

Synthetic Phenethylamines and Synthetic Cannabinoids (SP & SC) Prohibited

Effective date: 1/2/13

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, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Part 9, to be effective upon publication of a Notice of Adoption in the New York State Register.

A new Part 9 is added to read as follows:

Part 9

Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited

Sec.

9.1 Definitions

9.2 Possession, Manufacture, Distribution, Sale or Offer of Sale of Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited

9.3 Exemptions

9.4 Penalties

9.5 Commissioner's Order

9.6 Severability

§ 9.1 Definitions.

(a) Synthetic Phenethylamine means any of the following chemical compounds, that are not listed as a controlled substance in Schedules I through V of § 3306 of the Public Health Law, and are not approved by the federal Food and Drug Administration ("FDA"):

3,4-Methylenedioxyethcathinone (Methylone);
4-Methoxyethcathinone;
3-Fluoroethcathinone;
4-Fluoroethcathinone;
Ethylpropion (Ethcathinone);
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P); and
any compound that has a chemical structure that is substantially
similar to these compounds.

(b) Synthetic Cannabinoid means any 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 (analogs), and salts of isomers and homologues (analogs), unless specifically exempted, whenever the existence of these salts, isomers, homologues (analogs), and salts of

isomers and homologues (analogs) is possible within the specific chemical designation:

- i) 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-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 015, JWH 018, JWH 019, JWH 073, JWH 081, JWH 122, JWH 200, JWH 210, JWH 398, AM 2201, and WIN 55 212).
- ii) Naphthylmethylinindoles. 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).
- iii) 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).
- iv) 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).

v) Phenylacetylindoles. Any compound containing a 3-phenylacetylindole 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 250, JWH 203, JWH-251, and JWH-302).

vi) 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 (analogs)), cannabicyclohexanol, and CP 55,940).

vii) 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, and AM-679).

viii) [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).

ix) (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).

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

xi) 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).

xii) 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.

(c) Possession means to have physical possession or otherwise to exercise dominion or control over synthetic phenethylamine or synthetic cannabinoid, or a product containing the same. For purposes of this definition, among other circumstances not limited to these examples, the

following individuals and/or entities shall be deemed to possess synthetic phenethylamine or synthetic cannabinoid, or a product containing the same:

- (1) any individual or entity that has an ownership interest in a retail, distribution or manufacturing establishment that possesses, distributes, sells or offers for sale a synthetic phenethylamine or synthetic cannabinoid, or a product containing the same; and
- (2) any clerk, cashier or other employee or staff of a retail establishment, which establishment possesses, distributes, sells or offers for sale a synthetic phenethylamine or synthetic cannabinoid, or a product containing the same, who interacts with customers or other members of the public.

§ 9.2 Possession, Manufacture, Distribution, Sale or Offer of Sale of Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited. It shall be unlawful for any individual or entity to possess, manufacture, distribute, sell or offer to sell any synthetic phenethylamine or synthetic cannabinoid or product containing the same, except as expressly exempted by this Part.

§ 9.3 Exemptions. The provisions of this Part prohibiting the possession of any synthetic phenethylamine or synthetic cannabinoid, or product containing the same shall not apply to:

- (a) public officers or their employees in the lawful performance of their official duties requiring possession of synthetic phenethylamines or synthetic cannabinoids, or products containing the same;
- (b) temporary or incidental possession by employees or agents of persons lawfully entitled to possession, or persons whose possession is for the purpose of aiding public officers in performing their official duties;

- (c) a person in the employ of the United States government or of any state, territory, district, county, municipal or insular government, obtaining or possessing synthetic phenethylamines or synthetic cannabinoids, or products containing the same, by reason of his or her official duties;
- (d) common carriers or warehousemen, while engaged in lawfully transporting or storing synthetic phenethylamines or synthetic cannabinoids, or products containing the same, or to any employee of the same within the scope of his or her employment;
- (e) laboratories with a federal Drug Enforcement Administration (“DEA”) license to purchase and use schedule I controlled substances for research and/or analytical testing; and
- (f) manufacturers that are registered with the DEA to synthesize and distribute controlled substances.

§ 9.4 Penalties. A violation of any provision of this Part is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each packet, individual container or other separate unit of synthetic phenethylamine or synthetic cannabinoid, or product containing the same, that is possessed, manufactured, distributed, sold, or offered for sale, shall constitute a separate violation under this Part.

§ 9.5 Commissioner’s Order. The Commissioner has authority to issue orders to address dangers to the health of the people as set forth in Public Health Law § 16. The Commissioner can exercise such authority to address a violation of this Part if, in his or her opinion, such a danger exists. It is hereby recognized that, dependent upon the opinion and discretion of the Commissioner as applied to each circumstance, he or she may issue such an order in the event of a continuing or repeat violation of this Part at or by a retail establishment when the entity and/or

its owner(s) or employee(s) knew or should have known of the violation. As determined by the Commissioner, such an order could require the closure of the retail establishment, among other relief. Although not required, this section serves as notice that such an order could be issued. The circumstances and relief described in this notice are only examples and in no way bind the Commissioner or limit his or her authority to issue such an order, or the relief set forth in such an order, under any circumstance whatsoever.

§ 9.6 Severability. If any provisions of this Part or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Part or the application thereof to other persons, entities, and circumstances.

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:

This rulemaking is in accordance with the legislative objective of PHL Section 225(4) authorizing the 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. Specifically, this regulation prohibits the possession, manufacture, distribution, sale or offer of sale of substances and products containing synthetic phenethylamines and synthetic cannabinoids, chemical compounds which are causing serious adverse health outcomes and particularly affecting New York State teenagers and young adults.

Needs and Benefits:

This regulation pertains to synthetic phenethylamines that are commonly packaged and marketed online, in convenience stores, gas stations and smoke shops as “bath salts,” plant food and other ordinary household goods, and which are not approved by the federal Food and Drug Administration (“FDA”). The compounds stimulate the body’s central nervous system, and cause effects similar to those caused by cocaine and amphetamines, including but not limited to increased heart rate and blood pressure, hallucinations, paranoia, suicidal thoughts, violent behavior, nausea and vomiting. Some synthetic phenethylamines are also commonly referred to

as “designer drugs” because they are specifically synthesized with a similar, but slightly modified structure of a Schedule I controlled substance in order to avoid existing drug laws, and can be continually chemically modified to avoid legal repercussions, while maintaining their intended effects and usages. Certain synthetic phenethylamines are prevalent drugs of abuse.

From January 2011 through April 2012, poison control centers throughout the United States have received over 7,000 calls regarding instances of poisoning from products containing synthetic phenethylamines, including instances resulting in accidental death and suicide. Calls received by poison control centers generally reflect only a small percentage of actual instances of poisoning, and many additional New York residents are likely to have been harmed as a result of using products containing synthetic phenethylamines. In addition, between January 1, 2011 and August 2, 2012, there were approximately 230 emergency department visits in New York (not including New York City) in which effects from consuming a product with synthetic phenethylamines or “bath salts” were the patient’s chief complaint. One hundred twenty of these visits occurred in June and July, 2012, indicating that usage of these substances is increasing at a remarkable rate.

Poison control center experts, who have first-hand knowledge of the devastation that synthetic phenethylamines wreak on individuals and their families, say these substances are among the worst they have ever seen. They report that people high on these compounds can get very agitated and violent, exhibit psychosis and severe behavior changes, and have harmed themselves and others. Some have been admitted to psychiatric hospitals and have experienced continued neurological and psychological effects.

“Synthetic cannabinoids” encompass a wide variety of chemicals that are synthesized and marketed to mimic the action of the cannabinoid 9-tetrahydrocannabinol (THC). Synthetic

cannabinoids have been linked to severe adverse reactions, including death and acute renal failure, and 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).

Synthetic cannabinoids are frequently applied to plant materials and then packaged and marketed online and in convenience stores, gas stations and smoke shops 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, produced, distributed, marketed and sold, as a supposed “legal alternative” to marijuana and for the purpose of being consumed by an individual, 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, especially among teens and young adults. Calls to New York State Poison Control centers relating to the consumption of synthetic cannabinoids have increased dramatically, with a total of 105 reported incidents of exposure to these substances since 2011, compared to four reported instances in 2009 and 2010. Over half of the calls to the Upstate Poison Control Center this year involved children under the age of 19, which is 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. Nationally, poison control centers have received over 10,000 calls relating to exposure to these substances from January 2011 to June 2012. Calls received by poison control centers generally reflect only a small percentage of actual

instances of poisoning. Therefore, it is clear that many additional New York residents have been harmed as a result of using products containing synthetic cannabinoids.

On May 20, 2011, pursuant to Public Health Law § 16, the Commissioner issued an Order for Summary Action that, among other things, prohibited the sale or distribution of bath salts. Thereafter, on March 28, 2012, pursuant to Public Health Law § 16, the Commissioner issued an Order for Summary Action that, among other things, prohibited the sale or distribution of synthetic cannabinoids. However, abuse of synthetic phenethylamines and synthetic cannabinoids has escalated in New York State, and stronger measures therefore are required to protect the public from the dangerous effects of these substances.

Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law. Costs will be offset further by a reduction in occasions needing emergency response and/or law enforcement involvement, as well as a reduction in health care and other State and local resources currently being used to respond to and address the negative effects of usage of the substances at issue.

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 this new Part, 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:

On May 20, 2011, the Commissioner of Health of the State of New York issued an Order for Summary Action banning the sale and distribution of certain products containing synthetic cathinone (a category of phenethylamines). On March 28, 2012, the Commissioner of Health of the State of New York issued an Order for Summary Action banning the sale and distribution of products containing synthetic cannabinoids. These Commissioner's Orders, unlike this regulation, are not enforceable by local governments or criminal authorities, and the sole enforcement mechanism for violations of the Order is a civil enforcement proceeding for an injunction and civil penalties through the State Attorney General. In addition, the Commissioner's Orders do not prohibit possession or manufacture of some synthetic phenethylamines and/or synthetic cannabinoids. Further, the Commissioner's Orders are only binding on and enforceable against those individuals and entities who received personal service of the Commissioner's Orders.

On July 9, 2012 President Barack Obama signed a Bill (S.3187) into law which, in relevant part, enacted the federal Synthetic Drug Abuse Prevention Act of 2012. The law banned the sale and distribution of products containing most of the types of synthetic phenethylamines and 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 because the federal law does not provide for state and local authority enforcement.

Alternatives:

The alternative of continued sole reliance on the May 20, 2011 and March 28, 2012 Commissioner's Orders was considered. Promulgating this regulation, however, was decided upon in order to provide enhanced enforcement authority and regulatory authority for state and local governments to more effectively address this emergent and expanding public health threat.

Federal Standards:

The New York regulation is broader than the recent federal Synthetic Drug Abuse Prevention Act of 2012 in that it covers additional classes of stimulant compounds. Further, it anticipates future synthesis of stimulant compounds not yet developed, specifically cannabinoid receptor agonists. Analysis methodologies will need to be developed as additional related compounds are synthesized.

Compliance Schedule:

Regulated parties should be able to comply with these regulations effective upon publication of a Notice of Adoption in the New York State Register.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The rule will affect only the small businesses which are engaged in selling products containing certain harmful substances known as synthetic phenethylamines and synthetic cannabinoids. At this time, it is not possible to determine the number of small businesses that sell these products. However, in 2011 and 2012, Commissioner's Orders were issued banning certain synthetic phenethylamines and synthetic cannabinoids and resulted in approximately 7,000 establishments being served with one or both of such Orders by public health authorities.

This regulation affects local governments by establishing a minimum standard regarding the possession, manufacture, distribution, sale or offer of sale of synthetic phenethylamines and synthetic cannabinoids. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including this new Part, utilizing any civil and criminal remedies that may be available. PHL §§ 228, 229, 309(1)(f) and 324(e).

Pursuant to PHL § 228, the State Sanitary Code establishes a minimum standard for health and sanitation. Under that same authority, local governments are empowered to establish a local sanitary code that is more restrictive than the State Sanitary Code. Many local governments already have local sanitary codes that are 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 synthetic phenethylamines and 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:

Any enforcement costs incurred by State and local governments cannot be predicted, but are likely to be offset by fines and penalties imposed pursuant to Public Health Law. Moreover, any such costs will be further offset by a reduction in emergency responder, law enforcement, health care and other State and local resources currently being used to respond to and address the negative effects of usage of the prohibited substances.

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.

Although the costs of local enforcement are not precisely known at this time, the benefits to public health are anticipated to outweigh any such costs. Regarding technical feasibility, as new designer drugs become available, new tests will need to be developed.

This regulation is necessary to protect public health. It is as narrowly tailored as possible

while still addressing the public health threat.

Minimizing Adverse Impact:

The New York State Department of Health will assist local government, e.g. consultation, coordination and providing information and updates on its website.

Small Business and Local Government Participation:

Local governments are aware of and have been involved in notifying certain small businesses regarding prior Commissioner's Orders on this same matter.

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 employments opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.