

In crafting Pennsylvania's medical marijuana law, known as Act 16 of 2016, the legislature expressed a desire to "provide a safe and effective method of delivery of medical marijuana to patients." In 2021, the legislature amended the medical marijuana law by the passage of Act 44 to further the efficiency of the program. However, certain provisions that were amended in 2021 to address pharmacist staffing in retail dispensaries have not been properly effectuated by the Pennsylvania Department of Health ("PADOH").

Specifically, Section 801 was amended in 2021 to ensure a physician or pharmacist was available at all times to consult with patients, while also eliminating the need for each physical dispensary premises to have a physician or pharmacist onsite. The changes made in 2021 were intended to instead require per permit² coverage, by giving operators the flexibility to staff their locations in a manner that ensured responsiveness to patients, while also maintaining operational efficiency.

Section 801. Dispensing to patients and caregivers.

(B) REQUIREMENTS.--A DISPENSARY SHALL HAVE A PHYSICIAN OR A PHARMACIST [ONSITE] AVAILABLE, EITHER IN PERSON OR REMOTELY BY SYNCHRONOUS INTERACTION, TO VERIFY PATIENT CERTIFICATIONS AND TO CONSULT WITH PATIENTS AND CAREGIVERS AT ALL TIMES DURING THE HOURS THE DISPENSARY IS OPEN TO RECEIVE PATIENTS AND CAREGIVERS. IF A DISPENSARY HAS MORE THAN ONE SEPARATE LOCATION, A PHYSICIAN ASSISTANT OR A CERTIFIED REGISTERED NURSE PRACTITIONER MAY [BE ONSITE AT] VERIFY PATIENT CERTIFICATIONS AND CONSULT WITH PATIENTS AND CAREGIVERS, EITHER IN PERSON OR REMOTELY BY SYNCHRONOUS INTERACTION, AT EACH OF THE OTHER LOCATIONS IN LIEU OF THE PHYSICIAN OR PHARMACIST. A PHYSICIAN, A PHARMACIST, A PHYSICIAN ASSISTANT OR A CERTIFIED REGISTERED NURSE PRACTITIONER SHALL, PRIOR TO ASSUMING DUTIES UNDER THIS PARAGRAPH, SUCCESSFULLY COMPLETE THE COURSE ESTABLISHED IN SECTION 301(A)(6). A PHYSICIAN MAY NOT ISSUE A CERTIFICATION TO AUTHORIZE PATIENTS TO RECEIVE MEDICAL MARIJUANA OR OTHERWISE TREAT PATIENTS AT THE

These 2021 statutory changes were intended to relieve dispensary operators from the burden of having a practitioner onsite, as long as they provided "synchronous interaction" between a patient and a practitioner. In the post-COVID healthcare environment, this is easily accomplished by a single practitioner covering multiple locations remotely. Notwithstanding, the PADOH ignored the legislature's directive to reduce the burden on

DISPENSARY.

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¹ Section 102 (3) (ii)

² Under Pennsylvania law, each individual dispensary permit allows the holder to open up to three medical dispensary storefronts.

operators by instead passing rules that undermine the 2021 amendments by require a one-to-one medical professional-to-premises ratio:

§ 1161a.25. Licensed medical professionals at facility.

- (a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is [present at the facility] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers.
- (b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be [present onsite] available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always [present] available, either in person or by synchronous interaction, at one of the facilities.

 Furthermore, no less than one dedicated medical professional must be present either, physically or by synchronous interaction, for each distinct dispensary facility location and shall not cover more than one dispensary facility location regardless of whether in-person coverage or synchronous interaction is used. (italics added).

The italicized language in the Department's final form regulation is an end-run around the 2021 legislative amendments. Underscoring the disconnect, the PADOH further disregarded the Act 44 changes in the following excerpt from the Department's Frequently Asked Questions:

Is a dispensary required to have a physician or a pharmacist available, either in person or by synchronous interaction, to verify patient certifications and provide consultations at all times during the hours of operation?

Yes, except when a dispensary is authorized to operate more than one facility under its permit. If there are other dispensary locations under its permit, a physician assistant or a certified registered nurse practitioner may conduct these services at each of the other locations instead of a physician or pharmacist. These medical professionals are permitted to rotate coverage of the facilities provided that a physician or pharmacist is always available, either in person or by synchronous interaction, at one of the facilities. *See* § 1161a.25(b).

We are aware that the Department is now issuing Notices of Deficiencies for alleged violations of § 1161a.25, resulting from targeted inspections of medical marijuana permit holders. Given the clear intention of the legislature in passing the 2021 amendments to Act 16, we anticipate that the Department will face appeals or litigation if it continues to ignore the legislative intent of the statute.

In the context of the Commonwealth's medical marijuana program, practitioners in dispensaries are limited to verifying patient certifications and providing patient-initiated consultations to patients and caregivers. Under these circumstances, medical professionals can cover more than one location at a time, working off-site to serve more locations with no discernible impact to patients.

According to the <u>Hospital and Health Association of Pennsylvania</u>, services delivered through telehealth can save time and money, as well as enhance health outcomes and support population health. Telehealth can support the right care, at the right time, and in the right setting for Pennsylvanians. The Senate is currently considering Senate Bill 739 which would permanently align the Commonwealth with this telehealth priority among others.

While enrollment in the medical marijuana program continues, the rate of growth is flagging in the post-COVID era. In addition to sluggish enrollment, consumers are increasingly choosing to participate in the legal adult-use cannabis markets of our surrounding states. Indeed, dispensaries are receiving fewer requests for medical consultations. This allows pharmacists to cover multiple locations without sacrificing a patient's desire for information about medical cannabis.

As Pennsylvania considers adult-use policy, it is critical to recognize the cost drivers of maintaining the medical program. The average salary for a pharmacist in Pennsylvania as of December 2023 is \$150,757³. Over the course of a year, the cost differential between compliance with the statute as intended, and compliance with the Department's own rule can amount to millions of dollars per permitted operator. *Spending millions to comply with a regulation that is inapposite with the statute is costing Pennsylvania medical marijuana patients more for their medicine.*

If maintaining a robust medical program remains a policy goal of the Administration, this unnecessarily costly regulation must be brought in line with the statute. The impact on the bottom line of medical marijuana operators will make the choice to maintain dual licenses in an adult use market untenable and patients will lose all access to medical professionals at those locations.

We request that you begin an immediate review of § 1161a.25 and issue a Statement of Policy that brings the Department's regulations in line with statute.

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³ https://www.salary.com/research/salary/benchmark/pharmacist-salary/pa