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Medical Marijuana Comes to Pennsylvania (Part 2): State Finalizes Act 16's Temporary Physician and Practitioner Regulations

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Following closely on the heels of the first anniversary of the passage of Act 16, known as the Medical Marijuana Act (the "Act"), the Pennsylvania Department of Health ("PA DOH") published the final Temporary Physician and Practitioner Regulations. This marks the most recent step by the PA DOH in the implementation of the state's medical marijuana program.

Act 16 presents significant business and clinical treatment opportunities for physicians interested in becoming prescribers. However, physicians should be wary of legal and regulatory considerations. As discussed in more detail below, physicians must comply with statutory prescription guidelines, and need to be in continuous contact with the PA DOH regarding changes to patient conditions. The regulations enact physician bans on advertising, receiving remuneration for medical marijuana prescriptions, and holding direct or indirect interests in any medical marijuana organization. It remains to be seen how federal HIPAA (Health Insurance Portability and Accountability Act) and Stark Law concerns will interact with these regulations. Likewise, how will insurance companies handle marijuana-motivated malpractice claims? Moreover, does the prohibition on holding a direct or indirect interest in a marijuana organization present a complete bar to physicians being both investors and prescribers?

The first installment of this series, entitled "Medical Marijuana Comes to Pennsylvania: What to Expect as the Keystone State Rolls Out its New Medical Marijuana Program," provided an overview of the Act generally, including its emphasis on medical research incentives and its temporary regulations for growers, processors, and laboratories. This alert will detail the regulations governing physicians who wish to prescribe medical marijuana in Pennsylvania.

Final Physician and Practitioner Regulations¹

Physician Application Requirements

Physicians who wish to prescribe medical marijuana must apply to be registered with the PA DOH as a "practitioner." This application must include the physician's full name, business address, e-mail address, telephone number, whether the physician owns or is affiliated with a medical practice (and if so, the name of that practice), education and specialty training information with supporting documentation, and a copy of the physician's medical license.² The physician must include a certification that states if his or her license is active and in good

¹ The complete set of draft physician regulations are codified at 28 Pa. Code § 1181.21–1181.32, or online through the Pennsylvania Bulletin, available here.

² 28 Pa. Code § 1181.24(b)(1–3). The physician must have an active medical license in accordance with the Medical Practice Act of 1985 (codified at 63 P.S. § 422.1–422.51a) or the Osteopathic Medical Practice Act (codified at 63 P.S. § 271.1–271.18).

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standing, whether the individual has faced any type of professional disciplinary action (and if so, an explanation of that action), and an affirmation that the physician does not hold a direct or economic interest in any medical marijuana organization(s).³ Furthermore, the physician must be qualified to treat patients with one or more serious medical conditions.⁴

Once the state approves the physician to prescribe marijuana, the physician must complete a four hour training course, which covers the responsibilities of practitioners and medical professionals under the Act, general information regarding marijuana under federal and state law, the latest scientific research on marijuana including its risks and benefits, informed consent issues, and recommendations for marijuana prescription to aid in pain management, risk management, palliative care, and opioid addiction.⁵ The course will also cover the use of the Prescription Drug Monitoring Program and best practices for selecting marijuana forms and dosage for individual patients based on the patient's condition and the practitioner or medical professional's specialty.⁶ The successful completion of this course will count toward a practitioner's continuing education credits as determined by the State Board of Medicine, the State Board of Osteopathic Medicine, the State Board of Pharmacy, and the State Board of Nursing.⁷

Once a practitioner notifies the PA DOH that he or she has completed the required course, the physician will be placed on the state's publically-available online registry.⁸ The registry will be reviewed annually by the PA DOH, and any physicians whose licenses are found to be inactive, expired, suspended, revoked, or limited will be removed from the registry.⁹ A practitioner may also be removed from the registry if he or she is subject to professional disciplinary action.¹⁰ Any physician who is removed from the registry may reapply for certification per 28 Pa. Code § 1181.24 and may be added back to the registry if the event leading to removal is resolved to the PA DOH's satisfaction.¹¹

Issuing, Modifying, and Revoking Patient Certifications

A physician may issue a patient certification if he or she determines that the patient has a serious medical condition and has included that condition in the patient's health care record, and is likely to receive therapeutic or palliative benefit from the use of medical marijuana.¹² The certification should include a patient's name, date of birth, and contact information as

³ 28 Pa. Code § 1181.24(b)(4).

⁴ 28 Pa. Code § 1181.24(a)(2). As defined by Act 16, "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.

⁵ The PA DOH is also soliciting persons who would like to apply for the training. Applications to become a trainer can be found here at the PA DOH website.

⁶ See generally, 28 Pa. Code § 1181.32.

⁷ 28 Pa. Code § 1181.32(c).

⁸ 28 Pa. Code § 1181.24(c); 28 Pa. Code § 1181.25.

⁹ 28 Pa. Code § 1181.26(a).

¹⁰ 28 Pa. Code § 1181.26(b).

¹¹ 28 Pa. Code § 1181.26(c). If removed from the registry, a practitioner may no longer have access to patient certifications and may not provide a copy of existing certifications to any person. 28 Pa. Code § 1181.26(d)(1-3).

¹² 28 Pa. Code § 1181.27(1-2). A physician's judgment as to the benefit received may come from the professional opinion of the prescribing physician and a review of the patient's prior medical history and controlled substance history if such records are available. 28 Pa. Code § 1181.27(2)(i-ii). See also, 28 Pa. Code § 1181.30 ("Prescription Drug Monitoring Program").

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well as the practitioner’s name, contact information, medical license number, and area of specialty.¹³ It should detail the date of the consultation and the patient’s specific serious medical condition,¹⁴ and must include a statement by the practitioner that the patient is under the practitioner’s continuing care for said condition (and for how long).¹⁵

The prescribing physician can include the recommended form of marijuana at the time of issuing a patient certification, however it is not mandatory. The regulations permit the practitioner to recommend that the patient discuss the form of medical marijuana with a physician or pharmacist at a dispensary.¹⁶ Prescribing practitioners hold a duty to immediately notify a dispensary of a patient’s adverse reaction to medical marijuana dispensed at that location.¹⁷

Other miscellaneous information to be included on a certification includes:

- whether a patient is terminally ill;
- a statement that a patient will be homebound or an inpatient during the time for which the certification is issued due to a medical or physical condition and is therefore unable to visit a dispensary to obtain the marijuana;
- a statement that the practitioner has reviewed the potential risks and benefits of using medical marijuana and has documented in the patient’s record that such explanation was given and informed consent was obtained;
- any additional information the practitioner believes to be relevant.¹⁸

When the certification is complete, the prescribing physician shall provide a copy of the certification to the patient, or if the patient is a minor, to the patient’s adult caregiver, provide the original certification to the PA DOH, and file a copy of the certification in the patient’s health record.¹⁹

Prescribing practitioners are not permitted to modify the form of medical marijuana on a patient certification for 30 days from when the receipt is entered into the tracking system by the dispensary, unless the practitioner notifies the PA DOH.²⁰ Furthermore, practitioners are required to provide written notice to the PA DOH if a patient no longer has the qualifying serious medical condition, the patient’s use of marijuana would no longer be therapeutic or palliative, or the patient has died.²¹ The PA DOH will notify a medical marijuana cardholder immediately if the patient’s certification is revoked; this information will then be available via the electronic tracking system.²²

Prescribing Practitioner Prohibitions

¹³ 28 Pa. Code § 1181.27(b)(1–2).

¹⁴ 28 Pa. Code § 1181.27(b)(3–4).

¹⁵ 28 Pa. Code § 1181.27(b)(5–6). Per § 1181.21, “continuing care” is defined as “treating a patient, in the course of which the practitioner has completed a full assessment of the patient’s medical history and current medical condition, including a patient consultation.”

¹⁶ 28 Pa. Code § 1181.27(b)(7)(i–ii).

¹⁷ 28 Pa. Code § 1181.22(c).

¹⁸ 28 Pa. Code § 1181.27(b)(8–11).

¹⁹ 28 Pa. Code § 1181.27(c)(1–3)(emphasis added).

²⁰ 28 Pa. Code § 1181.28(a).

²¹ 28 Pa. Code § 1129(a)(1–3).

²² 28 Pa. Code § 1129(d).

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The temporary regulations include five primary prohibitions that practitioners must be aware of. First, prescribing practitioners may not “accept, solicit or offer any form of remuneration from or to any individual, prospective patient, patient, prospective caregiver, caregiver, or medical marijuana organization . . . to certify a patient, other than accepting a fee for service with respect to a patient consultation . . .”²³

A practitioner may not hold a direct or indirect economic interest in any medical marijuana organization.²⁴ Practitioners are prohibited from advertising any ability to certify patients to receive medical marijuana.²⁵ A practitioner may not receive or provide samples of medical marijuana.²⁶ Finally, practitioners cannot issue a patient certification for the practitioner’s own use or for the use of a family or household member.²⁷

Additional Updates

Though uncertainty as to the enforcement of marijuana as a Schedule I drug persists at the federal level, Pennsylvania continues to advance the implementation of the Act.

On June 5, the PA DOH released its temporary regulations for clinical registrants and is accepting public comments on these regulations through June 15.²⁸ Throughout the next month, the PA DOH will continue documenting and analyzing grower/processor and dispensary applications and anticipates notifying successful permit awardees in late June. Up to twelve grower/processor licenses and twenty-seven dispensary permits may be allocated in Pennsylvania. To date, the PA DOH has received 500 applications in total, and has so far logged 258 applications for evaluation. A running list of applicants by region is available here.²⁹

The PA DOH has issued 231 Safe Harbor Letters as of April 26, 2017.³⁰ These letters certify that it is not a violation of Pennsylvania’s Medical Marijuana Act or Pennsylvania’s Controlled Substance, Drug, Device and Cosmetic Act if an individual lawfully obtains medical marijuana from outside of the state for the purposes of treating a minor with a serious medical condition.

In addition, Pennsylvania recently awarded a \$10 million contract to Denver-based MJ Freeway to track marijuana from “seed-to-sale.”³¹ PA DOH Secretary Karen Murphy sees this action as having two purposes: tracking medical marijuana from growth through sale at a dispensary, and “creating a registry for patients, caregivers, and practitioners to participate in the program.”³² Further, the data collection efforts of the tracking system will permit PA DOH

²³ 28 Pa. Code § 1181.31(a).

²⁴ 28 Pa. Code § 1181.31(b).

²⁵ 28 Pa. Code § 1181.31(c).

²⁶ 28 Pa. Code § 1181.31(f).

²⁷ 28 Pa. Code § 1181.31(d).

²⁸ The temporary clinical registrant regulations are available here. Members of the public interested in commenting on the clinical registrant regulations can do so here.

²⁹ Eric Hagarty, “Medical Marijuana Program Update,” PA DOH (Apr. 26, 2017).

³⁰ *Id.*

³¹ Wallace McKelvey, “Pa. awards \$10M ‘seed-to-sale’ medical marijuana tracking contract,” Penn Live (Apr. 20, 2017), http://www.pennlive.com/politics/index.ssf/2017/04/pa_awards_10m_seed-to-sale_med.html.

³² “Department of Health Selects Vendor for Medical Marijuana ‘Seed-to-Sale’ Tracking System, Pennsylvania Department of Health (Apr. 20, 2017), <http://www.media.pa.gov/Pages/Health-Details.aspx?newsid=422>.

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employees to detect violations of law and will ultimately enhance overall enforcement efforts.³³

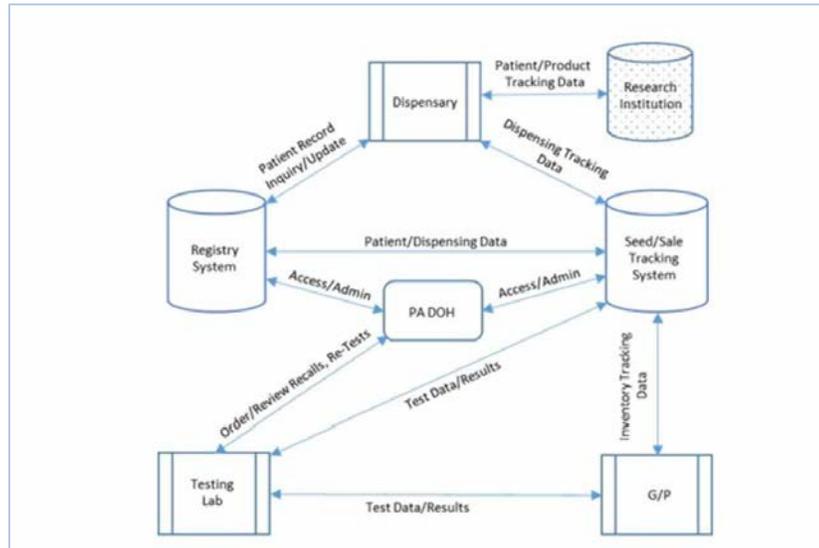


Photo Credit: PA DOH

HOW TO GET MEDICAL MARIJUANA IN PENNSYLVANIA WHEN THE PROGRAM IS FULLY IMPLEMENTED



Photo Credit: PA DOH

³³ 28 Pa. Code § 1161.23 provides dispensary and physician instructions for utilizing the tracking system. In particular, dispensaries are to review a patient’s most recent certification by utilizing the tracking system, and must file the receipt from any sale with the PA DOH through the tracking system. Further, pursuant to 28 Pa. Code § 1161.23(a)(2)(i-ii), physicians can place recommendations, requirements, or limitations as to form and dosage of marijuana on the patient’s file through use of the tracking system.

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