PDMP House Bill 437, Chapter 147 (2016), Section 9 Contingency Met Appendix

As part of the Department's efforts to fully utilize the PDMP as an effective clinical tool to address the opioid epidemic, the Department must require prescribers of controlled dangerous substances ("CDS") and pharmacists to use the PDMP when prescribing or dispensing an opioid in certain situations. Section 3 (the Use Mandate) of House Bill 437 (2016) grants the Department this authority only after Section 9 of House Bill 437 (2016)[1] is satisfied.

Section 9 of HB 437 provides:

> (a) Section 3 of this Act is contingent on a determination by the Secretary of Health and Mental Hygiene, made in consultation with the Advisory Board on Prescription Drug Monitoring, the Joint Committee on Behavioral Health and Opioid Use Disorders, and stakeholders, that:
> (1) the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and pharmacists; and
> (2) requiring a prescriber to request prescription monitoring data for a patient in accordance with § 21–2A–04.2 of the Health – General Article, as enacted by Section 3 of this Act, is important to protect public health and promote good patient care.
> (b) The Secretary of Health and Mental Hygiene shall notify the Department of Legislative Services and, in accordance with § 2–1246 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee within 5 days after the Secretary determines that the contingencies under subsection (a) of this section have been satisfied.
> (c) If the notice required under subsection (b) of this section is not received by the Department of Legislative Services on or before June 30, 2023, Section 3 of this Act shall be null and void without the necessity of further action by the General Assembly.

The following sections are a discussion of 1) the consultations required under Section 9(a), 2) the information used to evaluate technical capabilities under Section 9(a)(1) and (2), and 3) the requirements of the Section 3 use mandate for CDS prescribers and dispensers.

1) Attestation of Consultation under Section 9(a) of HB 437

As required by Section 9(a) of HB 437, the Department requested consultation from the Joint Committee on Behavioral Health and Opioid Use Disorders, various professional boards and associations, and the Advisory Board on Prescription Drug Monitoring in May and June 2018.

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Having received one comment from the Maryland Psychiatric Society[2], the Department is moving forward with the Use Mandate.

In addition, the Department also requested input from the following stakeholders: (1) the Maryland State Medical Society; (2) the Maryland Nurses Association; (3) the Maryland Nurse Practitioner Association; (4) the Maryland Hospital Association; (5) the Maryland Podiatric Medical Association; (6) the Maryland State Dental Association; (7) the Maryland Pharmacist Association; (8) Maryland Institute for Emergency Medical Services Systems; and (9) Opioid Operational Command Center. In addition to those industry and community stakeholders, the Department continues to work with the Board of Physicians; Board of Pharmacy; Board of Nursing; State Board of Dental Examiners; Board of Podiatric Medical Examiners; for their input and comments.

The Advisory Board on Prescription Drug Monitoring (PDMP Advisory Board) has been consulted throughout the development and deployment of new authorities and requirements of the PDMP. At its recent meeting on April 19, 2018, the PDMP Advisory Board was also presented with the requirements in Section 9, including the results of the Chesapeake Regional Information System for our Patients (CRISP) system performance testing. Board members were provided the opportunity to ask questions and were satisfied by the presentation.

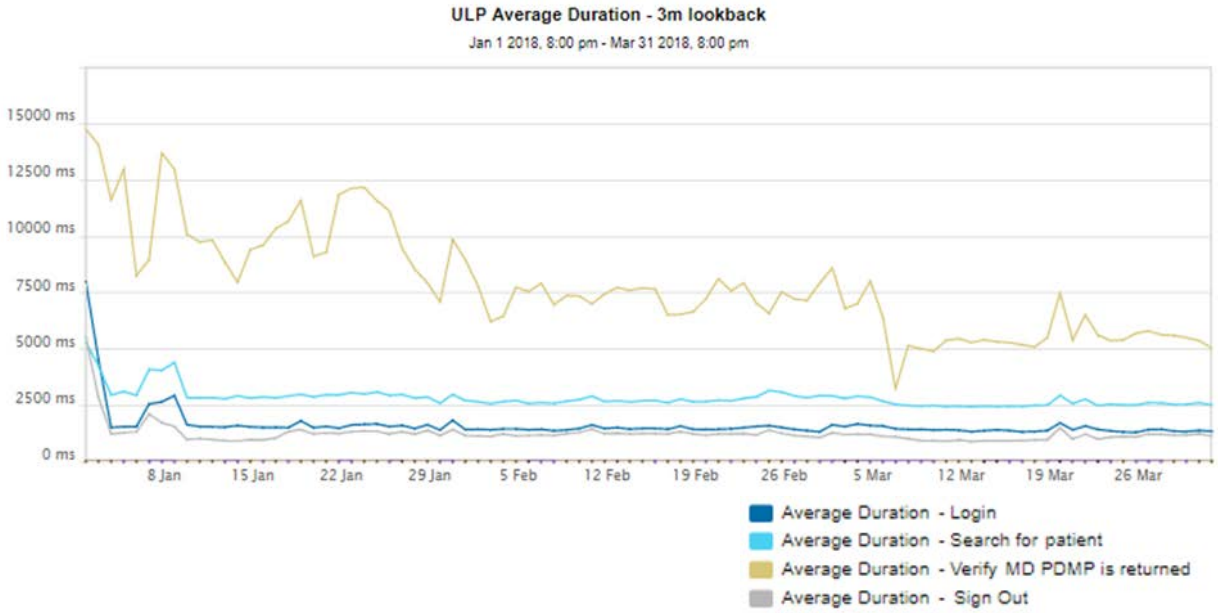
2) Contingency Determination

To demonstrate that "the technical capabilities of the Prescription Drug Monitoring Program are sufficient to achieve a reasonable standard of access and usability by prescribers and Pharmacists", the Department directed the PDMP information technology (IT) vendor and state-designated health information exchange (HIE) Chesapeake Regional Information System for our Patients (CRISP) to complete a test of system performance. The test was designed to stress the CRISP infrastructure to mimic anticipated increases in usage of CRISP after implementation of the use mandate, and to determine that this increased volume would not reduce responsiveness of CRISP's system to its end users nor crash the system.

[2] The comment from the Maryland Psychiatric Society was received on June 27, 2018 and advised on four areas: (1) a requirement that an opioid or benzodiazepine prescription check would add to a prescriber's administrative burden; (2) whether a PDMP use mandate would cause distress to a patient due to fear that a CDS prescription might be cut off; (3) the administrative requirement of asking a prescriber to check on a patient every 90 days might be excessive; and (4) the need for more education and support for all prescribers as the mandate rolls out. The Department intends to work with the Maryland Psychiatric Society to resolve these issues, but it believes that in light of the ongoing opioid emergency, that it is in the health and safety interest of Marylanders to implement the PDMP Use mandate.

Baseline performance and upgrades

Baseline metrics of how quickly the CRISP system processes user queries (logging into system, searching for a patient, displaying data, and logging out of the system) were used as a benchmark for performance under the stress testing. Figure 1 shows baseline performance of approximately



10 seconds start to finish, based on queries made in the ULP with a three-month look-back (January 1 – March 31, 2018).
Figure 1. Baseline CRISP system performance of time to complete a query

To ensure optimal performance, CRISP continues to invest in system upgrades. In 2017-18, PDMP data was moved to its own separate database in the Microsoft Azure Cloud, a cloud-based storage system that allows for automatic system-scaling based on demand or use of the system. This allows Maryland PDMP queries to be completed without any performance impact based on other data being stored by CRISP.

System stress testing

In March 2018, the CRISP system was load tested to simulate conditions where the maximum expected number of concurrent clinical users would be querying for PDMP at the same time on the Unified Landing Page (ULP), the CRISP query portal hosting the PDMP Search functionality. The results of the system testing are as follows: if 40,000 queries were performed by concurrent users within an 8-hour period, it would take a provider 15 seconds to log in, query for a patient, view the results, and log out. This is consistent with current query times, demonstrating no measurable degradation in performance.

The secondary goal of the testing was to validate that the system remains available even under intense load, which was simulated by doubling the number of queries hitting the system over the same time period. If 80,000 queries were performed within an 8-hour period, it would take a

provider 20 seconds to log in, query for a patient, view the results, and log out. Although the workflow time increased on average by 5 seconds, at no point did CRISP experience service interruption and the system was still usable. These results demonstrate CRISP's ability to provide access to PDMP data within reasonable standards of accessibility and usability.

CRISP and MDH will continue to monitor performance and conduct auxiliary testing. Throughout 2018, additional servers are being added to ensure redundancy and scalability for the ULP workflow.

3) Effect of a Mandatory Use requirement for CDS Prescribers: The requirements and exemptions of the use mandate are summarized below:

Prescribers include the following practitioners with CDS prescriptive authority: physicians, physician assistants, dentists, podiatrists, nurse practitioners, and advanced practice nurse midwives. Prescribers must query and assess PDMP data (through the CRISP portal or integration within a Electronic Health Record (EHR) system, where available, before beginning a new course of treatment with opioids or benzodiazepines. and when a course of treatment extends beyond 90 days. In this case, prescribers must query again at least every 90 days thereafter before prescribing or dispensing opioids or benzodiazepines. Prescribers must view at least the last 4 months of data. A prescriber delegate may pull the PDMP data, but the prescriber remains responsible for assessing the data prior to making a prescribing decision. A prescriber is NOT REQUIRED to request PDMP data if the opioid or benzodiazepine is prescribed or dispensed to an individual:

- For a period of 3 days or less (<3 days)
- For cancer treatment or cancer-related pain
- For a patient who is:
    - Receiving treatment in an inpatient unit of a hospital
    - Part of a general hospice program
    - Diagnosed with a terminal illness
    - Residing in a nursing home, long-term care, developmental disability, or assisted living facility
- To treat or prevent acute pain for a period of 14 days or less (<14 days) following:
    - Surgical procedure
    - Bone Fracture
    - Significant trauma
    - Childbirth

Pharmacists must query and assess the PDMP data when they suspect any CDS prescription is being filled for something other than treatment of an existing medical diagnosis. Communication will be made to applicable health occupation licensing boards and professional organizations about the effective date of the use mandate. Online materials will also be updated to reflect this change.