

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: Phar 18 (CSB 4)

Relating to: Operation of PDMP

Rule Type: Permanent

1. Finding/nature of emergency (Emergency Rule only): N/A

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to make necessary changes to the rule resulting from 2015 Act 55 transferring the Prescription Drug Monitoring Program (PDMP) from the Pharmacy Examining Board to the Controlled Substance Board and to make minor clean-up changes.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Due to the transfer of authority from the Pharmacy Examining Board to the Controlled Substance Board, there are several definitions and references which need clarification or updating. In addition, there is minor clean-up which is necessary to repeal unnecessary definitions, make language gender neutral, correction of the words “dispenser” and “dispenser delegate” which should be “pharmacist” or “pharmacist delegate” and the repeal of Phar 18.03(2) and (3) which are no longer necessary due to the recent scheduling of tramadol and 2013 Act 124. These proposed changes do not change policy and are a clean-up to remove redundancy and create clarity.

In addition, 2015 Act 55 requires rules defining what constitutes suspicious or critically dangerous conduct or practices for purposes of disclosure to relevant state boards and agencies, relevant agencies of other states and relevant law enforcement agencies under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner or patient.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

s. 961.385 (2) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

75 hours

6. List with description of all entities that may be affected by the proposed rule:

Licensees who are authorized to prescribe and dispense controlled substances (physicians, advanced practice nurse prescribers, physician assistants, dentists, podiatrists, optometrists, pharmacists and pharmacies) and PDMP staff.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

There is no existing or proposed federal regulation that is intended to address the activities regulated by the proposed rule as it relates to PDMP.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

Minimal or no economic impact. It is not likely to have a significant economic impact on small businesses.

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