STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2

Relating to: Removing [^{123}I]ioflupane as a controlled substance

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 exclude [^{123}I]ioflupane as a controlled substance

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 September 11, 2015, the U.S. Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [^{123}I]ioflupane from the federal Controlled Substances Act. The scheduling action was effective September 11, 2015. The Controlled Substances Board did not receive an objection to similarly remove [^{123}I]ioflupane from schedule II under ch. 961, Stats within 30 days of the date of publication in the federal register of the final order removing[^{123}I]ioflupane as a controlled substance.

Pursuant to s. 961.11(4), Stats, the Controlled Substances Board took affirmative action to similarly treat [^{123}I]ioflupane under chapter 961, Stats. by creating the following:

CSB 2.40 Exclusion of [^{123}I]ioflupane.

Sections 961.16(2)(b) is amended to read:

961.16(2)(b) *Coca leaves and any salt, compound, derivative or preparation of coca leaves. Decocainized coca leaves or extractions which do not contain cocaine or ecgonine are excluded from this paragraph. [^{123}I]ioflupane is excluded from this paragraph. The following substances and any of their salts, esters, isomers and salts of esters and isomers that are theoretically possible within the specific chemical designation, are included in this paragraph.*

The Affirmative Action order, dated October 13, 2015, took effect on October 19, 2015 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(2) After considering the factors enumerated in sub. (1m), the controlled substances board shall make findings with respect to them and promulgate a rule controlling the substance upon finding that the substance has a potential for abuse.

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:

Pharmacists, prescribers, courts, police 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 September 11, 2015, the United States Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing [^{123}I]ioflupane from schedule II of the federal Controlled Substances Act. The scheduling action was effective September 11, 2015.

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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Chair

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Date Submitted