

O&B MEDICAL CANNABIS & HEALTH LAW CLIENT ALERT

October 2016

CHANGES TO THE PUERTO RICO DEPARTMENT OF HEALTH'S REGULATION ON MEDICINAL CANNABIS

REGULATION NUMBER 8766 OF 2016

During the summer of 2016 the Commonwealth of Puerto Rico's Department of Health (the "Department of Health") adopted Regulation No. 8766 of 2016 ("Regulation No. 8766"), repealing Regulation No. 155 of 2015, which had been enacted to regulate the use, possession, farming, manufacture, dispensation, distribution and investigation of medical marihuana in Puerto Rico. This newsletter discusses some of the changes introduced by Regulation No. 8766.

Main Changes Introduced by Regulation No. 8766

License Applicant Requirements

- **Prior accusations or convictions**—Under Regulation No. 155 a person who had been *accused or convicted* of a felony or a crime involving moral turpitude, drugs, controlled substances, fraud, falsification or a crime that was against the public treasury could not be an agent, employee or affiliate of an entity applying for or holding a license to cultivate, manufacture, produce, distribute, perform quality tests or dispense medical cannabis. Regulation No. 8766 eliminates this prohibition by allowing those who have been convicted of a felony to be agents, employees or affiliates of the licensed entity, after 5 years of having served their full sentence. The prohibition against a person who had been merely *accused* of a felony or any of the other crimes was eliminated.
- **Primary Resident**—Though Regulation No. 8766 requires that every license applicant be a resident of the Commonwealth of Puerto Rico, it introduces the concept of the "primary resident" as a way to allow foreign investors to participate in licensed cannabis establishments. Regulation No. 8766 requires that all medical cannabis establishments have a primary resident.
- **Financial Capacity instead of a Surety Bond**—Regulations No. 155 allowed the Department of Health to require applicants to provide a surety bond. Though these regulations did not state the bond amount required to be paid, the Department of Health's Administrative Order No. 352 of 2016 ("AO No. 352") had established that the bond could not be less than the application fee. Regulation No. 8766 eliminates the surety bond requirement and instead establishes that all persons applying for a license must demonstrate the financial capacity to operate the licensed facility for a period of 12 months.

Licensing Process

- ***Application Period***—Regulation No. 8766 clarifies that the period to apply for a license begins with the submission of the first application form and will continue until the Department of Health reaches the previous amounts determined to be needed in order to meet patient demand. The Department of Health may make an invitation to present new applications when it determines that more facilities are needed.
- ***Mandatory Background Checks***—Applicants (including the officers, directors, members and manager of a legal entity requesting a license) and the employees, subcontractors and managers working for applicants will be subject to background checks by the Department of Health.
- ***Selection Process based on Merit***—Applications will be evaluated based on the principles of merit. Article 22 (F) (1) of Regulation No. 8766 lists the criteria the Department of Health will take into account in order to establish merit; each of which will be assigned a numeric value by the Department. Licenses will be awarded to those applicants that score the highest points.

Temporary Tracking System

- AO No. 352 had established that, until the Department of Health chose a system for the tracking/monitoring of inventory medicinal cannabis, licensed establishments had to maintain a tracking/monitoring system that meets the requirements set in Regulation No. 155, saves the data indefinitely and makes it accessible at all times. Regulation No. 8766 incorporates AO No. 352's language, requiring all licensees to maintain a temporary tracking system.

Elimination of Cultivation and Manufacturing Cap

- Regulation No. 155 had established a maximum of 1,500 cannabis plants could be cultivated, produced, manufactured or distributed. Regulation No. 8766 eliminates this cap and substitutes it for different licensing alternatives depending on the cultivation and/or manufacturing area's square footage. Other services, such as the transportation and distribution of medical cannabis, now have fixed tariffs that do not change according to factors such as volume or quantity.

Other Changes

- Establishes a complete process to allow tourists that qualify under Regulation No. 8766 to obtain the medicinal cannabis during their stay in Puerto Rico.
- Clarifies that the prohibition establishing that a licensed facility may not operate at a distance of less than 400 meters from a school, a preschool or child care center, only applies when these institutions remain open. Furthermore, the prohibited distance is decreased to 304.8 meters, which is the distance established by the federal Drug Free Zone Act.

Public Hearings and other considerations

Regulation No. 8766 was enacted as an emergency regulation. Though regulations adopted through the emergency procedure, they are immediately enforceable, Puerto Rico law requires agencies to comply with the full rule adoption procedures (which includes allowing the public an opportunity to

submit comments and/or celebrating hearings) once the emergency regulations or amendments are filed with the Department of State.

On August 22 and 23 of this year the Department of Health celebrated public hearings to discuss Regulation No. 8766. Some of the participants included the University of P.R.'s School of Public Health, the Legal Aid Society, the P.R. Multiple Sclerosis Foundation, Puerto Rican League Against Cancer, Pro Cannabis Patients Alliance Inc. and the Puerto Rico Mental Health & Anti-Addiction Services Administration, amongst others.

Up to this date no official comments have been made by the Department of Health regarding its findings or any proposed amendments to the regulations, though the latter should be expected in light of some of the comments presented at the hearings. These include allegations that the regulation discriminates against patients, hinders the participation of small businesses and promotes a monopoly in the sale of the product. Parties also voiced concerns over how pharmacies, doctors and patients should proceed given the fact that, up to this date, marihuana is still considered an illegal drug under federal law.

Considering that the regulatory changes that have legalized the medicinal cannabis industry at a state level are executive in nature, the upcoming election process may imply a certain degree of uncertainty. Notwithstanding, to date, all aspiring candidates to the governorship have endorsed the industry.

Note: Because of the general nature and informative purpose of this newsletter, nothing herein should be considered as legal advice or a legal opinion or that it establishes in any way whatsoever an attorney-client relation or engagement for legal services with any reader. In addition, there are relevant issues as to the applicability and interaction of Regulation 8766 with federal and state laws in Puerto Rico which are not addressed in the instant Alert. Thus, for further information, please contact any of our Medicinal Cannabis and Health Law Practice Group attorneys who can provide legal assistance in accordance with applicable state and federal laws and regulations.



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