MEDICAL MARIJUANA COMES TO PENNSYLVANIA: WHAT TO EXPECT AS THE KEYSTONE STATE ROLLS OUT ITS NEW MEDICAL MARIJUANA PROGRAM

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A lack of consensus regarding both medical and recreational marijuana has sparked intense debate across the country. Combined with federal law prohibitions, the state-by-state mosaic creates a dynamic legal landscape. Marijuana remains illegal federally and retains its classification as a Schedule I drug under the Controlled Substances Act. However, 26 states and the District of Columbia have enacted state laws legalizing marijuana in some form. On April 17, 2016, Pennsylvania joined other states that have recognized some medical use for marijuana when Governor Tom Wolf signed the Medical Marijuana Act ("Act 16")[1] into law.

The Pennsylvania Department of Health ("DOH") is charged with implementing Act 16, and it promptly developed the medical marijuana program. The DOH has been rolling out temporary regulations (three sets so far) and it anticipates that medical marijuana will become available in Pennsylvania in early 2018. The first critical date for those interested in becoming a medical marijuana organization is January 17, 2017, when the DOH releases its applications for grower/processors and dispensaries through its website.

ACT 16 GENERALLY

Act 16 legalizes medical marijuana for individuals determined by their physicians to suffer from a "serious medical condition."[2] The Act provides the authority for Pennsylvania to grant grower/processor licenses as well as dispensary licenses. Act 16 allows the Department of Health to allocate 50 dispensary licenses.[3] Essentially, the growers or processors are the manufacturers of the product, while the dispensaries serve as the distributors. Act 16 permits the DOH to divide Pennsylvania into "a minimum of three regions . . . for the purpose of granting permits . . ."[4]

After a period of public input, the DOH has settled on six regions, per the requirements of Act 16.[5] In determining how many licenses would be allocated per region, the DOH considered regional population, the number of patients suffering from serious medical conditions in those regions, the types of serious medical conditions, access to public transportation in the regions, and other factors that the department deemed to be relevant.[6]

Click here to view the Pennsylvania Department of Health medical marijuana regions.

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Notably, a southeastern Pennsylvania region which includes Philadelphia and eight total counties will receive ten dispensary permits and two grower/processing permits. A central Pennsylvania region which includes Harrisburg and fourteen total counties will receive four dispensary permits and two grower/processing permits. The southwestern Pennsylvania region, including Pittsburgh, will receive five dispensary permits and two grower/processing permits. Three regions across Pennsylvania's northern border will receive two dispensary permits and two grower/processing permits.

PENNSYLVANIA INCENTIVIZES MEDICAL MARIJUANA RESEARCH

Chapter 19 of Pennsylvania's Act 16 states that the DOH "shall establish and develop a research program to study the impact of medical marijuana on the treatment and symptom management of serious medical conditions."[7] The state will engage what the act calls "health care medical marijuana organizations" to perform clinical research on which strains of marijuana perform best in treating individual ailments.[8] Importantly such clinical research is not expressly prohibited under federal law.[9] Act 16 streamlines the research application process by directing the DOH to petition the U.S. Food and Drug Administration ("FDA") and the Drug Enforcement Agency for approval to conduct research.[10]

In order to participate as a clinical research center, schools and hospitals will need a partner to grow and dispense marijuana to the institution. The institution must have at least $15 million in capital. Ideally, the state hopes to attract research interest from its health systems and universities and will grant eight total permits.[11]

Such attraction should not be difficult, given the fact that participating research organizations stand to profit significantly from their lab discoveries. Participating institutions that develop treatments for specified illnesses will likely hold the patents for that particular strain.[12] Then, the patent can be licensed out.[13]

In addition to funding obtained through federal sources, Act 16 uses its Medical Marijuana Program Fund to raise money for research. The funding stems from fees and taxes paid by medical marijuana organizations under Act 16. According to the Act, 30 percent of the funds from these fees will be used to research: "(1) medical marijuana treatment for serious medical conditions defined in the Act; and (2) the use of medical marijuana as a treatment for other medical conditions for which medical marijuana may have legitimate medicinal value."[14]

The full text of Act 16 is available on the Pennsylvania General Assembly's website.

DOH RELEASES 2016 TEMPORARY REGULATIONS

A series of temporary regulations released by the DOH govern the practical implementations of Act 16. These regulations provide guidance to growers, processors, dispensaries, and laboratories in advance of the 2018 medical marijuana rollout in Pennsylvania.

Growers and Processors

Grower/processor regulations are available at Title 28, Chapter 1151 of the Pennsylvania Code. Growers and processors may obtain seeds or immature medical marijuana plants from outside of Pennsylvania as part of their start-up inventory within 30 days of being deemed operational by the DOH.[15] Receipt of each seed and

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immature marijuana plant must be entered into the DOH electronic tracking system.[16] Within six months of achieving operational status, growers and processors must provide the DOH with a "forecast of the amount of medical marijuana it projects it will produce and in what form."[17] Seeds, immature plants, and expired plants must be stored in a separate locked area of the facility and should be disposed of according to DOH directives.[18] Any pesticides, fungicides, or herbicides used on medical marijuana must be approved by the Pennsylvania Department of Agriculture.[19] Finally, the grower/processor regulations detail the application process for obtaining a facility license, regulations on labeling and transporting marijuana, and facility security requirements and visitor restrictions.

Dispensaries

Dispensary regulations are available at Title 28, Chapter 1161 of the Pennsylvania Code. Each dispensary license holder may provide medical marijuana at a maximum of three separate locations, which must be indoor, enclosed, and secure.[20] The regulations contain restrictions on where dispensaries may operate in order to ensure the safety of children, and stipulate that dispensaries cannot share office space with practitioners or other physicians.[21] After receiving a doctor's certification, patients and caregivers must present valid medical marijuana identification cards at the dispensary which are issued by the DOH.[22] Dispensary employees must certify the authenticity of identification cards and review certification instructions through the DOH database, and must prepare and file a receipt with the DOH using the mandatory electronic tracking system.[23] Physicians may, in their discretion, place limitations relevant to method of consumption or duration of use on the patient's certification.[24] Importantly, physicians may not issue patient certifications while present at a dispensary facility.[25]

Dispensary employees must be 18 or older, and must handle filling all patient prescriptions.[26] A physician or pharmacist must be present at the facility to dispense the marijuana.[27] For dispensaries with more than one location, ancillary sites may have a physician's assistant or certified nurse practitioner fill this role.[28] No self-administration by individual patients at dispensary facilities is permitted.[29] Dispensaries may only allot a 30-day supply of medical marijuana at a given time, until the patient has consumed all but a seven-day supply as prescribed by his or her doctor.[30] The tetrahydrocannabinol, or THC, concentration in products sold by dispensaries may not exceed 0.3 percent.[31]

Dispensary employees must follow strict labeling requirements as set forth by the DOH. The medical marijuana must be sold in a sealed, labeled package which includes the packaging date, the "use by" date, a use disclaimer,[32] a warning that the marijuana must be kept in its original container, a warning regarding unauthorized use, the number of doses within the package, the strain and percentage of THC and cannabidiol, and a safety insert.[33] This label may not bear resemblance to any trademarked product[34] nor may it contain any "cartoon, color scheme, image, graphic, or feature" that might make it attractive to children.

Laboratories

Laboratory regulations are available at Title 28, Chapter 1171 of the Pennsylvania Code. The DOH must approve those laboratories wishing to "identify, collect, handle and conduct tests on samples and test samples used by a grower/processor" as is required by Act 16.[35] Laboratories must employ at least one director who meets the minimum educational requirements set forth in § 1172.22(b)(1-3). Growers and processors must enter into written

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contracts approved by the DOH in order for labs to ensure stability tests for product potency and purity.[36] Testing is conducted at the request of the grower/processor from each harvest batch at six-month intervals for one year.[37] Labs must report the occurrence and results of each test to the DOH.[38]

The full temporary regulations for growers/processors, dispensaries, and laboratories are available online via the Pennsylvania Bulletin.[39]

CONCLUSION

As the official rollout of medical marijuana in Pennsylvania draws near, time is of the essence for those interested in becoming involved in marijuana production and distribution. The initial certification process will be competitive, so those interested should begin familiarizing themselves with the state's temporary regulations. This includes entrepreneurs and companies interested in serving as growers or dispensaries, as well as physicians and health systems focused on obtaining a coveted research license or dispensary permit. The state requires applicants to pay a permit fee, display proof of capital, and complete training courses and background checks. According to the Pennsylvania Health Department Secretary Karen Murphy, applications for growers and processors as well as dispensary permit applications will become available on January 17 and will be accepted by the state from February 20 to March 20.

NOTES:

[1] 35 P.S. § 10231.101 (2016).

[2] As defined by the statute, "serious medical conditions" include: cancer, HIV/AIDS, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, Crohn's disease, PTSD, intractable seizures, glaucoma, sickle cell anemia, severe chronic or intractable pain of neuropathic origin or pain in which conventional therapeutic intervention/opiate therapy is ineffective, and autism. 35 P.S. § 10231.103.

[3] 35 P.S. § 10231.616(2).

[4] 35 P.S. § 10231.603(d).

[5] 35 P.S. § 10231.603(d)(1–5).

[6] *Id.*

[7] 35 P.S. § 10231.1902(a).

[8] 35 P.S. § 10231.1907.

[9] "The FDA also has an important role to play in supporting scientific research into the medical uses of marijuana and its constituents in scientifically valid investigations as part of the agency's drug review and approval process. As a part of this role, the FDA supports those in the medical research community who intend to study marijuana." *See FDA and Marijuana*, Public Health Focus: News and Events (July 7, 2016), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.html.

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[10] Scott Kraus, *Pennsylvania Wants to Lead Research Into Pot's Curative Properties*, The Morning Call (Aug. 6, 2016), available at http://www.mcall.com/news/nationworld/pennsylvania/mc-pa-medical-marijuana-research-leader-20160716-story.html.

[11] 35 P.S. § 10231.1903(a) ("The department shall engage universities within this Commonwealth to participate in the collection, collation, analysis and conclusive findings of the research studies").

[12] Kraus, *supra* at n. 13.

[13] *Id.*

[14] *See generally*, 35 P.S. § 10231.1902.

[15] 28 Pa. Code § 1151.24(a).

[16] 28 Pa. Code § 1151.24(b).

[17] 28 Pa. Code § 1151.29(b).

[18] 28 Pa. Code § 1151.31(a). *See also* 28 Pa. Code § 1151.40.

[19] 28 Pa. Code § 1151.27(a).

[21] 35 P.S. § 10231.902 (a-c).

[22] 28 Pa. Code § 1161.26(a), (b)(1–3).

[23] 28 Pa. Code § 1161.23(a).

[24] 28 Pa. Code § 1161.23(b)(1); § 1161.23(c). Notice of the availability of the electronic tracking system will be published 60 days prior to its implementation. *See* 28 Pa. Code § 1161.39.

[25] 35 P.S. § 10231.403(b)(6).

[26] 35 P.S. § 1161.25(e).

[27] 28 Pa. Code § 1161.22(b)(2).

[28] 28 Pa. Code § 1161.25(a).

[29] 28 Pa. Code § 1161.25(b). *See also* 28 Pa. Code § 1161.25(c)(These individuals must complete a four-hour training course which will qualify for continuing education credits in each respective field).

[30] 28 Pa. Code § 1161.22(b)(3).

[31] 28 Pa. Code § 1161.24(b).

[32] 28 Pa. Code § 1161.27(b).

[33] 28 Pa. Code § 1161.28(c)(4)("This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.")

[34] 28 Pa. Code § 1161.28(e). The insert will include information regarding the method for administering individual doses of medical marijuana, potential dangers stemming from its use, how to recognize problematic

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usage and obtain treatment, the side effects which may cause harm to the patient, how to deter misuse of marijuana by minors, and any other information the DOH deems necessary to enhance patient safety.

[35] 28 Pa. Code § 1161.28(d)(1–4).

[36] 28 Pa. Code § 1171.23(a).

[37] 28 Pa. Code § 1171.26(b).

[38] 28 Pa. Code § 1171.26(a).

[39] 28 Pa. Code § 1171.35(a).

[40] These regulations are valid for two years from date of enactment.

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