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Overview of House Bill 437/Senate Bill 537 Prescription Drug Monitoring Program

I. Registration Requirements:

- An authorized provider who prescribes a Schedule II–IV controlled dangerous substance (CDS) must register with PDMP before obtaining a new or renewal CDS registration from DHMH.
Note: This requirement is contingent on the Secretary’s determination that (1) the requirement will not adversely affect or delay the issuance of a new or renewal registration and (2) the process for obtaining a new or renewal registration is capable of delivering the registrations in a timely manner.
- A prescriber must register with PDMP before obtaining a new or renewal CDS registration from DHMH or by July 1, 2017, whichever is sooner. Example: If a prescriber is registering either for the first time or for a renewal after October 1, 2016, the prescriber will be required to also register with the PDMP at that time. All others will need to register before July 1, 2017.
- A pharmacist must register with PDMP by July 1, 2017.

II. Education Requirements:

Before registering with PDMP, both prescribers and pharmacists must complete a course of instruction and training on the effective use of PDMP. The instruction course and training will be developed by DHMH.

III. Dispenser Reporting:

As of October 1, 2016, dispensers will be required to submit information to the PDMP once every 24 hours rather than the current requirement of three business days.

IV. Query Use Requirements:

- Beginning July 1, 2018: a prescriber must:
 - (1) request at least the prior 4 months of a patient’s prescription monitoring data before initiating a course of treatment for the patient that includes prescribing or dispensing an opioid or benzodiazepine;
 - (2) request a patient’s prescription monitoring data at least every 90 days until the course of treatment that includes an opioid or benzodiazepine has ended; and
 - (3) assess the prescription monitoring data before deciding whether to prescribe or dispense or continue to prescribe or dispense an opioid or benzodiazepine
- A prescriber must document in the patient’s medical record that the prescription monitoring data was requested and assessed.

- V. Query Not Required: A prescriber is not required to query if the opioid or benzodiazepine is prescribed or dispensed to an individual:
- (1) For amounts prescribed for 3 days or less;
 - (2) For the treatment of cancer or cancer-related pain;
 - (3) Who is:
 1. A patient receiving treatment in an inpatient unit of a hospital
 2. A patient in a general hospice care program or any other patient diagnosed with a terminal illness
 3. A patient who resides in an assisted living facility; a long-term care facility; a comprehensive care facility; or a developmental disabilities facility
 - (4) To treat or prevent acute pain for a period of 14 days or less following:
 1. A surgical procedure in which general anesthesia was used;
 2. A fracture;
 3. Significant trauma; or
 4. Childbirth

- VI. Exceptions to Query: A prescriber may not be required to query when:
- (1) Prescribing or dispensing an opioid or benzodiazepine drug that has been listed by the Secretary as having a low potential for abuse;
 - (2) Accessing would result in a delay in the treatment of a patient that would negatively impact the medical condition of the patient;
 - (3) Electronic access is not operational; or
 - (4) Data cannot be accessed due to a temporary technological or electrical failure

If a prescriber does not access the prescription monitoring data, the prescriber must:

- Use reasonable medical judgment when determining whether to prescribe or dispense an opioid or a benzodiazepine; and
- Document an appropriate record in the patient's medical chart, including the reason why the data was not accessed

Note: The Secretary may adopt regulations to provide additional clinical, technical, or administrative exemptions based on new standards of practice.

- VII. Delegate Authority: A prescriber or pharmacist may authorize a prescriber delegate or pharmacist delegate to query on behalf of the prescriber or pharmacist if:
- (1) The prescriber or pharmacist takes reasonable steps to ensure that the delegate is competent in the use of PDMP;
 - (2) The prescriber remains responsible for:
 1. Ensuring that delegate access is limited to purposes authorized by law;
 2. Protecting the confidentiality of the data; and
 3. Any breach of confidentiality by the delegate
 - (3) The decision whether to prescribe or dispense a monitored prescription drug:
 1. Remains with the prescriber or pharmacist; and
 2. Is reasonably informed by the prescription monitoring data obtained

- VIII. Pharmacist Query Requirements: When a pharmacist or pharmacist delegate has a reasonable belief that a patient may be seeking a monitored prescription drug for any purpose other than the treatment of an existing medical condition, before dispensing the monitored prescription drug, the pharmacist or pharmacist delegate must request the patient's prescription monitoring data to

determine if the patient has received other prescriptions that indicate misuse, abuse, or diversion of a monitored prescription drug and abide by the responsibility described in 21 C.F.R. § 1306.04.

IX. Program Review and Notification Requirements:

- PDMP may review the data for indications of a possible violation of law or a possible breach of professional standards by a prescriber or a dispenser
- If PDMP's review indicates a possible violation or breach, the program may:
 1. Notify the prescriber or dispenser of the possible violation or breach; and
 2. Provide education to the prescriber or dispenser
- Before providing such notification to the prescriber or dispenser, PDMP must obtain from the Technical Advisory Committee:
 1. Clinical guidance regarding indications of a possible violation or breach; and
 2. Interpretation of the data that indicates a possible violation or breach

X. Liability: A prescriber or pharmacist who violates the registration or query requirements is subject to disciplinary action by the appropriate licensing authority.

XI. Additions to Membership of the Technical Advisory Committee: The Technical Advisory Committee currently consists of members with certain qualifications, appointed by the Secretary. In addition to these members, the Committee will also consist of at least the following members, appointed by the Secretary. Additional members may be appointed at the discretion of the Secretary.

1. Two medical professionals, licensed and practicing in the State with expertise or experience in providing care for patients with substance-related or mental health disorders;
2. A dentist licensed and practicing in the State; and
3. A medical professional licensed and practicing in the State in the field of internal medicine or family practice.

XII. Uncodified Language – Requiring Additional Reports and Contingencies:

- Parts III, IV, V, and VII of this Memo are contingent on the Secretary's determination that (1) the technical capabilities of PDMP 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 is important to protect public health and promote good patient care.
- On or before November 1, 2016, DHMH must report to the Joint Committee on Behavioral Health and Opioid Use Disorders on the feasibility and desirability of analyzing prescription monitoring data through the regular and ongoing use of statistical and advanced analytical techniques, including outlier detection, cluster analysis, and unsupervised data analysis techniques, for the purpose of:
 - (1) Understanding patterns in pain management care, patient opioid use, and treatment plans;
 - (2) Detecting possible high risk opioid behavior;
 - (3) Improving detection of multiple provider episodes; and
 - (4) Facilitating the sharing of information contained in State health and criminal justice records, as allowed by State and federal law, and available from interstate data sources.

- DHMH must report to the Senate Finance Committee, the House Health and Government Operations Committee, and the Joint Committee on Behavioral Health and Opioid Use Disorders, regarding the ongoing implementation and use of the PDMP, including:
 - (A) On or before December 1, 2016: (1) the technical capacity of PDMP to analyze prescription drug monitoring data for possible violations of law and possible breaches of professional standards; and (2) an analysis of the possibility of reporting possible violations or breaches to law enforcement agencies, licensing entities, or units of DHMH
 - (B) On or before September 1, 2017: (1) the status of the implementation of providing education and notice of a possible violation or breach to prescribers and dispensers; and (2) a recommendation on whether the authority of PDMP to report possible violations or breaches should be expanded to allow reporting to law enforcement agencies, licensing boards, or units of DHMH
- DHMH must develop and implement a plan to conduct outreach to and education of prescribers and pharmacists about the process for registering with PDMP.