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Donna Little REGULATIONS COMPILER

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Inspector General

3 Division of Audits and Investigations

4 (Amendment)

5 902 KAR 55:015. Schedule I substances.

6 RELATES TO: KRS 218A.010-218A.050, 21 C.F.R. 1308.11

7 STATUTORY AUTHORITY: KRS 194.050, 218A.020, 218A.040, 218A.250

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020 authorizes the

9 Cabinet for Health and Family Services [~~Human Resources~~] to add substances to or
10 delete or reschedule substances enumerated in KRS Chapter 218A. After considering the
11 criteria set forth in KRS 218A.020 and 218A.040 and applicable federal regulations, the
12 Cabinet for Health and Family Services [~~Human Resources~~] designates the substances
13 set forth in this administrative regulation as Schedule I controlled substances. This
14 emergency administrative regulation differs from the federal regulation because it
15 designates substances that are substantially similar to synthetic cannabinoids as
16 Schedule I controlled substances. The Cabinet for Health and Family Services
17 recognizes that synthetic cannabinoids have significant abuse potential and inclusion on
18 Kentucky's Schedule I list will help reduce the risk to public health.

19 Section 1. Opiates. The Cabinet for Health and Family Services [~~Human Resources~~]
20 hereby designates as Schedule I controlled substances, in addition to those specified by
21 KRS 218A.050, any of the following opiates, including their isomers, optical isomers,

- 1 esters, ethers, salts, salts of isomers, esters, and ethers, unless specifically excepted,
2 whenever the existence of these isomers, esters, ethers, and salts is possible within the
3 specific chemical designation:
- 4 (1) Alphacetylmethadol (except Levo-alphacetylmethadol LAAM);
 - 5 (2) Acetyl-alpha-methylfentanyl, N-1-(1-methyl-2-phenethyl)-4-piperidiny -N-
6 phenylacetamide;
 - 7 (3) Alpha-methylfentanyl, N-1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl
8 propionanilide, 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);
 - 9 (4) Alpha-methylthiofentanyl, N-1-methyl-2-(2-thienyl) ethyl-4-piperidiny-N-
10 phenylpropanamide;
 - 11 (5) Benzylfentanyl, N-1-benzyl-4-piperidyl-N-phenylpropanamide;
 - 12 (6) Beta-hydroxyfentanyl, N-1-(2-hydroxy-2-phenethyl)-4-piperidiny-N-
13 phenylpropanamide;
 - 14 (7) Beta-hydroxy-3-methylfentanyl, N-1-(2-hydroxy-2phenethyl)-3-methyl-4-piperidiny-
15 N-phenylpropanamide;
 - 16 (8) DifenoXin;
 - 17 (9) 3-Methylfentanyl, N-3-methyl-1-(2-phenylethyl)-4-piperidyl-N-phenylpropanamide;
 - 18 (10) 3-methylthiofentanyl N-3-methyl-1-(2-thienyl) ethyl-4-piperidiny-N-
19 phenylpropanamide;
 - 20 (11) 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP);
 - 21 (12) Para-fluorofentanyl, (N-(4-fluorophenyl)-N-1-(2-phenethyl)-4-
22 piperidiny)propanamide;
 - 23 (13) 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);

- 1 (14) Thenylfentanyl, N-1-(2-thienyl) methyl-4-piperidyl-N-phenyl-propanamide;
2 (15) Thiofentanyl N-phenyl-N-1-(2-thienyl)ethyl-4-piperidinypropan-amide; and
3 (16) Tilidine.

4 Section 2. Opium Derivatives. The Cabinet for Health and Family Services [~~Human~~
5 ~~Resources~~] hereby designates as Schedule I controlled substances, in addition to those
6 specified by KRS 218A.050, any of the following opium derivatives, their salts, optical
7 isomers, isomers and salts of isomers, unless specifically excepted, whenever the
8 existence of these salts, isomers, optical isomers, and salts of isomers is possible within
9 the specific chemical designation:

- 10 (1) Drotebanol; and
11 (2) Etorphine (except hydrochloride salt).

12 Section 3. Hallucinogenic Substances. The Cabinet for Health and Family Services
13 [~~Human Resources~~] hereby designates as Schedule I controlled substances, in addition
14 to those specified by KRS 218A.050, any material, compound, mixture, or preparation
15 which contains any quantity of the following hallucinogenic substances, their salts,
16 isomers and salts of isomers, unless specifically excepted, whenever the existence of
17 these salts, isomers, and salts of isomers is possible within the specific chemical
18 designation (for purpose of this paragraph only, the term "isomer" includes the optical
19 position and geometric isomers):

- 20 (1) alpha-ethyltryptamine (alpha-ethyl-1H-indole-3-ethanamine,3-(2-
21 aminobutyl)indole);
22 (2) 4-bromo-2, 5-dimethoxy-amphetamine (4-bromo-2,5-DMA,4-bromo-2,5-
23 dimethoxy-alpha-methylphenethylamine);

- 1 (3) 2,5-dimethoxyamphetamine (2,5-DMA);
- 2 (4) 2,5-dimethoxy-4-ethylamphetamine (DOET);
- 3 (5) Ethylamine analog of phencyclidine (N-ethyl-1-phenylcyclohexylamine,
- 4 cyclohexamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine,
- 5 PCE);
- 6 (6) 3,4-methylenedioxyamphetamine (MDMA);
- 7 (7) 4-methoxyamphetamine (PMA, 4-methoxy-alpha-methylphen-ethylamine,
- 8 paramethoxyamphetamine);
- 9 (8) 3,4-methylenedioxy-N-ethylamphetamine (N-ethyl-alpha-methyl-
- 10 3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);
- 11 (9) N-hydroxy-3,4-methylenedioxyamphetamine (N-hydroxy-alpha-methyl-
- 12 3,4(methylenedioxy)phenethylamine, N-hydroxy MDA);
- 13 (10) Parahexyl (Synhexyl, 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-
- 14 6H-dibenzo b,d pyran);
- 15 (11) Pyrrolidine analog of phencyclidine (1-(1-phenylcyclohexyl)-pyrrolidine, PCPy,
- 16 PHP);
- 17 (12) Thiophene analog of phencyclidine (1-(1-(2-thienyl)cyclo-hexyl)piperidine, TCP,
- 18 TPCP); and
- 19 (13) 1-1-(2-thienyl) cyclohexylpyrrolidine (TCPy).

20 Section 4. Depressants. The Cabinet for Health and Family Services [Human
21 Resources] hereby designates as Schedule I controlled substances, in addition to those
22 specified by KRS 218A.050, any material, compound, mixture, or preparation which
23 contains any quantity of the following substances having a depressant effect on the

1 central nervous system, including their salts, isomers, and salts of isomers whenever the
2 existence of such salts, isomers, and salts of isomers is possible within the specific
3 chemical designation:

4 (1) Mecloqualone; and

5 (2) Methaqualone.

6 Section 5. Stimulants. The Cabinet for Health and Family Services [Human
7 Resources] hereby designates as Schedule I controlled substances, in addition to those
8 specified by KRS 218A.050, any material, compound, mixture, or preparation which
9 contains any quantity of the following substances having a stimulant effect on the central
10 nervous system, including their salts, isomers, and salts of isomers whenever the
11 existence of such salts, isomers, and salts of isomers is possible within the specific
12 chemical designation:

13 (1) Aminorex (aminoxaphen, 2-amino-5-phenyl-2-oxazoline, 4,5-dihydro-5-phenyl-2-
14 oxazolamine);

15 (2) Cathinone (2-amino-1-phenyl-1-propanone, alpha-aminopro-piophenone, 2-
16 aminopropiophenone, and norephedrone;

17 (3) (±) cis-4-methylaminorex ((±) cis-4,5-dihydro-4methyl-5-phenyl-2-oxazolamine);

18 (4) N,N-dimethylamphetamine (N,N-alpha-trimethyl-benzeneetha-namine, N,N,alpha-
19 trimethylphenethylamine), its salts, optical isomers and salts of optical isomers;

20 (5) N-ethylamphetamine;

21 (6) Fenethylamine; and

22 (7) Methcathinone (2-(methylamino)-propiofenone, alpha (methylamino)-
23 propiofenone, alpha (methylamino)-propiofenone, 2-(methylamino)-1-phenylpropan-1-

1 one, alpha-N-methylaminopropiophenone, monomethylpropion, ephedrone, N-
2 methylcathinone, methylcathinone, AL-464, AL-422, AL-463 and UR1431) its salts,
3 optical isomers and salts of optical isomers.

4 Section 6. Synthetic Cannabinoids. The Cabinet for Health and Family Services
5 hereby designates as Schedule I controlled substances, in addition to those specified by
6 KRS 218A.050, any substance, compound, mixture, or preparation which contains any
7 quantity of any synthetic cannabinoid and is not an FDA approved drug, including the
8 following:

9 (1) (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

10 (2) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-
11 11);

12 (3) 2-(2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5H-NBOMe);

13 (4) 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5K-
14 NBOMe);

15 (5) 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5B-
16 NBOMe); and

17 (6) 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2,5C-
18 NBOMe).

902 KAR 55:015

Mary Reine Begley 12/4/2012
Date
Mary Reine Begley
Inspector General
Office of Inspector General

APPROVED:

Audrey Tayse Haynes 12/12/12
Date
Audrey Tayse Haynes
Secretary

PUBLIC HEARING AND PUBIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on February 21, 2013, at 9:00 a.m. in Auditorium A, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by February 14, 2013, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business February 28, 2013. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 902 KAR 55:015
Contact Person: Mary Reinle Begley, Inspector General
Stephanie Brammer-Barnes, Internal Policy Analyst
Office of Inspector General
502-564-2888

(1) Provide a brief summary of:

(a) What this administrative regulation does: The substances set forth in this administrative regulation are designated as Schedule I controlled substances.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 218A.020.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 218A.020 mandates that the Cabinet for Health and Family Services add, delete, or reschedule substances enumerated in the schedules set forth in KRS Chapter 218A. This administrative regulation designates Schedule I controlled substances.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by designating Schedule I controlled substances.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Under existing state law, certain formulations of synthetic cannabinoids are illegal. However, new variants of these drugs have appeared on the market as a legal alternative to marijuana. This amendment classifies substances that are substantially similar to synthetic cannabinoids as Schedule I controlled substances, thereby effectuating a complete ban on these types of products.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to address the growing threat of synthetic cannabinoids to the health, safety, and welfare of Kentucky's citizens. Additionally, this action is consistent with the National Association of State Controlled Substances Authorities' (NASCSA) October 2011 resolution encouraging the Drug Enforcement Administration and states to make synthetic cannabinoids Schedule I substances. A copy of NASCSA's resolution may be downloaded at the following link:
<http://www.nascsa.org/Resolutions/res11.09.pdf>.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by designating substances that are substantially similar to synthetic cannabinoids as Schedule I substances.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by designating substances that are substantially similar to synthetic cannabinoids as Schedule I substances.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation bans, from legal sale, chemical variations of synthetic cannabinoids that have been formulated as a legal alternative to marijuana. Since these products are sold at commercial retail shops, the ban imposed by this regulation would compel retailers to stop selling these substances and enable law enforcement to halt illegal sales.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Commercial retail shops that currently sell chemical variations of synthetic cannabinoids that have been formulated as a legal alternative to marijuana would be required to stop selling these products.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs will be incurred by retailers in order to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with this amendment will help address the growing threat of synthetic cannabinoids to the health, safety, and welfare of Kentucky's citizens.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This administrative body will not incur additional costs to implement the changes made by this amendment.

(b) On a continuing basis: This administrative body will not incur additional costs to implement the changes made by this amendment.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be agency funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary to implement this amended administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The amendment to this administrative regulation will not establish or increase any fees.

(9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or

entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 902 KAR 55:015

Contact Person: Stephanie Brammer-Barnes

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Local governments will expend funds to arrest, prosecute, and incarcerate convicted defendants for trafficking, possessing, and manufacturing synthetic cannabinoids. Additionally, as these substances are new types of illegal drugs, there may be some additional cost in training law enforcement officers to recognize these drugs and deal with individuals under the influence. However, this regulation, in combination with existing law, will accomplish a total ban on these drugs before they get a foothold in Kentucky and thereby eradicate the problem of use and abuse.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.020

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? There will be no additional revenue generated for state or local government for the first year that this administrative regulation is in effect.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? There will be no additional revenue generated for state or local government during subsequent years after this administrative regulation becomes effective.

(c) How much will it cost to administer this program for the first year? There may be additional incarcerations related to this administrative regulation. While the expense of housing inmates may vary widely by jail, each additional inmate will increase facility costs by an estimated average of \$31.34 per day.

(d) How much will it cost to administer this program for subsequent years? There may be additional incarcerations related to this administrative regulation. While the expense of housing inmates may vary widely by jail, each additional inmate will increase facility costs by an estimated average of \$31.34 per day.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):
Other Explanation

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 902 KAR 55:015

Agency Contact: Stephanie
Brammer-Barnes

1. Federal statute or regulation constituting the federal mandate.

21 C.F.R. Section 1308.11 establishes the federal listing of Schedule I controlled substances.

2. State compliance standards.

KRS 218A.020 permits the Cabinet for Health and Family Services to adopt a regulation to control a substance if it finds the substance has a potential for abuse.

3. Minimum or uniform standards contained in the federal mandate.

The federal schedules of controlled substances are established in the federal mandate.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

This administrative regulation adds substances that are substantially similar to synthetic cannabinoids to Kentucky's list of Schedule I controlled substances. Synthetic cannabinoids are not listed on the federal listing of Schedule I controlled substances.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

This amendment recognizes that synthetic cannabinoids have significant abuse potential and inclusion on Kentucky's Schedule V list will help reduce the risk to public health.