

Medical Marijuana in Massachusetts – DPH Proposes Amendments to Regulations

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The **Massachusetts Department of Public Health (DPH)** has released for public comment [proposed amendments](#) to DPH's Medical Marijuana Regulations ([105 CMR 725](#)) (the "regulations"). DPH believes that the proposed amendments will streamline the [Medical Use of Marijuana Program](#) (the "Program") by updating existing processes, providing additional clarity, and creating consistency with changes made to related laws, all with the goal of promoting patient access while assuring public safety is maintained. At a meeting of the Public Health Council (PHC) held on September 14, 2016, DPH representatives, including Program Director Bryan Harter, MBA, LICSW, presented the proposed amendments. DPH's [presentation](#) to the PHC at the meeting includes a summary of the proposed amendments, as well as a brief history of the Program, including applications received, provisional Certificates of Registration to operate a Registered Marijuana Dispensary (RMD) (41), and number of RMDs currently open and dispensing marijuana for medical use (7).

Amendments are undoubtedly necessary. The current regulations, which became effective on May 24, 2013, were implemented in connection with the creation of the Program, and DPH now has the benefit of experience with the RMD process to amend its regulations to reflect, in some cases, lessons learned. As with proposed amendments to other regulations, these amendments are also necessary to comply with Governor Baker's [Executive Order 562](#), which directed all executive branch state agencies to review and, where possible, streamline, simplify and improve their regulations.

Some of the proposed amendments are technical in nature and will be of most interest to RMDs and applicants or those planning to apply for an RMD license (e.g., pricing, insurance, security plans, physical plant requirements, and background check procedures). Others have broader implications for Certifying Healthcare Providers, Caregivers, Laboratories and the patients served by the RMDs.

Certifying Healthcare Provider

To obtain medical marijuana, a patient must be a "qualifying patient." Under the current regulations, a qualifying patient is a Massachusetts resident, 18 or older, who has been diagnosed by a Massachusetts "certifying physician" as having a debilitating medical condition. The amendments replace certifying physician with "healthcare provider" and permit both physicians and certified nurse practitioners (CNPs) to certify that the potential benefits of the medical use of marijuana would likely

outweigh the health risks for the qualifying patient. This change reflects, in part, the evolution of the role of the CNP as healthcare provider, generally. Note that DPH proposes that the physician supervising the CNP's prescriptive practice must attest that the CNP is certifying patients pursuant to mutually-agreed upon guidelines between the supervising physician and the CNP. As do physicians, certifying CNPs must register DPH.

At the PHC meeting, a PHC member raised concerns about physicians acting as "certification mills" who don't truly have an ongoing care relationship with patients they are certifying. A related concern was raised that by permitting CNPs to certify patients, DPH may be opening the door to physicians employing CNPs solely for the purpose of processing certifications.

Personal Caregiver/Institutional Caregivers/Caregiving Institutions

DPH proposes that a hospice program, long term care facility, nursing, or medical facility may obtain a certificate of registration as a caregiving institution. A registered caregiving institution, in turn, would apply for an institutional caregiver registration for its employees who will facilitate a registered qualifying patient's use of marijuana while a patient of the institution. Such employees may serve as the registered caregiver for more than one registered qualifying patient at the institution. The institutional caregiver may receive, prepare and administer (or facilitate consumption of) marijuana by the qualifying patient. An institutional caregiver may not cultivate marijuana for patients. Similarly, non-institutional personal caregivers may not cultivate marijuana on behalf of a registered qualifying patient who has a hardship cultivation registration, unless s/he is a visiting nurse, personal care attendant or home health aide serving as a personal caregiver. Licensed facilities should remain mindful that DPH's regulations do not relieve facilities of their obligations under federal law with respect to cannabis. The DEA has [recently confirmed](#) its policy that marijuana is a Schedule 1 controlled substance.

In response to concerns expressed at the PHC meeting regarding how marijuana would be handled in non-smoking facilities, DPH noted that the proposed amendments do not require that smoke-free facilities permit marijuana to be smoked on-site.

Laboratories

[Section 34](#) of The Massachusetts Controlled Substances Act was amended in 2015 to provide legal protection for independent testing laboratories qualified to test marijuana under the regulations and Section 34:

[A] laboratory may possess, store, analyze, process and test medical marijuana and medical marijuana-infused products; provided, however, that such laboratory shall do so in accordance with the department's regulations and written guidelines governing procedures for quality control and testing of products for potential contaminants.

The proposed amendments provide that independent testing laboratories must obtain a certificate of registration as an independent testing laboratory prior to serving as an independent testing laboratory for a RMD. With that certificate, laboratories can register their own agents (employees who transport or test marijuana) directly with the Program, rather than through the RMDs for which they provide services. The proposed amendments clarify that labs are a protected destination and require the

same protocols for transportation of marijuana and infused products as for RMDs.

Some Details of Interest

At the risk of getting too far into the weeds (it had to be said somewhere in this post...), certain of the more technical proposed amendments seem to reflect the Program's desire to reflect lessons learned since the inception of the Program.

For example, the proposed amendments formally replace the cumbersome and controversial RMD application "scoring" process with an "evaluation" process, which is consistent with current Program policy and process. Security is addressed in the addition of a cash handling policy requirement, the permitted use of motion detection cameras if the RMD can show adequate recording capabilities, and the permitted use of alternative security safeguards other than a second back-up alarm company. With disclosure of the location of cultivation/MIP production facilities common at the municipal level, DPH proposes to remove the requirement that the location of these facilities remain secret.

On the cultivation front, organic cultivation is only required if the product is labeled as such, although non-organic pesticides require DPH approval. RMDs may cultivate from clones, not just seeds, although the "seed to sale" nomenclature still applies for the RMD's tracking methodology, which must track all seeds, plants, and products in a form and manner approved by DPH.

Marijuana in Massachusetts – What's Next?

Massachusetts voters will soon have the chance to vote yes or no on [Question 4, The Regulation and Taxation of Marijuana Act](#), an initiative petition that is on the November 2016 ballot. The stated purpose of the proposed law is to "control the production and distribution of marijuana under a system that licenses, regulates and taxes the businesses involved in a manner similar to alcohol and to make marijuana legal for adults 21 years of age or older." Although so-called recreational marijuana would be regulated through a Cannabis Control Commission, the proposed law does require the Commission and DPH to work collaboratively to effectively regulate the production and distribution of marijuana.

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