

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 225 of the Public Health Law, section 9.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon filing with the Department of State.

Subdivision (b) of section 9.1 is amended as follows:

(b) Synthetic Cannabinoid means any manufactured chemical compound that is a cannabinoid receptor agonist and includes, but is not limited to any material, compound, mixture, or preparation that is not listed as a controlled substance in Schedules I through V of § 3306 of the Public Health Law, and not approved by the federal Food and Drug Administration (FDA), and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analog), and salts of isomers and homologues (analog), unless specifically exempted, whenever the existence of these salts, isomers, homologues (analog), and salts of isomers and homologues (analog) is possible within the specific chemical designation:

(1) Naphthoylindoles. Any compound containing a 3-(1-Naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidiny)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH 007, JWH 015, JWH 018, JWH 019, JWH 073, JWH 081, JWH 98, JWH 122, JWH 164, JWH 200, JWH 210, JWH 398, AM 2201, MAM 2201, EAM 2201 and WIN 55 212.)

(2) Naphthylmethylindeles. Any compound containing a 1 H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH-175, and JWH-184.)

(3) Naphthoylpyrroles. Any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH 307.)

(4) Naphthylmethylindenes. Any compound containing a naphthylmethyl indenenes structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH-176.)

(5) Phenylacetylindeles. Any compound containing a 3-phenylacetylindele structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any

extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: RCS-8 (SR-18), JWH 201, JWH 250, JWH 203, JWH-251, and JWH-302.)

(6) Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. (Other names in this structural class include but are not limited to: CP 47,497 (and homologues (analog)), cannabicyclohexanol, and CP 55,940.)

(7) Benzoylindoles. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: AM 694, Pravadoline (WIN 48,098), RCS 4, AM-2233 and AM-679.)

(8) [2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-de]-1, 4-benzoxazin-6-yl]-1-naphthalenylmethanone. (Other names in this structural class include but are not limited to: WIN 55,212-2.)

(9) (6aR,10aR)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo[c]chromen-1-ol. (Other names in this structural class include but are not limited to: HU-210.)

(10) (6aS, 10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo{c}chromen-1-ol (Dezanabinol or HU-211)

(11) Adamantoylindoles. Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the adamantyl ring system to any extent. (Other names in this structural class include but are not limited to: AM-1248.)

(12) Adamantoylindazoles including but not limited to Adamantyl Carboxamide Indazoles. Any compound containing a 3-(1-adamantoyl)indazole structure with substitution at the nitrogen atom of the indazole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the adamantyl ring system to any extent. (Other names in this structural class include but are not limited to: AKB-48, MAB-CHMINACA, 5F-AKB-48.)

(13) Tetramethylcyclopropylcarbonylindoles or any compound structurally derived from 3-(2,2,3,3-tetramethylcyclopropylcarbonyl) indole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent, including without limitation the following: UR-11, XLR-11, A-796,260.

(14) Any other synthetic chemical compound that is a cannabinoid receptor agonist that is not listed in Schedules I through V of § 3306 of the Public Health Law, or is not an FDA approved drug.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC) subject to the approval of the Commissioner of Health. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

Legislative Objectives:

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. Accordingly, PHHPC has issued 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. This amendment would add additional chemicals to the list of explicitly prohibited synthetic cannabinoids.

Needs and Benefits:

“Synthetic cannabinoids” encompass a wide variety of chemicals that are designed to stimulate the same receptor in the body as cannabinoid 9-tetrahydrocannabinol (THC). However, they cause additional side effects that mimic other controlled substances and have been linked to severe adverse reactions, including death and acute renal failure. Reported side effects include: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities;

seizures; and syncope (loss of consciousness). Additional signs and symptoms of synthetic cannabinoids include: anxiety; tremor; hallucinations; and violent behavior. These effects can be similar to those of phencyclidine (PCP). It has been reported that some recent patients have presented with both somnolence (drowsiness) and bradycardia (decreased heart rate), some requiring endotracheal intubation.

Synthetic cannabinoids are frequently applied to plant materials and then packaged as incense, herbal mixtures or potpourri. They often carry a “not for human consumption” label, and are not approved for medical use in the United States. Products containing synthetic cannabinoids are, in actuality, consumed by individuals, most often by smoking, either through a pipe, a water pipe, or rolled in cigarette papers.

Products containing synthetic cannabinoids have become prevalent drugs of abuse. In 2012, before 10 NYCRR Part 9 was promulgated, calls to New York State Poison Control Centers relating to the consumption of synthetic cannabinoids had increased dramatically. Over half of the calls to the Upstate Poison Control Center in 2011 involved children under the age of 19, which was consistent with the results of a 2011 “Monitoring the Future” national survey of youth drug-use trends that showed that 11.4% of 12th graders used a synthetic cannabinoid during the twelve months prior to the survey, making it the second most commonly used illicit drug among high school seniors at the time.

In 2012, the Department issued 10 NYCRR Part 9, which addressed this emergent threat to public health by prohibiting the possession, manufacture, distribution, sale or offer of synthetic cannabinoids and other substances. Thereafter, New York State experienced a substantial decrease in reported cases of adverse health effects related to synthetic cannabinoid use, an achievement that was sustained until the early part of this year.

Recently, however, New York State experienced a dramatic increase in synthetic cannabinoid-related adverse events and emergency department visits. During April 1 to June 30, New York State has seen more than 1,900 emergency department visits and 680 poison control center calls due to reports of adverse health effects associated with synthetic cannabinoid use. This represents more than a tenfold increase over the same time period in 2014, when there was more than 150 emergency department visits and 50 poison control center calls reported. Nationally, there have been 15 synthetic cannabinoid-related deaths reported to poison control centers during from January to May of 2015. In New York, no fatalities have been reported to date, although there has been a 44% increase in the proportion of patients being admitted to critical care units from April 6 to June 30, 2015 when compared to the proportion of patients admitted to the critical care unit from Jan 1, 2011 to April 5, 2015. Calls received by poison control centers generally reflect only a small percentage of actual instances of poisoning.

Testing has identified synthetic cannabinoids that were not known to the Department in 2012, when 10 NYCRR Part 9 was first issued, and that are associated with the recent increase in cannabinoid-related adverse events and emergency department visits. Identifying these new synthetic cannabinoids in the regulation will simplify and enhance the efforts of local governments to control these dangerous chemicals.

Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

There will be no additional cost to State Government. Local governments are already enforcing 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. The addition of these chemicals is expected to have negligible cost on local enforcement programs.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. PHL § 228. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Paperwork:

The regulation imposes no new reporting or filing requirements.

Duplication:

The federal Synthetic Drug Abuse Prevention Act of 2012 banned the sale and distribution of products containing the synthetic cannabinoids identified in this regulation, by placing them on the federal schedule I list of substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]). This regulation does not conflict with or duplicate that federal law, because it provides local enforcement authority, which the federal law does not provide.

Alternatives:

The Department considered relying on the existing regulation to address these recently identified synthetic cannabinoids. However, the Department determined that amending the regulation to explicitly identify these substances would enhance state and local enforcement authority and more effectively address this public health threat.

Federal Standards:

As noted above, the Synthetic Drug Abuse Prevention Act of 2012 places synthetic cannabinoids on the federal schedule I list of substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]). This regulation does not conflict with or duplicate that federal law, because it provides local enforcement authority, which the federal law does not provide.

Compliance Schedule:

Regulated parties should be able to comply with these regulations effective upon filing with the Secretary of State.

Contact Person:

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect only the small businesses that are engaged in selling products containing synthetic cannabinoids. The Department does not have information concerning the number of small businesses that currently sell these products. However, in 2011 and 2012, Commissioner's Orders were issued banning certain synthetic phenethylamines and synthetic cannabinoids, resulting in approximately 8,000 establishments being served with one or both Orders by public health authorities. Banned product was found in 286 of these locations. Subsequent to these efforts, the number of related complaints dropped significantly.

This regulation affects local governments by establishing a minimum standard regarding the possession, manufacture, distribution, sale or offer of sale of additional synthetic cannabinoids. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including Part 9, utilizing any civil and criminal remedies that may be available. PHL §§ 228, 229, 309(1)(f) and 324(e). Local governments are also empowered to establish a local sanitary code that is more restrictive than the State Sanitary Code.

Compliance Requirements:

Small businesses must comply by not engaging in any possession, manufacturing, distribution, sale, or offer of sale of the additional synthetic cannabinoids.

Local governments must comply by enforcing the State Sanitary Code. Local boards of health may impose civil penalties for a violation of this regulation of up to \$2,000 per violation, pursuant to PHL § 309(1)(f). Pursuant to PHL § 229, local law enforcement may seek criminal penalties for a first offense of up to \$250 and 15 days in prison, and for each subsequent offense

up to \$500 and 15 days in prison.

Professional Services:

Small businesses will need no additional professional services to comply. Local governments, in certain instances where local governments enforce, will need to secure laboratory services for testing of substances.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

There will be no additional cost to State Government. Local governments are already enforcing 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. The addition of these chemicals is expected to have negligible cost on local enforcement programs.

Economic and Technological Feasibility:

Although there will be an impact on small businesses that sell these products, the prohibition is justified by the extremely dangerous nature of these products.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing

consultation, coordination and information and updates on its website.

Small Business and Local Government Participation:

The Department will work with local governments to provide technical information concerning the newly-listed synthetic cannabinoids.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by these substances, the risk that some small businesses will not comply with regulations and continue to make or sell or distribute the substance justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

The Department of Health does not expect there to be a positive or negative impact on jobs or employment opportunities.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the amended rule.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employment opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

Emergency Justification

“Synthetic cannabinoids” encompass a wide variety of chemicals that are designed to stimulate the same receptor in the body as cannabinoid 9-tetrahydrocannabinol (THC). However, they cause additional side effects that mimic other controlled substances and have been linked to severe adverse reactions, including death and acute renal failure. Reported side effects include: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte abnormalities; seizures; and syncope (loss of consciousness). Additional signs and symptoms of synthetic cannabinoids include: anxiety; tremor; hallucinations; and violent behavior. These effects can be similar to those of phencyclidine (PCP). It has been reported that some recent patients are also presenting with both somnolence (drowsiness) and bradycardia (decreased heart rate), some requiring endotracheal intubation.

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during the twelve months prior to the survey, making it the second most commonly used illicit drug among high school seniors at that time.

In 2012, the Department issued 10 NYCRR Part 9, which addressed this emergent threat to public health by prohibiting the possession, manufacture, distribution, sale or offer of specified synthetic cannabinoids and other substances. Thereafter, New York State experienced a substantial decrease in reported cases of adverse health effects related to synthetic cannabinoid use, an achievement that was sustained until the early part of this year.

Recently, however, New York State experienced a dramatic increase in synthetic cannabinoid-related adverse events and emergency department visits. During April 1 to June 30, New York State has seen more than 1,900 emergency department visits and 680 poison control center calls due to reports of adverse health effects associated with synthetic cannabinoid use. This represents more than a tenfold increase over the same time period in 2014, when there was more than 150 emergency department visits and 50 poison control center calls reported. Nationally, there have been 15 synthetic cannabinoid-related deaths reported to poison control centers during from January to May of 2015. In New York, no fatalities have been reported to date, although there has been a 44% increase in the proportion of patients being admitted to critical care units from April 6 to June 30, 2015 when compared to the proportion of patients admitted to the critical care unit from Jan 1, 2011 to April 5, 2015. Calls received by poison control centers generally reflect only a small percentage of actual instances of poisoning.

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governments to control these dangerous chemicals.

Because synthetic cannabinoids continue to be an urgent public health issue, and because the Department has learned of additional specific synthetic cannabinoids since the regulation was first promulgated, the Commissioner of Health and the Public Health and Health Planning Council have determined it necessary to file these regulations on an emergency basis. Public Health Law § 225, in conjunction with State Administrative Procedure Act § 202(6), empowers the Council and the Commissioner to adopt emergency regulations when necessary for the preservation of the public health, safety or general welfare and that compliance with routine administrative procedures would be contrary to the public interest.