr. Orr noted that due to the new legislation, PMP staff may now forward names indicative of either doctor shopping or forgery by recipients to the Virginia State Police Drug Diversion Unit. Ms. Morris noted that oftentimes the threshold of one (1) prescriber may not catch many patients

attempting to pass forged prescriptions because they also may go to their regular doctor as well as attempt to obtain prescriptions from a physician whose DEA they have obtained. Mr. Clouse suggested that he, Ralph and a representative from the Virginia State Police meet to discuss the best parameters for unsolicited reports in order to forward the names for further investigation. Discussion then centered on how to follow up to determine if forwarding names for investigation actually results in arrest or conviction. Mr. Casway noted that in some jurisdictions you can follow an individual to arrest but not through conviction. The recommendation was made to explore adding to an MOU with the Virginia State Police language requiring the State Police to track the possible arrest and conviction of individuals forwarded by the Virginia PMP.

EDUCATION AND OUTREACH INITIATIVES

Ms. McKann shared a list of outreach and educational activities provided by PMP staff during the last twelve months. Approximately twice per month either Mr. Orr or Ms. McKann have provided either a brief overview of the Virginia PMP or other educational activity to a constituent group in Virginia. Mr. Orr described his demonstration of the Virginia PMP to Dr. Howard Koh, Assistant Secretary for Health at the U. S. Department of Health and Human Services. Dr. Koh had never seen the use of an operational PDMP before and was impressed by the ease of use and speed of the Virginia PMP. In addition, Mr. Orr provided an overview of the PMP to two pharmacy schools in Virginia, and Ms. McKann provided several overviews of the PMP during three weekends at locations in southwest Virginia for several collaborative substance abuse forums.

HOWARD CASWAY: DISCUSSION OF PMP REQUESTS RELATED TO CIVIL MATTERS

Mr. Casway indicated that the majority of special requests for PMP data are related to criminal matters. Mr. Casway stated that the best course in this situation is to educate the U. S. Attorney on the process on how to obtain a Court Order. With respect to civil matters. Mr. Casway indicated that the party requesting the information is given the portion of the PMP regulations that indicates that PMP data is protected information and they cannot obtain it. §54.1-2523 basically says that the information contained in the PMP cannot be used in a civil case, and you cannot obtain the information unless you can demonstrate extraordinary circumstances. However, Mr. Casway pointed out that if an individual had obtained their own PMP report from the PMP, the information contained within the report would be discoverable. Mr. Casway presented a suggested addendum to §54.1-2523, Para A, which would remedy many of these situations and add clarification: "In no event shall confidential information received, maintained or developed by the Prescription Monitoring Program be available for discovery or court subpoena or introduced into evidence in any civil action."

PROJECT: ENHANCING PMP REGISTRATION PROCESS Mr. Orr mentioned that there has been interest in the past by PMP registrants that the registration process be simpler. Mr. Orr noted that while in an exploratory stage, there has been some consideration in coordinating with the license renewal process to this end. Since approximately 95% of licensees register on-line, this would be an excellent opportunity to ask registrants to either renew their registration or use the PMP registration page or other mechanism to simplify the registration process. Mr. Orr noted that leveraging the licensee database would increase efficiency, particularly for PMP staff, while increasing ease of access to the program by prescribers and pharmacists.

Mr. Orr briefly discussed using the Alert system in the PMP software for certain uses such as a stolen prescription pad or forgeries, cautioning that the Alert system should not be used in such a manner that the PMP program might be accused of denying due process to individuals who might be mentioned in the alert. Therefore, the advisory panel agreed that the best use of the alert system may be to notify registered users in the event of a stolen prescription pad.

NEXT MEETING ADJOURN:

The next meeting will be held on a date yet to be determined. With all business concluded, the committee adjourned at 2:00 p.m.

Randall Clouse, Chairman
Ralph A. Orr. Program Manager