MEDICAL MARIJUANA COMES TO PENNSYLVANIA (PART 3): HOW PA PATIENTS CAN ACCESS MEDICAL CANNABIS

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Pennsylvania's patient and caregiver regulations answer the *who* and the *how* questions in obtaining medical marijuana. [1] For example, how does the law distinguish caregivers from patients? What are the rights of each class of persons? How do patients register with the state? What type of identification is needed when a patient goes to their local dispensary? The regulations answer these questions and detail the state ID card application process, the responsibilities of cardholders, the process by which identification cards can be modified or updated, and the penalties for misusing identification cards.

The first installation of this series, entitled <u>"Medical Marijuana Comes to Pennsylvania: What to Expect as the Keystone State Rolls Out its New Medical Marijuana Program,"</u> provided an overview of Act 16 generally, including its emphasis on medical research incentives and its temporary regulations for growers, processors, and laboratories. The second installation, titled <u>"Medical Marijuana Comes to Pennsylvania (Part 2): State Finalizes Act 16's Temporary Physician and Practitioner Regulations,"</u> detailed the rules governing physicians who seek to prescribe medical marijuana as a method of treatment in Pennsylvania. This alert will detail the regulations governing Pennsylvania patients and caregivers.

RECENT UPDATES ON ACT 16 IMPLEMENTATION

In the final days of June 2017, the Pennsylvania Department of Health ("DOH") announced the recipients of the 12 medical marijuana grower and processor licenses and 27 medical marijuana dispensary permits.[2] The competitive process required the DOH to select the final awardees from a pool of 457 total applicants: 177 grower and processer licenses and 280 dispensary licenses.[3] At the end of July 2017, the DOH launched its practitioner registry for the Medical Marijuana Program. When the DOH surveyed 193 Pennsylvania physicians, approximately 73 percent stated that they might participate in Pennsylvania's medical marijuana program.[4] The Department of Health currently reports over 100 approved physician prescribers on its website.[5] It remains to be seen how widespread physician buy-in will be statewide; the success of Act 16's implementation depends on the willingness of doctors in all areas of Pennsylvania to register, attend training, and understand the complex regulatory framework associated with prescribing medical marijuana as a treatment.[6]

In late September, the DOH approved the first two medical marijuana laboratories that will preform quality control testing on individual products.[7] Specifically, the labs test the ratios of cannabidiol) and tetrahydrocannabinol and ensure that the products are labeled correctly.[8] State-approved laboratories must also test for pesticides,

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solvents, moisture content, and other substances.[9] In this spirit of safety, DOH will not place a limit on the number of labs that can gain state approval to test products.[10]

An estimated two million Pennsylvanians may be eligible to obtain medical marijuana when it is available in early 2018 — but how do they get it? The DOH's November 11, 2017 finalization of its temporary regulations for patients and caregivers provides the long-awaited answer to this question. The highly-regulated process is not as simple as walking in to your nearest dispensary and making a purchase. Rather, the state's system requires seamless interactions among the DOH and laboratories, prescribers, caregivers, and patients themselves to ensure that the program's rollout runs smoothly. These interactions provide significant business and clinical treatment opportunities for businesses, health systems, research centers, academic institutions, and individual prescribers alike. For professionals who are still interested in being a part of Act 16's implementation, it is not too late. For example, the state is still accepting prescribing physician applications, as well as applications for testing laboratories and research facilities. Particularly with the continued conflicts between federal and state marijuana laws, it is important that all parties remain keenly aware of Pennsylvania's participation requirements to achieve full compliance with the statutory framework.

Pennsylvania remains optimistic that its Act 16 program will be fully operational in early 2018. However, law suits from growers and processors whose applications were denied by Pennsylvania may threaten this timeline. Some failed applicants have filed for injunctive relief to prevent Act 16's implementation due to the "arbitrary, capricious, and unreasonable" nature of the state's selection and licensing procedures.[11] Some argue that the selection process runs rampant with bias or favoritism, since panelists who scored the applications are kept secret, in alleged violation of Pennsylvania's Right-to-Know law.[12] In response, the Office of Open Records recently ruled that the state must disclose the identities of the 12 individuals who sit on the panel.[13]

While Pennsylvania's medical marijuana program presses on, the legal risks of participating in state medical marijuana programs persist. Attorney General Jeff Sessions continues to emphasize that federal laws prohibiting marijuana legalization remain in effect, although Washington is still deciding whether or not to formally overturn the Obama administration's position that states could implement their own laws without significant federal intervention. Attorney General Sessions has shown a slight willingness to consider further medical marijuana research and has encouraged growers to expand the supply of medical marijuana that is available to be tested for research. For this reason, Pennsylvania's deliberate and responsible implementation of its research-focused medical marijuana program could have a persuasive effect on decisions being made as to marijuana's legality at the federal level.

THE REGULATORY APPROACH TO PATIENTS AND CAREGIVERS

An "adult patient" can obtain medical marijuana in Pennsylvania if the individual (i) is over 18 years of age; [14] (ii) has a serious medical condition; (iii) has met the requirements for certification under the act; and (iv) is a resident of Pennsylvania. Similarly, a "minor patient" fulfills the same criteria as stated above, but is under 18 years of age. A "caregiver," however, is "an individual designated by a patient to obtain on behalf of a patient, and provide to a patient, a medical marijuana product."[15] If the patient is a minor, a caregiver must be either (i) a parent or legal guardian of the patient; (ii) an individual designated by the minor patient's parent or legal guardian; or (iii) an appropriate individual approved by the department upon a sufficient showing that no parent or legal guardian is

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appropriate or available.[16] Likewise, the DOH may issue an identification card to an individual under the age of 21 to serve as a caregiver when a sufficient showing is made.[17]

If a patient is homebound and is unable to appear at the dispensary in person, a prescriber may recommend that the patient utilize a caregiver's services. The regulations governing caregivers are largely the same as those governing patient cardholders, as described in more detail below. However, the initial application process to become a caregiver is more rigorous. Caregivers follow the same process online to apply to the DOH for an identification card. The card is issued to the caregiver only after the caregiver submits fingerprints and passes a criminal background check to determine their "character, fitness, and suitability" to serve as caregiver.[18] Notably, no criminal background check is required for patients to participate in the state's program. On the other hand, caregivers do undergo background checks in order to become state-certified. The state will pay particular attention to whether a caregiver has been convicted of a criminal offense relating to the sale or possession of drugs, narcotics, or controlled substances in the past five years.[19]

Further, the regulations permit the DOH to review the Prescription Drug Monitoring Program database prior to approving a caregiver's application card. If the caregiver has "a history of drug abuse or of diverting controlled substances or illegal drugs," the state reserves the right to deny the application.[20]

STATE-ISSUED IDENTIFICATION CARDS

In order to obtain medical marijuana from a Pennsylvania dispensary, a patient first needs a recommendation letter signed by a medical professional who has officially registered with the state's Act 16 program.[21] This letter must be signed by a medical practitioner, submitted to the DOH, approved by the DOH, and accessed by a dispensary through the electronic tracking system during each visit.[22] Then, patients must submit an identification card application and the required \$50 fee to the DOH.[23] The DOH may waive or reduce identification card fees at its discretion if an applicant demonstrates sufficient financial hardship.[24]

By submitting this application, which is available on the DOH website, [25] patients are applying to be placed on the patient registry maintained by the state and accessed by dispensaries and physicians. [26] More than 5,000 Pennsylvania patients signed up online in the first launch week of the registry. [27] Notably, the information maintained by the DOH on patients, including medical information provided on a patient's physician certification and information relating to a patient's specific serious medical condition, is confidential and is not subject to public disclosure. [28] If a patient's application is incomplete or factually inaccurate, the DOH will notify an applicant in writing and advise the patient as to what documents are outstanding. [29] At that time, the applicant has 60 days to submit the requested materials, or their application may be denied. [30]

It remains to be seen how long the complete application process will take. The ID card will contain the following information: the name and address of the cardholder, a designation of whether the cardholder is the patient or caregiver, the date of the card's issuance and expiration, a unique ID number for the medical marijuana license, a photograph of the cardholder, the parameters of form and dosage of medical marijuana as set by the cardholder's prescribing physician, and additional information deemed necessary by the DOH.[31] With the ID card, cardholders can purchase medical cannabis from any state-approved dispensary.

CONCLUSION

Provided that the rollout of the remainder of Pennsylvania's Act 16 is not enjoined by pending litigation or the significant number of administrative grower, processor, and dispensary appeals currently sitting with the DOH, medical marijuana will be accessible in the state sometime in early 2018. Patients and caregivers must take note of their responsibilities and obligations under the regulations discussed above. Likewise, prescribing physicians and dispensaries should be aware of how their responsibilities interact and overlap with patient responsibilities to ensure a fully integrated, safe, and compliant patient experience.

[4] Christina Tatu, *Doctors needed for Pennsylvania medical marijuana program*, The Morning Call (Jul. 8, 2017), available at <u>http://www.mcall.com/news/nationworld/pennsylvania/mc-nws-medical-marijuana-doctor-participation-</u>20170627-story.html.

[5] http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-

P/MedicalMarijuana/Documents/DOH%20Approved%20Practitioners%2011-7-17.pdf

[6] A list of DOH-approved practitioners (broken down by region) is availablehere.

[7] ACT Laboratories of Pennsylvania LLC in Clearfield, PA and Keystone State Testing LLC in Julian, PA have been approved by the state to test medical marijuana products.

[8] Jan Murphy, *First two medical marijuana labs to provide 'quality control' approved by health department,* PennLive.com (Sept. 28, 2017),

http://www.pennlive.com/politics/index.ssf/2017/09/first_two_medical_marijuana_la.html.

[9] Id. The full statutory regulations governing testing laboratories can be found at 28 Pa. Code § 1171.

[10] Companies interested in become state-approved medical marijuana testing laboratories can be found on the DOH's website <u>here</u>.

[11] Sam Wood, *Suit to halt Pa. marijuana program may cause 'pain, agony, & death,'* The Philadelphia Inquirer (Sept. 11, 2017), <u>http://www.philly.com/philly/business/cannabis/suit-to-halt-pa-marijuana-program-may-cause-pain-agony-death-20170911.html</u>.

[12] *Id. See also,* Christopher Ullery and Calkins Media v. Pennsylvania Department of Health, Pennsylvania Office of Open Records, No. AP 2017-1548 (Sept. 18, 2017), <u>http://www.openrecords.pa.gov/Documents/2017-1420_Ullery_PaDeptofHealth.pdf</u>; Seth Tipton v. Pennsylvania Department of Health, Pennsylvania Office of

Open Records, No. AP 2017-1667 (Oct. 5, 2017), http://www.openrecords.pa.gov/Documents/2017-

<u>1667_Tipton_PaDOH.pdf;</u> Columbia Care v. Pennsylvania Department of Health, Pennsylvania Office of Open Records, No. AP 2017-1613 (Oct. 23, 2017) (holding that redacted competitor applications for grower/processor

^[1] The complete set of draft patient and caregiver regulations are codified at 28 Pa. Code § 1191.21-1191.33, or online via the Pennsylvania Bulletin, available <u>here.</u>

^[2] Pennsylvania Department of Health, *Department of Health Releases 12 Medical Marijuana Permits for Growers/Processors*, PA.gov (Jun. 20, 2017), <u>http://www.media.pa.gov/Pages/Health-Details.aspx?newsid=435</u>; *see also* Pennsylvania Department of Health, *Department of Health Grants Medical Marijuana Permits for Dispensaries*, PA.gov (Jun. 29, 2017), <u>http://www.media.pa.gov/Pages/Health-Details.aspx?newsid=436</u>.

^[3] Pennsylvania Department of Health, *Department of Health Grants Marijuana Permits for Dispensaries*, *supra* note 1.

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permits are subject to PA's Right to Know Law), <u>http://www.openrecords.pa.gov/Documents/2017-1613_ColumbiaCare_PaDOH.PDF</u>.

[13] Sam Wood, *Pa. must reveal names of secret marijuana panelists*, The Philadelphia Inquirer (Sept. 1, 2017), <u>http://www.philly.com/philly/business/cannabis/pa-must-reveal-names-of-secret-marijuana-panelists-</u> 20170901.html.

[14] 28 Pa. Code § 1191.21.

[15] *Id.*

[16] 28 Pa. Code § 1191.23(d)(1–3).

[17] 28 Pa. Code § 1191.23(c).

[18] 28 Pa. Code § 1191.27(b).

[19] 28 Pa. Code § 1191.30(a)(3).

[20] 28 Pa. Code § 1191.25(e).

[21] 28 Pa. Code § 1191.31(b).

[22] Note that if a patient's card was lost, stolen, destroyed, or is illegible, the applicant must submit a \$25 fee. 28 Pa. Code § 1191.26(b)(1).

[23] 28 Pa. Code § 1191.26(a). The regulations reserve the state's right to charge higher fees for the issuance of second (and subsequent) replacement identification cards, and plans to post fair notice of such fees on is website each January. The fees will also be publicized in the *Pennsylvania Bulletin.* 28 Pa. Code § 1191.26(c).

[24] 28 Pa. Code § 1191.26(d). The state will publicize a list of required documents on its website that an application must submit to request a fee waiver.

[25] 28 Pa. Code § 1191.25(a). To access the PA DOH patient and caregiver registry, visit

https://padohmmp.custhelp.com/app/login.

[26] See generally, 28 Pa. Code § 1191.21.

[27] Ben Schmitt, *More than 4,000 Pennsylvania residents register for medical marijuana in 1st week,* Tribune-Review (Nov. 8, 2017), http://triblive.com/local/valleynewsdispatch/12927341-74/story.

[28] 28 Pa. Code § 1191.22(b)(1-5).

[29] 28 Pa. Code § 1191.25(f). The DOH will also notify an applicant in writing if the application is denied outright.

[30] 28 Pa. Code § 1191.25(g).

[31] 28 Pa. Code § 1191.25(b)(1-9).

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