

**Significant Legislative Rule Analysis**  
**Chapter 246-71 WAC (New)**  
**A Rule Concerning Medical Marijuana Authorization Database**  
**December 7, 2015**

**Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.**

The Washington State Department of Health (department) is proposing a new rule chapter that would:

- Establish the requirements for the department to contract with an entity to create, administer and maintain a medical marijuana authorization database; and
- Establish a process for patients and designated providers who are authorized to use medical marijuana to obtain recognition cards.

On April 24, 2015, Gov. Inslee signed Second Substitute Senate Bill (2SSB) 5052, (chapter 70, Laws of 2015) the Cannabis Patient Protection Act. This act creates licensing and regulation of all marijuana producers, processors and retail stores under the oversight of the renamed Washington State Liquor and Cannabis Board (LCB). The proposed rule is one element of the overall implementation of Second Substitute Senate Bill 5052 (2SSB 5052) which aims to align the medical market into the regulated market that includes:

- Contracting with a third party to create and administer a medical marijuana authorization database, and adopting rules relating to the operation of the database;
- Adopting rules regarding products sold to patients and their designated providers;
- Consulting with the LCB about requirements for a retail store to get a medical marijuana endorsement;
- Creating a medical marijuana consultant certification program, including developing and approving continuing education for healthcare practitioners who authorize the medical use of marijuana; and
- Completing three reports: Making recommendations to the legislature about establishing medical marijuana specialty clinics; Reporting costs of establishing the authorization database, and Examining the feasibility of changing marijuana designation under Schedule I of the Controlled Substances Act.

Section 21 of 2SSB 5052 requires the Department of Health to contract with a third-party vendor to establish the requirements for a third party vendor to create, administer and maintain the database, and authorized the department to adopt rules governing operation of the database. The purpose of the database is to provide a process for issuing recognition cards to patients and designated providers who are authorized to use medical marijuana, and allow access to the

database to various entities who need to verify a card's validity or perform other regulatory work.

**Is a Significant Analysis required for this rule?**

Yes, as defined in RCW 34.05.328(5)(c), the department has determined that some sections of the proposed rules require a significant analysis. The department, however, has determined that no significant analysis is required for the following sections.

Table: Non-Significant Rule Identification

#	WAC Section	Section Title	Reason
1	WAC-246-71-010	Definitions	Does not meet the definition of a legislatively significant rule under RCW 34.05.328(5)(c).
2	WAC 246-71-150	Release of aggregate information from the database	Does not meet the definition of a legislatively significant rule under RCW 34.05.328(5)(c).

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

The intent of 2SSB 5052 is to establish the cannabis patient protection act, creating a viable regulated medical marijuana market which provides for the oversight and protection of patients. The legislation ensures safe, consistent, and adequate access to marijuana for qualifying patients. The proposed rules provide consistent and enforceable standards for implementation of the medical marijuana authorization database established in 2SSB 5052, section 21, and in other relevant statutes including chapter 69.51A RCW regarding medical cannabis, and Initiative 502 that legalized the sale of recreational marijuana.

The proposed rule would establish:

- Definitions of terms used throughout the chapter
- The steps and requirements for adding and renewing qualifying patients and designated providers to the database
- The requirements for recognition cards
- Requirements for database access by marijuana retailers holding a medical marijuana endorsement (from the state Liquor and Cannabis Board).
- The requirements for database information access by qualifying patients or designated providers, as well as by health care providers who may issue medical marijuana authorizations. Requirements for database access by local, tribal, and federal law enforcement and prosecutorial officials, and by the state Department of Revenue
- Database confidentiality requirements.
- Penalties and sanctions the department may take in case of a database access violation

- The process to obtain a replacement recognition card.
- The steps and requirements for removal of a qualifying patient or designated provider from the database, and for the revocation of a designated provider
- Requirements for the release of aggregate information from the database.
- Requirements for collection of a \$1 recognition card fee charged to patients or designated providers.

**Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.**

Section 21 of 2SSB 5052 authorizes the Department of Health to adopt rules to implement a medical marijuana authorization database. Where a statute is not explicit, rules are needed to establish consistent and enforceable requirements. As a result, no alternatives to rulemaking are available.

**Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.**

During the rulemaking process the department collected input from stakeholders interested in the proposed rule.

A total of sixteen sections of rule were created in this proposal. There are 14 significant sections analyzed below:

**1. WAC 246-71-020 Adding qualifying patients and designated providers to the database**

**Description of the proposed rule:** The proposed rule establishes the steps and requirements for adding qualifying patients and designated providers to the database. Under 2SSB 5052, only a marijuana retailer with a medical marijuana endorsement may add a patient or designated provider to the database. The rule also lists the required information that must be entered into the database for each patient and designated provider. The rule requires a medical marijuana consultant certificate holder (issued under chapter 246-72 WAC) to enter a qualifying patient's or designated provider's information into the authorization database. The rule requires consultant to:

- Ensure that the authorization form provided is valid and meets all requirements specified in 2SSB 5052 and from the form's instructions, printed on approved tamper resistant paper.
- Verify the identity of every patient age 18 and older and every designated provider's valid photographic identification. Except for patients under the age of 18, a person cannot be entered into the database without valid photographic identification. The law requires that patients under age 18 must have an adult designated provider.

- Ensure that a designated provider is not currently the designated provider for a different patient in the database, before associating them with a new patient in the database. If a designated provider is still associated to a different patient, the consultant cannot enter the designated provider into the database as associated with the new patient.

**Cost/Benefit Analysis:**

The department assumes that the data entry process will take between 15-30 minutes for a medical marijuana consultant to complete. Based on a projected consultant wage of up to \$22 per hour (including benefits), entering required information into the database and producing a recognition card would cost between \$5.40 and \$11.00 per card. The projected annual labor cost per medical outlet is \$137,808, based on employing three full time certified consultants. Projected staffing levels are indeterminate at this time, but stakeholders indicate there will be a need to increase staff at the majority of medical outlets in the first year of business to meet demands.

Using the state of Colorado’s medical marijuana registry and its population we estimate that we will have approximately 80,000 cards created per year. This is based on the assumption that since the card is optional for those 18 and over that approximately half of all patients who could receive a card will. We estimate a five percent new application rate or 4,000 after the initial year and a ninety-five percent renewal rate or 76,000. So each year we estimate receiving \$80,000 in card fees. Projected staffing levels are indeterminate at this time, but stakeholders indicate there will be a need to increase staff at the majority of medical outlets in the first year of business to meet demands.

The benefit of the proposed rule is that it clearly establishes the process and identifies the required information for consultants to enter into the database on patients and designated providers. Joining the medical marijuana database is voluntary for patients and designated providers. But they would benefit by getting a recognition card that makes their purchases exempt from marijuana excise taxes charged to anyone purchasing marijuana without a recognition card, and they may purchase a larger amount of marijuana. Patients and designated providers with a database recognition card also are exempt from arrest or prosecution in Washington state for marijuana possession, whereas persons who have a medical marijuana authorization but do not obtain a recognition card have only an affirmative defense to use if arrested.

**2. WAC 246-71-030 Renewing qualifying patients and designated providers in the database.**

**Description of the proposed rule:**

The renewal requirements were set in RCW 69.51A. Patients under eighteen and their designated providers must renew information in the database at least every six months. Patients eighteen years and older, and their designated providers must renew at least annually. The requirements include reexamination of qualifying patients by a healthcare practitioner, prior to receipt of a new authorization by the patient or designated provider. The

proposed rules establish the process for renewing qualifying patients and designated providers in the database.

**Cost/Benefit Analysis:**

The department assumes that the process for renewing a patient/designated provider recognition card before the expiration date listed on the card will take between 10 - 20 minutes for a medical marijuana consultant to complete. Based on a projected consultant wage of up to \$22 per hour (including benefits), entering required information into the database and producing a recognition card would cost between \$3.60 and \$7.20 per card. The benefits of the proposed rule are the same as for proposed WAC 246-71-020. Timely renewal also ensures that patients/designated providers continue to enjoy the benefits of having a recognition card, and that retailers can verify lawful sales to and excise tax status of patients and designated providers.

Requirements for patients to be reexamined and renew their cards are set in law, therefore those requirements are not analyzed in the rule and there are no costs as a result of the proposed rule.

**3. WAC 246-71-040 Requirements for recognition cards.**

**Description of the proposed rule:** The proposed rule states the requirements for recognition cards. The rule identifies equipment requirements and establishes the steps and requirements for issuing recognition cards at retail stores with a medical marijuana endorsement. The rule also states the requirements that must be met by the database vendor.

**Cost/Benefit Analysis:**

The marijuana retailer must pay the equipment and operating costs to connect to the department's medical marijuana authorization database and to issue recognition cards. The department assumes that retailers will have existing computer equipment in place with internet access to track the seed to sale process. Installation of the authorization database software is free of charge and provided by the department. Total costs for purchase of a computer printer and recognition card laminator range from \$75.00 to \$125.00. The cost for a digital camera that meets the requirements for recognition card photos ranges from \$50.00 to \$125.00. These are one time costs, based on the useful life of the equipment. The estimated monthly cost for card printing supplies is \$100.00. There may be labor or professional costs for training consultant to properly use the equipment. The benefit of the proposed rule is that it clearly establishes what consultants are required to do to enter patients and designated providers into the database. Purchase of the equipment allows the retailer with a medical marijuana endorsement to participate in authorization database. The rule also allows stores to provide access to products with the tax savings available only to patients and designated providers who have a recognition card.

#### 4. WAC 246-71-050 Database access by marijuana retailers with medical endorsements

**Description of the proposed rule:** The proposed rule states the requirements for database access by marijuana retailers with a medical marijuana endorsement.

- Any employee of a medical outlet wanting access to the database shall register with the department in order to receive credentials for access, under a process established by the department.
- The department verifies the employee's identity and employment status before providing credentials to access the database.
- The employee shall access the database using the security credentials issued by the department or the department's designee. If the credentials issued are lost or missing, or the security of credentials is comprised, the employee shall notify the department by telephone and in writing as soon as reasonably possible.
- A medical outlet owner must inform the department and the system vendor in writing immediately upon the termination of employment of an employee with access.
- All requests for, uses of, and disclosures of information from the database by authorized persons must be consistent with the statute and this chapter.

**Cost/Benefit Analysis:**

The costs of compliance are minimal, mainly administrative to retail stores and employees, involving registration for database access and notice to the department if security credentials are lost or terminated. Compliance with the rule allows the retail outlet to continue selling products to patients and designated providers, and for the patients and designated providers to continue having the benefits of purchase products that meet their needs with tax benefits available only to those with a recognition card.

#### 5. WAC 246-71-060 Database access by qualifying patients or designated providers

**Description of the proposed rule:** The proposed rule establishes the process for patients or designated providers to access their own information. Patients or designated providers may request and receive their own healthcare information from the database or information on any person or entity that has queried their name or information, using a process and format established by the department.

**Cost/Benefit Analysis:**

There are no costs for patients or designated providers to access their own healthcare information in the database, other than time. Patients and designated providers benefit by being informed of what data or information about them is stored in the medical marijuana authorization database.

## **6. WAC 246-71-070 Database access by prescribers and dispensers**

**Description of the proposed rule:** The proposed rule establishes the requirements for voluntary access to the authorization database by healthcare practitioners who are allowed by law to issue medical marijuana authorizations. These practitioners may register for access to patient information in the database for the purpose of providing care for their patients.

### **Cost/Benefit Analysis:**

There is no cost for healthcare practitioners accessing information online in the authorization database, other than their time.

Patients and the public benefit from ensuring that only health care professionals who are authorized may access patient or designated provider information in the database.

## **7. WAC 246-71-080 Database access by local, state, tribal, and federal law enforcement and prosecutorial officials.**

**Description of the proposed rule:** The proposed rule establishes the requirements for voluntary access to the authorization database by local, state, tribal, and federal law enforcement by law. Officials who are engaged in a bona fide specific investigation of suspected marijuana-related activity that may be illegal under Washington state law may access the database to confirm the validity of the recognition card of a patient or designated provider.

### **Cost/Benefit Analysis:**

There is no cost for local, state, tribal, and federal law enforcement and prosecutorial officials, other than their time.

Patients and the public benefit from ensuring that only authorized law enforcement entities may access patient or designated provider information in the database. Another benefit of the rule is that it ensures the process for requesting and receiving information is established by the department, the database vendor, and law enforcement.

## **8. WAC 246-71-090 Database access by the department of revenue.**

**Description of the proposed rule:** The proposed rule establishes the requirements for access to the authorization database by the department of revenue. The Washington department of revenue may access information in the database to verify tax exemptions under chapters 82.08 and 82.12 RCW. The process and format shall be established by the department and the database vendor in coordination with the department of revenue.

### **Cost/Benefit Analysis:**

There is no cost for the department of revenue to access information in the database, other than their time.

The benefit of the rule is that it ensures that only entities that are authorized may access patient or designated provider information in the database for investigative purpose. Another benefit of the rule is that it ensures the process for request and receiving information is established by the department, the database vendor, and the department of revenue.

## **9. WAC 246-71-100 Confidentiality.**

**Description of the proposed rule:** This proposed rule establishes the confidentiality requirements for records in the authorization database. The requirements include:

- Records in the database containing names and other personally identifiable information of qualifying patients and designated providers are exempt from public disclosure, inspection, or copying.
- The vendor must retain database records for at least five calendar years to permit the LCB and Department of Revenue to verify eligibility for tax exemptions.

### **Cost/Benefit Analysis:**

Any costs of maintaining confidentiality requirements and database records are covered in the contract between the department and the database vendor. The benefit of the rule is that confidentiality of information in the database is maintained; ensuring that personally identifiable information on qualifying patients and designated providers is stored in a manner that limits disclosure, inspection, or copying only to those authorized by law or the proposed rules.

## **10. WAC 246-71-110 Penalties and sanctions.**

**Description of the proposed rule:** This proposed rule establishes the actions taken if the department or the vendor determine a person or entity has intentionally, knowingly or negligently accessed, used or disclosed information in violation of chapter 69.51A RCW or this chapter. The department may take action including:

- Terminating access to the system
- Filing a complaint with appropriate health profession disciplinary authority
- Reporting the violation to law enforcement

### **Cost/Benefit Analysis:**

There is no cost of compliance. Sanctions in the rule apply only if a person or entity is found to have violated the rules in this chapter. The benefit of the rule is that provides a deterrent to violations through potential penalties and sanctions

## **11. WAC 246-71-120 Process to obtain a replacement recognition card.**

**Description of the proposed rule:** This proposed rule describes the process requirements for a patient or designated provider to get a replacement recognition card. The rule also identifies the expiration date of a replacement recognition card and the requirements of consultants that may issue a replacement card to a patient or designated provider.

### **Cost/Benefit Analysis:**

There are only paperwork costs for patients or designated providers to get a replacement card if information about their medical marijuana authorization is current. Data entry by a medical marijuana consultant and replacement card printing are expected to take 5 to 10 minutes, at a labor cost of up to \$3.60 per replacement card, plus minor costs for the card and lamination. The benefit of the proposed rule is it ensures that issuance of a replacement recognition card adheres to the process requirements as determined by the department and a patient or designated provider can continue to obtain product sales tax free and at the medical purchase amounts.

## **12. WAC 246-71-130 Removal of a qualifying patient or designated provider from the database.**

**Description of the proposed rule:** This proposed rule establishes the process requirements for removal of a qualifying patient or designated provider from the database. The requirements include the following:

- The vendor must automatically deactivate patient and designated provider records in the database upon expiration of a recognition card.
- Patients and designated providers may request to be removed from the database before the expiration of their recognition card.
- An authorizing healthcare practitioner may request removal of a patient or designated provider from the database if the patient no longer qualifies for the medical use of marijuana.

### **Cost/Benefit Analysis:**

There are only administrative costs for patients or designated providers who voluntarily withdraw from the database, or for a healthcare practitioner who requests removal of a patient. Data entry by a medical marijuana consultant is expected to take up to 10 minutes, at a labor cost of up to \$3.60 per transaction. It is indeterminate at this time what the number of patients or designated provider records will be that are removed from the database. The benefit of the proposed rule is that it ensures a process established by the department is available for removal of patient and designated provider records from the database. This helps protect a patient or designated providers personal and medical information, and assures that only valid recognition cards are issued from the database system.

### **13. WAC 246-71-140 Revocation of a designated provider.**

**Description of the proposed rule:** This proposed rule establishes the process requirements for a qualifying patient to revoke their designation of a specific designated provider from the database, and identifies the requirements for the vendor to verify the authenticity of written documentation submitted by a patient to revoke a designated provider in the database. The rule also establishes the process a qualifying patient will use to designate a new provider, and establishes the process for a person to stop serving as a designated provider for a qualifying patient.

#### **Cost/Benefit Analysis:**

There are only administrative costs for a patient to revoke a designation. Verification of the authenticity of written documentation and data entry by a medical marijuana consultant to revoke a designated provider are expected to take up to 10 minutes, at a labor cost of up to \$3.60 per revocation action. The number of designated provider revocations is indeterminate at this time. The benefit of the rule is that it ensures that the process established by the department is followed for revocation of a designated provider record from the database, and assures that only valid recognition cards are issued from the database system.

### **14. WAC 246-71-990 Recognition card fees.**

**Description of the proposed rule:** The proposed rule establishes the process for medical outlets to collect and remit a one dollar fee for each initial, replacement, and renewal recognition card.

#### **Cost/Benefit Analysis:**

The department anticipates a small amount of administrative costs for employees to remit the one dollar fees on a periodic basis. The one dollar fee is set in law.

### **Cost Benefit Summary**

The proposed rules create an effective, consistent and enforceable process for adding qualifying patients and designated providers to the authorization database, and ensuring confidentiality of patient information. The cost to retail stores for the equipment required for the database, and access and enter information into the database, and to print recognition cards are reasonable when compared with the benefits of maintain a secure system that protects confidential patient information from unauthorized access. The rules establish a system that allows patients and their designated providers to purchase products that meet their needs while enjoying the tax and legal benefits of holding a recognition card. Therefore the total probable benefits of the rule exceed the total probable costs.

**Identify alternative versions of the rule that were considered, and explain how the department determined 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 state previously.**

During the collaborative rulemaking process the department discussed each of the regulatory components with the stakeholders and advisory groups. The database access and confidentiality requirements were discussed at length, and the process for printing recognition cards was accepted by the groups. Other alternatives discussed are not permitted by law such as having the department build and host the database, or having healthcare practitioners be responsible for entering patient information into the database.

**Determine that the rule does not require those to whom it applies to take an action that violates another state law?**

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

The proposed rule also does not require any person to violate federal law. However, those persons who voluntarily choose to become certified as a medical marijuana consultant are technically violating federal law by possessing and selling marijuana, a schedule 1 controlled substance. On August 29, 2013, Deputy U.S. Attorney James M. Cole issued a memorandum entitled “Guidance Regarding Marijuana Enforcement.” In the memo, Deputy Attorney General Cole listed eight priorities related to marijuana. He stated the federal government’s expectation that states that “have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement databases that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests.” Jurisdictions that “implement strong and effective regulatory and enforcement databases” are less likely to threaten the federal priorities. States whose regulation is not as robust may be challenged by the federal government and individuals may be prosecuted.

The rule puts limits and requirements on certificate holders. This contributes to a strong and effective regulatory database in Washington and complies with the Cole memo.

**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 proposed rule does not impose more stringent performance requirements on private entities than on public entities. It only applies to private recreational marijuana retail stores that voluntarily choose to become medical marijuana endorsed.

**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.**

The rule differs from federal law because federal law prohibits the possession and sale of marijuana. However, the rule conforms to the Cole memo because it contributes to a strong and effective regulatory database and is consistent with the federal government’s eight priorities.

While marijuana remains an illegal substance under federal laws under the current administration guidance regarding marijuana enforcement was provided that allows states to pursue legalization. The guidance does require states that do legalize marijuana to: “implement strong and effective regulatory and enforcement databases that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. The department works carefully with other state agencies to ensure our work to enact 2SSB 5052 follows this guidance.

**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 proposed rule is coordinated to the maximum extent practicable with other applicable laws, including current medical cannabis law under chapter 69.51A RCW.

The rule has been coordinated with other state rules to ensure a consistent and comprehensive regulatory system in Washington. While it inherently conflicts with federal law, it conforms to the Cole memo.