Rhode Island Department of Health

Licensing Analytical and Testing Laboratories for Sampling including Marijuana and Industrial Hemp

216-RICR-60-05-6

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Background

The Rhode Island Department of Health (RIDOH) is proposing to revise *Licensing for Sampling and Testing Medical Cannabis including Marijuana and Industrial Hemp* [216-RICR-60-05-6] to add several references, definitions, and sections regarding the testing of industrial hemp among other amendments.

The benefits of marijuana use by those with chronic and terminal illness have been studied extensively over the last several decades. In 1996, California voted in support of Proposition 215 which allowed those who were seriously ill to obtain and use marijuana without criminal prosecution or sanction provided they had a doctor's recommendation. This was the first law allowing for the use of medical marijuana in the United States.[1] Within two years, twelve further states had laws similar to Proposition 215 or had passed ballot initiatives permitting the use of medical marijuana.

In 1999, the National Academy of Science's Institute of Medicine published *Marijuana and Medicine: Assessing the Science Base* which outlined the potential medicinal benefits of marijuana. This study was ultimately the basis for the Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act which was enacted by the Rhode Island State Legislature in 2005.[2]

In addition to extolling the findings of the IOM study, this statute notes: "According to the U.S. Sentencing Commission and the Federal Bureau of Investigation, ninety-nine (99) out of every one hundred (100) marijuana arrests in the United States are made under state law, rather than under federal law. Consequently, changing state law will have the practical effect of protecting from arrest the vast majority of seriously ill people who have a medical need to use marijuana."[3] Based upon this statement, it is clear that the intent of the Medical Marijuana Program has been to allow those who would benefit from the use of medical marijuana to do so without the risk of criminality.

In 2016, R.I. Gen. Law § 21-28.6-16 was passed which stated "Medical marijuana cultivators shall be subject to any regulations promulgated by the department of health or department of business regulation that specify how marijuana must be tested for items, including, but not limited to, potency, cannabinoid profile, and contaminants."[4] This statement provided RIDOH with the authority to pass regulations regarding the testing of medical marijuana. 216-RICR-60-05-6 was adopted in 2018 in conjunction with R.I. Gen. Laws § 21-28.6-12 which grants RIDOH the authority to promulgate regulations establishing methodology and processes for testing medical marijuana at compassion centers.[5]

On July 24, 2019, Amy Abernethy, Md, Phd., Principal Deputy Commissioner, Office of the Commissioner, Food and Drug Administration, provided testimony before the Senate Committee on Agriculture, Nutrition, and Forestry regarding hemp production and the 2018 Farm Bill.[6] In her testimony, Dr. Abernathy noted that the 2018 Farm Bill removed hemp, which was defined as

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[1] Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, (Washington, D.C.: 1999), pg. 17.
[2] R.I. Gen. Laws § 21-28.6-2, http://webserver.rilin.state.ri.us/Statutes/TITLE21/21-28.6/21-28.6-2.HTM.
[3] R.I. Gen. Laws § 21-28.6-2, http://webserver.rilin.state.ri.us/Statutes/TITLE21/21-28.6/21-28.6-2.HTM.
[4] R.I. Gen. Laws § 21-28.6-16, http://webserver.rilin.state.ri.us/Statutes/TITLE21/21-28.6/21-28.6-16.HTM.
[5] R.I. Gen. Laws § 21-28.6-12, http://webserver.rilin.state.ri.us/Statutes/TITLE21/21-28.6/21-28.6-12.HTM.
[6] U.S. FDA, Testimony: Hemp Production and the 2018 Farm Bill, 24 July 2019, https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019.

cannabis and derivatives of cannabis with no more than 0.3% delta-9-tetrahydrocannabinol (THC) on a dry weight basis, from the definition of marijuana which appeared in the Controlled Substances Act (21 C.F.R. Part 1308). This ultimately identified hemp as a product with a set threshold for THC.[7]

In 2019, R.I. Gen. Laws § 21-28.6-3 added the definition of "cannabis" and included in that definition the terms "industrial hemp" and "marijuana," identifying industrial hemp as a subpart of cannabis and thus making it regulatable by RIDOH.

As of February 2023, there are four licensed marijuana sampling and testing laboratories in the State of Rhode Island. Two of the licenses were issued in 2020, one was issued in 2021 and the final license was issued in 2022.[8]

Proposed Amendments

The following changes are proposed for this regulation:

- The title is being revised to incorporate the changes from "medical marijuana" to "cannabis" and to incorporate the regulation of industrial hemp.
- Additional materials are incorporated by reference.
- Several definitions are added for a number of terms relating to testing of marijuana and industrial hemp.
- Several definitions are revised to expand upon the intended terminology.
- Sections were added regarding the provisions for licensing industrial hemp testing laboratories.
- Delta 8-tetrahydrocannabinol was added to sections regarding cannabis potency.
- Additional requirements for laboratories were added in several sections.
- Further recordkeeping and safety measures were added for laboratories.
- Parameters for batch size in required testing were added.
- Tables were updated with revised data.

Status Quo

If the status quo were to be maintained, these regulations would not contain provisions for the licensing of laboratories that test industrial hemp. Changes to the state legislation have necessitated revisions to these regulations.

Without an expansion of the regulations overseeing the testing of marijuana and industrial hemp, there may be deficiencies in the testing procedures. The proposed regulations are intended to prevent any such deficiencies. It is difficult to quantify how many people would be impacted if these regulations were not amended, however, it is apparent that there will be benefits to the more stringent testing procedures.

[7] U.S. FDA, Testimony: Hemp Production and the 2018 Farm Bill, 24 July 2019, https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019.
[8] Rhode Island Department of Health, Licensees, https://health.ri.gov/lists/licensees/.

Benefits

One valuable benefit of the proposed amendments is the addition of reference material which includes sampling and testing guidelines for domestic hemp production. The addition of reference material will result in improved guidance for those subject to regulation by RIDOH. A much larger overall benefit of these regulations which is partly a result of the added reference material is the more clearly defined testing and sampling procedures that are required. The revised language to include industrial hemp and marijuana as subsets of cannabis makes the required procedures more easily understood.

One prerequisite being added as part of the proposed amendments is the condition that a laboratory experiencing any of a number of changes unexpectedly (such as change in ownership or director, merger, dissolution or entity conversion, or change to approved floor plan, among others) is required to report these changes to RIDOH. This section provides for a waiver to be signed which will indicate the procedures to be followed to carry on operations in response to any changes. This will simplify the testing procedure for both RIDOH and the laboratory in question as issues that would arise during testing can be noted prior to said testing.

Another proposed amendment to this regulation is the addition of a section covering the final licensing process for analytical laboratories. This process includes submission of documentation from the State Fire Marshall and the Department of Business Regulation. The addition of these requirements allows RIDOH to better regulate the facilities charged with testing and sampling marijuana and industrial hemp in the state. This new section also lays out the procedure for final laboratory inspections and clearly provides information that would be necessary for a facility to begin operations as a licensed laboratory in Rhode Island.

Under the proposed amendments, laboratories will also be required to have scales certified and sealed by the Department of Labor and Training's Office of Occupational Safety. Ensuring scales are correctly calibrated and certified by DLT provides another safeguard to consumers and licensees to verify that the information provided by licensed analytical laboratories is accurate.

Additional precautions are included in the proposed amendments in an effort to better track and record information. One such precaution is a more detailed labeling procedure which is required by sample collectors to improve chain of custody management on samples for testing. Improvements to the required record keeping procedures are critical in that they will both improve overall testing quality and increase accountability from cultivators and licensed analytic laboratories.

Costs

Costs to Licensees

Many of the costs associated with the proposed amendments will be incurred by the licensee. This includes all costs and expenses for the testing and retesting of marijuana performed by an approved laboratory. The proposed amendments state that "all industrial hemp, hemp derivatives, and/or hemp-derived CBD products being sold at retail, grown and/or produced within a licensed area" are subject to sampling by a licensed facility. The expenses associated with this sampling is to be incurred by the licensee and represents an additional cost.

Cost to Labs
Approved laboratories will be subject to additional costs as well, however, the increase in costs to these laboratories will be fairly minimal. The laboratory will be responsible for any costs that may be associated with the certifying and sealing of balances and scales as required by the proposed amendments. Additionally, a cost may be incurred in the added procedures of signing in and supervising visitors, maintenance workers, and/or repairmen as stipulated by the proposed amendments. While the actual cost to the laboratory for the latter is impossible to quantify, they must account for the loss of labor involved with having to supervise these individuals.

Costs to the State
The costs to the state resulting from the proposed amendments will be largely administrative in nature. With the added requirement of licensing industrial hemp producers, RIDOH will need to process more licenses, resulting in additional labor hours spent on this work. Given that there are currently only four license holders for marijuana sampling and testing laboratories in the state, this increase is likely to be minimal. The extra work that will be required will largely be due to license holders needing to submit State Fire Marshall Approval of Occupancies and Registry Identification Cards to RIDOH.

Another cost to RIDOH would be the expenses involved in conducting final laboratory inspections. Unlike other procedures in these regulations, these inspections are not funded by the licensee, and therefore, the cost will be undertaken by RIDOH in the form of labor hours and other associated costs.

Regulatory Alternatives, Results and Determination

In developing the proposed amendments, the Department considered the following alternatives:

Not including laboratories that test and sample industrial hemp in these regulations

RIDOH considered not adding provisions for laboratories that test and sample industrial hemp in these proposed amendments. It was determined, however, that this would cause the regulations to not align with current standards regarding the definitions of hemp, marijuana, and cannabis. More recent guidance regarding the distinction between these three terms has made the regulation of laboratories that test industrial hemp a necessity.

Not requiring sign-in and supervision for visitors, maintenance workers, and/or repairmen at laboratories

RIDOH considered not adding the provisions from the proposed amendments that visitors, maintenance workers, and/or repairmen sign in at licensed laboratories and be supervised at all times during their visit. RIDOH ultimately found, however, that this was a necessary requirement to ensure proper safety and inventory control procedures are followed.

Based on the information presented above, RIDOH has determined that the proposed amendments are the most effective options available and therefore, they will be presented as proposed.