

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.95

Relating to: Scheduling Ganaxolone

Rule Type: Permanent

1. Finding/nature of emergency:

N/A

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

The objective of the proposed rule is to schedule Ganaxolone as a schedule V controlled substance under s. 961.11 (4), Stats.

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 June 1, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Ganaxolone into schedule V of the federal Controlled Substances Act. The scheduling action was effective June 1, 2022.

The Controlled Substances Board did not receive an objection to similarly listing Ganaxolone as a schedule V under ch. 961, Stats. within 30 days of the date of publication in the federal register of the interim final order listing Ganaxolone as a schedule V controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Ganaxolone under chapter 961, Stats. by creating the following:

CSB 2.95 Addition of Ganaxolone to schedule V. Section 961.22 (11), Stats., is created to read:

961.22 (11) GANAXOLONE. Ganaxolone.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:

Section 961.11 (1), Stats. provides that “[t]he 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.”

Section 961.11(4), Stats. provides that “[i]f 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:

Approximately 80 hours.

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

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:

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8. Anticipated economic impact of implementing the rule:

None to minimal.

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