REQUEST FOR TECHNICAL CHANGE

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

RULE CITATION: 10A NCAC 26F .0106

DEADLINE FOR RECEIPT: Friday, December 7, 2018

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 this Rule using 1.5 line spacing. [See Rule 26 NCAC 02C .0108(1)(g)]

In the Introductory Statement, please state "10A NCAC 26F .0106 is amended <u>with changes</u> without notice or hearing pursuant to G.S. 90-88(d) as follows:"

As the agency is using 21 CFR 1308.15 as its lodestar, I wanted to ask – is the exclusion of Brivaracetam and Pregabalin in Paragraph (d) intentional?

In (e), on line 30, delete the (1), as there is no (1) without a (2). Please use Paragraph (c) as the template for this Paragraph.

In the History Note, please insert the amended effective date on a new line. It will look like this:

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; <u>Amended Eff. January 1, 2019.</u>

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

Amanda J. Reeder Commission Counsel Date submitted to agency: November 27, 2018

1 10A NCAC 26F .0106 is proposed for amendment without notice or hearing pursuant to G.S. 90-88(d) as follows: 2 **SCHEDULE V** 3 10A NCAC 26F .0106 4 (a) Schedule V shall consist of the drugs and other substances by whatever official name, common or usual name, 5 chemical name or brand name designated and listed in either G.S. 90-93 or this Rule. Each drug or substance is set forth 6 below with its corresponding Drug Enforcement Administration (DEA) controlled substances code number set forth in 7 the Code of Federal Regulations, Title 21, Section 1308.15. 8 (b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation 9 containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited 10 quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient 11 proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed 12 by narcotic drugs alone: 13 not more than 200 milligrams of codeine per 100 milliliters or per 100 grams, (1)14 not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams, (2)15 (3) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams, 16 (4)not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per 17 dosage unit, 18 not more than 100 milligrams of opium per 100 milliliters or per 100 grams, (5) 19 not more than 0.5 milligrams of difenoxin and not less than 25 micrograms atropine sulfate per dosage (6) 20 unit. 21 (c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, 22 mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central 23 nervous system, including its salts, isomers and salts of isomers: Pyrovalerone - DEA controlled substances code number 24 1485. 25 (d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, 26 mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central 27 nervous system, including its salts: 28 Lacosamide - DEA controlled substances code number 2746; and (1)29 (2)Ezogabine - DEA controlled substances number 2779. 30 (e) Approved cannabidiol drugs. (1) A drug product in finished dosage formulation that has been approved by the U.S. 31 Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols -32 33 DEA controlled substances code number 7367. 34 35 History Note: Authority G.S. 90-88; 90-93; 143B-147; 36 Eff. June 30, 1978; 37 Amended Eff. January 1, 2019; July 1, 2012; February 1, 2010; April 1, 1992; August 1, 1988; 38 December 1, 1987; April 1, 1983;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.