Controlled Substances

Effective date: 10/30/18

Pursuant to the authority vested in the Commissioner of Health by section 3307 of the Public Health Law (PHL), Section 80.3 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective upon filing with the Secretary of State, to read as follows:

Paragraph (b) of Section 80.3 is amended to read as follows:

(b) *Reclassifications.*

(1) The following drugs listed in schedule II(c) of section 3306 of the Public Health Law are hereby reclassified as schedule III substances.

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(2) The following drug classified under schedule I of section 3306 of the Public Health Law is hereby reclassified as a schedule V substance:

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.

Regulatory Impact Statement

Statutory Authority:

The Commissioner of Health is authorized pursuant to Section 3307(5) of the Public Health Law (PHL) to reclassify, by regulation or emergency regulation, any compound, mixture or preparation containing any substance listed as a schedule I substance, to a schedule II, III, IV or V substance, if that same compound, mixture or preparation is redesignated or rescheduled other than under schedule I under the federal Controlled Substance Act, or deleted under the federal Controlled Substances Act.

Legislative Objectives:

Section 3307(5) of the Public Health Law permits the Commissioner to respond quickly and flexibly to actions by the U.S Drug Enforcement Agency (DEA) that reclassify scheduled substances, particularly in circumstances where a new medical use of a scheduled substance has been approved by the U.S. Food and Drug Administration (FDA) and is permitted as a result of the reclassification. The purpose of this statute is to ensure that patients in New York can have access to medication that would otherwise be prohibited under the Public Health Law.

Needs and Benefits:

On September 28, 2018, the DEA issued a final order placing certain drug products that have been approved by the U.S. Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act. Specifically, the order places FDA-approved drugs containing CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. These FDA-approved CBD products have been found to

be effective for the treatment of seizures associated with severe and dangerous forms of epilepsy that are notoriously treatment-resistant. This regulation is necessary to immediately reclassify these products as schedule V substances, allowing patients in New York state to be prescribed these medications as soon as possible.

Costs:

Costs to the Regulated Entity:

The Department of Health (Department) does not anticipate any additional costs to regulated entities.

Costs to Local Government:

This regulation does not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

The Department does not anticipate any additional costs.

Local Government Mandates:

This amendment does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

The department does not anticipate any change in required paperwork by the adoption of this amendment.

Duplication:

No relevant rules or legal requirements of the State government duplicate or conflict with this rule. The amendment reflects federal reclassification of FDA approved cannabidiol substances.

Alternatives:

An alternative to this regulatory amendment would be to not reclassify FDA-approved cannabidiol products as schedule V controlled substances. However, by not reclassifying these FDA approved drugs, patients in New York state would not be able to benefit from these medications.

Federal Standards:

The DEA, on September 28, 2018, reclassified FDA approved cannabidiol products as schedule V substances. This regulatory amendment would reflect that change.

Compliance Schedule:

There is no compliance schedule imposed by these amendments, which shall be effective upon filing with the Secretary of State.

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Statement in Lieu of Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The regulation does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Statement in Lieu of Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

Statement in Lieu of Job Impact Statement

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

Emergency Justification

On September 28, 2018, the Drug Enforcement Administration recently issued a final order placing certain drug products that have been approved by the U.S. Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act. Specifically, the order places FDA-approved drugs containing CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. These FDA-approved CBD products have been found to be effective for the treatment of seizures associated with severe and dangerous forms of epilepsy that are notoriously treatment-resistant. This regulatory amendment is necessary to immediately reclassify these products as schedule V substances. This will allow patients in New York state to be prescribed these medications as soon as possible. Any delay in reclassifying these FDA-approved products containing CBD would limit access to these medications and could put patients at risk.