

# STATEMENT OF SCOPE

## CONTROLLED SUSTANCES BOARD

Rule No.: CSB 5

Relating to: Approval of pharmacies and physicians that may dispense cannabidiol

Rule Type: Permanent

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

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

If the federal Food and Drug Administration issues an investigational drug permit to a physician for cannabidiol as treatment for a seizure disorder or if cannabidiol is determined not to be a schedule I drug in the federal Controlled Substances Act, the Controlled Substances Board is required to approve which pharmacies and physicians may dispense cannabidiol to patients. The objective is to develop rules for the approval of pharmacies and physicians.

**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:**

Currently there are no rules governing how the Controlled Substances Board will approve pharmacies and physicians who may dispense cannabidiol to patients if the federal Food and Drug Administration issues an investigational drug permit to a physician for cannabidiol as treatment for a seizure disorder or if cannabidiol is determined not to be a schedule I drug in the federal Controlled Substances Act.

The Controlled Substances Board is proposing to have rules in place prior to an investigational drug permit to a physician for cannabidiol as treatment for a seizure disorder is issued or cannabidiol is determined not to be a schedule I drug in the federal Controlled Substances Act. The Controlled Substances Board believes it is in the best interest of patients to have rules in place so that a delay in obtaining cannabidiol does not occur once an investigational drug permit is issued or cannabidiol is no longer a schedule I drug in the federal Controlled Substances Act.

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

961.34 (2) (a) ...If the federal food and drug administration issues an investigational drug permit, the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients.

(b) If cannabidiol is removed from the list of controlled substances, or if cannabidiol is determined not to be a controlled substance, under schedule I of 21 USC 812 (c), the controlled substances board shall approve which pharmacies and physicians may dispense cannabidiol to patients as treatment for a seizure disorder.

227.10 (1) Each agency shall promulgate as a rule each statement of general policy and each interpretation of a statute which it specifically adopts to govern its enforcement or administration of that statute...

(3)(c) Each person affected by a rule is entitled to the same benefits and is subject to the same obligations as any other person under the same or similar circumstances.

227.11 (2) (a) Rule making authority is expressly conferred on an agency as follows: Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation...

Promulgating a rule for approval of pharmacies and physicians to dispense cannabidiol is necessary to provide notice to pharmacies and physicians as to how to obtain approval and to ensure each physician or pharmacy is entitled to the same benefits and obligations as any other physician or pharmacy under the same or similar circumstances. Rule making authority is expressly conferred to interpret the provision of the statutes being administered by the Controlled Substances Board which requires it to approve which pharmacies and physicians may dispense cannabidiol.

**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 :**

Physicians, pharmacies, pharmacists, and patients

**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 :**

The federal government does not have any regulation specific to the designation of pharmacies or physicians for the dispensing of cannabidiol.

**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. There is not likely to be a significant economic impact on small businesses.

**Contact Person:** Sharon Henes, Administrative Rules Coordinator, (608) 261-2377



Authorized Signature

2 June 2017

Date Submitted