

Legislative Analysis



SCHEDULE 2 CONTROLLED SUBSTANCES DISPENSED IN LOCKABLE VIALS

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House Bill 5857 as introduced
Sponsor: Rep. Joseph N. Bellino, Jr.
Committee: Health Policy
Complete to 8-29-18

SUMMARY:

House Bill 5857 would add a section to Part 73 of the Public Health Code, which concerns the Manufacture, Distribution, and Dispensing of Controlled Substances. It would provide that, when a pharmacist dispenses a prescription for a Schedule 2 controlled substance in solid oral dosage form, the pharmacist must comply with all of the following:

- Dispense the controlled substance in a *lockable vial*, except in either of the following circumstances:
 - To a patient who would have difficulty opening the lockable vial or who meets any other circumstance described by the Department of Licensing and Regulatory Affairs (LARA) by rule.
 - If the dispensing occurs in an institutional health care setting and the controlled substance is administered to the patient in that setting.
- Ensure that the form described below is provided with the controlled substance at the time it is dispensed.
- If the controlled substance is dispensed to a patient in a lockable vial with a locking-cap closure mechanism that uses an alphanumeric or numeric combination code, store the combination code in the notes for the patient for use by the pharmacy when refilling or dispensing a prescription.

The bill would require LARA to develop and distribute a form that educates patients on the potential for abuse and the diversion of controlled substances (including stealing them). LARA would also be allowed to promulgate rules to implement this change.

Under the bill, manufacturers would have to reimburse pharmacies for the cost of dispensed lockable vials for the manufacturers' Schedule 2 controlled substances.

The bill would also amend Part 177 (Pharmacy Practice and Drug Control). Currently, unless the patient requests otherwise, a prescription must be dispensed in a qualifying safety closure container. Under the bill, that provision would not apply to Schedule 2 controlled substances in solid oral dosage form.

Lockable vial would be defined as a disposable container that is considered special packaging (defined in the U.S. Code as packaging designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and

not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time) and that has a *locking-cap closure mechanism*.

Locking-cap closure mechanism would mean either a cap that can be unlocked using a numeric or alphanumeric combination code that has a minimum of 10,000 possible combinations, is selected by the patient or the patient's parent or legal guardian if the patient is a minor, and is encoded into the cap by the pharmacist during the dispensing process; or a cap that can be unlocked using biometric voice or facial recognition authentication technology.

The bill would take effect 90 days after enactment.

MCL 333.17761 and proposed MCL 333.7333c

FISCAL IMPACT:

House Bill 5857 would not have a significant fiscal impact on LARA or on other units of state or local government. Under the bill, LARA would be responsible for developing and distributing a form to educate patients on the potential for the abuse and diversion of controlled substances and for promulgating rules. These functions (specifically development and distribution of the patient form) would entail negligible costs that would likely be entirely supported by existing departmental appropriations.

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