Final

Significant Analysis

for Rule Concerning Medical Marijuana - Definition of 60-Day Supply WAC 246-75-010

Briefly describe the proposed rule.

RCW 69.51A.080 (Chapter 371, Laws of 2007) requires the Department of Health to define a presumptive 60-day supply of medical marijuana for qualifying patients.

The proposed rule:

- Establishes that the intent of the rule is to provide clarification to patients, law enforcement and others about the presumptive amount of medical marijuana that constitutes a 60-day supply; to allow medical practitioners to exercise their best professional judgment; and to allow designated providers to assist patients.
- Defines a presumptive 60-day supply of medical marijuana as 24 ounces of useable marijuana and no more than 15 plants.
- Is consistent with chapter 69.51A RCW, states that the 60-day supply is the total amount that may be possessed between the qualifying patient and designated provider.
- Is consistent with chapter 69.51A RCW, states that the presumptive 60-day supply may be overcome with evidence of a qualifying patient's necessary medical use.
- Defines the terms "designated provider", "qualifying patient", "plant" and "useable marijuana."

Is a Significant Analysis required for this rule?

State law makes the sale and possession of marijuana subject to penalty. The medical marijuana law creates an affirmative defense for the possession of medical marijuana. These rules clarify the law by defining a presumptive 60-day supply of medical marijuana. The department has chosen to complete an analysis of WAC 246-75-010 (3)(a) - Presumptive 60-Day Supply.

WAC 246-75-010 subsections (1), (2) and (3)(b) and (c) clearly do not require analysis because they clarify proposed intent, restate provisions of the law, or only define terms.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The goal of RCW 69.51A.080 is to clarify the medical marijuana law so that the lawful use of marijuana is not impaired, medical practitioners are able to exercise their best judgment, qualifying patients may fully participate in the medical use of marijuana, and designated providers may assist patients in the manner provided by the law. It is also intended to provide clarification to law enforcement and all participants in the judicial system.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

RCW 69.51A.080 directs the department to adopt rules defining a presumptive 60-day supply of marijuana for qualifying patients. The statute provides no alternatives.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rule does not create a cost to patients, physicians, designated providers, law enforcement, or the court system. The use of medical marijuana is a patient's choice, and physicians may choose to recommend it as a therapy. There may be a cost savings to law enforcement, the court system and defendants/patients as a result of defining a 60-day supply (for example, reduced costs of litigation). However, there is no way to calculate the cost-savings that may result from clarifying what a 60-day supply is. This analysis considers only the qualitative benefits of defining a 60-day supply.

In addition, this analysis does not establish or analyze the medicinal value of marijuana. Washington voters approved the use of medical marijuana by passage of Initiative 692 in 1998. Also, this analysis does not address the means and methods to obtain medical marijuana.

The department conducted extensive research and outreach to stakeholders on development of the rule. The department held four public workshops in the fall of 2007, and a formal hearing in August 2008. The department also developed a dedicated website and email box for receiving comments throughout the process. The department received and reviewed well over 800 comments and staff spent many hours reviewing studies, searching out information on the internet, and exploring laws in other countries and states.

The proposed rule is based on information available in studies, comments received through the workshops, hearing, email and website, and consideration of other state laws.

Considering the information available, there are limitations that could not be resolved or addressed, including:

- The Washington State medical marijuana law and adopted rule conflict with other state and federal laws that prohibit the possession of marijuana as a Schedule I controlled substance.
- There are too many variables to create a "one-size-fits-all" rule. Examples of variables include the patient's condition or disease, tolerance level, varying method of use (e.g., smoking, ingestion, vaporization, tinctures, lotions, or suppositories), the skill of a particular grower, physical limitations, levels of active ingredients such as THC in the plant, type and size of plant, and growing environment.
- There are published studies, but there is no definitive research available at this time on dosing standards that addresses all those variables.

• Washington State law does not authorize the department to address patient-to-patient transfers, co-ops or "group grows."

The rule considers the following:

- Patients indicated that they use a combination of different methods to administer medical marijuana.
- Patient comments and studies suggest that using other forms, such as eating, vaporizing, tinctures, lotions and suppositories requires more marijuana than smoking it.
- Allowing possession of plants at varying stages of growth assists patients and designated providers with maintaining a consistent supply of useable medical marijuana.
- Although use of medical marijuana is a health care issue, and patients should rely on their physician for guidance, the rule must be clear to all individuals who rely on the law and to individuals enforcing the law.
- Law enforcement comments indicated that defining a large quantity as a 60-day supply could encourage illegal trafficking.
- Other states have experience with creating and enforcing specific supply limits for patients and providers.
- Patients can overcome the presumptive amounts with evidence of medical necessity.

1. WAC 246-75-010 (3) Presumptive 60-Day Supply

Description:

The presumptive 60-day supply is defined as 24 ounces of useable marijuana and no more than 15 plants.

Analysis:

The proposed rule is based on the average daily amount of 8.24 grams of marijuana prescribed to patients in the federal government's Compassionate Investigational New Drug (IND) Program, Oregon medical marijuana law, and Chris Conrad's "Cannabis Yields and Dosage: A Guide to Production and Use of Medical Marijuana," August 2007.

Patients in the IND program receive on average about 17.5 ounces of medical marijuana in a 60-day period. The IND program assumes that participants in the study only use marijuana by smoking. Oregon has adopted a higher amount, allowing for other methods of use, such as ingestion.

Conrad's study, based on DEA research completed in 1992, indicates the average plant grown outdoors was about 11.25 square feet and yielded an average of .41 ounces of air-dried bud per square foot. Although the study was based on ideal growing conditions outdoors, the study also suggests that indoor gardens can be harvested more often than outdoor gardens and when harvested three times a year will yield often about the same as outdoors.

The proposed amounts are similar to those in the Oregon law. They allow flexibility for using different methods, such as ingesting or inhaling; are based on the average amount provided to patients in the only federally recognized program in existence; and provide plant counts that should yield the amount of marijuana necessary for the proposed 60-day supply.

The benefits of the proposed 60-day supply include:

- Clarity for patients, designated providers, physicians, law enforcement, the court system, and others.
- Similarity with the state of Oregon.
- Flexibility to allow patients the option of using medical marijuana through methods other than just smoking.
- Clearly identifiable plant count and amount that is easy to coordinate between a patient and designated provider.
- Ability for patients and designated providers to have plants in various stages of growth.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

The following alternative versions of the rule were considered:

Alternative version #1: 24 ounces, 6 mature plants, and 18 immature plants (proposed version)

Compared to this alternative version, the final rule is less burdensome for those required to comply with it because:

- The alternative version restricts the number of mature plants a patient or caregiver can have to six.
- The final rule does not restrict the number of mature plants or immature plants a patient can have within the limit of 15 plants. The final version allows more flexibility for the patient or caregiver to manage his/her supply.

Alternative version #2: 71 ounces and 99 plants

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because:

• Amounts this large could promote illegal activity, which would violate state and federal drug laws, and could negatively affect medical marijuana use for qualifying patients.

Store

- This plant amount is not based on a rational analysis of medical need. Rather, it is based on the federal sentencing guidelines, which reduce penalties for possession of less than 100 plants.
- This alternative is not consistent with any other state. It is greater than the limits under California law where some counties allow for dispensaries, and cooperative and collective cultivation.
- During public comment, we heard from a number of concerned and affected individuals that this amount could put patients and designated providers at risk of being robbed.

Alternative version #3: 35 ounces and 100 square feet of canopy

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because:

- Although canopy is a reliable predictor of plant yield, using canopy instead of plant count creates coordination issues for patients and designated providers not living together. It is also more complicated to determine canopy size if plants are in different stages of growth and grown in different areas.
- Amounts this large could promote illegal activity, which would violate state and federal drug laws, and could negatively affect medical marijuana use for qualifying patients.
- This alternative is not consistent with any other state. It is greater than California where some counties allow for dispensaries, and cooperative and collective cultivation.
- During public comment, we heard from a number of concerned and affected individuals that this amount could put patients and designated providers at risk of being robbed.

Alternative version #4: In inverse proportion, up to 35 ounces and up to 100 square feet of canopy. The amounts in each category would change in order to create a combined potential amount of no more than 35 ounces. For example, a patient could have 100 square feet of canopy and 0 ounces of marijuana or 0 square feet of canopy and 35 ounces of marijuana.

This amount is closer to the proposed rule, however the proposed rule is less burdensome for those required to comply with it because:

- Although canopy is a reliable predictor of plant yield, using canopy instead of plant count
 creates coordination issues for patients and designated providers not living together. It is
 also more complicated, for patients, caregivers and law enforcement, to determine canopy
 size if plants are in different stages of growth and grown in different areas.
- The patient and/or designated caregiver would have to monitor and adjust the 60-day supply more often.
- Amounts this large could promote illegal activity, which would violate state and federal drug laws, and could negatively affect medical marijuana use for qualifying patients.
- This alternative is not consistent with any other state. It is greater than California where some counties allow for dispensaries, and cooperative and collective cultivation.

• During public comment, we heard from a number of concerned and affected individuals that this amount could put patients and designated providers at risk of being robbed.

Alternative version #5: 17.5 ounces

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because:

- Patients indicated that this is an insufficient amount to meet most needs.
- The proposed rule allows a greater amount to account for other methods of using marijuana other than smoking.
- The proposed rule allows for growing plants in order to maintain a supply of medical marijuana.
- The proposed rule provides more clear guidance.
- E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

Washington has enacted medical marijuana laws that conflict with other laws. The proposed rule only clarifies the law that already exists; it does not eliminate the conflicts.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

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

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

Washington has enacted medical marijuana laws that conflict with the federal law. The proposed rule is required by RCW 69.51A.080 in order to clarify the state law that already exists.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The department has coordinated with other laws to the extent allowed by mandate.