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August 9, 2019

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis, MD 21401-1991

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

The Honorable Adrienne A. Jones
Speaker of the House
State House, H-101
Annapolis, MD 21401-1991

RE: House Bill 115 (Chapter 435, Acts of 2018) -- Electronic Prescription Records System – A Report to the Governor and the General Assembly

Dear Governor Hogan, President Miller, and Speaker Jones:

The Maryland Health Care Commission (MHCC) is pleased to submit the enclosed final report on “**Electronic Prescription Records System – A Report to the Governor and the General Assembly**” in response to House Bill 115 (Chapter 435, Acts of 2018).

This final report is the result of a comprehensive and inclusive effort that last over a year that engaged over 80 stakeholders. MHCC convened interested stakeholders to form an Electronic Prescription Records System workgroup for purposes of conducting a study to assess the benefits and feasibility of developing an electronic system or statewide repository of patient prescription medication history. The workgroup consisted of representative of diverse stakeholder groups, including providers, pharmacists, and consumers. The workgroup met seven times from July 2018 through February 2019, with additional subgroup meetings focused on technology. After the workgroup meetings concluded, a substantial number of members participated in the review of the several drafts that culminated in this final report.

This final report includes a recommendation by the workgroup to implement a statewide electronic non-controlled drug substances (CDS) prescription repository to improve patient safety. The system would collect information on non-controlled dangerous substances (non-CDS) dispensed in Maryland and make that information available to health care providers and

dispensers. The non-CDS repository will complement CDS reporting requirements in Maryland (CDS prescriptions are reported to the prescription drug monitoring program, or PDMP).

The workgroup recommends that consumers be allowed to opt-out from including their data in the non-CDS repository. The workgroup also recommends that MHCC form a stakeholder advisory committee to propose policy recommendations for non-CDS reporting and other operational matters.

MHCC would like to thank all the stakeholders that participated in the development of this report. We look forward to continuing work on improving the safety of patient care through the support of health information technology in Maryland.

Please do not hesitate to me at Ben.Steffen@maryland.gov or 410-764-3566 with questions or comments about this issue.

Sincerely,



Ben Steffen
Executive Director
Maryland Health Care Commission

Enclosure

cc:

The Honorable Delores G. Kelly, Senate
The Honorable Shane E. Pendergrass, House of Delegates
Andrew N. Pollak, MD, Chair, Maryland Health Care Commission
Mathew J. Palmer, Deputy Legislative Officer, Governor Hogan
Webster Ye, Director, Office of Governmental Affairs, Maryland Department of Health
Sarah Albert, Department of Legislative Services, (MSAR #11620) (5 copies)

House Bill 115

Electronic Prescription Records System



A Report to the Governor and General Assembly

July 2019

Andrew N. Pollak, MD, Chairman
Ben Steffen, Executive Director



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Overview

House Bill 115, *Maryland Health Care Commission – Electronic Prescription Records System – Assessment and Report* (or bill), was passed during the 2018 legislative session. The law (Chapter 435)¹ required the Maryland Health Care Commission (MHCC) to convene interested stakeholders² for purposes of conducting a study to assess the benefits and feasibility of developing an electronic system (system or statewide repository) of patient prescription medication history.³ The system would collect and make available to treating health care providers (providers or practitioners) and dispensers (collectively authorized users) information on non-controlled dangerous substances (non-CDS)⁴ dispensed in Maryland. Currently, the Prescription Drug Monitoring Program (PDMP) makes available to authorized users information on CDS⁵ Schedules II through V dispensed in Maryland.⁶

The MHCC convened an Electronic Prescription Records System Workgroup (workgroup) that was tasked with assessing specific aspects of a statewide repository, including:

1. Whether the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP), is capable of including a patient's prescription medication history;
2. Enhancements to CRISP required to ensure that the exchange is able to continue to meet other State mandates, including operating an effective PDMP;
3. Resources required for individual health care practitioners, health care facilities, prescription drug dispensers, and pharmacies to provide the information collected in a statewide repository of prescription medication information;
4. Cost to the State to develop and maintain an electronic prescription medication system and the cost to prescribers to access the system;
5. Resources required to ensure that health care practitioners and prescription drug dispensers can maximize the benefit of using the system to improve patient care;
6. Scope of prescription medication information that should be collected in the system, including any specific exemptions; scope of health care providers that would report prescription medication information in the system, including any specific exemptions;
7. Potential for development or use of systems other than CRISP for access to patients' prescription medication history;

¹ Governor Larry Hogan approved House Bill 115 on May 8, 2018. See Appendix A for a copy of the law.

² See Appendix B for a copy of the Workgroup Roster. See *Approach* section for more information on membership.

³ See Appendix C for a copy of the Workgroup Charter. See *Approach* section for more information, including development of the Workgroup Charter.

⁴ For purposes of this study and report, non-CDS includes medications prescribed to treat medical conditions such as high blood pressure, diabetes, and bacterial infections, not classified as a CDS.

⁵ State and federal law define CDS as substances that have abuse potential. This includes drugs listed in Schedules II, III, IV and V that have accepted medical uses, such as opioid pain relievers like oxycodone (OxyContin, Percocet, Percodan, Roxicet), hydrocodone (Vicodin, Lortab), and methadone; anti-anxiety and sedative medications like alprazolam (Xanax) and diazepam (Valium); and stimulants like Adderall and Ritalin.

⁶ See *PDMP Mandates and Infrastructure – Prospects for Non-CDS* section for more information about the Maryland PDMP and those in others states.

8. Privacy protections required for the system, including the ability of consumers to choose not to share prescription data, to ensure the prescription data is used in a manner that is compliant with State and federal privacy requirements, including 42 U.S.C. § 290dd-2 and 42 C.F.R Part 2;
9. Feasibility of ensuring that the data in the system is used only by health care practitioners to coordinate the care and treatment of patients;
10. Standards for prohibiting the use of the data in the system by a person or an entity other than a health care practitioner, including any exceptions for the use of data with identifying information removed for bona fide research; and
11. Any other matters of interest identified by MHCC or stakeholders.

The MHCC must report to the Governor and General Assembly on findings and proposed recommendations from the study on or before January 1, 2020. This report includes relevant information about the law and the current landscape in Maryland and the nation as it relates to mandated reporting of prescription information. A summary of workgroup deliberations on key discussion items and suggested recommendations for legislative action are also included in this report.⁷

Framing the Study

Rationale

Electronic access to comprehensive medication history has great potential to provide clinical value by way of improving the medication reconciliation process.^{8, 9} This particularly holds true for hospital emergency departments, the origin of at least half of all hospital admissions in Maryland and the nation.^{10, 11, 12} Medication reconciliation is a key component of patient safety across the care continuum.¹³ This is important for an aging population at greater risk for adverse drug events (ADEs),¹⁴ especially those with comorbidities that take multiple medications and are more prone to transitions between health care settings with interventions from multiple providers.¹⁵ The benefit to all providers in accessing complete and accurate medication history can minimize the potential for

⁷ This report was reviewed by the workgroup. See Appendix I for commentary provided by workgroup members.

⁸ Frisse ME, Tang L, Belsito A, Overhage JM. Development and use of a medication history service associated with a health information exchange: architecture and preliminary findings. *AMIA Annu Symp Proc.* 2010; 2010:242-245. Published 2010 Nov 13.

⁹ Medication reconciliation is a process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route. More information available at: www.ih.org/Topics/ADEsMedicationReconciliation/Pages/default.aspx.

¹⁰ Percent of hospital admissions originating from the ED in Maryland: FY 2017 (56.68 percent), FY 2018 (56.63 percent), FY 2019 through March (56.53 percent).

¹¹ Schuur JD, Venkatesh AK. The growing role of emergency departments in hospital admissions. *N Engl J Med.* 2012;367(5):391-393.

¹² Tamblyn R, Poissant L, Huang A, et al. Estimating the information gap between emergency department records of community medication compared to on-line access to the community-based pharmacy records. *J Am Med Inform Assoc.* 2014; 21(3):391-398.

¹³ Barnsteiner JH. Medication Reconciliation. In: Hughes RG, editor. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 38. Available at: www.ncbi.nlm.nih.gov/books/NBK2648/.

¹⁴ ADEs involve harm to a patient due to medication use, including adverse drug reactions, allergic reactions, and overdoses.

¹⁵ Goeen, LG. Medication reconciliation in long-term care and assisted living facilities: opportunity for pharmacists to minimize risks associated with transitions of care. *Clinical Geriatric Medicine.* 2017; 33(2): 225-239. Available at: www.ncbi.nlm.nih.gov/pubmed/28364993.

medication errors, discrepancies, and other medication-related problems, while improving efficiencies. Manual medication reconciliation processes often require lengthy conversations with patients and/or their caregivers along with multiple calls to pharmacies. Health information technology (health IT)¹⁶ can facilitate medication reconciliation through innovative solutions that exist today, such as those made available through an HIE.¹⁷

Medication errors¹⁸ are among the most common causes of morbidity and mortality in a hospital.^{19, 20} Clinical information about a patient is often times lacking or incomplete in an emergency department,²¹ a major challenge since decisions need to be made quickly. Studies find that inaccuracies in medication histories account for upwards of 50–70 percent of admitted patients; over one quarter of these errors are attributable to incomplete information at the time of admission.^{22, 23} Medication discrepancies can lead to interrupted or inappropriate drug therapy during and after a hospitalization. Almost half of the preventable ADEs occurring within 30 days of discharge are due to medication discrepancies.^{24, 25}

Prescriptions frequently involved in medication errors expand beyond CDS to include cardiovascular drugs, sedatives, antibiotics, antithrombotic drugs, and analgesics.²⁶ Newer drug classes (e.g., novel oral anticoagulants or NOAC commonly used today) can result in potentially fatal consequences when administration is disrupted.²⁷ The complexities of certain drugs, such as those with varying dose ranges (e.g., 10-20mg) and frequency of administration, make the clinical benefit of having access to patient medication history compelling to help providers across the care continuum manage potential drug-drug interactions²⁸ and inform clinical decision making about diagnosis and treatment. Enabling

¹⁶ Health IT encompasses an array of technologies that store, share, and analyze health information.

¹⁷ See n.12, *Supra*.

¹⁸ The Mayo Clinic defines medication errors as mistakes in prescribing, dispensing, and administering medications.

¹⁹ Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, editors. *To Err is Human: Building a Safer Health System*. Washington (DC): National Academies Press (US); 2000. 2, Errors in Health Care: A Leading Cause of Death and Injury. Available at: www.ncbi.nlm.nih.gov/books/NBK225187/.

²⁰ Drug classifications have grown in complexity and volume in the last twenty years; drug products approved by the U.S. Food and Drug Administration (FDA) have more than doubled. More information available at: www.fdalawblog.net/2015/02/delving-into-the-bowels-of-the-orange-book-what-do-the-data-reveal/.

²¹ Hripcsak G, Sengupta S, Wilcox A, Green RA. Emergency department access to a longitudinal medical record. *J Am Med Inform Assoc*. 2007;14(2):235–238.

²² See n.12, *Supra*.

²³ Agency for Healthcare Research and Quality, *Medication Reconciliation: Whose Job Is It?*, 2007. Available at: psnet.ahrq.gov/webmm/case/158/medication-reconciliation-whose-job-is-it.

²⁴ Salameh L, Abu Farha R, Basheti I. Identification of medication discrepancies during hospital admission in Jordan: Prevalence and risk factors. *Saudi Pharmaceutical Journal*. 2018;26(1):125-132. Available at: www.sciencedirect.com/science/article/pii/S1319016417301688.

²⁵ See n.23, *Supra*.

²⁶ Fitzgerald RJ. Medication errors: The importance of an accurate drug history. *British Journal of Clinical Pharmacology*. 2009;67(6):671-5.

²⁷ Diagnostic and Interventional Cardiology, *Advantages and Disadvantages of Novel Oral Anticoagulants*, July 2016. Available at: www.dicardiology.com/article/advantages-and-disadvantages-novel-oral-anticoagulants.

²⁸ A change in a drug's effect on the body when the drug is taken together with a second drug that results in an unexpected side effect. U.S. FDA: www.fda.gov/drugs/resources-you/drug-interactions-what-you-should-know.

access to longitudinal prescription records in real-time can reduce ADEs and subsequent health care utilization, particularly among vulnerable populations with comorbidities.^{29, 30, 31}

History of House Bill 115

Delegates Dan Morhaim and Joseline Peña-Melnyk introduced the *Electronic Prescription Records Cost Saving Act of 2018* during the 2018 legislative session. If passed as introduced, the bill would have required MHCC to adopt regulations for pharmacies to report non-CDS prescriptions dispensed using the existing PDMP infrastructure supported by CRISP. The notion of moving the bill forward to require a non-CDS reporting mandate generated strong support in concept, but also prompted opposition among some stakeholders. Privacy advocates expressed concern about the lack of consumer control of their non-CDS data.³² Technology vendors viewed the bill as anti-competitive. Health care professional associations objected to not having sufficient time to engage their members to determine and justify the estimated cost of a system; they also raised questions about the lack of patient privacy protections, including the ability to opt out. The General Assembly concluded that a study was needed to evaluate these issues and others identified before advancing a bill that mandated non-CDS reporting.

PDMP Mandates and Infrastructure – Prospects for Non-CDS

Nation

PDMPs are widely implemented across states and have evolved from an enforcement tool for reducing prescription drug abuse and diversion to a clinical tool used to guide decision making.^{33, 34} These programs collect data on CDS dispensed by pharmacies and practitioners (as defined by federal and state laws) and increase awareness and monitoring by practitioners regarding the use of CDS by their patients. Some PDMPs, including Maryland, are beginning to monitor and analyze CDS data to support practitioner education about appropriate prescribing or investigate prescribing practices that may be of concern. PDMPs with provisions for mandated reporting have been implemented in 49 states, the District of Columbia, Puerto Rico, and Guam.^{35, 36} Access to PDMP data is regulated by state laws, which generally authorize access to practitioners and pharmacists for patients under their care. States may

²⁹ Agency for Healthcare Research and Quality, *Advances in Patient Safety and Medical Liability*, August 2017. Available at: www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/liability/advances-in-patient-safety-medical-liability/neumiller.html.

³⁰ See n. 12, *Supra*.

³¹ Anthem and The Network for Excellence in Health Innovation, *Reducing Hospital Readmissions Through Medication Management and Improved Patient Adherence*. Available at: www.nehi.net/writable/publication_files/file/anthem-reducinghospitalreadmissions-digital-final.pdf.

³² This includes but is not limited to adolescent health care. See Appendix H for information on confidentiality concerns in adolescent health care.

³³ A variety of state agencies administer PDMPs. More information is available at: www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

³⁴ Federal legislation passed in 2018, including the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act and the VA Maintaining Internal Systems and Strengthening Integrated Outside Network (MISSION) Act, encourages data sharing between states and supports prevention and research activities related to controlled substances, including education and awareness, among other things. More information available at: energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/H.R.%206%20Section-by-Section%209.26.18.pdf and www.veterans.senate.gov/imo/media/doc/VA%20Mission%20Act%20Section%20by%20Section.pdf.

³⁵ See Appendix G for information about state PDMPs.

³⁶ National Alliance for Model State Drug Laws, *Reporting Requirements and Exemptions to Reporting*, May 2016. Available at: namsdl.org/wp-content/uploads/Reporting-Requirements-and-Exemptions-to-Reporting.pdf.

provide PDMP access to other authorized users, such as law enforcement and licensing and regulatory boards.³⁷ More than three-quarters of states, including Maryland, mandate prescribers to query the PDMP before prescribing drugs that contain CDS.³⁸

On January 1, 2018, Nebraska became the first state to mandate reporting of non-CDS data to its PDMP.^{39, 40} Nebraska reports a relatively smooth transition from a CDS-only PDMP to one that tracks all prescriptions. Data reported has increased nearly tenfold, consistent with estimates of the proportion of prescriptions that are non-CDS (about 90 percent). Currently, Nebraska does not mandate that prescribers or pharmacists query the PDMP. Well over 40 percent of prescribers and pharmacists have registered with the PDMP. Since the implementation of the non-CDS reporting mandate, queries have increased from about 9,000 in December 2017 to over 41,000 by the end of 2018. Data are made available to registered dispensers and prescribers through an HIE, the Nebraska Health Information Initiative (NeHII). NeHII hosts the Nebraska PDMP, which is supported through a combination of public (federal and state) and private (hospital and payer) funding through 2019.^{41, 42}

Maryland

In 2011, Maryland law⁴³ mandated the State to establish a PDMP to monitor the prescribing and dispensing of CDS. The PDMP primarily assists providers and public health efforts by the Maryland Department of Health (MDH) in identifying and reducing prescription drug abuse of CDS Schedules II through V.^{44, 45, 46} The law requires dispensers (including practitioners and pharmacies) to report prescription fill information for CDS drugs dispensed to a patient or a patient's agent in Maryland.⁴⁷

³⁷ More information on other authorized users is available at: www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

³⁸ Brandeis University, The Heller School for Social Policy and Management, Prescription Drug Monitoring Program Training and Technical Assistance Center. Available at: www.pdmpassist.org.

³⁹ NE LB 471 (2016).

⁴⁰ Exemptions as they apply in 2019 include: (i) the delivery of prescription for immediate use for purpose of inpatient hospital care or emergency department care; (ii) the administration of a prescription drug by an authorized person upon the lawful order of a prescriber; (iii) a wholesale distributor of a prescription drug monitored by the prescription drug monitoring system; (iv) pharmacy chooses to never dispense any prescription drugs including both controlled and non-controlled substances or dispenses only medical supplies or devices in Nebraska or to a Nebraska address; (v) pharmacy does not dispense any prescription drugs including both controlled and non-controlled substances in Nebraska or to a Nebraska address; and (vi) veterinarian, veterinarian clinic, or veterinarian pharmacy chooses to never dispense any controlled substance prescriptions schedules II-IV in Nebraska or to a Nebraska address. More information available at: www.surveymonkey.com/r/Exemption_Form.

⁴¹ The Nebraska PDMP has received approximately \$8.26 million dollars (as of August 2018) from federal and state grants, and is in the process of exploring a PDMP user fee funding model.

⁴² Presentation by Kevin Borchert, Nebraska Health Information Initiative PDMP Program Director, August 2018.

⁴³ The PDMP is authorized under Health-General Article, Section 21-2A, Annotated Code of Maryland (Chapter 166, 2011). PDMP regulations can be found under Code of Maryland Regulations (COMAR) 10.47.07.

⁴⁴ See n. 5, *Supra*.

⁴⁵ The PDMP is a core component of Maryland's comprehensive strategy for reducing prescription drug abuse throughout the State, and a major goal in the Maryland Opioid Overdose Prevention Plan. More information available at: bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/MarylandOpioidOverdosePreventionPlan2013.pdf.

⁴⁶ The PDMP also assists federal, State and local law enforcement agencies, health occupations licensing boards and certain MDH agencies in the investigation of illegal CDS diversion, health care fraud, illegitimate professional practice, and other issues.

⁴⁷ The law includes reporting exemptions to the PDMP for the following: 1) a licensed hospital pharmacy that only dispenses a monitored prescription drug for direct administration to an inpatient of the hospital; 2) an opioid treatment service program; 3) a veterinarian licensed under Agriculture Article, Title 2, Subtitle 3, Annotated Code of Maryland, when prescribing controlled substances for animals in the usual course of providing professional services; 4) a pharmacy issued a waiver permit under COMAR 10.34.17.03 that provides pharmaceutical specialty services exclusively to persons living in assisted living facilities, comprehensive care facilities, and developmental disabilities; and 5) dispensing to hospice inpatients, provided that the dispensing pharmacy has applied for and been granted a waiver by the Department pursuant to §G of COMAR 10.47.07.03.

Approximately 94 percent of pharmacies in Maryland are registered and report to the PDMP.^{48, 49} Effective July 1, 2018, CDS prescribers are required to review a patient's PDMP data before prescribing an opioid or benzodiazepine, and every 90 days during the course of that treatment; pharmacists must consult the PDMP prior to dispensing a CDS drug if they reasonably suspect a patient is seeking the drug for non-medical use.^{50, 51, 52}

The Office of Provider Engagement and Regulation at the MDH, Public Health Services is responsible for oversight of the PDMP. The PDMP utilizes information technology (IT) services provided by CRISP. CRISP contracts with NIC, Inc.⁵³ to support PDMP-specific IT services that facilitate collection, analysis, and disclosure of prescription information for CDS. Authorized PDMP users are given electronic access to PDMP data through a secure online portal or within a provider's electronic health record. Originally, dispensers were required to report within three business days after a CDS drug was dispensed. As of October 8, 2018, dispensers must report within 24 hours of dispensing a CDS drug; this new requirement aligns with industry trends nationally.^{54, 55} Reporting is mainly automated, though some processes require manual intervention to ensure data quality and reconcile error reports.⁵⁶

Limitations

The recommendations reflect a consensus decision-making process among workgroup members. Some workgroup members expressed less than full support for certain recommendations, which are noted to the extent possible. The views of individuals representing stakeholder groups are not necessarily the official position of those groups.

Approach

The workgroup was representative of diverse stakeholder groups consisting of 81 members, including providers, pharmacists, consumers, and others.^{57, 58} A Charter⁵⁹ was developed to guide the work and inform the workgroup about study deliverables. The workgroup convened nine times from July 2018

⁴⁸ About 87 pharmacies only dispense non-CDS drugs and are thus not required to register/report to the PDMP.

⁴⁹ Deena Speights-Napata. Executive Director, Maryland Board of Pharmacy. Phone interview with The Hilltop Institute; September 26, 2018.

⁵⁰ Prescribers and pharmacists may delegate PDMP access to staff working in the same practice or facility.

⁵¹ Behavioral Health Administration, *Maryland Prescription Drug Monitoring Program*. Available at: bha.health.maryland.gov/pdmp/Pages/Home.aspx.

⁵² PDMP data was accessed by over 30,000 unique authorized users in Q1 2019.

⁵³ CRISP previously contracted with Health Information Designs/Appriiss.

⁵⁴ COMAR 10.47.07.03(B) is currently being phased in; enforcement began July 1, 2019; dispensers were encouraged to report daily prior to this date. More information available at: www.dsd.state.md.us/comar/comarhtml/10/10.47.07.03.htm.

⁵⁵ The majority of states, approximately 42, require dispensers to conduct daily reporting of CDS data. More information available at: <https://namsdl.org/wp-content/uploads/Frequency-of-Prescription-Drug-Monitoring-Program-PMP-Data-Reporting-Map.pdf>.

⁵⁶ Presentation by Matthew Shimoda, Pharmacy Director of SuperValu, October 2018.

⁵⁷ Representation included pharmacies, health systems, payers, managed care organizations, the National Council for Prescription Drug Programs (NCPDP), consumer groups, technology vendors, State agencies and programs including the PDMP, CRISP, and MedChi. See Appendix B for a copy of the Workgroup Roster.

⁵⁸ The MHCC engaged The Hilltop Institute at The University of Maryland Baltimore County to support research activities.

⁵⁹ See n. 3, *Supra*.

through February 2019.⁶⁰ Meeting information and materials were made available to the public through the workgroup’s web page on MHCC’s website.^{61, 62}

The MHCC facilitated workgroup meetings. At the kick-off meeting, staff provided information about the law and the workgroup’s charge. Subsequent meetings included stakeholder presentations to inform workgroup deliberations on select technology, policy, and other related matters.⁶³ Meetings were structured in a roundtable-like approach to foster a collaborative discussion about topics that aligned with study requirements in the law. Information gathering grids (grids) identified benefits, barriers/challenges, and potential solutions, and supported an objective approach to the discussions.⁶⁴

A Technology Subgroup was convened for exploratory discussions on the technical infrastructure for non-CDS. During these discussions, members assessed opportunities to leverage innovative solutions for collecting, aggregating and exposing non-CDS data to providers and pharmacists. A Draft Recommendations Subgroup was established to formulate informal draft recommendations. The Draft Recommendations subgroup assessed key themes from concepts identified in the grids to guide development of draft recommendations. Participation in both subgroups was open to all members of the workgroup.

Key Themes and Suggested Recommendations

Summary

The workgroup supports implementing an electronic non-CDS statewide repository to improve patient safety. A stakeholder advisory committee (or committee) was recommended to guide policy development. The workgroup agrees a committee is necessary to ensure strong consumer protections and address matters related to access, use, and disclosure of non-CDS information. Many strongly believe that a consumer opt-out provision is needed and should be supported by consumer education at the point of care. Federal and State privacy laws and certain PDMP and HIE regulations⁶⁵ were deemed suitable to govern a non-CDS repository. The estimated cost to develop and implement a non-CDS statewide repository is approximately \$750,000, and the annual system maintenance and support cost is about \$500,000.⁶⁶

Commercial technology solutions currently make available non-CDS medication history. The workgroup recognized limitations with these solutions, namely lack of technical integration with existing EHRs, cost, and incomplete dispensed data for Maryland consumers. The workgroup is divided about a multi-vendor versus a single vendor technology approach to develop and maintain a non-CDS repository. The workgroup finds that a State recognition process is needed to ensure at least one or more vendors meet appropriate technical standards, and maintain adequate privacy and security controls to safeguard consumers’ non-CDS data.

⁶⁰ Includes two meetings of the Technology Subgroup and one meeting of the Draft Recommendations Subgroup.

⁶¹ Workgroup web page: mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hit_electronic_prescription.aspx.

⁶² See Appendices D and E for copies of meeting summaries and presentations for details on the focus of meeting discussions.

⁶³ See *Overview* section for study requirements identified in the law.

⁶⁴ See Appendix F for a copy of the grids.

⁶⁵ For example, PDMP regulations can help guide governance of data submission; HIE regulations can help guide access, use, and disclosure of data.

⁶⁶ Projected costs through July 2021. Annual system maintenance and support costs are anticipated to increase based on market trends.

Key Categories

1. **Implementation**

Key Themes

- a) Limit reporting of dispensed non-CDS data to dispensers for the majority of medications (e.g., retail and mail order) and exclude institutional pharmacies⁶⁷
- b) Strongly consider a multi-vendor approach to support reporting and access to a non-CDS repository
- c) Minimize disruption to prescriber and dispenser workflows
- d) Complementary and user-friendly display format for viewing CDS and non-CDS dispensed medication history
- e) Only authorized users should be permitted access to non-CDS data through adequate privacy and security controls that safeguard patient protected health information (PHI) and prevent unauthorized or inappropriate access

Suggested Recommendations

- a) *Competitively recognize (through a State recognition process) one or more non-CDS vendors that meet and maintain required privacy and security controls and standards for technical performance*
- b) *Leverage existing vendor solutions for dispenser reporting of non-CDS and in making that information accessible to prescribers and dispensers within existing workflows*
- c) *Convene a stakeholder advisory committee to propose policy recommendations for non-CDS reporting and other operational matters*

Discussion

The workgroup favors a non-CDS vendor State recognition process that ensures certain technical standards and privacy and security safeguards are in place. The workgroup deems privacy and security controls, reporting functionality, integration with EHRs, interoperability with the State-Designated HIE, and alignment with pharmacy information management systems as essential for State recognition. Some on the workgroup suggest there should be a multi-vendor approach for non-CDS reporting that integrates with the State-Designated HIE. The advisory committee should propose implementation policies, including exclusions or waivers and potential pilot programs.

2. **Consumer Privacy and Education**

Key Themes

- a) The benefit of a non-CDS repository does not outweigh the public health need to ensure consumers feel safe in seeking care

⁶⁷ Institutional pharmacies provide services to an acute care, rehabilitation, transitional care, chronic care, or mental health hospital as defined in COMAR 10.34.03, *Institutional Pharmacy*.

- b) Implications of incomplete data, including the impact of exempting publically funded clinics, nursing homes, and institutional pharmacies
- c) Ensure patient privacy from inclusion in the statewide repository through awareness and understanding of an opt-out process at the point of care
- d) Certain classifications of medications should be excluded as consumer concerns about privacy could lead them to forego care
- e) More consideration is needed to protect the privacy of minors who consent to their own care

Suggested Recommendations

- a) *Implement a consumer non-CDS opt-out process*
- b) *Provide consumers with opt-out information at the point of care*
- c) *Codify consumer protections in statute*

Discussion

The workgroup realizes that reporting exemptions for select non-CDS medications and provider services are necessary to address privacy concerns regarding medical conditions that can lead consumers to sacrifice care. The workgroup supports enabling a consumer to opt-out; however, some providers worry the option to opt-out puts a consumer at greater risk of harm due to the potential for information gaps in their prescription medication history. The workgroup recognizes that consumer control of their non-CDS information is paramount and important to address complexities surrounding sensitive and stigmatized illnesses and medical needs (e.g., behavioral health, sexual and reproductive health, and certain medical conditions). Consumer control should also allow minors, who consent to their own care, to protect their privacy. However, the workgroup noted that safeguards established for a non-CDS repository will not prevent prescription information from being exchanged through other methods or systems currently in place. Consumer education regarding the purpose of sharing prescription information with treating providers and potential disadvantages of opting out is viewed by many on the workgroup as essential.⁶⁸

3. Governance and Funding

Key Themes

- a) Non-CDS reporting requires a mandate in State law
- b) Rely on relevant federal and State privacy laws and appropriate State regulations for the PDMP (e.g., data submission) and HIE (access, use, and disclosure of data) to guide governance
- c) Non-CDS requirements should not be included under the existing PDMP program

⁶⁸ The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care is considered an appropriate framework to guide messaging. It aims to advance health equity, improve quality, and eliminate health care disparities. More information is available at: www.thinkculturalhealth.hhs.gov/clar/standards.

- d) A sustainable funding source is required

Suggested Recommendations

- a) *Develop non-CDS reporting regulations informed by federal and State regulations, including COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information and COMAR 10.47.07, Prescription Drug Monitoring Program*
- b) *Rely on a public funding approach to support a non-CDS repository*

Discussion

The workgroup considers existing HIE and PDMP regulations as foundational for guiding the development of non-CDS reporting requirements. HIE privacy and security regulations include requirements regarding PHI accessed, used, or disclosed through HIEs operating in the State; PDMP regulations include provisions for CDS reporting. Some workgroup members view the current CDS reporting infrastructure as not well-suited to support non-CDS reporting, in part because considerable re-engineering would be required. The workgroup believes the cost to support non-CDS reporting should not be funded by prescribers and dispensers. The workgroup was unable to identify funding sources other than public funds for non-CDS reporting.

Conclusion

Medication reconciliation is a matter of patient safety; bridging gaps in medication reconciliation using health IT can reduce costly errors that result in patient harm. A non-CDS repository will complement CDS reporting requirements in Maryland. The vision is to improve patient safety; however, equally important is respecting consumer privacy wishes and building provider and consumer trust through education. Consumer control of their information is an essential feature of a non-CDS repository. The workgroup believes the recommendations included in this report provide a practical foundation for the Governor and General Assembly in developing legislation that mandates reporting to a non-CDS repository.

Acknowledgments

The MHCC commends the commitment of stakeholders that served on the workgroup and contributed to the preparation of this report. A sincere thanks is extended to The Hilltop Institute at The University of Maryland Baltimore County for assisting with this study.

Appendix A: Chapter 435 (2018)

LAWRENCE J. HOGAN, JR., Governor

Ch. 435

Chapter 435

(House Bill 115)

AN ACT concerning

Maryland Health Care Commission - Electronic Prescription Records ~~Cost~~
Saving Act of 2018 System - Assessment and Report

FOR the purpose of requiring ~~a dispenser of a prescription drug to submit certain prescription information to a certain health information exchange; requiring certain prescription information to be submitted in a certain manner; prohibiting a certain health information exchange from imposing certain fees or assessments; requiring a certain health information exchange to make certain prescription information available to a health care provider for certain purposes; requiring the Maryland Health Care Commission to adopt certain regulations; requiring that certain regulations include certain provisions; stating the purpose of this Act; defining certain terms~~ the Maryland Health Care Commission, in consultation with interested stakeholders, to assess the benefits and feasibility of developing an electronic system to allow health care providers to access a patient's prescription medication history; requiring the Commission to report its findings to the Governor and the General Assembly on or before a certain date; specifying the intent of the General Assembly; providing for the termination of this Act; and generally relating to an assessment and report by the Maryland Health Care Commission regarding an electronic prescription information and the health information exchange system.

~~BY adding to~~

~~Article Health General~~

~~Section 10-145~~

~~Annotated Code of Maryland~~

~~(2015 Replacement Volume and 2017 Supplement)~~

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
That ~~the Laws of Maryland read as follows:~~

~~Article Health General~~

~~10-145.~~

~~(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED:~~

~~(2) (i) "DISPENSE" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE.~~

~~(ii) "DISPENSE" DOES NOT INCLUDE:~~

~~1. DIRECTLY ADMINISTERING A PRESCRIPTION DRUG TO A PATIENT; OR~~

~~2. GIVING OUT PRESCRIPTION DRUG SAMPLES.~~

~~(3) (i) "DISPENSER" MEANS A PERSON AUTHORIZED BY LAW TO DISPENSE A PRESCRIPTION DRUG TO A PATIENT OR THE PATIENT'S AGENT IN THE STATE.~~

~~(ii) "DISPENSER" INCLUDES A NONRESIDENT PHARMACY.~~

~~(iii) "DISPENSER" DOES NOT INCLUDE A PERSON DESCRIBED IN § 21-2A-01(D)(3) OF THIS ARTICLE.~~

~~(4) "PRESCRIPTION DRUG" HAS THE MEANING STATED IN § 21-201 OF THIS ARTICLE.~~

~~(b) THE PURPOSE OF THIS SECTION IS TO ALLOW A HEALTH CARE PROVIDER TO ACCESS A PATIENT'S MEDICATION HISTORY, INCLUDING MEDICATIONS PRESCRIBED FOR THE PATIENT BY ANOTHER HEALTH CARE PROVIDER.~~

~~(c) (1) AFTER DISPENSING A PRESCRIPTION DRUG, A DISPENSER SHALL SUBMIT PRESCRIPTION INFORMATION TO THE HEALTH INFORMATION EXCHANGE DESIGNATED FOR THE STATE UNDER § 19-143(A) OF THIS SUBTITLE.~~

~~(2) THE PRESCRIPTION INFORMATION SHALL BE SUBMITTED:~~

~~(i) BY ELECTRONIC MEANS;~~

~~(ii) WITHOUT UNDULY INCREASING THE WORKLOAD AND EXPENSE ON A DISPENSER;~~

~~(iii) IN A MANNER AS COMPATIBLE AS POSSIBLE WITH EXISTING DATA SUBMISSION PRACTICES OF DISPENSERS;~~

~~(iv) USING INFORMATION TECHNOLOGY SOFTWARE PROVIDED TO THE DISPENSER BY THE STATE DESIGNATED HEALTH INFORMATION EXCHANGE; AND~~

~~(v) AS OTHERWISE REQUIRED THROUGH REGULATIONS ADOPTED BY THE COMMISSION.~~

~~(3) THE STATE DESIGNATED HEALTH INFORMATION EXCHANGE MAY NOT IMPOSE ANY FEES OR OTHER ASSESSMENTS TO SUPPORT THE OPERATION OF THE EXCHANGE ON PRESCRIBERS OR DISPENSERS.~~

~~(D) THE STATE DESIGNATED HEALTH INFORMATION EXCHANGE SHALL MAKE PRESCRIPTION INFORMATION SUBMITTED UNDER SUBSECTION (C) OF THIS SECTION AVAILABLE TO A HEALTH CARE PROVIDER FOR PURPOSES OF TREATMENT AND CARE COORDINATION OF A PATIENT.~~

~~(E) THE COMMISSION, IN CONSULTATION WITH STAKEHOLDERS, SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.~~

~~(F) THE REGULATIONS ADOPTED BY THE COMMISSION UNDER SUBSECTION (E) OF THIS SECTION SHALL INCLUDE:~~

~~(1) THE SPECIFIC PRESCRIPTION INFORMATION REQUIRED TO BE SUBMITTED UNDER SUBSECTION (C) OF THIS SECTION;~~

~~(2) THE TIME FRAME FOR SUBMITTING PRESCRIPTION INFORMATION UNDER SUBSECTION (C) OF THIS SECTION;~~

~~(3) THE ELECTRONIC MEANS AND MANNER BY WHICH PRESCRIPTION INFORMATION IS TO BE SUBMITTED UNDER SUBSECTION (C) OF THIS SECTION;~~

~~(4) WHO MAY ACCESS PRESCRIPTION INFORMATION AFTER IT IS SUBMITTED UNDER SUBSECTION (C) OF THIS SECTION;~~

~~(5) PERMISSIBLE USES OF PRESCRIPTION INFORMATION SUBMITTED UNDER THIS SECTION; AND~~

~~(6) PRESCRIPTION INFORMATION SUBMISSION REQUIREMENTS THAT ALIGN WITH THE DATA SUBMISSION REQUIREMENTS ON DISPENSERS OF MONITORED PRESCRIPTION DRUGS UNDER TITLE 21, SUBTITLE 2A OF THIS ARTICLE.~~

(a) The Maryland Health Care Commission shall convene interested stakeholders to assess the benefits and feasibility of developing an electronic system to allow health care providers to access a patient's prescription medication history, including assessing:

(1) whether the health information exchange designated for the State under § 19-143 of the Health - General Article is capable of including a patient's prescription medication history;

(2) the enhancements to the State-designated health information exchange required to ensure that the exchange is able to continue to meet other State mandates, including operating an effective Prescription Drug Monitoring Program;

(3) the resources required for individual health care practitioners, health care facilities, prescription drug dispensers, and pharmacies to provide the information collected in a statewide repository of prescription medication information;

(4) the cost to the State to develop and maintain an electronic prescription medication system and the cost to prescribers to access the system;

(5) the resources required to ensure that health care practitioners and prescription drug dispensers can maximize the benefit of using the system to improve patient care;

(6) the scope of prescription medication information that should be collected in the system, including any specific exemptions;

(7) the scope of health care providers that would report prescription medication information in the system, including any specific exemptions;

(8) the potential for development or use of systems other than the State-designated health information exchange for access to patients' prescription medication history;

(9) the privacy protections required for the system, including the ability of consumers to choose not to share prescription data, to ensure the prescription data is used in a manner that is compliant with State and federal privacy requirements, including 42 U.S.C. § 290dd-2 and 42 C.F.R Part 2;

(10) the feasibility of ensuring that the data in the system is used only by health care practitioners to coordinate the care and treatment of patients;

(11) the standards for prohibiting the use of the data in the system by a person or an entity other than a health care practitioner, including any exceptions for the use of data with identifying information removed for bona fide research; and

(12) any other matters of interest identified by the Commission or the stakeholders.

(b) On or before January 1, 2020, the Maryland Health Care Commission, in consultation with interested stakeholders, shall report its findings and recommendations to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly.

SECTION 2. AND BE IT FURTHER ENACTED, That it is the intent of the General Assembly that the Maryland Health Care Commission work toward the development of an electronic system within the health information exchange designated for the State under § 19-143 of the Health – General Article for the purpose of providing a health care provider access to a patient’s medication history, including medications prescribed to a patient by another health care provider, to coordinate the care of or provide treatment to the patient.

SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October 1, 2018~~ July 1, 2018. It shall remain effective for a period of 2 years and, at the end of June 30, 2020, this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect.

Approved by the Governor, May 8, 2018.

Appendix B: Roster

Electronic Prescription Records System Workgroup Roster (As of April 2019)		
#	Name	Organization
1	Alan Friedman, R.Ph. ⁺	Kaiser Permanente
2	Anna Schoenbaum, DNP ⁺	University of Maryland Medical System
3	Anne Copeland, R.Ph.	Maryland Pharmacists Association
4	Ashley Kinder, M.D.	Saint Agnes Healthcare
5	Brandon Neiswender	The Chesapeake Regional Information System for our Patients
6	Bridgitte Gourley, DNP, CRNP	University of Maryland School of Nursing
7	Bruce Taylor, M.D. ⁺	Taylor Service
8	Cailey Locklair Tolle ⁺	Maryland Retailers Association
9	Camille Bash, Ph.D., CPA, FHFMA, MBA, MA, NHA	Totally Linking Care in Maryland Regional Partnership
10	Camille Fesche	Rifkin Weiner Livingston LLC
11	Catherine Graeff, R.Ph., MBA* ⁺	National Association of Chain Drug Stores
12	Charlie Oltman	National Council for Prescription Drug Programs
13	Christopher DiBlasi	Surescripts
14	Clay House	CareFirst BlueCross BlueShield
15	Courtney Oatts	Maryland School Psychologists Association
16	Cynthia Macri, M.D.* ⁺	EagleForce Associates, Inc.
17	Dan Morhaim, M.D. ⁺	Maryland House of Delegates
18	Danna Kauffman	Schwartz, Metz and Wise, P.A.
19	Darja Lee	Surescripts
20	David Lehr	Anne Arundel Medical Center
21	Dawn Seek	Maryland National Capital Homecare Association
22	Deb Rivkin	CareFirst BlueCross BlueShield
23	Dixie Leikach, R.Ph.*	Pharmacy Ethics, Education & Resources
24	Doug Lawrence	McKesson
25	Elizabeth (CeCe) Bower, M.D.	Saint Agnes Healthcare
26	Greg Anderson	Surescripts
27	Janet Hart	Rite Aid
28	Jennifer Bailey, Pharm.D., BCPS, AAHIVP	Notre Dame of Maryland University
29	Jennifer Hardesty, Pharm.D.	Remedi
30	Jennifer Thomas, Pharm.D. ⁺	Maryland Pharmacists Association
31	Jermaine Smith, R.Ph.	Rite Aid
32	Ji Changrong	CareFirst BlueCross BlueShield

Electronic Prescription Records System Workgroup Roster

(As of April 2019)

#	Name	Organization
33	Jim Gutman ¹	AARP
34	John Morgan	EagleForce Associates, Inc.
35	Jonathan Thierman, Ph.D., M.D.*	LifeBridge Health
36	Josh Chou, Pharm.D. ¹	University of Maryland Peter Lamy Center on Drug Therapy and Aging
37	Josh White	Perry, White, Ross & Jacobson
38	Joy Strand, MHA	Maryland Medical Cannabis Commission
39	Justin Ross	Perry, White, Ross & Jacobson
40	Karen Guinan*	Wegmans Food Markets, Inc.
41	Kate Jackson ¹	Maryland Department of Health, Behavioral Health Administration
42	Ken Lee, M.D.	LifeBridge Health
43	Ken Whittemore	Surescripts
44	Kevin Borchert, Pharm.D.*	Nebraska Prescription Drug Monitoring Program
45	Kim Mayhew	Surescripts
46	Laura Ludvigsen ¹	Kaiser Permanente
47	Lenna Israbian-Jamgochian, Pharm.D., R.Ph.	Safeway
48	Lindsey Ferris* ¹	The Chesapeake Regional Information System for our Patients
49	Lisa Carnevale	Kaiser Permanente
50	Magaly Rodriguez de Bittner, Pharm.D.	University of Maryland School of Pharmacy, Center for Innovative Pharmacy Solutions
51	Mansoor Beg	Rite Aid
52	Matthew Bohle	Rifkin, Weiner, and Livingston
53	Matthew Shimoda, Pharm. D.*	Supervalu Shoppers Food and Pharmacy
54	Melanie Chapple, Pharm.D.	University of Maryland Shore Regional Health
55	Michael Grimes, Pharm.D., MBA ¹	Johns Hopkins Specialty Infusion Services
56	Michael Johansen	Rifkin, Weiner, and Livingston
57	Michael Vitz	EagleForce Associates, Inc.
58	Michele Davidson, R.Ph.*	Walgreens
59	Min Kwon, Pharm.D., BCPS	LifeBridge Health
60	Nicole Brandt, Pharm.D., MBA, BCGP, BCPP, FASCP	University of Maryland Peter Lamy Center on Drug Therapy and Aging
61	Nicole Russell*	National Council for Prescription Drug Programs
62	Patrick Harris*	RelayHealth
63	Patty Ciotta	CareFirst BlueCross BlueShield
64	Philip Nicholson	Versa Integrated Solutions
65	Prince Howard* ¹	Pathway Partners , LLC

Electronic Prescription Records System Workgroup Roster

(As of April 2019)

#	Name	Organization
66	Quintus Brown [‡]	Versa Integrated Solutions
67	Robyn Elliott [‡]	Maryland Nurses Association, the Suburban Psychiatric Society, and Planned Parenthood of Maryland
68	Roxanne Zaghab	University of Maryland School of Pharmacy, Center for Innovative Pharmacy Solutions
69	Salim Jarawan, Pharm.D.	Doctors Community Hospital and Affiliates
70	Sara Roberson, MSW	Maryland Department of Health, Behavioral Health Administration
71	Sean McCarthy	Remedi SeniorCare
72	Serena Han	Surescripts
73	Sinthi Acey, Pharm.D.	EagleForce Associates, Inc.
74	Stacy Ward-Charlerie, Pharm.D., MBA ^{*‡}	Surescripts
75	Stanley Campbell ^{*‡}	EagleForce Associates, Inc.
76	Stephen Mullenix	National Council for Prescription Drug Programs
77	Teresa Strickland*	National Council for Prescription Drug Programs
78	Terry Talbott, R.Ph.*	CVS
79	Tracy Russell [‡]	McKesson
80	Will Price [‡]	Public Health Exchange & Resource Solutions
81	Will Tilburg	Maryland Medical Cannabis Commission

**Indicates participation on the Technology Subgroup*

‡Indicates participation on the Draft Recommendations Subgroup

Appendix C: Charter

DRAFT: Version 1



Electronic Prescription Records System – Assessment and Report CHARTER

Purpose

During the 2018 legislative session, House Bill 115, *Maryland Health Care Commission – Electronic Prescription Records System – Assessment and Report*, was passed and requires the Maryland Health Care Commission (MHCC) to convene interested stakeholders to assess the benefits and feasibility of developing an electronic system (or statewide repository) to allow health care providers to access a patient’s prescription medication history. Study requirements includes assessing:

- whether the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP), is capable of including a patient’s prescription medication history;
- enhancements to CRISP required to ensure that the exchange is able to continue to meet other State mandates, including operating an effective Prescription Drug Monitoring Program (PDMP);
- resources required for individual health care practitioners, health care facilities, prescription drug dispensers, and pharmacies to provide the information collected in a statewide repository of prescription medication information;
- cost to the State to develop and maintain an electronic prescription medication system and the cost to prescribers to access the system;
- resources required to ensure that health care practitioners and prescription drug dispensers can maximize the benefit of using the system to improve patient care;
- scope of prescription medication information that should be collected in the system, including any specific exemptions;
- scope of health care providers that would report prescription medication information in the system, including any specific exemptions;
- potential for development or use of systems other than CRISP for access to patients’ prescription medication history;
- privacy protections required for the system, including the ability of consumers to choose not to share prescription data, to ensure the prescription data is used in a manner that is compliant with State and federal privacy requirements, including 42 U.S.C. § 290dd-2 and 42 C.F.R Part 2;
- feasibility of ensuring that the data in the system is used only by health care practitioners to coordinate the care and treatment of patients;

- standards for prohibiting the use of the data in the system by a person or an entity other than a health care practitioner, including any exceptions for the use of data with identifying information removed for bona fide research; and
- any other matters of interest identified by MHCC or stakeholders.

A report detailing findings and recommendations from the study is required to be submitted to the Governor and General Assembly on or before January 1, 2020.⁶⁹

Background

In 2011, Maryland law⁷⁰ established the PDMP to monitor the prescribing and dispensing of certain drugs that contain controlled dangerous substances (CDS).⁷¹ The PDMP assists health care providers and public health and law enforcement agencies in reducing non-medical use, abuse, and diversion of such drugs while preserving the professional practice of health care providers and legitimate patient access to optimal pharmaceutical-assisted care. Dispensers, including pharmacies and health care providers, are required⁷² to report to the PDMP prescription fill information for drugs listed in CDS Schedules II through V that are dispensed to a patient or a patient's agent in Maryland.⁷³

The PDMP utilizes information technology services provided by CRISP.⁷⁴ Authorized PDMP users⁷⁵ are given electronic access to PDMP data through a secure, online portal or within a health care provider's electronic health record system. The PDMP is a core component of Maryland's comprehensive strategy for reducing prescription drug abuse throughout the State, a major goal of the Maryland Opioid Overdose Prevention Plan.⁷⁶ The existing infrastructure and technical processes already in place for the PDMP could potentially be leveraged to expand reporting of non-CDS data.

Rationale

Health care providers and consumers benefit from electronic access to patient prescription medication histories to deliver appropriate and high quality care. Health care providers can encounter challenges in compiling complete and accurate prescription information when patients cannot recall their current medications and dosages. Additionally, patients in emergent situations may be unable to communicate this information to health care providers. Incomplete information on patients' prescription medication histories is a major cause for medication errors that trigger more than one million emergency department visits and over a quarter of a million hospitalizations each year.⁷⁷ Making electronic prescription

⁶⁹ A study and report was recommended rather than advancing an original version of House Bill 115 that would have required MHCC to adopt regulations for reporting of and access to patient prescription medication information.

⁷⁰ Chapter 166 of 2011.

⁷¹ State and federal law define CDS as substances that have abuse potential. This includes drugs listed in Schedules II, III, IV and V that have accepted medical uses, such as opioid pain relievers like oxycodone (OxyContin, Percocet, Percodan, Roxicet), hydrocodone (Vicodin, Lortab) and methadone; anti-anxiety and sedative medications like alprazolam (Xanax) and diazepam (Valium); and stimulants like Adderall and Ritalin.

⁷² Health-Gen. § 21-2A-03.

⁷³ The Office of Provider Engagement and Regulation at the Maryland Department of Health (MDH), Public Health Services is responsible for oversight of the PDMP. For more information, visit: bha.health.maryland.gov/pdmp/Pages/-PDMP_FAQs.aspx.

⁷⁴ CRISP has contracted with Health Information Designs (HID) to support PDMP-specific IT services. HID is a web-based program that facilitates the collection, analysis, and disclosure of prescription information.

⁷⁵ The PDMP requires system users, which includes health care providers and public health and law enforcement agency investigators as permitted by State law, be authenticated and credentialed before they can obtain PDMP data.

⁷⁶ MDH, *Maryland Opioid Overdose Prevention Plan*, January 2013. Available at:

bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/MarylandOpioidOverdosePreventionPlan2013.pdf.

⁷⁷ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, *National Action Plan for Adverse Drug Event Prevention*, 2012. Available at: health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf.

information more accessible can generate efficiencies and improve patient safety by enabling health care providers to have more complete information, which could reduce adverse drug events.

Approach

The MHCC will convene a Prescription Study Workgroup (workgroup) to formulate recommendations to the study requirements. The workgroup will consist of interested stakeholders who may include, but is not limited to, representation from State agencies, health care providers, health care facilities, payers, HIEs, consumer groups, and technology vendors. The MHCC anticipates that some discussions will potentially require the formation of subgroups, and it is likely that subgroups will have a Chair appointed by MHCC. In addition to presiding at meetings, a subgroup Chair will take an active role in guiding and developing policy recommendations, among other things. In general, formation of subgroups and key discussion topics may include the following:

1) Technology and Cost

- Capabilities of CRISP to make available prescription data and enhancements needed to ensure the continuous operation of the PDMP and other State mandates
- Potential development or use of systems other than CRISP
- Resource requirements for reporting prescription data to a statewide repository and maximizing the benefit of using the electronic system to improve patient care
- Cost to develop and maintain the electronic system and cost to prescribers to access the EPR system
- Privacy and security

2) Policy and Operations

- Scope of prescription medication information that should be reported and specific exemptions
- Scope of health care providers required to report prescription medication information and specific exemptions
- Patient privacy, including opt-out procedures
- Feasibility of ensuring data in the repository is used only by health care practitioners
- Standards prohibiting use of data in the repository by a person or entity other than a health care practitioner and any exceptions where identifying information is removed for bona fide research

Meetings

All workgroup meetings are open to the public. A simple majority of workgroup members shall constitute a quorum for convening meetings. The majority of meetings will take place via teleconference. In-person meetings will be held at MHCC offices or another location if circumstances permit; members are strongly encouraged to attend on-site and teleconference information will be made available. Members participating via teleconference shall count for quorum purposes, and their position (i.e., support, oppose, abstain) on matters will be recorded. Reasonable notice of all meetings including date, time, teleconference information, and location (if applicable) will be provided by email to all workgroup members. Information on meetings is posted on MHCC's website [here](#).

Timeline and Deliverables

Meetings are anticipated to begin in July 2018 and take place about every four to six weeks for the next 10 months. Additional meetings may be needed if a discussion topic warrants continued deliberation about a proposed recommendation. The output from these meetings will be compiled into a final draft report targeted for release in July 2019. The report will include the names of all workgroup members, meeting work papers, and recommendations that could influence future legislation.

Appendix D: Meeting Summaries

Electronic Prescription Records System Workgroup

July 12, 2018

Meeting Summary

Key discussion items include:

- The Maryland Health Care Commission (MHCC) structured the meeting to provide important background context about the law, purpose and role of the workgroup, and information about the current landscape of prescription medication reporting and availability in Maryland.
- Dan Morhaim, M.D., member of the Maryland House of Delegates, explained the driver for House Bill 115, *Maryland Health Care Commission – Electronic Prescription Records System – Assessment and Report*, and the reason MHCC was tasked to convene interested stakeholders to assess the feasibility of developing a statewide repository of patient prescription medication history. Dr. Morhaim also provided perspective as an emergency room physician about the difficulties of not having access to patients' medication histories, noting the increased complexity of various drug classifications and the need for a user friendly, clinically helpful solution to reduce the risk of medication errors.
- Representatives from the Prescription Drug Monitoring Program (PDMP) and the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP), provided an overview of the role of their programs in the State and services available to the health care community. The PDMP aims to reduce prescription drug abuse and diversion by collecting and making available information on Controlled Dangerous Substances (CDS) Schedule II-V drugs dispensed to patients in Maryland. CDS data is viewable through the CRISP Clinical Query Portal to authorized users, and can also be ingested into electronic health record (EHR) systems; mandated use became effective July 1, 2018. Representatives from pharmacies stated there was no cost to upgrade their IT systems given the mandatory use requirement in statute; otherwise, vendors would likely charge.
- Representatives from Surescripts discussed their services that are integrated with EHR systems, including e-prescribing, prior authorization, and medication history. Surescripts is an HIE that operates nationally and has dispensed prescription medication data for about three quarters of U.S. patients. The workgroup discussed certain circumstances when Surescripts does not have data (e.g., when a pharmacy is not connected, instances when a patient pays cash/does not use insurance, closed systems like Kaiser, etc.)
- *Resources: Workgroup members are encouraged to review the [CRISP](#), [PDMP](#), and [Surescripts](#) websites for more information.*
- *Action Items: Review and provide suggested edits on the draft listing of workgroup discussion items, including recommendations on the prioritization of these items in future workgroup discussions. The draft listing is available [here](#); a Word document was e-mailed to the workgroup on July 13, 2018.*
- *Upcoming Meeting: The workgroup will convene again at MHCC offices on Thursday, August 2, 2018 from 1:00pm to 3:00pm EDT. Meeting materials will be posted to the workgroup [webpage](#) on the day prior.*

Electronic Prescription Records System Workgroup

August 2, 2018

Meeting Summary

Key discussion items include:

- Alice Middleton of the Hilltop Institute and Kevin Borchert of the Nebraska Health Information Initiative presented on elements of the Nebraska Prescription Drug Monitoring Program (PDMP), the first in the nation to require reporting of all dispensed medication prescriptions as of January 1, 2018 (presentation slides available [here](#)). The presentation highlighted aspects related to implementation, funding, cost, reporting, and access. Preliminary results include a notable increase in data reported and queried since Nebraska mandated that all non-CDS prescriptions be reported. Lessons learned and future opportunities were also shared with the workgroup.
- The workgroup reviewed draft discussion items (version 2 available [here](#)), which included grids to map out key considerations for each as they relate to benefits, barriers, solutions, and challenges. The approach for using this framework was explained with the goal to narrow the focus and scope of discussions, identify discussion topics for future workgroup meetings, and guide the development of recommendations. Based on input from workgroup members, it was decided to organize key considerations based on the perspective of the patient, provider/prescriber, and dispenser).
- The workgroup reviewed discussion item 3, *Resource impact of mandated reporting*. Members identified a preliminary listing of potential benefits, including downstream effects that could improve patient safety, patient counseling, and medication reconciliation. Kate Jackson of the Maryland PDMP noted benefits of having diagnosis code if that information were included in the prescription data, and suggested the workgroup consider this in its deliberations.
- Discussions among the workgroup identified a need to consider reporting of medical cannabis and desirability to close the gap in missing information from hospitals and long-term and post-acute care settings, such as institutional pharmacies.
- *Action Items: Review the draft listing of workgroup discussion items and provide feedback on key considerations for each quadrant of the grid. The draft listing is available [here](#).*
- *Upcoming Meetings: The workgroup will convene again at MHCC offices on Wednesday, October 3, 2018 from 2:00pm to 4:00pm EDT. Refer to the workgroup [web page](#) for meeting dates and times through the end of this year.*

Electronic Prescription Records System Workgroup

October 3, 2018

Meeting Summary

Key discussion items include:

- Kate Jackson, Director of the Prescription Drug Monitoring Program (PDMP), provided an overview of current processes for reporting Schedule II-V controlled dangerous substances (CDS) (presentation slides available [here](#)). Of note, Maryland will soon require daily reporting of dispensed CDS medications (a change from the current requirement of three business days); about half of all states already require daily reporting. Use of the American Society for Automation in Pharmacy (ASAP) Standard Version 4.2 was discussed in addition to the editing process and data error reports.⁷⁸ A follow-up item came from one inquiry about reporting requirements for correctional facilities.
- Mathew Shimoda, PharmD, Pharmacy Director of SuperValu, provided a personal perspective about current and potential new State mandates (presentation slides available [here](#)). Dr. Shimoda discussed automated and manual processes for CDS and the additional resources that would be needed for reporting non-CDS (an estimated 10 fold increase in volume). Discussion among the workgroup also highlighted the need for pharmacy access to clinical data available through the State-Designated Health Information Exchange, the Chesapeake Regional Information System for our Patients (CRISP).
- The workgroup reviewed Version 3 of the discussion items/grids to continue information gathering about potential benefits, barriers/challenges, and solutions for specific components of an electronic prescription records system. Item 3A (i.e., investing new resources to expand reporting of non-CDS) brought to light limitations in utilizing the current PDMP infrastructure and potential vendor options to support non-CDS, including existing claims-based networks that are connected to many pharmacies and health care providers. The need to assess contractual issues for information sharing and data integration across various systems to avoid duplication was discussed.
- *Action Items: The MHCC will be forming two subgroups that will collaborate virtually over the next month. A Technology Subgroup will convene on Wednesday October 17th from 2:00 to 3:30pm EDT to discuss a vendor neutral technical infrastructure for non-CDS data that does not require use of existing PDMP technology. An Information Gathering Grids Subgroup will work together in GoogleDocs to deliberate on benefits, barriers/challenges, and solutions for key discussion items identified in the law. Please contact Eva Lenoir at eva.lenoir@maryland.gov if you would like to participate in one or more subgroups.*
- *Upcoming Meeting: The workgroup will convene again at MHCC offices on Thursday, November 8, 2018 from 1:00pm to 3:00pm EST. Refer to the workgroup [webpage](#) for meeting dates and times through the end of this year.*

⁷⁸ Errors are classified as minor, serious, or fatal. For more information, refer to Dispenser's Implementation Guide: rxsentry.net/assets/files/mdpdmp/2017/MD_PDMP_Dispensers_Implementation_Guide.pdf.

Electronic Prescription Records System Workgroup

Technology Subgroup

October 17, 2018

Meeting Summary

Key discussion items include:

- The Maryland Health Care Commission (MHCC) explained the purpose of the Technology Subgroup (subgroup) and its charge to explore a technical infrastructure for non-CDS data that is vendor neutral and does not require use of existing Prescription Drug Monitoring Program (PDMP) technology.
- Representation from the State-Designated Health Information Exchange (HIE) provided information on current technology used to collect data on controlled dangerous substances (CDS), highlighting aspects related to data quality checks, use of standards (NCPDP⁷⁹ and ASAP⁸⁰), and patient matching.
- Participants discussed current NCPDP standards⁸¹ including SCRIPT (electronic prescribing) and Telecommunication (eligibility, benefit, and claims transactions). The Telecommunication standard has the ability to capture cash payments, which is estimated to be about five to eight percent of all prescriptions dispensed. A new NCPDP Dispensed Medication Reporting Standard (reporting standard) is under development and expected to become nationally accredited in 2019 and available to pharmacies in 2021. This new standard will facilitate standardized one-way reporting to an HIE or other entity; it will not make data available through electronic health record systems like the SCRIPT and Telecommunication standards.
- There was general consensus among the subgroup that force of law/regulation would enable adoption of the reporting standard and ensure prioritization among vendors in the industry. It was mentioned that pharmacies would need at least one year to implement, and how education will be key in communicating value in using the new standard.
- Representation from SureScripts mentioned that more than ~70 percent of Maryland NPIs actively use their solution to request and receive medication history data.
- Consideration of cost to pharmacies was discussed, noting that oftentimes, absent funding, fees are indirectly passed onto customers through vendor maintenance or other fees. A physician noted concerns about creating a false sense of security if the medication record is incomplete, and going by processed date (when data is transmitted to the pharmacy) as opposed to dispensed date (when a prescription is picked up at the pharmacy).
- *Upcoming Meetings: The subgroup will convene again virtually on Tuesday, October 30, 2018 from 2:30pm to 4:00pm EDT. For more information, refer to the workgroup's [webpage](#).*

⁷⁹ National Council for Prescription Drug Programs.

⁸⁰ American Society for Automation in Pharmacy.

⁸¹ NCPDP standards are developed to ensure consistency and facilitate electronic exchange of information regarding pharmacy services and prescription drug data.

Electronic Prescription Records System Workgroup

Technology Subgroup

October 30, 2018

Meeting Summary

Key discussion items include:

- The meeting began with a presentation from the National Council for Prescription Drug Programs (NCPDP) (slides available [here](#)) with an overview of current NCPDP standards used in electronic prescribing (e-prescribing), medication history, and billing. A forthcoming dispensed medication reporting standard that is communication agnostic for systems and patients will facilitate reporting to a health information exchange (HIE) or other entity. Participants walked through a graphic depicting the e-prescribing process today capturing use and capabilities of the SCRIPT and Telecommunication standards⁸² and how information can be reported to an HIE. Discussion also examined factors affecting adoption of standards, such as federal mandates (i.e., HIPAA⁸³ requires use of the Telecommunication standard and MMA⁸⁴ requires use of the SCRIPT standard).
- Discussion of a vendor neutral infrastructure assessed opportunities to encourage competition and support multiple use cases for non-CDS; this included consideration of ways to leverage but not burden (with ten times more data) the existing PDMP infrastructure. Options for collecting non-CDS data included consideration of switches (i.e., other vendor intermediaries), such as electronic health record systems, HIEs, and electronic health networks (or clearinghouses). There was general consensus that pharmacies were the best source for reporting non-CDS, emphasizing preference to send data (both CDS and non-CDS) in one batch. This would help ensure more data was captured, including Medicaid, home health, nursing care, specialty, etc. Options for exposing data to end-users (e.g., physicians and pharmacies) includes pushing non-CDS data to the existing PDMP platform,⁸⁵ and/or other innovative solutions already available on the market.
- Representation from Surescripts highlighted how their solution, along with other vendors offering similar services, can collect, aggregate, filter, and expose prescription data to providers, pharmacies, and payers. A potential concept of recognizing multiple vendors to collect and expose data in collaboration with the State-Designated HIE was recommended to enable a broader, more complete business model. Consideration of the financial model will need to be evaluated, including opportunities to incentivize vendors.
- *Upcoming Meeting: To be determined. Eva Lenoir will be in touch with next steps. You can also refer to the Electronic Prescription Records System Workgroup [web page](#).*

⁸² See October 17, 2018 Technology Subgroup meeting summary for more information about these standards: mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/electronic_prescription/EPRS_Meeting_Summary_20181017.pdf.

⁸³ Health Insurance Portability and Accountability Act of 1996.

⁸⁴ Medicare Modernization Act of 2003.

⁸⁵ Includes the CRISP Query Portal or in-context alerts within existing workflows/other systems.

Electronic Prescription Records System Workgroup

November 8, 2018

Meeting Summary

Key discussion items include:

- The workgroup reviewed a preliminary listing (version 1) of key themes and conceptual ideas as a first phase in framing informal draft recommendations. The listing was developed based on workgroup discussions from previous meetings, including information gathered in the discussion items/grids document. Discussions highlighted essential elements to be considered in building out the supporting rationale for each key theme.
- There was general consensus about key theme 1 (*electronic access to a more complete medication history is necessary to improve quality of care*) as it relates to the purpose of the study (the “WHY”). Workgroup members mentioned the need to define access (by whom and when) and balance patient safety with patient privacy, as well as opportunities to explore other loopholes in medication reconciliation and potential solutions (e.g., awareness of medications discontinued by providers, medication history correction functionality, etc.).
- Discussion of key theme 2 (*legislating non-CDS reporting, as opposed to voluntary reporting, is required to ensure consistent reporting by dispenser, use of industry standards, and in managing program costs*) brought to light the utility of a vendor neutral approach to encourage competition and support multiple use cases for non-CDS. It was noted that more discussion about patient consent and confidentiality was needed to explore potential exemptions for reporting with emphasis that exemptions are not prematurely predefined (e.g., based on convenience rather than patient safety).
- Key theme 3 (*use a phased in implementation approach for non-CDS reporting by dispensers based on drug classifications, provider types, pharmacy size etc. with voluntary reporting permitted during ramp up phase*) considered options to test the business case through incremental reporting and access to the non-CDS repository. This could include pilot projects with certain provider/pharmacy types or by county (by drug classification was not recommended). It was reiterated that full data submission is preferred and easiest for pharmacies. Implications of incomplete data during the ramp up phase and flexibility for late adopters due to limited resources (e.g., Local Health Departments) were identified.
- Discussion of key theme 4 (*utilize a vendor neutral reporting technical infrastructure that encourages competition and supports multiple use cases in a non-CDS State reporting requirement and, if appropriate, leverage existing PDMP technology to support vendor neutral reporting of non-CDS*) highlighted various means to leverage existing market solutions to collect and expose non-CDS data without burdening the existing PDMP infrastructure.
- *Upcoming Meeting: The workgroup will convene again at MHCC offices on Thursday, December 6, 2018 from 2:00pm to 4:00pm EST. Refer to the workgroup [web page](#) for meeting dates and times through March 2019.*

Electronic Prescription Records System Workgroup

December 6, 2018

Meeting Summary

Key discussion items include:

- The workgroup continued discussions about key themes and conceptual ideas taking into consideration benefits, barriers/challenges, and potential solutions identified in the information gathering grids (Version 5). It was suggested that key themes be organized by categories (e.g., infrastructure, legislative, funding, etc.). Deliberations of key themes are intended to help frame informal draft recommendations, including supporting rationale for a statewide repository of non-controlled dangerous substances (non-CDS).
- Key themes identified in grid 1A (*expanding use of existing CRISP infrastructure to make available non-CDS data*) highlighted the need for a mandate and policies for non-CDS, a sustainable funding model, and a time limited implementation plan. Preference for having prescription data presented in a user friendly format was noted as well as the importance of differentiating the CDS platform CRISP uses for the Prescription Drug Monitoring Program. Discussions about technology to support non-CDS continues to explore a vendor neutral model.
- Discussion of grid 2A (*enhancing CRISP to support new and existing State mandates*) recognized the potential of existing and newly proposed State and federal mandates that may have an impact on non-CDS. Participants also noted the importance of ensuring good security posture by any vendor that collects and exposes non-CDS data. Funding options, including federal funding opportunities and potential savings from reduced hospital admissions and readmissions under Total Cost of Care were considered.
- Grid 3A (*investing new resources for reporting non-CDS data*) reiterated pharmacy preference to not develop separate processes for non-CDS (i.e., enable one batch reporting and the option to parse out CDS and non-CDS data to end-users). Reporting amnesty for certain dispensers with limited resources, including publicly funded settings like prisons was noted. Medical cannabis will remain a parking lot item due to its different operating system and unknown personal use of cannabis; it was recommended that absent any privacy issues, making patient registration with the Maryland Medical Cannabis Commission available to prescribers and dispensers should be considered.
- Key themes for grid 4A (*existing system requirements – access, use, and disclosure*) noted the importance of the pharmacist and physician partnership and a request that dispensers sharing data have access to certain patient information through CRISP. Access by payers for purposes of care coordination (not monitoring) was also recognized. Need for oversight and management for certain technical aspects of a non-CDS repository, including one or more vendors to collect and/or expose data was mentioned.
- *Upcoming Meeting: The workgroup will convene again at MHCC offices on Tuesday, January 8, 2019 from 1:00pm to 3:00pm EST. Please note the inclement weather policy posted on the workgroup [web page](#).*

Electronic Prescription Records System Workgroup

January 8, 2019

Meeting Summary

Key discussion items include:

- The workgroup discussed key themes for information gathering grid 5A (*exclusion of certain providers and non-CDS data elements to be reported*), which highlighted implications of incomplete patient medication records as well as consideration of potential exemptions to protect patient privacy.
- Providers noted patient safety risks from incomplete data and difficulty in making informed clinical decisions with limited information, particularly due to extensive drug classifications. Deliberations brought to light value of having prescription information on behavioral health drugs due to the complexity of these drugs and potential complications for drug-to-drug interactions.
- Debate about the inclusion of drugs for reproductive health was more nuanced. The workgroup discussed impact on adolescents seeking such drugs, including how this population is more likely to delay or avoid treatment for fear that their confidentiality will not be assured. It was noted that drugs associated with reproductive health tend to be lower risk, and there could potentially be exclusions, such as Title X providers.
- Consumer education about the value of having a complete medication record available to providers at the point of care and the potential need for an opt-out was discussed. In general, there was consensus that an opt-out process should be centralized.
- *Upcoming Meeting: The workgroup will convene again at MHCC offices on Wednesday, February 6, 2019 from 2:00pm to 4:00pm EST. Please note the inclement weather policy posted on the workgroup [web page](#).*

Electronic Prescription Records System Workgroup

Draft Recommendations Subgroup


February 6, 2019

Meeting Summary

Key discussion items include:

- The Draft Recommendations Subgroup (subgroup) reviewed key themes and a preliminary list of informal draft recommendations organized by the following key categories: technical infrastructure; providers, dispensers, and consumers; privacy and security; and governance and funding.
- Recommendations related to technical infrastructure highlight the capability of CRISP and collaboration opportunities with other vendors to support non-CDS; a phased-in implementation approach; and need to ensure adequate privacy and security controls.
- Recommendations for providers, dispensers, and consumers center on ensuring that reporting and accessing non-CDS data is built into existing workflows and consumer education, particularly as it relates to opt-out. The importance of a consumer education strategy for non-CDS was noted to detail the benefits and potential risks of opting-out.
- Privacy and security recommendations focus on development of oversight regulations for non-CDS that build upon existing federal and State privacy laws.
- Governance and funding recommendations focus on excluding oversight of non-CDS under the existing PDMP, engaging an independent third party to conduct a financial impact assessment, and identifying a sustainable funding source to support non-CDS long-term.
- *There is no upcoming meeting scheduled for March. The MHCC is preparing version 2 of the draft recommendations document to include supporting rationale. The document will be distributed for review in the coming weeks; workgroup members are invited to provide written comments. A final draft report is expected to be shared with the workgroup in the spring.*

Appendix E: Meeting Presentations




The Hilltop Institute
analysis to advance the health of vulnerable populations

Nebraska PDMP Case Study

August 2, 2018

Alice Middleton & Kevin Borchert



UMBC
UNIVERSITY OF MARYLAND

Nebraska Prescription Drug Monitoring Program (PDMP)

- Overview
- Implementation Model
- Funding and Costs
- Data Reporting and Provider Access
- Nebraska Results and Lessons Learned

Overview

- Nebraska (NE) set the precedent in Jan. 2018 by establishing the first PDMP to collect data on all prescription information
- NE has created a model for prescription information collection and usage
- The model has potential to aid in resolving opioid and substance use disorder issues, as well as allowing providers to make better informed treatment decisions

Legislation

- NE LB 237 (2011) – Creation of a PDMP
 - Prevent misuse of prescription drugs in an efficient and cost-effective manner
 - Allow doctors and pharmacists to monitor the care and treatment of patients for whom a prescription drug is prescribed
 - Identified NE Department of Health and Human Services (DHHS) and NE Health Information Initiative (NeHII) as collaborative partners to administer the PDMP
 - Prohibit use of state funding to implement or operate the PDMP

Legislation

- NE LB 1072 (2014)
 - Prevent misuse of controlled dangerous substances (CDS)
 - Repealed the no-funding stipulation

- NE LB 471 (2016)
 - Establish framework of the PDMP system
 - All CDS reported to the PDMP starting January 1, 2017
 - All prescriptions reported to the PDMP starting January 1, 2018
 - Allow prescribers and dispensers to access the system at no cost

Legislation

- NE LB 223 (2017)
 - Amend LB 471 to comply with HIPAA
 - Require veterinarians to submit CDS prescription drug information starting July 2018
 - Require new users of the PDMP to complete a training
 - Allow for a designee of a prescriber or dispenser

- NE LB 1034 (2018)
 - Language clarifications
 - Exclude animal non-CDS
 - Clarify pharmacist use
 - Remove conflicting dates for veterinarians to report data

Implementation Model

- Contracted with the NeHII Health Information Exchange (HIE) to host the PDMP
 - NeHII is a non-profit that runs the state HIE
 - Public/private governance model
 - Certified as a Qualified Clinical Data Registry by the Centers for Medicare & Medicaid Services (CMS)
- Implementation and participation fees covered through federal grant funding from various agencies

Implementation Model

- Surescripts supplies data from pharmacy benefit management (PBM) systems and retail feeds to capture self-pay prescriptions
- Data is accessible to registered and certified providers
- Data is available through NE DHHS online portal

Implementation Model

- Data is encrypted and stored on a HIPAA-compliant database
- Focus is on patient safety
- Data is stored by dispensing record
- Application access controlled through encryption

Funding

- Federal grants
 - Centers for Disease Control and Prevention: \$4 million over four years
 - Bureau of Justice Assistance: \$500,000 over two years
 - Office of the National Coordinator for Health Information Technology: \$3 million over two years
- Currently supported by a mix of public (grants, state) and private (hospitals and payers) funding

Cost

- Estimated revenues exceeded costs for the HIE in 2017
- No cost to access the PDMP for all providers and dispensers
- Hospitals and insurers payment for HIE access
 - Hospitals: \$500 monthly fee
 - Insurers: \$25,000 annual fee

Data Reporting

- Required to report: pharmacies, mail service pharmacies, veterinarians, other dispensers
- Who can access: physicians, nurses, pharmacists, designated licensed pharmacy staff, other credentialed health professionals, other dispensers
- As of 2018 all prescriptions including non-CDS are required to be submitted, with some exemptions

Data Reporting - Patient Consent

- Patients enrolled in HIE if provider is enrolled
- Patients can opt out of HIE, but not the PDMP
- Consumer education efforts are being pursued to increase confidence in HIE

Data Reporting

- Data uploaded to database daily by prescribers
- Dispensers required to report within one day of dispensing
- Systems either use software vendor for data entry or do manual entry

NEBRASKA: RESULTS TO DATE AND LESSONS LEARNED



PDMP Portal

The screenshot shows the PDMP Portal interface. On the left is a dark sidebar menu with the following sections: 'DASHBOARDS & APPS' containing 'My Apps' and 'Link Marketplace'; 'ACCOUNT' containing 'My Account' and 'Settings'; and 'HELP & SUPPORT' containing 'Help Center', 'Privacy & Terms', and 'Sign Out'. The main content area has a header with 'Link' on the right and 'Loading...' on the left. Below the header, there are two columns: 'NeHII HIE users' and 'PDMP users'. Under 'NeHII HIE users' is a box for 'Optum™ Data Exchange HIE 2.0'. Under 'PDMP users' is a box for 'Nebraska PDMP'. Below these boxes are two pathway boxes: 'HIE Pathway Any HIE participant' and 'PDMP Pathway Prescribers (MD, PA, APRN, DDS) Dispensers (RP) Designees (RN, Pharm tech)'. To the right of these boxes is a 'CONTACT US' section with 'Phone: 1-866-978-1799' and 'Email: Support@NeHII.org'. At the bottom left is the 'NEBRASKA Good Life. Great Mission.' logo, and at the bottom right is the 'NeHII Nebraska Health Information Initiative' logo. The page number '16' is visible at the bottom center.

HIE PDMP/ Medication History

[Home](#) [Patient](#)

[My Patients](#) [Patient Search](#) **Patient Profile**

Watson, John DOB: 06/04/1980 (37 y) MRN: (Family Practice of Grand Island) 1305711
 Gender: Male

Office Visit Est Level 3 Chest Discomfort Adelson, Michael, M.D. MARTINSBURG VAMC

Immunizations (2)

Date	Drug Name	Dose	RX By
09/19/2009	Influenza Virus Split 3 Yrs And Above For Intramuscular Use	0.25 ML	Adelson, Michael, M.D.
02/21/2008	Tetanus Immune globulin (TIG), human, for intramuscular use	0.25 ML	Adelson, Michael, M.D.

Allergies (7)

First Noted	Allergy *	Reaction	Severity	Group	Reported By
04/30/2010	Amoxicillin	Anemia/Blood Disorders	Severe	Drug allergy	Cynthia A. Grillo, M.D.
04/25/2000	Bee Stings	Skin Rashes/Itches	Severe	Allergy to substance	Cynthia A. Grillo, M.D.
09/24/2010	Egg or Chicken-derived Drugs	Shock/Unconsciousness	Severe	Allergy to substance	Cynthia A. Grillo, M.D.
01/13/2011	Metaxalone	Shock/Unconsciousness	Moderate to severe	Drug allergy	Cynthia A. Grillo, M.D.
01/13/2011	Telquin	Asthma/Shortness of Breath	Mild to moderate	Drug allergy	Cynthia A. Grillo, M.D.
04/25/2000	Tetracycline	Asthma/Shortness of Breath	Moderate	Drug allergy	Cynthia A. Grillo, M.D.
03/29/2010	Zyprexa	Nausea/Vomiting/Diarrhea	Mild	Drug allergy	Cynthia A. Grillo, M.D.

Medications (7) [Search Medication History](#)

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Patient PDMP Queries – Access through PDMP portal

[Search Medication History](#)

Enter Patient Information *Need help? Call us at 866-978-1799*

LAST NAME* via FIRST NAME* DOB Gender City ZipCode

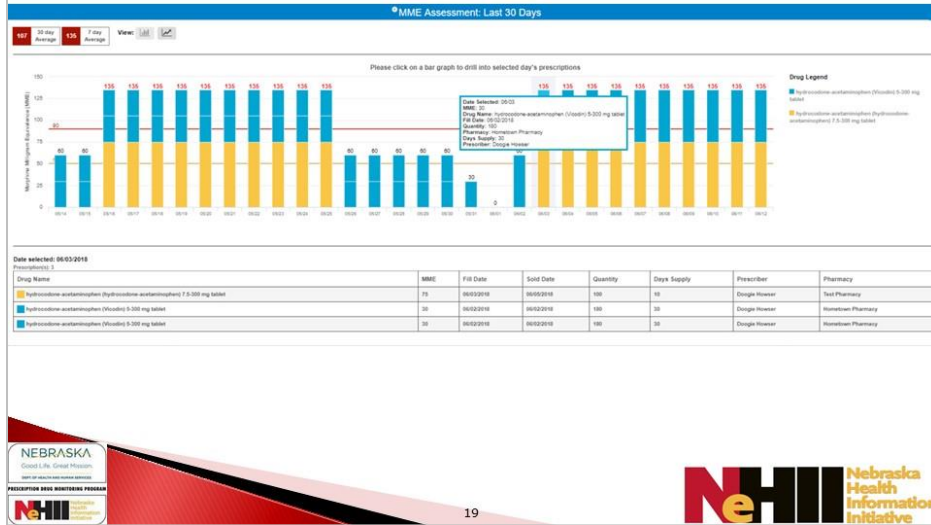
Patient Search Results

Disclaimer: You are selecting one or more patients to combine together into a single-use query. Please note any selections of multiple patients and use of query results are at the discretion of the user. Selections may or may not include all aliases for a particular patient. Patient selections will not be saved for future use.

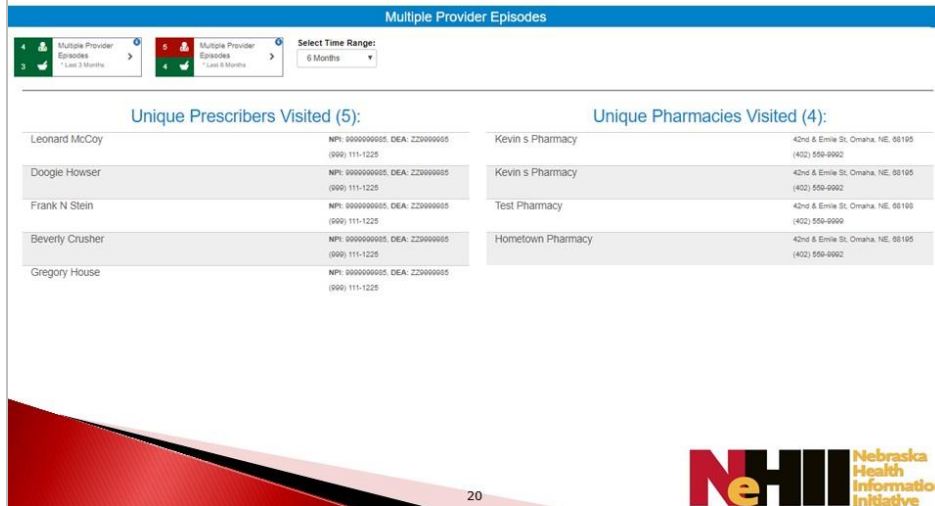
ID	Patient Name	DOB	Gender	Species	Address	City	Zip	Telephone #
1	John Watson	01/01/1990	U		123 First Street	Omaha	68111	
2	Jon Watson	06/04/1980	M		Thirteenth	Trith	69005	
3	Joan Watson	06/04/1980	F		1313 Mockinbird Lane	Mockinbird heights	69005	111123344
4	John Watson	06/04/1980	M		1234 EL CAMINO REAL	Mountain view	94035	
5	Johnny Watson	06/04/1980	M		1313 Mockinbird Lane	Mockinbird heights	69005	111123344
6	John (beagle) Watson	06/04/1980	M		1313 Mockinbird Lane	Mockinbird heights	69005	111123344

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MME Alert



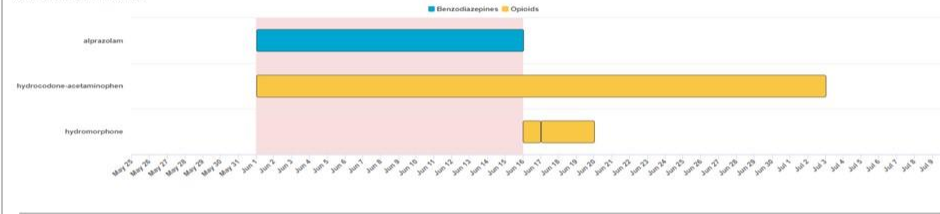
Multiple Provider Episode Detail



Overlapping Opioid/Benzodiazepine Alert Detail

Overlapping Therapy Alert: Last 45 days

Medications Timeline



Overlapping Medications

Category	Drug Name	Fill Start Date	Fill End Date	Sold Date	Day Supply	Quantity	Prescriber	Pharmacy
Overlapping Period: 06/01/2018 - 06/15/2018								
	alprazolam (alprazolam) 1 mg tablet	06/01/2018	06/15/2018	06/01/2018	15	15	Victoria Veterinarian	Newbie Pharmacy
	alprazolam (alprazolam) 1 mg tablet	06/01/2018	06/15/2018	06/01/2018	15	15	Victoria Veterinarian	Newbie Pharmacy
	hydrocodone-acetaminophen (Vicodin) 5-300 mg tablet	06/01/2018	06/30/2018	06/01/2018	30	180	Gregory House	Hometown Pharmacy
	hydrocodone-acetaminophen (Vicodin) 5-300 mg tablet	06/01/2018	06/30/2018	06/01/2018	30	180	Gregory House	Hometown Pharmacy
	hydrocodone-acetaminophen (hydrocodone-acetaminophen) 7.5-300 mg tablet	06/02/2018	06/11/2018	06/03/2018	10	100	Doogie Howser	Test Pharmacy
	hydrocodone-acetaminophen (hydrocodone-acetaminophen) 7.5-300 mg tablet	06/02/2018	06/11/2018	06/03/2018	10	100	Doogie Howser	Test Pharmacy
	hydrocodone-acetaminophen (Vicodin) 5-300 mg tablet	06/03/2018	07/02/2018	06/05/2018	30	180	Doogie Howser	Hometown Pharmacy
	hydrocodone-acetaminophen (Vicodin) 5-300 mg tablet	06/03/2018	07/02/2018	06/05/2018	30	180	Doogie Howser	Hometown Pharmacy
	hydrocodone-acetaminophen (hydrocodone-acetaminophen) 7.5-300 mg tablet	06/05/2018	06/14/2018		10	100	Doogie Howser	Test Pharmacy
	hydrocodone-acetaminophen (hydrocodone-acetaminophen) 7.5-300 mg tablet	06/05/2018	06/14/2018		10	100	Doogie Howser	Test Pharmacy
	hydromorphone (Dilaudid) 0.5 mg/0.5 mL syringe	06/16/2018	06/16/2018	06/17/2018	1	1	Beverly Crutcher	Kevin's Pharmacy
	hydromorphone (Dilaudid) 0.5 mg/0.5 mL syringe	06/16/2018	06/16/2018	06/17/2018	1	1	Beverly Crutcher	Kevin's Pharmacy
	hydromorphone (Dilaudid) 0.5 mg/0.5 mL syringe	06/17/2018	06/18/2018	06/18/2018	3	0.005	Beverly Crutcher	Kevin's Pharmacy

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Reporting all dispensed prescriptions

- ▶ Required reporting as of January 1, 2018
- ▶ Comprehensive medication history
 - 10 x more data than traditional PDMP's that include controlled substances only
- ▶ ***Patient safety tool***
- ▶ Allow clinicians to make better informed decisions
- ▶ Identify medications from multiple prescribers and pharmacies
- ▶ Identify potential drug interactions, allergies
- ▶ Provide a valuable resource in the event of natural disasters, system power interruptions
- ▶ Tool for medication reconciliation



By the Numbers – Prescriptions

- ▶ January 1 – December 31, 2017
 - 3,882,974 dispensed prescription records
- ▶ January 1 – June 30, 2018
 - 15,795,016 dispensed prescription records
 - 14,220,549 (90%) dispensed non-controlled substances
- ▶ 2017 Average 10,638 Rx/day
- ▶ 2018 Average 87,265 Rx/day



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By the Numbers – Enrolled Users

- ▶ 6,911 Enrolled users of the PDMP (as of 6/29/18)
 - 4,625 prescribers (MD, APRN, DDS, DVM, PA)
 - with address in NE, KS, MO, IA, SD, WY, CO
 - 1,883 dispensers (i.e., pharmacists)
 - with address in NE, KS, MO, IA, SD, WY, CO
 - 403 designees (e.g., nurses, pharmacy technicians, pharmacist interns, etc.)

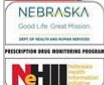
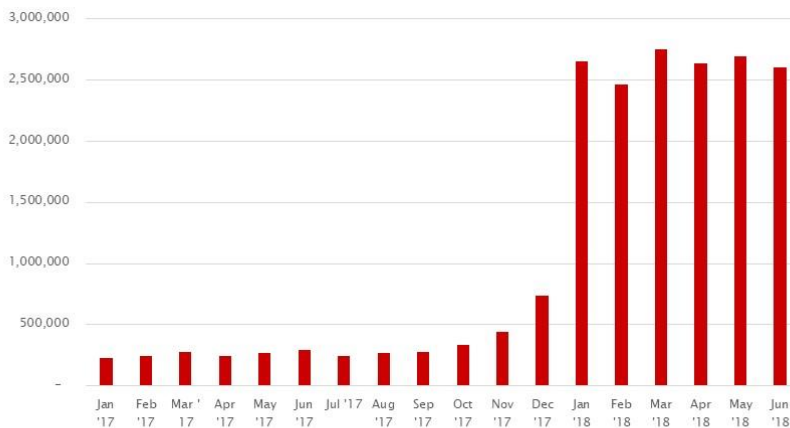


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Nebraska PDMP Reported Data January 2017 – June 2018

Monthly # Unique Dispensed Prescriptions Reported

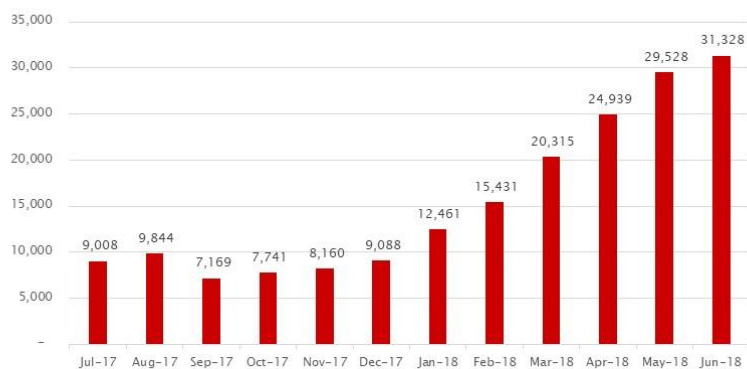


25



Queries July 2017 – June 2018

Unique Queries per Month



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Interoperability

- ▶ Federal recognition and involvement of addressing opioid epidemic
- ▶ Interstate data sharing
 - Two primary networks/hubs
 - Opportunities via HIE's
- ▶ Integration
 - Direct workflow integration
 - HIE
 - Electronic health record (EHR)
 - Pharmacy Software System



Opportunities for PDMPs

- Easy access
 - Workflow integration
 - Interoperability
 - Workflow integration
 - Directly access through HIE, EHR, or pharmacy software
 - Single Sign-On (SSO)
 - Interstate data sharing



Lessons Learned for Success

- ▶ **Communication**
 - Early, frequent notification to pharmacies and vendors
- ▶ **Cooperation**
 - Several pharmacies have never reported
- ▶ **Collaboration**
 - Relationship building
 - Call vendors
 - Status updates
 - Test accounts to validate files
- ▶ **Error monitoring**
- ▶ **Better quantity and quality of data**



Future Opportunities

- ▶ **Data analytics**
 - Tableau to develop metrics, measures, maps
- ▶ **Quality Improvement Initiatives**
 - Opioid use
 - Benzodiazepine use
 - Chronic disease
 - Diabetes without statin
- ▶ **Medication compliance/adherence**
- ▶ **Medication reconciliation**
- ▶ **Meaningful Use PDMP specialized registry**



About The Hilltop Institute

The Hilltop Institute at the University of Maryland, Baltimore County (UMBC) is a nationally recognized research center dedicated to improving the health and wellbeing of vulnerable populations. Hilltop conducts research, analysis, and evaluations on behalf of government agencies, foundations, and nonprofit organizations at the national, state, and local levels.

www.hilltopinstitute.org

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Maryland Prescription Drug Monitoring Program (PDMP)

Kate Jackson, MPH
Director, Office of PDMP and Overdose Prevention Applied Data Programs

October 3, 2018



PDMP Mission and Description



Mission (not formally adopted):

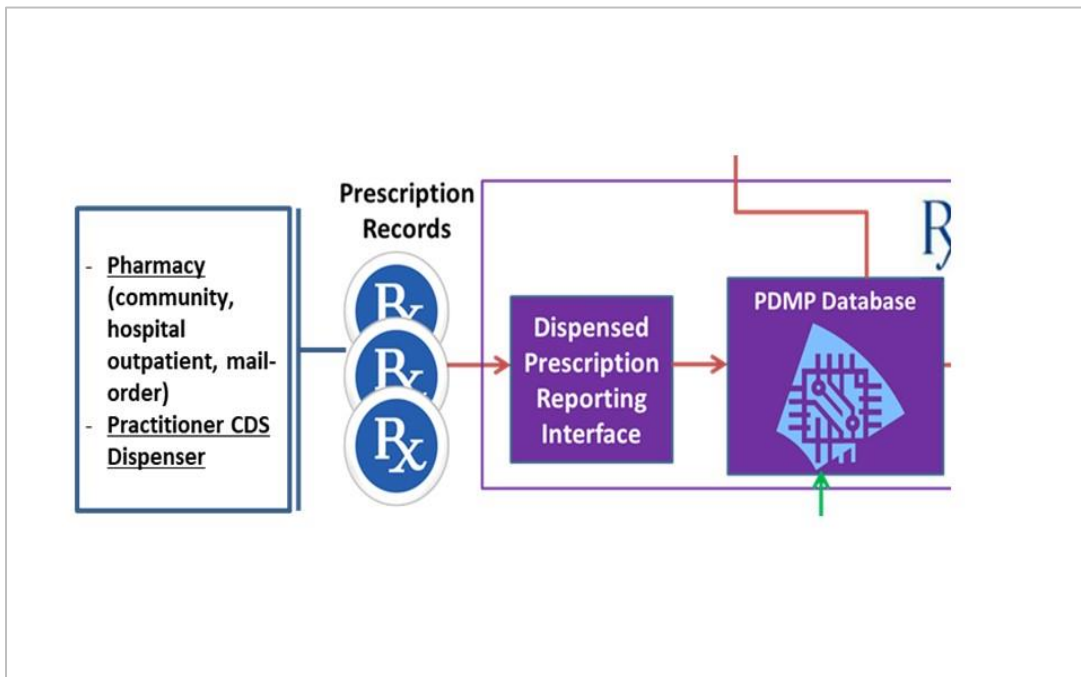
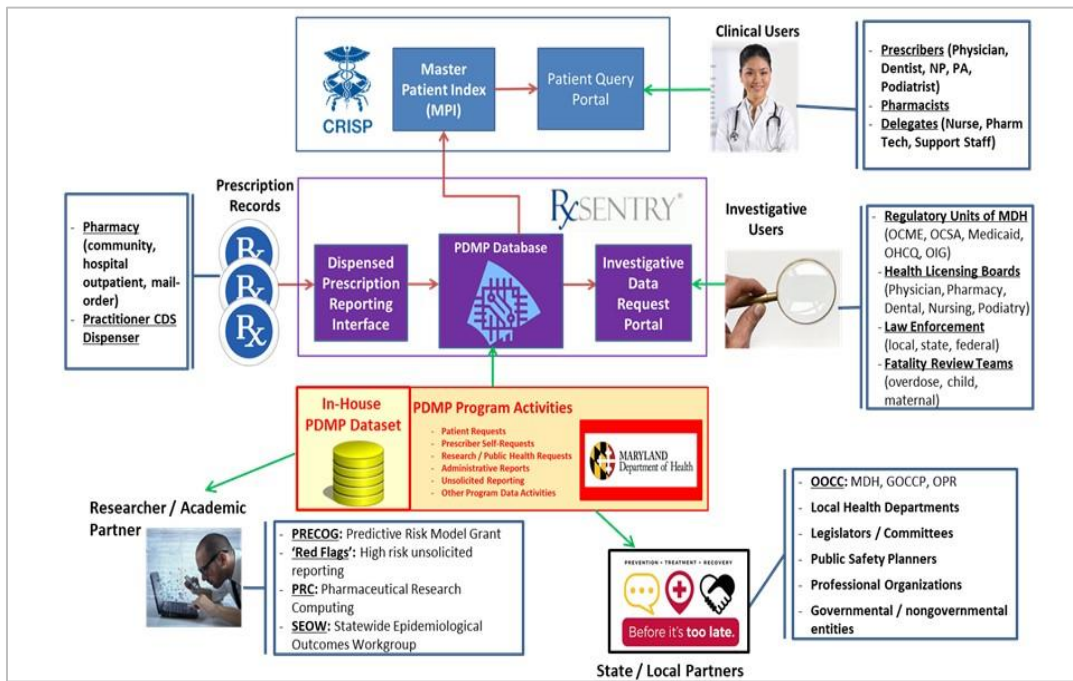
The Maryland PDMP collects controlled dangerous substance (CDS) prescription dispensing information and enables authorized users' access to these data for the purpose of improving the health and safety of Maryland patients and the public.

Basic Description of the Maryland PDMP:

- Secure, state-wide, electronic database
- Contains Schedule II-V pharmaceutical controlled dangerous substance (CDS) Rx dispensed in Maryland
- Rx data can be disclosed for clinical, investigative and research/public education purposes as allowed by law

1





What Data Can Be Found in the PDMP

- **Records of all Schedule II-V CDS dispensed to patient in Maryland, including identifying information for:**
 - Patient for whom the drug is prescribed,
 - Prescriber
 - Dispenser
 - Drug
- **Dispensers required to report:**
 - hospital outpatient pharmacies
 - community / retail pharmacies
 - mail-order pharmacies dispensing to Maryland address
 - Dispensing practitioners
- **Dispensers must report to the PDMP within 3 business days of dispensing a prescription**
 - Daily Reporting, including submission of 'zero reports' will be required soon!



What Data Are Not Reported to the PDMP

- **Direct administration** of CDS to a patient
- **Drug samples** provided to a patient
- Records from pharmacies that serve only **hospital inpatients**
- Records from **specialty pharmacies** that are waived by the Maryland Board of Pharmacy to serve exclusively assisted living, comprehensive care, and developmental disabilities facilities
- Dispensing by a pharmacy to **hospice inpatients** (if approved by DHMH for a waiver)
- **Opioid treatment programs (OTPs)** / methadone clinics
- Dispensing from a **veterinary clinic or hospital**



Main Data Elements in PDMP

DRUG / PRESCRIPTION

Prescription Number
Date Prescription Written
Date Prescription Filled
New / Refill Status of Rx
Refills ordered on orig Rx
NDC → populate drug info
Drug quantity dispensed
Days supply
Payment sources

PATIENT

Name (first, last)
DOB
Gender
Address

PRESCRIBER

DEA # → populate identity and geographic info (not reported from dispenser)

DISPENSER

DEA # → populate identity and geographic info (not reported from dispenser)



Who qualifies as a dispenser?

Dispensers are persons or entities authorized to dispense controlled dangerous substances (CDS) to a patient or a patient's agent in Maryland. This includes:

Pharmacies (both in-state and non-resident) with a permit from the Maryland Board of Pharmacy that are also registered with the federal Drug Enforcement Administration (DEA) and the MDH Office of Controlled Substances Administration to dispense CDS

Healthcare practitioners that are registered with DEA and the MDH Office of Controlled Substances Administration AND have a prescription drug dispensing permit issued by their licensing board.

<https://bha.health.maryland.gov/pdmp/Pages/Dispensers0106-5.aspx>



How do I report?

Dispensers are required to report to the program by **electronic means**.

- **Chain Pharmacy:** data likely submitted from corporate office.
- **Independent Pharmacy:** pharmacy system software vendor often receives reporting requirements. Makes any necessary system changes to create the data file and report on behalf of pharmacy.
- **Dispensing Practitioner:** if work with practice management system vendor, can do same as independent pharmacy; otherwise, UCF.

Methods of electronic submission:

- Secure FTP over SSH
- Encrypted File with OpenPGP Via FTP
- SSL Website
- Universal Claim Form (UCF) Submission (manual submission)

<https://bha.health.maryland.gov/pdmp/Pages/Dispensers0106-5.aspx>



What format do I report in?

Maryland requires that dispensers submit reports using the American Society for Automation in Pharmacy (ASAP) Standard for Prescription Monitoring Programs Version 4.2 (2011).

For more information regarding specifications or to acquire the full Implementation Guide for the ASAP4.2 Standard, contact the American Society for Automation in Pharmacy at www.asapnet.org.

The Maryland Implementation Guide includes field lengths, acceptable attributes, and examples.

(http://rxsentry.net/assets/files/mdpdmp/2017/MD_PDMP_Dispensers_Implementation_Guide.pdf)

<https://bha.health.maryland.gov/pdmp/Pages/Dispensers0106-5.aspx>



PDMP Vendor RFP

CRISP is the main IT vendor for the Maryland PDMP. CRISP sub-contracts for certain services. An RFP is currently underway for a number of PDMP core IT functionalities, including a data collection, validation and reporting compliance monitoring, and database storage solution.



Resources

Maryland PDMP Website:

<https://bha.health.maryland.gov/pdmp/Pages/Dispensers0106-5.aspx>

RxSentry Maryland Website:

<http://rxsentry.net/mdpdmp/>

RxSentry Dispenser's Implementation Guide:

[http://rxsentry.net/assets/files/mdpdmp/2017/MD PDMP Dispensers Implementation Guide.pdf](http://rxsentry.net/assets/files/mdpdmp/2017/MD_PDMP_Dispensers_Implementation_Guide.pdf)





Pharmacy Perspective: Implementing Complete Prescription Data Transfer via PDMP

Matthew Shimoda, PharmD
Pharmacy Director



Introduction:

- Current PDMP data transmissions as mandated by the State
 - Process is fairly easy and mostly transparent to the users
 - Vendors have adapted and are complying with the process currently in place
 - Pharmacy users have integrated PDMP into the daily routine of filling Controlled Substance Prescriptions and find it very beneficial
 - Nationwide access of this data would be the ultimate goal
 - Outlier drugs have added to the process
 - Pharmacy is very much in favor of access to more comprehensive patient data to aid in providing the best care to their patients

Addition of all Prescription Data to the Process:

- Would need to be mandated by the State and address any potential HIPAA or Security concerns
- Must be a reasonable timeline to facilitate it being required of all Pharmacies
- Cost factors should be considered
- Potential that some Vendors would have other requirements

Current Process at SVU for handling PDMP data:

- Each day a file generates for each individual store (Automatic)
- These files are sent to FTP sites to be transmitted to PDMP (Automatic)
- PDMP receives them and processes the files (Automatic)
- We receive an email confirmation back for each store indicating how many records were sent, how many had errors, how many were imported. If there are errors they are included in the email (Automatic)
- Each day we validate we receive a confirmation for each store to ensure all stores successfully reported. Emails don't come from CRISP, they come from HID, who is the processor. (Manual)
- If there were any errors identified we correct them in EPS and they are sent in the next day's run (Manual)
- On Friday's we resubmit the previous 11 days of data as a failsafe. This helps pick up any exceptions that may have somehow slipped through the cracks. (Automatic)

Thoughts:

- Actually would simplify the transmission process (in the beginning) because if all prescription data is being transmitted it would eliminate the need for dealing with the current exceptions such as Naloxone, Gabapentin, Tramadol etc.
- Files would be 10 times (or more) in size
- We currently spend up to 5-6 hours a week manually correcting errors. If we move to all prescriptions.....?
- This may require moving that process back to the Pharmacies and create workflow disruption
- Potential HIPAA and Security issues

Conclusion/Discussion:

- Potential Vendor Issues
- Managing a 10 fold increase in volume
- Handling rejections from CRISP
- Protection of Data
- Cost

National Council for Prescription Drug Programs

Overview of NCPDP Standards used in e-Prescribing, Medication History & Billing

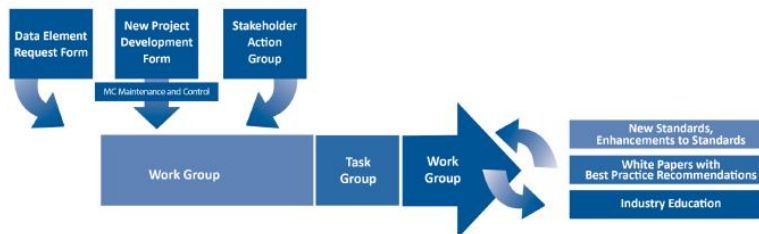
Nicole Russell | Senior Manager, Government Affairs

NCPDP

October 30, 2018



NCPDP's Process



- Obligation to be non-biased
- Credibility among members, public sector and government
- Getting the right people in the room, engendering trust
- Bottom-up commitment to a solution created by consensus
- Driven by clinical need, business need, patient safety
- Workflow-enabled solutions

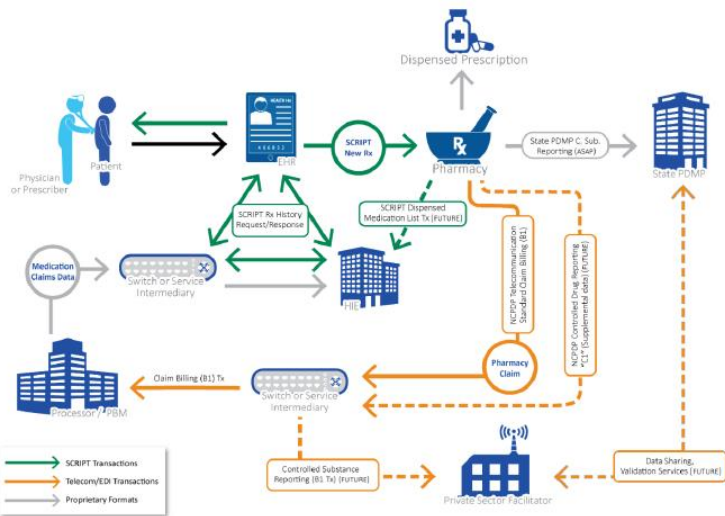


NCPDP the Organization

- **ANSI-Accredited Standards Development Organization**
- ANSI is the official U.S. representative to the International Organization for Standardization (ISO)
- **Composed of all healthcare industry participants**
- **Problem-solving forum for healthcare industry**
- **Consensus-based solutions – communication standards, industry guidance**



Dispensed Medication Reporting Options



SCRIPT Standard Message Capabilities

- Many transactions supported within the SCRIPT Standard including:
 - New Prescription Order (NewRx)
 - electronic prescription from the prescriber to the pharmacy
 - Medication History (RxHistory Request/Response)
 - Dispensed Medication List (in development)



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SCRIPT Medication History (“RxHistory Request/Response”)

- Designed for providers to request information on medication dispensed to a specific patient, within a specific timeframe
- Request is usually to an entity that aggregates this information from pharmacies and PBMs or an HIE. Receiving entity responds with a medication list in an “RxHistory Response” transaction



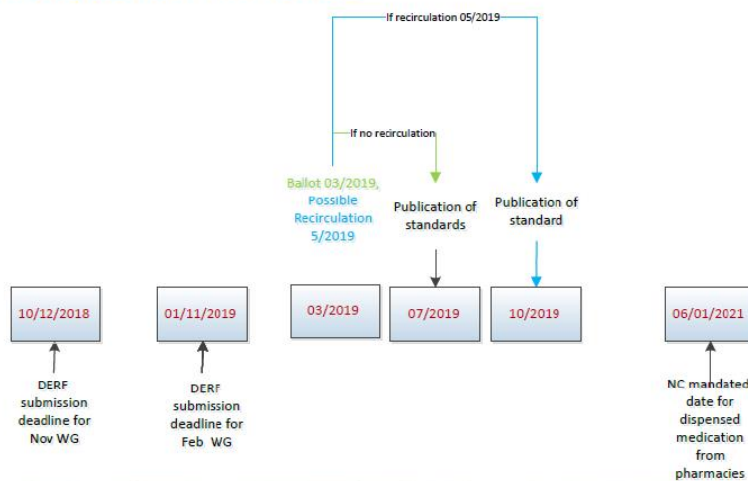
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SCRIPT Dispensed Medication List Transaction (in development)

- Reporting of dispensing events by the pharmacy within the reporting timeframe
 - Reports data needed for HIE to respond to a request or inquiry on patient’s medication history
 - Initial use will be in batch for daily pharmacy reporting. Real-time reporting is possible in the future.
 - Designed to become an ANSI national standard, enhancing interoperability of HIEs



SCRIPT Dispensed Medication List Transaction Timeline



NCPDP Telecommunication Standard Message Capabilities

- Many transactions in Standard. One being real-time Claim Billing (B1) transaction
- Allows aggregators to populate a database of patient's medication history
 - PBM's/Claims Processors
 - Medicare Part D TrOOP Facilitator
 - FDA REMS
 - Proposed transaction in Opioid ALERT bill



NCPDP Controlled Substance Reporting Standard ("C1")

- Designed to supplement Telecommunication Standard Claim Billing information and fill gaps in data required for state PDMPs
 - Includes purchaser information to B1
 - Includes cash prescriptions (if not sent via Telecommunication Standard).
- Currently under ballot and expect initial version published in spring 2019



Thank you!

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Appendix F: Information Gathering Grids

DRAFT: Version 7



Electronic Prescription Records System Workgroup

WORKGROUP DISCUSSION ITEMS/GRIDS

KEY THEMES AND CONCEPTUAL IDEAS FOR CONSIDERATION

TASK: The Maryland Health Care Commission (MHCC) is tasked with convening a workgroup of interested stakeholders to conduct a health information technology policy study that assesses the benefits and feasibility of developing an electronic system (or statewide repository) for health care providers to access complete patient prescription medication history. This pertains to information on non-controlled dangerous substances, not CDS Schedule II-V drugs that are already made available through the Prescription Drug Monitoring Program (PDMP). Refer to the Workgroup [Charter](#) for more information.

APPROACH: Discussion items that follow are in part, specified in law (Chapter 435)⁸⁶ and serve as a guide for workgroup deliberations. Discussion items have been simplified and are intended to be thought-provoking and help narrow the focus on specific components of a statewide repository using information gathering grids. Reflecting on workgroup discussions, including information gathered in the grids, identification of key themes and conceptual ideas will guide development of informal draft recommendations. In general, terms have the following meaning:

Benefit: Value derived from producing or consuming a service

Barrier/Challenge: A circumstance or obstacle (e.g. operational, economic, political, budgetary, etc.) that hinders or prevents progress

Solution: An idea aimed at solving a problem or managing a difficult or complex situation

Key Theme: A key takeaway statement that summarizes quadrants of the grid and can be used to formulate potential recommendations

Note: The discussion items/grids are a means to spur objective thinking about the feasibility of developing a statewide repository. Key themes and conceptual ideas take into consideration concepts identified in the grids. This is not an exhaustive list nor does it represent consensus among the workgroup. This document serves as a working draft for framing key elements of draft recommendations.

⁸⁶ Required by House Bill 115, *Maryland Health Care Commission – Electronic Prescription Records System – Assessment and Report*, passed during the 2018 legislative session (Chapter 435). For more information, visit: mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hit_electronic_prescription.aspx.

Discussion Item 1: Capability of the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP) to make available patient prescription medication history

1. Expanding use of existing CRISP infrastructure (availability, process integrity, and operating effectiveness) to make available non-CDS data	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> • CDS dispensers already required to report Schedule II-V drugs to the PDMP through CRISP (COMAR 10.47.07) • A high percentage of pharmacists are registered and trained on the CRISP system, minimal training required beyond awareness building of non-CDS data availability • Leverage aspects of existing CRISP infrastructure used for CDS 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> • Partitioning CDS and non-CDS data within CRISP • The technical impact of reporting non-CDS data at once versus a gradual phased in reporting approach (estimated ten-fold increase in data) • Increased privacy and security protections • Upfront and ongoing costs • Identifying a minimally disruptive strategy to accommodate non-CDS data
<p>SOLUTIONS (FOR USING CRISP TO MAKE NON-CDS DATA AVAILABLE THROUGH THE PDMP)</p> <ul style="list-style-type: none"> • A phased in approach for non-CDS reporting • Other vendor(s) for non-CDS data • Adequate load testing of the system prior to implementation • Appropriate penetration testing 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> • CRISP is capable of supporting non-CDS data and could leverage existing PDMP infrastructure • Other vendors should be considered • Need to identify a sustainable funding source • A phased in implementation plan that may include pilot projects 	
<p>PARKING LOT</p> <ul style="list-style-type: none"> • Funding source(s) to support up-front and ongoing costs • Elements of a phased in reporting approach for CRISP • Identify loopholes with potential for creating gaps that make information not clinically useful 	

Discussion Item 2: Required enhancements to the State-Designated HIE to ensure it can continue meeting other State mandates, including operating an effective PDMP

2. Enhancing CRISP to support new and existing State mandates	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> Established infrastructure and PDMP processes Increased value of the State-Designated HIE Expand use cases for improving care coordination Enhance patient matching algorithms 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> Obtaining legislative authority (compliance and enforcement; identify a bill sponsor) Funding source(s) up-front and ongoing to support non-CDS data, including additional cost for privacy and security Patient education/consent Policy requirements to change and manage non-CDS data reporting and patient consent Identifying a reasonable and minimally disruptive implementation timeline Implementing a streamlined workflow across various vendors
<p>SOLUTIONS (FOR SUPPORTING NEW SERVICES)</p> <ul style="list-style-type: none"> State mandate to require reporting of non-CDS data A chartered stakeholder workgroup to identify policy and technology solutions to support a phased implementation approach Develop a sustainable funding model that spreads investment and maintenance costs across users Provider value and communication strategy 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> Some enhancement to the existing PDMP infrastructure would be needed Ensure appropriate security controls in place to safeguard patient protected health information (PHI) 	
<p>PARKING LOT</p>	

Discussion Item 3: Resources required for individual health care practitioners, health care facilities, prescription drug dispensers, and pharmacies to provide the information collected in a statewide repository of prescription medication information; resources required to ensure health care practitioners and prescription drug dispensers can maximize the benefit of using the system to improve patient care

3. Investing new resources for reporting non-CDS data	
<p>BENEFITS (<i>VALUE ADD/PERCEIVED</i>)</p> <ul style="list-style-type: none"> • A more complete patient medication record available through CRISP • Improved medication reconciliation (patient safety) and care coordination • Opportunity to use existing vendor(s) and standards in the market that collect and make prescription information available, including prescriptions paid for with cash • Leverage existing workflows for consulting the PDMP • Potential for improving patient outcomes by addressing comorbid conditions that affect opioid use disorder and chronic pain syndromes beyond mental or behavioral health diagnoses 	<p>BARRIERS & CHALLENGES (<i>OBSTACLES/POTENTIAL ISSUES</i>)</p> <ul style="list-style-type: none"> • Start-up cost and implementation timeline for pharmacies • Outreach and education to new and existing users • Identifying a new reporting process for non-CDS, independent from the current PDMP infrastructure, including vendor(s) and standard(s) • Ensuring data gets in the right place in existing clinical workflows • Potential functionality and workflow challenges if medication reconciliation within EHR (e.g., view-only mode; duplication of data/alerts, etc.) • Potential contractual issues with different health care organizations types when sharing information • Burden on dispensers that have limited resources to expand reporting of non-CDS (e.g., local health departments)
<p>SOLUTIONS (<i>FOR INVESTING RESOURCES</i>)</p> <ul style="list-style-type: none"> • Naming standard(s) in law, if needed, to ensure prioritization in the industry • Developing an online training program to address implementation and reporting, among other things • A phased in implementation process • Mandate to facilitate contractual issues with data sharing 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> • Implication of incomplete data; impact from exempting publically funded clinics, nursing homes, and institutional pharmacies • CDS and non-CDS should be separated in viewing mode 	
<p>PARKING LOT</p> <ul style="list-style-type: none"> • Enable end-users to provide feedback/corrections to data in the repository • Exclude reporting of medical cannabis for now <ul style="list-style-type: none"> ○ Consider the degree of significance of having all schedule I drugs; person use unknown ○ Medical cannabis different system ○ Value in making registration information available to health care providers • Explore loopholes in medication reconciliation and potential solutions (e.g., awareness of medications discontinued by providers, medication history correction functionality, etc.) 	

Discussion Item 4: Feasibility of ensuring data in the system is used only by health care practitioners to coordinate the care and treatment of patients

4. Existing system requirements – access, use, and disclosure	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> • Mandatory registration and use of the PDMP <ul style="list-style-type: none"> ○ CDS prescribers and pharmacists in Maryland were required to register with the PDMP by July 1, 2017 (includes physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists, and veterinarians)⁸⁷ ○ Beginning July 1, 2018, CDS prescribers must consult a patient’s PDMP data before prescribing an opioid or benzodiazepine and every 90 days during the course of treatment with CDS; pharmacists must review a patient’s PDMP data prior to dispensing any CDS drug if they reasonably believe the patient seeks the drug for non-medical use • Prescribers and pharmacists may delegate PDMP access to staff working in the same practice or facility • CRISP has: <ul style="list-style-type: none"> ○ Role-based access controls to prevent misuse and security violations ○ AI to track and monitor user access to patient records ○ Privacy and security audits conducted at least annually ○ Established governance structure in place ○ EHNAC accreditation and HITRUST certification 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> • Developing policies regarding access, use, and disclosure or non-CDS data • Modifying existing participation agreements
<p>SOLUTIONS (FOR MAINTAINING AND ENHANCING CURRENT PROCESSES)</p> <ul style="list-style-type: none"> • Identifying minimum criteria for vendor(s) to ensure privacy and security • Establish policies for non-CDS prescription data handling practices (e.g., data sharing) • Expand user tracking of the PDMP 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> • Need to assess appropriate uses of prescription data by payers • Rely on existing PDMP and HIE regulations for consumer education, breach reporting, auditing, and misuse of data 	
<p>PARKING LOT</p> <ul style="list-style-type: none"> • Responsibility for disclosure of information for minors 	

⁸⁷ Other authorized users include law enforcement (with subpoena), health occupations licensing board (with administrative subpoena), MDH agencies (if there is an existing investigation), patients (for their own prescription history), other state PDMPs, and the PDMP Technical Advisory Committee. De-identified data may be made available for research, public education and reporting purposes.

Discussion Item 5: Scope of health care providers that would report prescription medication information in the system, including any specific exemptions; scope of prescription medication information that should be collected in the system, including any specific exemptions

5. Exclusion of certain providers and non-CDS data elements to be reported	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> Confidentiality protections for consumers (e.g., reproductive and behavioral health) Allay patient privacy concerns/need to adopt technology 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> Determination of providers and non-CDS data exempt from reporting, including sample prescriptions/non-OTC pharmaceuticals Responsibility to apply filters (dispenser or CRISP/other vendors) Incomplete data could decrease utility of the repository Impact of limited information available to treating providers Creates doubt and places a burden on providers to engage patients to identify a complete list of medications Potential impact on patients
<p>SOLUTIONS (FOR DETERMINING PROVIDERS THAT SHOULD BE EXCLUDED)</p> <ul style="list-style-type: none"> Phased approach to implementation Engage stakeholders in establishing non-CDS exemptions 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> Implications of incomplete data Balance need for patient safety with patient privacy through an opt-out approach Consumer education is paramount at the point of care delivery if opt-out permitted 	
<p>PARKING LOT</p> <ul style="list-style-type: none"> Reporting of hospital in-patient data Reporting of drugs used to treat co-occurring infectious diseases Reporting of emergency room, surgical centers, compounding pharmacies, first responders, and other circumstances where immediate administration to the patient occurs Data that is provided that is not correct requires a mechanism for correction 	

Discussion Item 6: Potential for development or use of systems other than CRISP for access to patients' prescription medication history

6. Public application programming interface (API) for vendors	
<p>BENEFITS (<i>VALUE ADD/PERCEIVED</i>)</p> <ul style="list-style-type: none"> • Enables third party developers to advance functionalities and/or innovative uses for the data • Increase use of data by vendors where the data is built into the workflow 	<p>BARRIERS & CHALLENGES (<i>OBSTACLES/POTENTIAL ISSUES</i>)</p> <ul style="list-style-type: none"> • Patient matching/various vendor MPIs • Oversight of open API management • Over 90% of EMRs have already adopted the necessary screens and backend data pipes to pull patient medication history within the provider workflow
<p>SOLUTIONS (<i>FOR ENABLING/MANAGING A PUBLIC API</i>)</p> <ul style="list-style-type: none"> • Use one or more vendors to collect and expose prescription data • Designate an entity required to provide oversight to the terms and use of the API, including criteria and corrective actions for misuse 	
<p>KEY THEMES</p> <ul style="list-style-type: none"> • Leverage existing market solutions to collect and expose non-CDS data 	
<p>PARKING LOT</p>	

Discussion Item 7: Privacy protections required for the system, including the ability of consumers to choose not to share prescription data and ensure the prescription data is used in a manner that is compliant with State and federal privacy requirements, including 42 31 U.S.C. § 290dd–2 and 42 C.F.R Part 2

7A. Existing State and federal privacy protections	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> • Floor for privacy protections and individual rights established by HIPAA/HITECH • Maryland HIE regulations (COMAR 10.25.18) expand upon federal requirements to enhance privacy and security protections when electronic health information is made available by an HIE 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> • Determining the appropriate balance between consumer privacy protections and a treating provider’s needs in care delivery for complete medication history • Addressing potential opt-outs (e.g., all in or all out; by diagnosis or classification of drugs; provider type, etc.) • Managing the opt-out process, including how incidental disclosures should be handled • Consumer notification
<p>SOLUTIONS (FOR ENHANCING PRIVACY PROTECTIONS)</p> <ul style="list-style-type: none"> • Consumer awareness campaign on the pharmacy reporting requirements and value to care delivery • Assessing lessons learned from other states that have similar reporting requirements 	
<p>KEY THEMES</p>	
<p>PARKING LOT</p> <ul style="list-style-type: none"> • Legislation 	

7B. Consumers' control on who can access their non-CDS data

BENEFITS (VALUE ADD/PERCEIVED)

- Consumer engagement
- Consumer autonomy to opt-out/choose if they want to share their medication history for non-CDS drugs
- Perceived confidentiality

BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)

- Reduced value of a system that does not include all non-CDS data
- Patient education/understanding
- Determining if all or certain types of non-CDS data should be included in the opt-out function
- Impact on care delivery, such as errors that can impact cost and patient health outcomes
- Messaging that is appropriate and inclusive of consumer's language, culture, etc.

SOLUTIONS (FOR ENABLING CONSUMER CONTROL OF THEIR NON-CDS DATA)

- A strategy that builds toward full reporting of non-CDS information where some consumer control exceptions are included in the design and where information is limited under certain situations
- Develop consumer education strategy

KEY THEMES

- Consumer opt-out process

PARKING LOT

- Feasibility study to determine what percentage of patients will opt in/opt out - High % of opt out will make system clinically not useful

Discussion Item 8: Standards for prohibiting use of the data in the system by a person or an entity other than a health care practitioner, including any exceptions for use of the data with identifying information removed for bona fide research

8A. Limiting use of non-CDS data to treatment, payment, and health care operations	
<p>BENEFITS (VALUE ADD/PERCEIVED)</p> <ul style="list-style-type: none"> • Limits secondary use of non-CDS data • Builds consumer confidence • Limits access to the information based on defined access rights 	<p>BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)</p> <ul style="list-style-type: none"> • Identifying an appropriate oversight authority • Engaging stakeholders to develop governing policies • Building consumer awareness – messaging
<p>SOLUTIONS (FOR LIMITING USE OF NON-CDS DATA)</p> <ul style="list-style-type: none"> • Expand PDMP user training to include best practices pertaining to the use of non-CDS data • Establish an appropriate level of user audits • Develop policies governing access, use, and disclosure • Develop policies for use of non-CDS data, including complaint handling procedures and remediation plans 	
<p>KEY THEMES</p>	
<p>PARKING LOT</p> <ul style="list-style-type: none"> • Oversight authority 	

8B. Use of non-CDS data for research purposes

BENEFITS (VALUE ADD/PERCEIVED)

- Existing regulation (COMAR 10.25.18.10) outlines requirements for accessing, using, or disclosing data through an HIE for secondary use
- Value to population health studies (health outcomes, patterns of health determinants, interconnected policies and interventions)
- Public health benefit (disease monitoring, prevention, eradication)

BARRIERS & CHALLENGES (OBSTACLES/POTENTIAL ISSUES)

- Who decides on the permitted use cases for non-CDS data
- Ensuring non-CDS data is appropriately de-identified when released
- Obtaining patient authorization and managing the approval process

SOLUTIONS (TO USE NON-CDS DATA FOR RESEARCH PURPOSES)

- Electronically capturing the patients' authorization during the encounter where non-CDS drugs are prescribed
- A phased in approach to using non-CDS data in research where further assessment of the challenges and identifying solutions can occur
- Establish data sharing policies for non-CDS data for research purposes

KEY THEMES

PARKING LOT

- Oversight authority
- Addressing social determinants of health across health care and other services

Appendix G: Prescription Drug Monitoring Programs by State

Prescription Drug Monitoring Programs by State <i>As of October 2018</i>								
State, District, or Territory	Year Enacted/ Year Operational	Drug Schedules Monitored <i>(including schedules II, III, and IV)**</i>	Frequency Data Collected in days <i>(other than Daily)</i>	Funding Source(s)	Mandatory Enrollment of Prescribers	Mandatory Enrollment of Dispensers	Mandatory Query by Prescribers	Mandatory Query by Dispensers
AL	2005/2006	V, DOC		Licensing/CSR	✓		✓	
AK	2008/2011	V		Federal Grant	✓	✓	✓	
AZ	2007/2008	V		SGR	✓		✓	✓
AR	2011/2013	V, DOC		SGR	✓	✓	✓	
CA	1939/1939		7	Licensing/CSR	✓	✓	✓	
CO	2005/2007	V		Licensing/CSR	✓		✓	
CT	2006/2008	V		SGR	✓		✓	
DE	2010/2012	V		Licensing/CSR	✓		✓	✓
DC	2014/2016	V, DOC		Licensing/CSR				
FL	2009/2011	V		SGR	✓	✓	✓	✓
GA	2011/2013	V		SGR	✓		✓	
GU	1998/2013	V	14	Licensing/CSR		✓	✓	
HI	1943/1943	V	7	SGR	✓	✓		
ID	1967/1967	V		Licensing/CSR	✓	✓		
IL	1961/1968	V		Federal Grant	✓	✓	✓	
IN	1997/1998	V, DOC		Licensing/CSR	✓		✓	
IA	2006/2009			Licensing/CSR	✓		✓	
KS	2008/2011	DOC		RBF				
KY	1998/1999	V, DOC		SGR	✓	✓	✓	
LA	2006/2008	V, DOC		Licensing/CSR	✓		✓	
ME	2003/2004			SGR	✓	✓	✓	✓
MD	2011/2013	V		SGR	✓	✓	✓	✓
MA	1992/1994	V, DOC		SGR	✓		✓	
MI	1988/1989	V		SGR	✓		✓	
MN	2007/2010	V, DOC		Licensing/CSR	✓	✓	✓	
MS	2005/2005	V, DOC		RBF	✓	✓	✓	
MO*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MT	2011/2012	V		Licensing/CSR				
NE	2011/2011	V, DOC		Federal Grant		✓		
NV	1995/1997			Licensing/CSR	✓		✓	
NH	2008/2011			SGR	✓	✓	✓	
NJ	2008/2011	V, DOC		Licensing/CSR	✓	✓	✓	✓
NM	2004/2005			Licensing/CSR	✓	✓	✓	

Prescription Drug Monitoring Programs by State

As of October 2018

State, District, or Territory	Year Enacted/Year Operational	Drug Schedules Monitored (including schedules II, III, and IV)**	Frequency Data Collected in days (other than Daily)	Funding Source(s)	Mandatory Enrollment of Prescribers	Mandatory Enrollment of Dispensers	Mandatory Query by Prescribers	Mandatory Query by Dispensers
NY	1972/1973	V, DOC	Point of Sale/24 hours	Other			✓	
NC	2005/2007	V		SGR	✓	✓	✓	✓
ND	2005/2007	V, DOC		Licensing/CSR			✓	✓
OH	2005/2006	V, DOC		Licensing/CSR	✓	✓	✓	✓
OK	1990/1991	V	Point of Sale	Federal Grant	✓		✓	
OR	2009/2011	DOC	3	Licensing/CSR	✓	✓		
PA	1972/1973	V		SGR	✓	✓	✓	✓
PR	2017/2018	V, DOC	15	Federal Grant				
RI	1978/1979			Federal Grant	✓	✓	✓	
SC	2006/2008			Licensing/CSR			✓	
SD	2010/2011	V		RBF	✓			
TN	2003/2006	V		Licensing/CSR	✓	✓	✓	✓
TX	1981/1982	V		SGR			✓	✓
UT	1995/1996	V		Licensing/CSR	✓		✓	✓
VT	2006/2009			Other	✓	✓	✓	✓
VA	2002/2003	V		Other	✓	✓	✓	
WA	2007/2011	V		Federal Grant			✓	
WV	1995/1995	V		Licensing/CSR	✓	✓	✓	
WI	2010/2013	V		Licensing/CSR			✓	
WY	2003/2004	V		Licensing/CSR	✓			

Notes:

*Missouri does not have a mandatory statewide PDMP; St. Louis County runs a voluntary PDMP that has been joined by 47 counties and 10 cities and covers around 80 percent of Missouri's prescribers and dispensers

**All states (except Missouri) monitor drugs schedules II, III, and IV

Key:

CSR = Controlled Substance Registration Fees

DOC = Drugs of Concern

Licensing = Licensing Fees

NBD = Next Business Day

RBF = Regulatory Board Fund

SGR = State General Revenue

CDS Drug Schedule Key

Schedules	Definitions	Narcotic Examples	Non-Narcotic Examples
Schedule I	Substances that currently have no accepted medical use in the US	Heroin, LSD, MDMA, Peyote	Cannabis
Schedule II	Substances with medical use but a high potential for abuse which may lead to severe psychological or physical dependence	Amphetamine (Adderall®), hydromorphone (Dilaudid®), oxycodone (OxyContin®)	Amobarbital, Glutethimide, Pentobarbital
Schedule III	Substances with potential for abuse less than schedules I or II that may lead to moderate to low physical dependence or high psychological dependence	Buprenorphine (Suboxone®)	Ketamine, anabolic steroids
Schedule IV	Substances with low potential for abuse relative to Schedule III	Alprazolam (Xanax®), clonazepam (Klonopin®), diazepam (Valium®)	N/A
Schedule V	Substances with low potential for abuse relative to Schedule IV; consist primarily of preparations of limited quantities of certain narcotics	Cough preparations containing not more than 200 mg of codeine per 100 mL (Robitussin AC®)	N/A

Drugs of Concern by State

Alabama	Codeine cough syrups, anabolic steroids, butabital products and combinations, and chlordiazepoxide and combinations
Arkansas	Nalbuphine
District of Columbia	Cyclobenzaprine, butalbital
Indiana	Ephedrine, pseudoephedrine
Kansas	Butalbital, acetaminophen products, caffeine products, fioricet, prescription sudafed products, promethazine with codeine
Kentucky	Nalbuphine, gabapentin
Louisiana	Butalbital, ephedrine products
Massachusetts	Gabapentin
Minnesota	Gabapentin, butalbital, human growth hormones, chorionic gonadotropin, pseudoephedrine, ephedrine
Mississippi	Ephedrine, pseudoephedrine
Nebraska	All prescription medications
New Jersey	Gabapentin, human growth hormones
New York	Chorionic gonadotropin
North Dakota	Gabapentin
Ohio	Gabapentin, medical marijuana
Oregon	Pseudoephedrine
Puerto Rico	Cannabis
Utah	Butalbital, acetaminophen products
Virginia	Gabapentin, naloxone
West Virginia	Opioid antagonists, gabapentin

Appendix H: Confidentiality Concerns in Adolescent Health Care

Perception about confidentiality can influence an individual's health seeking behaviors.⁸⁸ Nationally, approximately a quarter of adolescents have foregone necessary health care services due to distrust in the protection of their confidentiality and fear of parental notification.⁸⁹ This is especially prevalent among adolescents seeking and receiving reproductive health care services.⁹⁰ About 60 percent of adolescent girls would cease some or all health care services if prescribed contraceptives required parental notification.⁹¹

Assurance of confidentiality is linked with greater utilization of health care services.⁹² Effective communication about confidentiality between adolescents and their providers can enable a candid disclosure of sensitive health care needs, particularly for mental health and risky behaviors associated with sexual and reproductive health.⁹³ Adolescents who note confidentiality as a major barrier to seeking health care services have an increased prevalence of high risk characteristics related to mental health, sexual health, and substance use.⁹⁴ Maintaining confidentiality helps address these sensitive and potentially stigmatizing issues.

⁸⁸ Fuentes, L., Ingerick, M., Jones, R., & Lindberg, L. (2018). Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services. *Journal of Adolescent Health* 62 (2018) 36–43, January 2018.

⁸⁹ *Ibid.*

⁹⁰ Leichliter, J., Copen, C., Dittus, P. (2017). Confidentiality Issues and Use of Sexually Transmitted Disease Services Among Sexually Experienced Persons Aged 15-25 Years, United States, 2013-2015. Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, March 10, 2017.

⁹¹ Lehre, J., Pantell, R., Tebb, K., & Shafer, M. (2007). Forgone Health Care among U.S. Adolescents: Associations between Risk Characteristics and Confidentiality Concern. *Journal of Adolescent Health*, 40 (2007) 218-226, March 2007.

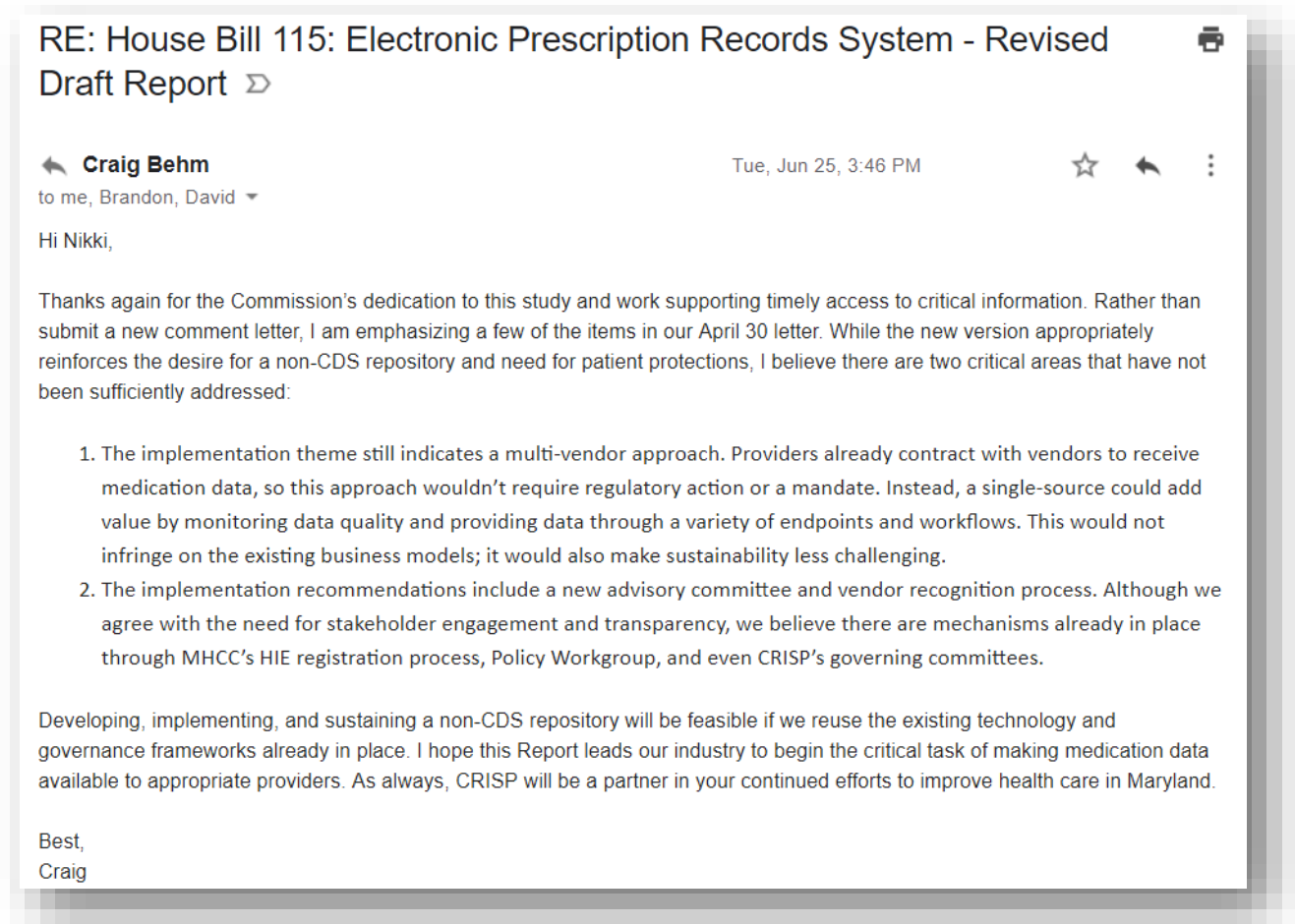
⁹² Thrall, J., McClosky, L., Ettner, S., Rothman, E., Tighe, J., & Emans, J. (2000). Confidentiality and Adolescents Use of Providers for Health Information and Pelvic Examinations. *Pediatric Adolescent Medicine*, Volume 154, September 2000.

⁹³ *Ibid.*

⁹⁴ See n. 74, *Supra.*

Appendix I: Workgroup Commentaries

Some members of the workgroup provided feedback on working drafts considered preliminary documents that were used to guide development of this final report. Workgroup comments on a final draft report follow:



RE: House Bill 115: Electronic Prescription Records System - Revised Draft Report

Craig Behm
to me, Brandon, David

Tue, Jun 25, 3:46 PM

Hi Nikki,

Thanks again for the Commission's dedication to this study and work supporting timely access to critical information. Rather than submit a new comment letter, I am emphasizing a few of the items in our April 30 letter. While the new version appropriately reinforces the desire for a non-CDS repository and need for patient protections, I believe there are two critical areas that have not been sufficiently addressed:

1. The implementation theme still indicates a multi-vendor approach. Providers already contract with vendors to receive medication data, so this approach wouldn't require regulatory action or a mandate. Instead, a single-source could add value by monitoring data quality and providing data through a variety of endpoints and workflows. This would not infringe on the existing business models; it would also make sustainability less challenging.
2. The implementation recommendations include a new advisory committee and vendor recognition process. Although we agree with the need for stakeholder engagement and transparency, we believe there are mechanisms already in place through MHCC's HIE registration process, Policy Workgroup, and even CRISP's governing committees.

Developing, implementing, and sustaining a non-CDS repository will be feasible if we reuse the existing technology and governance frameworks already in place. I hope this Report leads our industry to begin the critical task of making medication data available to appropriate providers. As always, CRISP will be a partner in your continued efforts to improve health care in Maryland.

Best,
Craig


Re: House Bill 115: Electronic Prescription Records System - Revised Draft Report



Nicole (Nikki) Majewski - MDH <nicole.majewski@maryland.gov>

Thu, Jun 27, 11:04 AM



to Craig, David, Brandon, Eva 

Hi Craig,

Thanks for your email. We appreciate the perspective CRISP has brought to this workgroup. Regarding those two areas mentioned in your email and the April 30th letter, we believe both have been amply addressed in the following areas of the report.

- On page 11 of the draft report, suggested recommendation "a)..." implies that "one or more" vendors should be competitively recognized. This is consistent with workgroup deliberations in which the preference by a number of participants was for the recommendations to remain vendor neutral. The discussion that follows notes that criteria for recognition of a vendor should include (among other things) interoperability with CRISP. It is worth noting this recommendation parallels with how the Prescription Drug Monitoring Program (PDMP) exists today in which multiple vendors report to the PDMP. The workgroup's recommendation differs to include a State recognition process to ensure that all data sharing vendors meet the same high bar around privacy and security. The role of CRISP in supporting non-CDS reporting would remain the same as its role in CDS reporting. We ask that CRISP please clarify its remarks if you believe that MHCC has misunderstood your comment.
- On page 11 of the draft report, suggested recommendation "c)..." conveys the importance of stakeholder engagement. Please note this recommendations does not suggest a new advisory committee. As you correctly noted, a number of existing stakeholder groups could be tasked with proposing policy recommendations for non-CDS reporting. The workgroup's decision not to identify a specific advisory committee in law reduces the need to make future changes in the law as stakeholder committees evolve over time. We ask that CRISP please clarify its remarks if you believe that MHCC has misunderstood your comment.

If you have any additional thoughts, please let me know.

Thanks so much,

Nikki



April 30, 2019

Nikki Majewski
Chief, Health Information Technology
Maryland Health Care Commission
Center for Health Information Technology and Innovative Care Delivery
4160 Patterson Avenue
Baltimore, MD 21215

RE: MHCC Electronic Prescription Records System Workgroup – Comments on Draft Final Report

Dear Ms. Majewski,

We would like to thank the Commission for reviewing this issue in such depth. As we shared during workgroup meetings, CRISP often receives requests for full medication lists. Hopefully the recommendations from your study will move us closer to meeting that demand. Before our comments, we thought it may be helpful to share utilization statistics for Maryland's PDMP system. You have policy and technical background on pages 6 and 7; the following utilization information may also be relevant:

- PDMP is queried through the CRISP portal over 40,000 times per week
- PDMP is queried directly by the user's EHR about 750,000 times per week
- PDMP data is placed directly within an EHR (positive queries) about 250,000 times per week
- In the first quarter of 2019, over 30,000 unique users accessed PDMP data

We are very much in favor of authorized users getting access to critical patient information. We also agree with the workgroup and Commission's emphasis on patient notice and an ability to opt-out. We are submitting the following specific comments for your consideration:

- We support the workgroup's broad recognition of the need for a non-CDS repository, and that this repository will have to meet standards for technical performance and controls.
- We agree on the importance of privacy in this undertaking.
 - It is essential that patients have meaningful choice about participation, and a "theoretical" opt-out that nobody uses would not suffice.
 - Might we begin by aggregating less sensitive drug classes, such as statins, which are important to know at the point of care? We could collectively expand from there.
 - Global HIE opt-out should apply to non-CDS data too.
 - Granular consent is a good aspiration but may be a complication out of the gates.
- We agree that a non-CDS records system, however it may proceed, cannot affect the critical information available through the PDMP and that it must be sustainable.
 - The costs cited seem about right, if this is run outside of PDMP. However, if we bolt the new functionality onto existing PDMP processes, the costs would be substantially smaller. This option should be reflected in the report.
 - We offer to work through our governance committees to determine how CRISP can appropriately leverage existing technology and process for a less expensive solution.
- We have concerns about the Implementation theme indicating a multi-vendor approach to the non-CDS repository.
 - Providers already contract with companies to access medication data; the purpose of a centralized electronic prescription records system is to enable a single source for medication history while maintaining privacy.



- We do not believe a centralized non-CDS repository infringes on business models, such as e-prescribing, that currently exist.
- Much of the success of PDMP is the use of a single source that monitors data quality and availability, and then makes the data available through appropriate end points – EHRs being the most frequently used. A multi-vendor approach makes normalizing data sets much more difficult and would make sustainability more challenging.
- If an organization other than CRISP were to run the repository, CRISP would, of course, stand prepared to connect to them and assist in getting the data to healthcare providers. While we could, in theory, aggregate data from multiple vendors in real time, that would be harder. A single technology provider holding the medication data would be a better solution and much easier for CRISP to connect.
- The Implementation recommendations indicate the need to “recognize existing vendor solutions” as well as “assemble a non-CDS reporting advisory committee.” While we understand details are to-be-determined, we have concerns about creating additional processes and policies.
 - The state already maintains a registration process for HIEs which requires procedural and technical controls as well as protocols for consumer opt-out. HIE registration or the state designation should be used rather than creating something new.
 - Similarly, the MHCC has an existing HIE Policy Workgroup and CRISP has multiple stakeholder committees reporting to the Board of Directors; these existing forums are capable of providing meaningful insight and feedback.

Our perspective, as you have gleaned from the comments above, is that existing infrastructure should be reused as much as possible when enabling new use cases. The PDMP regulations, policies, access processes, and submission processes are an appropriate starting point when considering parallel non-CDS services. Services to show medication history at the point of care through the state-designated HIE will significantly contribute to quality and cost goals under the Total Cost of Care Model and would not impede current business models.

Please don't hesitate to contact me if you have any questions. We look forward to our continued work together and once again thank you for your time and attention to this and other important health IT matters facing our State.

Sincerely,

Craig Behm
Executive Director – CRISP Maryland

RE: House Bill 115: Electronic Prescription Records System -
Revised Draft Report ➤ Inbox x



➡ **Nicole Russell**

Thu, Jun 27, 5:03 PM



to me ▾

Hi Nicole,

Thank you for the opportunity to submit comments.

Please find the following comments submitted by NCPDP:

NCPDP commends the work of the Maryland Health Care Commission and the Electronic Prescription Records Work Group.

NCPDP thanks the Maryland Health Care Commission for the opportunity to participate in the Work Group and provide comments on the final report and recommendations to the legislature.


The NCPDP SCRIPT Dispensed Medication Reporting Standard will be published in 2019 and will allow for the reporting of dispensed medications by a pharmacy or prescriber to a health information exchange. The SCRIPT Dispensed Medication Reporting Standard reports data needed for Health Information Exchanges (HIEs) to respond to a request or inquiry on patient's medication history. It is important to leverage existing, widely implemented standards in order to provide a consistent national format for reporting. Leveraging existing industry standards greatly enhances the interoperability and exchange of dispensed medication data between HIEs.

Nicole Russell, CAE

Senior Manager, Government Affairs

NCPDP



Re: House Bill 115: Electronic Prescription Records System -
Revised Draft Report  Inbox x



 **Cynthia Macri**

Jul 1, 2019, 3:56 PM



Nikki,

Really really well written! It wasn't even the least bit tedious reading through it, so unlike some documents, I think it will actually be read by some of the people who can inform policy or even legislation.

The only thing I might add, and I am only commenting on this because I have had to read the entire SUPPORT Act and MISSION Act which were signed into law in October 2018 and June 2018 respectively. Federal law now states that there must be bidirectional information sharing and interoperability among intrastate data bases, specifically mentioning the VA and Indian Health Service as well as worker's compensation, medical examiners, Pharmacy benefit managers, Medicaid, and others as well as prescribers having access to a "nationwide network of PDMPs" (which as you know does not exist). But it's the law. Also the SUPPORT act specifically requires that prescribers have access to complete prescription histories in "as close to real-time as possible" which is not the same as "near real-time," a concept that has been exploited by certain vendors to mean anything from 5 minutes to 24 hours. The industry knows that 20 millisecond turn around from the point of sale (transaction) is as close to real-time as possible, yet administrators are unwilling to enforce that standard. Nonetheless, the current law states that this is the standard.

I am not sure if it is required that Maryland follow the federal guidance, or if the state's rights trumps federal law where the intent is to protect the privacy of the residents of the state. The relevant section of the VA MISSION Act is section 134. For the SUPPORT Act it is written in several places, but most succinctly in Title VII, Subtitle Q, section 7162.

I would send you the sections, but my email account won't let me send attachments. I can try to send from my gmail account if you would like me to.

Thank you for your patience.

Re: House Bill 115: Electronic Prescription Records System - Revised Draft Report 

Nicole (Nikki) Majewski - MDH <nicole.majewski@maryland.gov> Tue, Jul 2, 4:38 PM



Hi Dr. Macri,

Thanks for your email. We appreciate the perspective you have brought to this study. You bring to light a good point about the aims of the SUPPORT and MISSION Acts. Both are aspirational for states as they consider additional policies and make more investments in addressing the opioid crisis, among many other things. We will be sure to include a note about these Acts in the final report to the legislature.

Thanks so much,

Nikki

July 3, 2019

To Whom It May Concern:

On behalf of the Lamy Center on Drug Therapy and Aging, thank you for the opportunity to provide comments on the House Bill 115: Electronic Prescription Records System A Report to the Governor and General Assembly. Overall, this was a well written document but below highlight some areas to consider:

- 1) Pg 5: "This includes elderly care,¹⁴ a population that is prone to increased medication use, acute and chronic illnesses .. 14 notes: "broad term encompasses services such as assisted living, adult day care, long-term care, nursing homes, hospice, and home health" : propose changing this to statement and the preceding to: *Medication reconciliation is a key component of patient safety across the care continuum. This is increasingly important especially for older adults, a population that is at a greater risk for adverse medication events due to multiple co-morbidities, medications and transitions in care.* Then also delete reference 14.
- 2) Pg 6: "for medication errors and inadvertent omissions, while improving efficiencies: change to *"for medication errors, discrepancies and other medication related problems, while improving workflow efficiencies."*
- 3) Pg 6: " along with multiple calls to community pharmacies": consider changing to: *" along with multiple calls to community, mail order and or health system pharmacists"*
- 4) Pg 7. In response, the legislature concluded that a study was needed to evaluate these issues and others that may be identified before advancing the bill. *Is this currently being done? Of note, there will be financial implications and has these costs been estimated?*
- 5) Pg 10: Implementation: "Limit reporting of dispensed non-CDS data to retail pharmacies (dispensers for the majority of medications)" : *would recommend utilizing a definition to what is meant by this. Would this include health system pharmacies; and mail order pharmacies and only exclude institutional pharmacies (e.g. LTC, hospital).*

Additionally, we recently published an article based on a small study that we conducted in Maryland, *Identifying Potential Medication Discrepancies During Medication Reconciliation in the Post-Acute Long-Term Care Setting* Heather Cook, PharmD; Janee Parson, PharmD; Nicole Brandt, PharmD, MBA, BCGP, BCPP, FASCP in the *July Journal of Gerontological Nursing*. 2019;45(7):5-10 <https://doi.org/10.3928/00989134-20190612-02> This may be helpful to support the case on why this bill is so important.

Feel free to reach out with any questions or if additional support is needed. Again, great work and look forward to the continued efforts.

Sincerely,

A handwritten signature in cursive script that reads "Nicole Brandt".

Nicole J. Brandt, PharmD, MBA, BCGP, BCPP, FASCP
Executive Director, Lamy Center on Drug Therapy and Aging
Professor, University of Maryland School of Pharmacy

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David Sharp, Ph.D., Director
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