

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 publication of a Notice of Adoption in the State Register, to read as follows:

Subdivision (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.

TRADE NAME OR OTHER DESIGNATION	COMPOSITION	MANUFACTURER OR SUPPLIER
Mediatric-tablets, capsules and liquid	Tablet and capsule: Conjugated estrogens-equine (Premarin (R)), 0.25 mg.; Methyltestosterone, 2.5 mg.; Ascorbic Acid (Vit. C), 100 mg. (for capsules, provided as ascorbic acid, 70 mg. and as Sodium ascorbate, 30 mg.); Cyanocobalamin, 2.5 mcg.; Thiamine mononitrate, 10.0 mg.; Riboflavin, 5.0 mg.; Niacinamide, 50.0 mg.; Pyridoxine HCl, 3.0 mg.; Calc. panto thenate, 20.0 mg.; Ferrous sulfate exsic., 30.0 mg.; Methamphetamine HCl, 1.0 mg. Liquid: Premarin (R) Conjugated estrogens, (U.S.P.), 0.25 mg.; Methyltestosterone, 2.5 mg.; Thiamine HCl, 5.0 mg.; Cyanocobalamin, 1.5 mcg.; Methamphetamine HCl, 1.0 mg.; Alcohol, 15%.	Ayerst
Phelantin-Kapseals	Phenobarbital (1/2 gr) 30 mg.; Dilantin (Diphenyl-hydantoin) (1-1/2 gr) 100 mg.; Methamphetamine Hydrochloride 2.5 mg.	Parke-Davis

[(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 Administration 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 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:

In May 2019, the Commissioner reclassified as a Schedule V controlled 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 0.10 percent (w/w) residual tetrahydrocannabinols.” This was in response to the U.S. Drug Enforcement

Administration issuing a final order placing certain drug products that have been approved by the U.S. Food and Drug Administration and which contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V of the Controlled Substances Act.

On January 23, 2020, Governor Andrew Cuomo signed into law Chapter One of the Laws of 2020 which, in part, amends the Public Health Law § 3302(21) definition of “marihuana” to specifically exclude, among other things, “hemp”, “cannabinoid hemp”, and “hemp extract” as those terms are defined in Agriculture & Markets Law § 505(1) and Public Health Law § 3398(2), and (5), respectively. Agriculture & Markets Law § 505(1) defines “hemp” as follows:

"Hemp" means the plant *Cannabis sativa* L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of a percent on a dry weight basis.

Public Health Law § 3398(2) defines “cannabinoid hemp” as follows:

"Cannabinoid hemp" means any hemp and any product processed or derived from hemp, that is used for human consumption provided that when such product is packaged or offered for retail sale to a consumer, it shall not have a concentration of more than three tenths of a percent delta-9 tetrahydrocannabinol.

Public Health Law § 3398(5) defines “hemp extract” as follows:

"Hemp extract" means all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers derived from hemp, used or intended for human consumption, for its cannabinoid content, with a delta-9 tetrahydrocannabinol concentration of not more than an amount determined by the department in regulation. For the purpose of this article, hemp extract excludes (a) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or (b) any hemp extract that is not used for human consumption. Such excluded substances shall not be regulated pursuant to the provisions of this article but are subject to other provisions of applicable state law, rules and regulations.

This new legislation, therefore, supersedes 10 NYCRR § 80.3's reclassification of "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" as a Schedule V controlled substance. Hence, under New York State law, it is no longer a controlled substance.

On March 20, 2020, U.S. Drug Enforcement Administration confirmed that the drug that goes by the trade name Epidiolex has been federally descheduled and that it is no longer subject to the Federal Controlled Substances Act. Additionally, the U.S. Drug Enforcement Administration also confirmed that if the drug's active pharmaceutical ingredient is cannabis-derived material (to include hemp) that contains no more than 0.3% delta-9-THC on a dry weight basis, that material would also not be considered a controlled substance.

As a result of the New York State legislation and the Federal descheduling action, “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” is not a controlled substance under either New York State or Federal law. Removal of the applicable section of 10 NYCRR 80.3 renders it consistent with controlling New York State law, and Federal law.

Costs:

Costs to the Regulated Entity:

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

Costs to State and Local Government:

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

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 leave a superseded and contradictory regulation in place. By not removing it, however, health care practitioners would be confused by the direct conflict between state statute and contradictory state regulation, their prescribing practices might be curtailed, and patients in New York state would face additional administrative burdens to access from these medications. Leaving the regulation in place would also create greater confusion among law enforcement agencies as they attempt to determine which rules apply to applicable substances.

Federal Standards:

In April 2020, the U.S. Drug Enforcement Administration removed U.S. Food and Drug Administration approved cannabidiol products from the federal schedule of controlled substances. This regulatory amendment is consistent with that change.

Compliance Schedule:

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a Notice of Adoption in the State Register.

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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

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.