REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 26F .0106

DEADLINE FOR RECEIPT: February 9, 2020

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Please format the Rule using 1.5 line spacing as required by 26 NCAC 02C .0108.

Please compare the list in (d) to the list of depressants in 21 CFR 1308.15. I see Brivaracetam, and Pregabalin are covered by the list in G.S. 90-93(a)(4). Were Cenobamate and Lasmiditan intentionally left out of the list in (d)? If you change the Rule, please remember to add "with changes" to the introductory statement after "amended."

G.S. 90-88(d) states the following:

> (d) If any substance is designated, rescheduled or deleted as a controlled substance under federal law, the Commission shall similarly control or cease control of, the substance under this Article unless the Commission objects to such inclusion. The Commission, at its next regularly scheduled meeting that takes place 30 days after publication in the Federal Register of a final order scheduling a substance, shall determine either to adopt a rule to similarly control the substance under this Article or to object to such action. No rule-making notice or hearing as specified by Chapter 150B of the General Statutes is required if the Commission makes a decision to similarly control a substance. However, if the Commission makes a decision to object to adoption of the federal action, it shall initiate rule-making procedures pursuant to Chapter 150B of the General Statutes within 180 days of its decision to object.

Has a "final order" been entered in the Federal Register regarding the proposed deletion of "approved cannabidiol drugs" in (e)? I see where the change was published and went into effect on August 21, 2020 as an "interim final rule" with a request for comments. Has a final rule been published? If not, does an "interim final rule" count as a "final order?"

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: January 26, 2021

10A NCAC 26F .0106 is amended without notice or hearing pursuant to G.S. 90-88(d) as follows:

10A NCAC 26F .0106 SCHEDULE V

(a) Schedule V shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name or brand name designated and listed in either G.S. 90-93 or this Rule. Each drug or substance is set forth below with its corresponding Drug Enforcement Administration (DEA) controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.l5.

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams,
(2) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams,
(3) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams,
(4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit,
(5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams,
(6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers: Pyrovalerone - DEA controlled substances code number 1485.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Lacosamide – DEA controlled substances code number 2746; and
(2) Ezogabine – DEA controlled substances number 2779.

~~(e) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2 [1R 3 methyl 6R (1 methylethenyl) 2 cyclohexen 1 yl] 5 pentyl 1,3 benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols DEA controlled substances code number 7367.~~

History Note: *Authority G.S. 90-88; 90-93; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 2012; February 1, 2010; April 1, 1992; August 1, 1988; December 1, 1987; April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. March 1, 2021; January 1, 2019.