



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

November 7, 2013

The Honorable Martin O'Malley
Governor
State House
100 State Circle
Annapolis, MD 21401-1925

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: Health - General Article § 21-2A-05(f)(3)(ii) - 2013 Report of the Analysis of the Advisory Board on Prescription Drug Monitoring on the Impact of the Prescription Drug Monitoring Program

Dear Governor O'Malley, President Miller and Speaker Busch:

Pursuant to Health - General Article, Section 21-2A-05(f)(3)(ii), the Advisory Board on Prescription Drug Monitoring (Board) submits this report on the analysis of the Board relating to the impact of the Prescription Drug Monitoring Program (PDMP) in the Department of Health and Mental Hygiene (DHMH) on patient access to pharmaceutical care and on curbing prescription drug diversion in the State, as well as the Board's recommendations related to modification or continuation of the PDMP. Senate Bill 883, Chapter 166 of the Acts of 2011 established a PDMP to assist prescribers, dispensers, and public health professionals in identifying and preventing prescription drug abuse, as well as identifying and investigating unlawful prescription drug diversion.

Thank you for your consideration of this report. If you have any questions regarding the report, please contact Michael Baier, PDMP Coordinator, at 410-402-8643.

Sincerely,

Laura Herrera, MD, MPH
Chair, Advisory Board on Prescription Drug Monitoring

Enclosure

Cc: The Honorable Thomas M. Middleton
The Honorable Peter A. Hammen
Michael Baier
Patrick Dooley
Marie Grant

Joshua M. Sharfstein
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Sarah Albert, DLS, MSAR # 8632

Introduction

Title 21, Subtitle 2A of the Health-General Article (enacted by Senate Bill 883, Chapter 166 of the Acts of 2011) requires that the Department of Health and Mental Hygiene (Department) create a Prescription Drug Monitoring Program (PDMP) to reduce the misuse, abuse and diversion of prescription drugs throughout the State. The duties of the PDMP, as outlined in the PDMP law, include:

- monitoring the prescribing and dispensing of prescriptions that contain controlled dangerous substances (CDS);
- creation of an electronic database of CDS prescription information; and
- making this data available to a statutorily-defined group of individuals and entities responsible for ensuring the health and welfare of patients and the lawful use of CDS.

Additionally, the PDMP will build upon the interest in and use of the database to develop a collaborative, interagency and interdisciplinary strategy to treat and prevent drug abuse, improve the quality of pain management and educate stakeholders and the general public on how to reduce the threat across the State. The Secretary of the Department has assigned responsibility for programmatic development of the PDMP to the Alcohol and Drug Abuse Administration (ADAA) in the Department.

Section 21-2A-05 of the Health-General Article provides for the creation of the Advisory Board on Prescription Drug Monitoring (Board). The Board is composed of a diverse array of stakeholders, including representatives from health professional licensing boards, physicians, pharmacists, a nurse practitioner, a local law enforcement representative and patient representatives. The Board has met seven times since the membership was first appointed in autumn 2011, and has provided feedback and recommendations on a number of topics, including regulations, information technology (IT), program evaluation, funding and educational initiatives.

Section 21-2A-05(f)(3)(ii) of the Health-General Article also requires that the Board provide annually to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly, an analysis of the impact on the Program on patient access to pharmaceutical care and on curbing prescription drug diversion in the State, including any recommendation related to modification or continuation of the Program. This 2013 Annual Report is submitted pursuant to this requirement.

Analysis of PDMP Impact on Patient Access to Pharmaceutical Care and on Curbing Prescription Drug Diversion

In its 2012 Annual Report, the Board noted that, as the PDMP was not yet operational, the Board could not report on the Program's impact on patient access to pharmaceutical care and on curbing prescription drug diversion in Maryland. Even though certain components of the PDMP are now operational, core Program functions that could have the greatest impact on these issues have not yet been implemented. This includes access to PDMP data by healthcare providers, law enforcement investigators and other authorized requesters. Those Program components that have been implemented, including dispenser reporting of CDS prescription information, have, at the time of writing, only been in place for a few weeks. This is not enough time for the Board to collect feedback from stakeholders on whether dispenser reporting or other activities have affected patients' ability to legitimately access pharmaceutical care or altered existing drug diversion trends. Therefore, the Board cannot report at this time that PDMP operations have had an impact.

The Department's timeline for PDMP implementation indicates that the Program should be fully operational by December, 2013. At that time, the Board may be able to provide a preliminary assessment of whether the commencement of basic PDMP operations has had any discernible impact. Regardless, the Board would like to take this opportunity to provide an update on the efforts of the Department and other PDMP stakeholders to implement the PDMP over the last year, focusing specifically on how implementation has aligned with the Board's recommendations for Program design detailed in its Interim Report (July, 2012). The Department has followed the Board's recommendations to a great extent. In some areas, practical experience with Program development has clarified outstanding questions about the most promising approaches. Details on these developments are provided below.

PDMP Implementation Update

Below, the Board has provided updates on PDMP implementation specific to its recommendations in the July, 2012, Interim Report to the General Assembly concerning Program design, regulations, legislation and funding. The Board has also provided updates on issues that were not addressed in the Interim Report, including educational initiatives regarding the Program and the potential for outside evaluation of the Program.

Program Design

Recommendation 1: The Department should pursue integration between the PDMP and the IT infrastructure of the statewide health information exchange (HIE) to the greatest extent possible.

After numerous planning meetings involving the Department, the Maryland Health Care Commission (MHCC) and Chesapeake Regional Information System for our Patients (CRISP), the statewide HIE, a formal project plan was finalized in November, 2012, for leveraging the infrastructure of the HIE to support PDMP IT services. CRISP developed a project proposal based on this plan and funding from federal grants awarded to ADAA and the Governor's Office of Crime Control & Prevention (GOCCP) for PDMP implementation was made available to CRISP beginning December 1 (see "Funding," below). CRISP's proposal incorporated elements outlined in the Interim Report as promising approaches to PDMP/HIE integration, including giving healthcare providers access to PDMP data through the HIE web portal and utilizing the HIE's Master Patient Index (MPI) to process patient-specific requests for PDMP data. This technology enables accurate identification of patients across care settings, using sophisticated probabilistic matching to account for the "volatility" and inconsistency of patient demographic information from one facility or source system to another.

As indicated in the Interim Report, the requirement to establish an electronic reporting infrastructure for every pharmacy and dispensing practitioner in the State presented a logistical challenge that the current HIE infrastructure was unable to support. Therefore, CRISP proposed to contract with a vendor capable of providing, at a minimum, IT support for dispenser reporting. CRISP issued a Request for Proposals (RFP) in December, 2012. The RFP included minimum requirements from bidders to support PDMP reporting and also allowed bidders to propose additional services that could be useful for PDMP operations. CRISP received proposals from Health Information Designs (HID) and Optimum Technology, the two companies that currently dominate the national market for PDMP IT services. The HID and Optimum proposals also included partnerships with Relay Health and Emdeon, respectively, to provide the ability for pharmacies to report PDMP data in real-time via those companies' electronic pharmacy claims adjudication networks, colloquially known as pharmacy "switches." A review team composed of CRISP and ADAA/PDMP personnel was assembled and between January and February, 2013, the proposals were reviewed and scored for responsiveness to the specific RFP requirements, experience in the PDMP IT space, data security, cost and a number of other factors. Teams from HID/Relay Health and Optimum/Emdeon provided live demonstrations of PDMP software for CRISP, MHCC and Department personnel in February. Following extensive discussions that included a two-day, in-person system specifications validation session, CRISP contracted with HID in May.

The final project plan for PDMP implementation divides responsibilities for implementing specific components among the Department, CRISP and HID and includes additional functionality not originally envisioned prior to CRISP's RFP. Below is an overview of each party's responsibilities:

Department Responsibilities

- Overall policy and program management of PDMP activities
- Coordination and information sharing with other government agencies affected by PDMP
- Customer support for prescribers, dispensers and other PDMP stakeholders who have questions and concerns about legal requirements, Program policy, exemptions, etc.

CRISP Responsibilities

- Overall program management of PDMP IT
- Registration, authentication and credentialing of healthcare providers
- Provide access to PDMP data and other clinical information through a unified user interface (Note: Pharmacists who register with CRISP will, by default, only be able to access prescription information made available by the PDMP)
- Host PDMP data for query by healthcare providers
- Provide training and technical assistance to system users related to access to and use of PDMP data

HID Responsibilities

- Provide IT and technical assistance for dispenser reporting
- Registration, authentication and credentialing of non-clinical users (law enforcement, licensing board and Department investigators)
- Provide customized RxSentry® PDMP web application to process non-clinical data requests and run reports on PDMP data
- Develop user training guides/manuals
- Host PDMP database for non-clinical queries

Additionally, CRISP and HID have worked together to develop an integrated approach to storage and query of PDMP data that utilizes the CRISP MPI as the backbone of clinical data request processing (see Recommendation 3, below).

The final timeline for PDMP implementation includes the following key milestones:

- **May 29, 2013:** Pharmacies and practitioners authorized by law to dispense CDS prescription drugs were notified by mail of the reporting requirement. This notification letter also included detailed information on the implementation timeline and a link to the new PDMP website: <http://www.hidinc.com/mdpdmp.html>. The website contains the *RxSentry Dispenser's Implementation Guide*, a dispenser manual with detailed guidance on the PDMP's legal requirements, reporting exemptions and data reporting procedures, step-by-step instructions for creating a data upload account and other information that dispensers need to ensure compliance. The notification letter also contained information on how to contact HID's technical support help desk and PDMP personnel at ADAA for more information.

- **June, 2013:** The Department requested nominations for the Program’s Technical Advisory Committee (TAC) from the professional organizations listed in the PDMP law. For those positions not requiring a nomination, the Department requested names of qualified individuals from MedChi, the Maryland Pharmacist Association and other relevant organizations.
- **July 29, 2013:** HID opened up registration for dispensers to create upload accounts. After registering, dispensers could begin sending test or production data to HID. To help ensure that the PDMP database contains a sufficient volume of prescription information when data access begins, the Department requested that dispensers provide as much data as possible retroactive to January 1, 2013.
- **August, 2013:** The Department received TAC nominations and began reviewing nominees. The Department’s Office of Appointments is working with the nominating organizations to identify additional candidates. Appointments are expected in October.
- **August 20, 2013:** The periodic PDMP reporting requirement becomes effective. By this date, dispensers must have created an upload account and must begin reporting CDS dispensing within 3 business days as required by PDMP regulations.
- **Late September, 2013:** CRISP will register pilot clinical users (emergency department physicians and community pharmacists) to begin accessing PDMP data through the CRISP web portal. The pilot phase will test user access procedures to ensure that query functionality is properly implemented.
- **October 1, 2013:** PDMP personnel at ADAA will have administrator access to HID’s RxSentry® web application and will begin running regular compliance reports on dispenser reporting and directly contacting non-compliant dispensers. ADAA will work with other units of the Department and relevant licensing boards to enforce the reporting requirement.
- **October, 2013:** The Department will work with GOCCP to identify law enforcement personnel from federal, state and local agencies who will be registered to submit data requests pursuant to existing investigations. Health professional licensing entities and DHMH units specified in the PDMP law will also identify investigators to be registered.
- **Mid- Late October, 2013:** Following successful experience with the pilot clinical users, CRISP will open general registration for healthcare providers to access PDMP data. The Department is working with CRISP to develop a PDMP training video that providers will watch as part of the registration process. The video will include information on the background, purposes and use of the PDMP, as well as identifying additional clinical education and training resources related to safe and effective opioid prescribing, screening for behavioral health disorders and referral to treatment and recovery services and other related topics.
- **November, 2013:** Investigative users (law enforcement, licensing boards, DHMH units) will begin submitting requests for PDMP data.
- **Q1, 2014:** The Department will work with CRISP and HID to establish interoperability with other states’ PDMPs through an established interstate data sharing hub.

Recommendation 2: The Department should issue an RFP for IT capable of supporting real-time data collection from dispensers.

As indicated above, both proposals for PDMP services received by CRISP included proposals from partner companies to establish the ability for dispensers to report PDMP data in real-time. Since

contracting with HID, CRISP has continued discussions with Relay Health (HID's partner in the original proposal) to identify the requisite resources and business relationships among Relay, its pharmacy clients and other partners that would be required to support real-time reporting via Relay's switch network. As this approach will require systems development work not only for Relay Health, HID and CRISP but also pharmacies that wish to report in real-time, the Department and CRISP are currently working to identify pharmacy partners to establish a real-time pilot. Therefore, real-time reporting is not an option for dispensers currently. However, HID provides a number of reporting options that meet the needs of different kinds of dispensers, including automated or manual batch file transfers appropriate for pharmacy systems and a web-based data entry form that may be appropriate for small-volume practitioner dispensers.

Recommendation 3: The data collection vendor must have the ability to reject incomplete or inaccurate dispensers' reports, and the PDMP should use the HIE's Master Patient Index to identify unique patients in the database.

HID's data collection technology has the ability to screen all data files submitted by dispensers for errors. When errors are detected, dispensers are notified by email with specific error reports and instructions for making corrections. Files with a large number of serious errors are rejected outright; dispensers must then resubmit the entire file. Given that the Department has required dispensers to report using the data standard used by all other PDMPs (ASAP 4.2) and that HID's reporting technology has been refined through experience in many other states, it is unlikely that dispensers submitting batch reports will have much difficulty. The Department has not received reports of significant problems with reporting implementation to date.

As referenced above, CRISP and HID are in the final stages of development related to utilization of the MPI. All prescription information reported to HID will be processed through the MPI, and individual prescription records will receive a "CRISP ID" number as a unique patient identifier. All requests for PDMP data from clinical users will return results based on the CRISP ID in manner identical to requests for hospital admission, discharge and transfer information, clinical documents and other information available through the HIE. This will ensure that results are consistent across queries for different types of clinical information. HID will store the CRISP ID in its PDMP database, and PDMP administrators will be able to query the data based on the CRISP ID should patients have concerns over the prescription history information retrieved by their healthcare provider.

Recommendation 4: The PDMP should use the HIE's web portal and authentication/credentialing procedures to facilitate electronic data disclosure to prescribers and dispensers. Disclosure requests from law enforcement, licensing boards, units of the Department, patients and researchers must be individually processed by PDMP personnel, and legal barriers to interoperability with other states' PDMPs must be removed.

As indicated above, CRISP will handle user registration, authentication and credentialing for healthcare providers. PDMP data will be accessible to providers under a medication history "tab" in the HIE query portal. PDMP data will be consolidated with other sources of medication history information available through the HIE, but the source of each dispensing record will be identified.

Although the Board had not envisioned that the PDMP would allow for automated processing of requests from law enforcement, licensing boards and units of the Department, HID's RxSentry® has the ability to manage investigative requests that require supporting documentation (e.g. a subpoena) and additional processing and review by the TAC as required by the PDMP law. HID will register, authenticate and credential investigative users through web-based registration forms and lists provided by the Department. These investigators will submit requests for PDMP data through the RxSentry® website by entering information into required fields and uploading electronic copies of required documentation. PDMP administrators will ensure that data requests match the scope and specifications identified in a law enforcement or licensing board subpoena. TAC members will also receive login credentials and will be able to review investigative requests and enter their clinical guidance and interpretation of the data requested within the RxSentry® web application. PDMP administrators may then approve or deny the request based on TAC and Department review, and the requester will receive an email notification. When disclosure is approved, the requester will login to RxSentry® to retrieve the PDMP data report and TAC report electronically. This web-based process will greatly improve the efficiency of processing investigative requests and provide enhanced capabilities for tracking and recording investigative disclosures.

Recommendation 5: The PDMP data collection vendor must provide T/TA to reporting dispensers and the HIE must do so for clinical end-users.

As indicated above, HID has established the Maryland PDMP Help Desk to provide technical support to dispensers required to report to the PDMP. The Help Desk will also support PDMP administrators, TAC members and investigators that use RxSentry® to process PDMP data requests and run reports. CRISP has existing staff support for HIE users that will be expanded to accommodate the influx of new users registering for PDMP access.

Regulations

Final regulations for the PDMP were adopted by the Secretary of the Department in December, 2012. In drafting the regulations, the Department adhered closely to the Board's recommendations detailed in the Interim Report, including:

- Establishing a deadline of three business days for reporting CDS dispensing;
- Not allowing for non-electronic means of reporting and not mandating a specific data standard or IT for reporting to allow for flexibility in a rapidly changing health IT environment;
- Requiring prescribers and dispensers who delegate PDMP access to a licensed healthcare practitioner to monitor their delegate's use of the system and report any suspected unlawful use to the delegate's relevant licensing board and the PDMP;
- Requiring the TAC to review and respond to data requests within 10 business days;
- Not mandating that prescribers and dispensers notify patients of their intent to access PDMP data; and
- Allowing for re-disclosure of PDMP data only for treatment purposes.

During the public comment period, the Department received feedback from a number of stakeholders, including professional societies representing physicians and pharmacists, hospitals, health systems and pharmaceutical companies. Most comments included requests for clarity on the application of certain provisions or the creation of reporting exemptions for specific dispensers and other alterations that would require changes to statute. Substantive comments included requests to reduce the number of data elements that dispensers are required to report and to increase the reporting deadline from three business days to one week or more. As the PDMP must collect data sufficient to accurately identify the drug, patient, prescriber and dispenser for each CDS dispensing, the Board supports the Department's decision to not alter the list of required elements. Similarly, as other states are moving to enact shorter reporting deadlines (including daily or real-time reporting) to increase the timeliness of PDMP data, the Board supports the Department's decision to retain a three-business-day deadline.

In September, 2013, the Department made two changes to the regulations as initially adopted. The first reflects the change to statute made by Senate Bill 80, Chapter 177 of the Acts of 2013, which includes the Division of Drug Control (DDC) among the units of the Department that may request PDMP data pursuant to an existing investigation. The second creates a specific authorization for re-disclosure of PDMP data in addition to the general allowance for re-disclosure for treatment purposes. The amended regulations will allow for re-disclosure "to a State or local child fatality review team established under Health-General Article, Title 5, Subtitle 7, Annotated Code of Maryland" or "to a medical review committee established under Health-Occupations Article, §1-401(b)(3), Annotated Code of Maryland, for the purpose of reviewing information on fatal drug and alcohol overdoses and preventing overdose deaths."

The second amendment was crafted to support the establishment of Overdose Fatality Review (OFR) teams at the local level, a component of the Department's statewide Opioid Overdose Prevention Plan and a number of jurisdictions' overdose prevention plans that were developed during 2013. These multi-disciplinary, multi-agency teams will conduct confidential reviews of information about residents who have died from overdose deaths, in a manner similar to the local Child Fatality Review Teams. The review process will allow the teams to identify risk and protective factors for fatal overdose; determine possible points of contact between high risk individuals and medical, public health, public safety and other social systems where interventions could be staged; and make recommendations to agencies, elected officials and others on systems changes to prevent future deaths. Inclusion of PDMP data in this process would be exceptionally useful. The Board reviewed and approved the proposed change at its April, 2013, meeting.

Legislation

In the Interim Report, the Board made only one recommendation for legislation: the inclusion of DDC among the units of the Department that may request PDMP data. As indicated above, the recommendation was enacted by Senate Bill 80, Chapter 177 of the Acts of 2013. At this time, the Board does not have any additional recommendations for changes to the PDMP law. Given that full PDMP implementation will take place over the next two months, the Board would like to have an opportunity to observe the Program in action before reassessing the need for possible further statutory changes.

Funding

As noted in the Board's October, 2012, update to the General Assembly, ADAA received a 2012 \$400,000 Harold Rogers PDMP (HRPDMP) grant from the US Department of Justice. This brings the total grant funding secured for the PDMP to \$1.3 million. The 2012 HRPDMP grant primarily covers costs related to CRISP's IT implementation, but also includes funds for program evaluation and educational initiatives. The grant term for GOCCP's 2011 HRPDMP grant will expire within the next six months. This grant has primarily funded personnel, travel and equipment costs at ADAA, but has also supported CRISP's IT development. GOCCP and ADAA have made arrangements to cover PDMP personnel costs through the end of State FY2014, but state funds will likely be needed to cover at least 2 positions at ADAA beginning in FY 2015. Current federal funding opportunities are for PDMP implementation and enhancement expenses, not to cover ongoing costs indefinitely. ADAA has received a 2013 HRPDMP grant under a new category for funding to support implementation of the OFR process and other prescription drug abuse and overdose prevention activities that will supplement and enhance the impact of the PDMP.

Actual expenses for PDMP IT implementation have been far less than originally envisioned. To date, CRISP's implementation costs (including contractual expenses related to HID and other CRISP vendors) are roughly \$337,000; CRISP estimates that total costs at the end of the implementation period (November 30, 2013) will be approximately \$443,000. As suggested in the Interim Report, the Board believes that long-term IT costs will be significantly reduced by PDMP/HIE integration.

Educational Initiatives

With full PDMP implementation fast approaching, the Department has worked with the Board and a number of stakeholder organizations to increase knowledge of the Program throughout the State. ADAA has engaged with the Boards of Pharmacy and Physicians, DDC and other agencies that oversee CDS dispensers to ensure that dispensers have up-to-date information on the reporting requirement and implementation timeline. In the months before and after implementation of the reporting requirement, ADAA and HID have fielded numerous inquiries from pharmacists and dispensing practitioners and have provided direct education and technical assistance on all manner of issues. The PDMP Coordinator, CRISP personnel and Board members have continued to give in-person presentations on the PDMP to a number of audiences/organizations, including the Boards of Pharmacy and Dental Examiners, local health department teams at the Department's Overdose Prevention Planning Conference, Kernan and Shady Grove Adventist Hospitals, the State Drug and Alcohol Abuse Council, the Maryland Violent Death Reporting System, the Partnership for a Safer Maryland, the State and Baltimore County Child Fatality Review Teams, the Mid-Atlantic Life Safety Conference and the Washington/Baltimore High Intensity Drug Trafficking Area (HIDTA) Executive Board. Upcoming presentations will take place at the Department of Veterans Affairs, Sheppard Pratt, the Maryland Chapter of the American Society Of Interventional Pain Physicians and at a continuing education (CE) event for over 200 pharmacists organized by the Board of Pharmacy.

One initiative that could have a broad impact is the CE program being developed by the Maryland Society of Addiction Medicine (MDSAM). MDSAM has received funding through the federal Food and Drug Administration's Risk Evaluation and Mitigation Strategies (REMS) program for extended release/long acting opioids to develop and implement CE training programs for healthcare providers on safe and effective opioid prescribing, screening and referral for treatment of substance use disorders, and other related topics. The MDSAM training program will be provided free-of-charge and include a PDMP module with information specific to Maryland's Program. The first training is scheduled for November 16, 2013, in Cecil County. MDSAM is working with ADAA and local jurisdictions to schedule regional trainings in other areas of the State for 2014.

Lastly, a number of local health departments have made PDMP education a component of their local overdose prevention plans. The Department is working with local authorities to provide educational materials that can be distributed to community healthcare providers.

Evaluation

The Department is working with researchers at the University of Maryland, School of Pharmacy to design an ongoing evaluation of PDMP impact and outcomes. Current discussions are centered on the specific questions the evaluation should address, including establishing pre- and post-implementation measures of CDS prescribing, dispensing and use in the State, assessing the impact of PDMP/HIE integration on system access and use by healthcare providers, identifying whether PDMP implementation has had an effect on indicators of prescription drug abuse and addiction (including drug treatment admissions and prescription drug-related overdoses) and evaluating any unintended consequences on legitimate patient access.

Conclusion

During 2012, the Department made substantial progress with implementing the PDMP while including a number of innovations that could greatly increase the Program's ability to support the prevention of prescription drug abuse and diversion. Therefore, the Board recommends that the Governor and General Assembly continue to support implementation and ongoing development of the PDMP. Over the next year, the Board will continue to support the Department by providing ongoing guidance on Program development and conducting trainings and other educational initiatives for the members' respective stakeholder groups.

Attachment

Advisory Board on Prescription Drug Monitoring – Membership

Chair

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Deputy Secretary for Public Health Services, Department of Health and Mental Hygiene

Andrea Mathias, MD, MPH
Chair, Maryland Board of Physicians
Health Officer, Worcester County Health Department

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