STATEMENT OF SCOPE

Controlled Substances Board

Rule No.: CSB 2.54

Relating to: Scheduling of oral solutions containing dronabinol

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 rule is to schedule oral solutions containing dronabinol as Schedule II controlled substance. The Controlled Substances Board determines the scheduling of oral solutions containing dronabinol as Schedule II controlled substance is in the best interest of the citizens of Wisconsin.

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:

On March 23, 2017, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing oral solutions containing dronabinol into Schedule II of the federal Controlled Substances Act. The scheduling action was effective March 23, 2017. The Controlled Substances Board did not receive an objection to similarly treat oral solutions containing dronabinol as Schedule II controlled substance under ch. 961, Stats within 30 days of the date of publication in the Federal Register of the final order designating oral solutions containing dronabinol as a controlled substance.

Pursuant to s. 961.11 (4), Stats., the Controlled Substances Board took affirmative action to similarly treat oral solutions containing dronabinol under ch. 961, Stats. by creating the following:

CSB 2.54 Addition of Oral Solutions containing dronabinol to schedule II. Section 961.16 (10), Stats., is created to read:

961.16 (10) (a) Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in an oral solution in a drug product approved by the U.S. food and drug administration.

The Affirmative Action order, dated May 12, 2017, took effect on May 15, 2017 to allow for publication in the Administrative Register and expires upon promulgation of a final rule.

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

961.11 (1) The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227.

961.11(4) If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2).

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

25 hours

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

Pharmacies, pharmacists, prescribers, patietns, law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board

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:

On March 23, 2017, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing oral solutions containing dronabinol into Schedule II of the federal Controlled Substances Act. The scheduling action was effective on March 23, 2017.

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

None to minimal. It is not likely to have a significant economic impact on small businesses.

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