

Significant Legislative Rule Analysis (SA)
WAC 246-887-100
Adding Synthetic Cannabinoids (Marijuana) and Substituted
Cathinones to the Schedule I Controlled Substances List
July 1, 2011

Section 1. What is the scope of the rule?

The proposed rule adds synthetic cannabinoids and substituted cathinones (including their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation) to Schedule I of the Uniform Controlled Substances Act (UCSA). The rule will make it illegal to sell, possess, manufacture or deliver these substances and will give law enforcement clear authority to prosecute these crimes.

The Board of Pharmacy (board) filed emergency rules on April 15, 2011 to immediately make these substances illegal by placing them into Schedule I. The emergency rule followed a previous emergency rule that made synthetic cannabinoids illegal. Based upon the findings described below, this rule will permanently add synthetic cannabinoids and substituted cathinones into Schedule I.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

The general goal of RCW 18.64.005(7) is to regulate the practice of pharmacy and protect and promote public health, safety and welfare of the citizens of the State of Washington. RCW 69.50.201 grants the board of pharmacy the authority to change schedules of controlled substances. RCW 69.50.203 directs the board of pharmacy to add a substance to Schedule I upon finding that the substance: has high potential for abuse; has no currently accepted medical use in treatment in the United States; and lacks accepted safety for use in treatment under medical supervision.

The statute's objectives the rule implements are:

- To protect and promote public health, safety and welfare of the citizens of the State of Washington;
- To add substances having a high potential for abuse, with no specific medical use, to the Schedule I listing; and
- To give law enforcement clear authority to prosecute violators for the sale, manufacture, possession and delivery of these substances under the UCSA.

Section 3. What is the justification for the proposed rule package?

Process to Schedule Controlled Substances

RCW 69.50.201 grants the board of pharmacy the authority to add substances to or delete or reschedule substances in Schedules I-IV. In making a determination regarding a substance, the board is directed to consider:

- (i) the actual or relative potential for abuse;
- (ii) the scientific evidence of its pharmacological effect, if known;
- (iii) the state of current scientific knowledge regarding the substance;
- (iv) the history and current pattern of abuse;
- (v) the scope, duration, and significance of abuse;
- (vi) the risk to the public health;
- (vii) the potential of the substance to produce psychic or physiological dependence liability; and
- (viii) whether the substance is an immediate precursor of a controlled substance.

After assessing the eight factors above, the board makes a determination whether or not a substance should be scheduled, and if so, where in the schedule the substance should be listed. The board can place a substance in “controlled status” by designating it as Schedule I through IV. Schedule I substances have the highest level of actual or potential for abuse including but not limited to potential for addiction. Schedule I drugs are illegal in the U.S. Drugs assigned to Schedule II or Schedule III usually show abuse potential during their drug development and the Food and Drug Administration (FDA) assigns the schedule before approval. A drug is categorized as a Schedule IV controlled substance when clinical usage demonstrates the drug has actual or relative potential for misuse and abuse, but less potential than Schedule I-III substances. The board is further guided on what schedule a substance should be designated based upon schedule criteria in chapter 69.50 RCW and chapter 246-887 WAC.

RCW 69.50.203 directs the board to place substance into Schedule I if they find that the substance:

- (1) has high potential for abuse;
- (2) has no currently accepted medical use in treatment in the United States; and
- (3) lacks accepted safety for use in treatment under medical supervision.

Background and Justification for Scheduling Synthetic Cannabinoids and Substituted Cathinones

Synthetic Cannabinoids

Synthetic cannabinoids are psychoactive substances which, when consumed, mimic the effects of tetrahydrocannabinol (THC), the active ingredient in marijuana.¹ These products have been marketed as safe and legal herbal products, also known as Spice, K2 and other names, which produce a “marijuana-like” high making them appealing to teens and young adults. Products containing these substances are sold as incense to hide their intended purpose. They are available through retail outlets, tobacco/smoke shops, paraphernalia/head shops and over the internet. The Drug Enforcement Administration (DEA) does not approve these substances for human consumption and does not oversee their manufacturing.

Since 2009, the DEA has received an increasing number of reports from poison centers, hospitals and law enforcement regarding these substances. Several countries, as well as fifteen states, have already taken action to make one or more of these substances illegal.

Locally, the Washington State Poison Center (WSPC) reported eight cases of Spice ingestion in the last half of 2009 and sixty-eight cases of Spice ingestion in 2010.

Emergency rules filed by the DEA went into effect on March 1, 2011, placing five types of synthetic cannabinoids into Schedule I of the federal Controlled Substances Act, under the temporary scheduling provision of Title 21 of the United States Code.

Substituted cathinones

Cathinone and methcathinone are substances listed as Schedule I controlled substances by the DEA and in Washington statute since the 1990's. Designer drugs have been manufactured by substituting chemical groups on the cathinone structure. Products containing substituted cathinones also present a clear and imminent danger to the public. Marketed as “bath salts” and “pond cleaner” and known by a variety of names, such as Ivory and Purple Wave, Red Dove, Blue Silk, and Zoom, these products are sold legally as synthetic powder both over the internet and in drug paraphernalia stores. Doctors and clinicians at U.S. poison centers have indicated that ingesting or snorting “bath salts” containing synthetic stimulants can cause chest pains, increased blood pressure, increased heart rate, agitation, hallucinations, extreme paranoia, and delusions. These effects are similar to the effects of methamphetamine, ecstasy, and cocaine². There have also been news reports of self-mutilations, suicides, and homicides linked to the drug.³

¹ National Institute on Drug Abuse - <http://www.drugabuse.gov/infofacts/Spice.html> National Institute for Drug Abuse

² National Institute on Drug Abuse - <http://www.drugabuse.gov/about/welcome/MessageBathSalts211.html>.
ACMD Advisory Council on the Misuse of Drugs – Consideration of Cathinones March 2010 - http://www.erowid.org/chemicals/4_methylmethcathinone/4_methylmethcathinone_article1.pdf

³ http://seattletimes.nwsources.com/html/localnews/2014851970_bathsalts23m.html

Data from all national poison centers and the WSPC show increasing ingestion exposures related to “bath salts.” Data from 2010 through March 2011 shows that poison centers are reporting a three-fold increase in cases.⁴

The chemicals in the proposed rule are analogs, a structural derivative that may only be different by a single element. The Federal Analog Act does not apply to these analogs because they are marketed as “incense” and “bath salts” that are labeled as “not for human consumption.”

Under the UCSA, drugs with potential abuse are placed into five schedules. The placement is based upon the drug’s medicinal value, harmfulness, and potential for abuse or addiction. Drugs placed in Schedule I have no medicinal value and are considered to be very dangerous (e.g. heroin, mescaline). The prescribing, administering, and dispensing of controlled substances is highly regulated.

Finding

In making a determination, the board has considered the provisions outlined in both RCW 69.50.201 and RCW 69.50.203 and has determined that both synthetic cannabinoids (marijuana) and substituted cathinones meet the criteria of a Schedule I drug and is proposing to place both onto the Schedule I list permanently.

Rulemaking

The proposed rule will achieve the authorizing statute’s goals and objectives by protecting public health and giving clear authority to law enforcement to prosecute for the sale, manufacture, possession and delivery of synthetic cannabinoids (marijuana) and substituted cathinones under the UCSA.

The Department of Health has assessed and determined that there are no feasible alternatives to rulemaking because these substances need to be placed into Schedule I in order to make them illegal.

If this rule is not adopted, the result would be continued sale and abuse of these substances that could potentially result in more deaths in the State of Washington.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

Significant Rule Analysis

WAC 246-887-100

Rule Overview

⁴ National Institute for Drug Abuse - <http://www.drugabuse.gov/about/welcome/MessageBathSalts211.html>.

The rule places synthetic cannabinoids (marijuana) and substituted cathinones (including their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation) onto the list of Schedule I controlled substances. This will make it illegal to sell, possess, manufacture or deliver these substances.

Rule Cost/Benefit Analysis

Businesses that sell products containing these substances have had to remove them from their shelves because of the emergency rule. This rule will make it permanently illegal to sell these products and may result in a decrease in revenue gained from the sale of products containing the substances. Based on anecdotal information, it is apparent that before the restrictions took place, stores that sold these substances generated considerable revenue. Adam Eiding, owner of Capitol Hemp, a store in Washington D.C., said that “in the 18 months he has been stocking Spice, the demand has doubled every month and it is now making up a third of his revenue”.⁵

Listing the substances may result in additional costs to law enforcement for enforcing the restriction through an increase in arrests and prosecution.

The benefit of the rule is that it will permanently remove these potentially harmful substances from the market. Data and news reports have tied the substances to hospitalizations, self-mutilations, suicides and homicides. Because these products will no longer be readily available to the public, it will reduce the number of patients that hospitals, EMS agencies, and the WSPC will have to treat and work with. The rule will also give law enforcement clear authority to prosecute for the sale, possession, manufacture or delivery of products containing these substances.

Cost-Benefit Conclusion

The proposed rule may affect businesses that sell or manufacture these substances. Because these substances will no longer be legal to sell, possess, manufacture, or deliver some businesses may lose revenue from future sales of these products. The loss of future revenue to businesses is clearly offset with the benefit of reducing injury, hospitalizations, and death associated with the use of these substances. Thus, the total probable benefit of the rule outweighs the total probable costs.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

No alternatives were considered because these substances need to be listed in Schedule I of the UCSA in order to make it illegal to sell, manufacture, possess or deliver the substances.

Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?

⁵ <http://blogcritics.org/politics/article/synthetic-marijuana-sales-soar-as-demand1/#ixzz1QbiiFAVs>

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

The rule differs from the DEA's emergency ban that went into effect March 2011, which placed a ban on five synthetic cannabinoids. That difference is justified by the current proposed rule which includes not only the five synthetic cannabinoids banned by the DEA, but also adds substituted cathinones and some additional chemicals suggested by the Washington State Patrol Crime Lab.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

Yes. The rule includes the chemicals currently banned by the DEA in federal law through emergency rules. There are no other applicable laws.