

July 19, 2022

Independent Regulatory Review Commission (IRRC)
333 Market Street, 14th Floor
Harrisburg, PA 17101



Dear Members of the Independent Regulatory Review Commission,

My comments are my own personal opinions and not the opinions of my employers (past, present or future). My comments pertain to *Section 1161a.25 Licensed Medical Professionals At Facility*.

My name is Marci Lee. I am a licensed pharmacist practicing in Pennsylvania. I started working in a dispensary in June 2019. I have assisted thousands of patients (and caregivers) with initial creation and optimization of their cannabis regimens.

I am writing to express my concern regarding the access to pharmacists/medical professionals inside the dispensary for our patients in the PA Medical Cannabis program.

There is a significant difference in the impact that a pharmacist has on patient care and cannabis education by being INSIDE the dispensary versus a pharmacist that is available for telemedicine and covering multiple locations remotely. Inside the dispensary, the pharmacist sets the tone of professionalism for the dispensary staff. The pharmacist is a critical support for medical patients that are not seeking to get high but to manage their symptoms and improve their quality of life.

Since 2019, there have been many changes in the PA program as a result of mergers and acquisitions. Subsequently, we saw at least three times (since November 2021 so far) that a multiple-state-operator (MSO) acquires one or more groups of PA dispensaries followed by a layoff of many pharmacists. The effect of these changes was massive since it involved multiple dispensary locations for each pharmacist layoff. A dispensary without a pharmacist becomes a general retail operation. A dispensary with a pharmacist onsite is operating as a patient care facility or medical care facility. Leadership teams at each MSO may not have experience in running a patient care facility and they may prefer to run a general retail operation.

At this time, there are two activities that are the primary focus of many of the pharmacists working in cannabis dispensaries in PA. One focus is patient consultations and clinical patient care activities for new patients and for existing patients. Some patients require multiple follow-up consultations about their regimen for adjustments. The second focus is the verification of each patient certification.

Until the verification process for each patient certification is automated, a pharmacist is manually checking for any restrictions on a patient certification. This can be time-consuming and take the pharmacist away from answering patient clinical questions via email, telephone or in-person at the dispensary. From my perspective, it is critical to automate the verification process as soon as possible by allowing two different computer systems to communicate with each other so that the pharmacist is free to provide patient care, solve drug related problems and assist patients/caregivers with their cannabis regimens.

With fewer pharmacists in the dispensary, patients are no longer getting the level of care they were once used to getting from us. We have fragile and cannabis-naïve patients entering dispensaries now where there may not be a pharmacist there to assist them. From a patient safety perspective, this is not safe.

Ambiguity and some interpretations of the temporary regulations from COVID around a virtual or remote model for medical professionals versus the in-person model has resulted in dispensaries opting for increased remote pharmacist coverage of their dispensary locations. While the question for clarification has been asked several different ways, there are still some dispensaries that interpret it is within the regulation to staff the pharmacists remotely and have each of them working in more than one location remotely at the same time. *This practice is not in the best interest of patient care or patient safety.* By specifying which type of medical professional may work at which locations, it seems that the point of the question that remains is not about which type of professional can be where but more of about *how many medical professionals need to be hired to provide adequate care for our patients in-person versus remotely*. From my perspective, mostly pharmacists are filling these roles in the PA dispensaries. No one is asking for clarification about which type of professional should be where exactly. It would be fine to simply state "medical professional" instead of the specific types of medical professionals in the future regulation because "medical professional" is already clearly defined.

Before returning to patient care in the dispensary in 2019, my work was in medication safety, medication error prevention and patient safety. I trained as a Fellow for one year at the Institute for Safe Medication Practices (ISMP). After my fellowship, I continued to work in medication error prevention and patient safety for ISMP/Med-ERRS and then at the FDA for three years and then I returned to ISMP/Med-ERRS for many years. I learned about systems in health care and how to design error out of these systems. I learned about high-alert medications and high-risk patient populations. There is increased risk for patients in general during transitions in the level of care as well such as upon discharge from a hospital stay or a transfer from the Intensive Care Unit to the General Medical Floor. I am also highly trained in evaluating the safety of medication container labels/carton labeling, packaging and instructions for use.

While cannabis is not inherently dangerous, I have guided several patients after they experienced some unexpected results from the cannabis medicines. When patients that are new to cannabis take too much, it can result in some discomfort or may be frightening for them. Pharmacists may be a source of information that can help these patients understand what happened so that they are not turned off from the idea of using cannabis again in the future.

Although our non-medical professional staff members may have good intentions, their assessment skills may not be adequate for providing a safe or appropriate cannabis product recommendations for certain patients. I have always enjoyed worked collaboratively with our non-medical professional staff members and I appreciate their perspective. I learn from everyone. Our communication is open and we can call on each other for help as needed. I am not sure that all dispensaries are operating collaboratively with the pharmacists. If the pharmacists are not inside the dispensary, it is less likely for this type of collaboration to occur.

There is a subset of patients in our PA program that simply need more help than others. All of these are examples of when the patients may be better served by a medical professional.

1. Patients that need to adjust their regimen either before and after surgeries
2. Patients with debilitating anxiety and that are afraid of walking into the dispensary
3. Patients that may be in shock to learn that their spouse or family member is not permitted to enter the dispensary with them for their very first visit
4. Patients with seizure disorders
5. Patients with memory issues

6. Patients taking an extensive number of prescription medications and over-the-counter (OTC) medications
7. Patients recently discharged from an inpatient hospital stay or rehabilitation facility
8. Patients getting physical therapy
9. Patients that cannot drive themselves to the dispensary
10. Patients that use alcohol
11. Patients that take benzodiazepine medications (e.g., Xanax/alprazolam, Valium/diazepam, Klonopin/clonazepam, etc)
12. Patients that ask for something stronger than what they tried so far
13. Patients that are rapid metabolizers
14. Patients that have an ultra-high tolerance for cannabis medications
15. Patients that do not want to use inhaled forms of cannabis
16. Patients that need help to find an alternative to a tincture or solution that is out of stock
17. Patients that need help to find an alternative to a capsule that is out of stock
18. Patients with allergy to linalool/lavender
19. Patients that are super sensitive to medications in general
20. Patients that have nerve-based pain
21. Patients that have inflammation-based pain
22. Patients that walk with assistance such as a walker, cane
23. Patients that have limited mobility and may be at a high risk for falls
24. Advanced-age patients (some of our patients are in their 90s)
25. Young patients (minors under 18 years old; some of our patients are 5 or 7 years old)
26. Cannabis naïve patients
27. Fearful patients that are not sure if cannabis is right for them yet
28. Patients that purchased items (from a CBD shop) that are not actually CBD but contain DELTA-8-THC and can cause side effects, etc.
29. Patients looking for a replacement for something they ran out of from an adult-use state.
30. Patients that are former police enforcement and need some extra information to accept that cannabis is a medicine
31. Patients that grew up in a lifetime of conditioning that cannabis is "bad"
32. Patients that have chronic severe pain that are still using opioid medications
33. Patients that are using blood thinning medications
34. Patients that had a terrible experience with a long-acting form in an adult-use state (usually a gummy that was too much and lasted a very long time)
35. Patients that have a lot of questions about cannabis
36. Patients that need help to make their own edible forms of cannabis
37. Patients that need help with math for their cannabis medicines
38. Patients that cannot see the markings on a dropper to measure their doses of tincture or solution
39. Patients that have deformed hands from severe arthritis and cannot use certain forms of cannabis because it is too hard for them to handle
40. Patients with a closet full of cannabis medicines that "didn't work" for them

Additional reasons for why we need pharmacists/medical professionals to support our patients inside the dispensary:

1. Some patients (especially our advanced-age patients) do not have access to their own computer or smart phone (for learning about cannabis, for seeing the menu, for finding cannabis information resources)
2. Some patients are very nervous and need some gentle reassurance about if cannabis is a good choice for them.
3. Some patients are medically complicated with an extensive health history that may take them 40 minutes to describe before we even talk about their goals cannabis because they are taking a long list of OTC and prescription medications.
4. Some patients are homebound or nonverbal and we are speaking with a family member, caregiver or friend. These caregivers need help to know how to monitor and indirectly assess for side effects and efficacy.
5. Some patients are minors/young children and we are assisting them indirectly via a parent/caregiver.
6. There is a terminology challenge in cannabis and many people need some education to get to a place to speak in common language to declare what the goals are for the cannabis regimen.
7. There is a challenge for dose discovery and dosing of ingested cannabis medicines that can take weeks or months to discover the smallest effective dose for each patient. Cannabis dosing is very individualized and ranges widely. There is no "usual" dose for everyone. The dose has nothing to do with the size of the patient either. This is generally shocking to parents of young children using cannabis medicines.
8. There are appropriate follow-up questions that should be asked in a consultation with a patient. These questions will assist with fine tuning the products that could be useful and then we ask about the patient's preferences in terms of forms of cannabis they want to try versus forms that they want to avoid.
9. We need medical professionals to support patients with questions about side effects and adverse reactions to cannabis medicines and as we integrate new cannabis medicines into an existing prescription regimen. Patients need help to know what to monitor for and when to increase or decrease the cannabis doses.
10. The pharmacist has a unique understanding of the product labels for the cannabis medicines.
11. Pharmacists/medical professionals can assist with questions about drug interactions especially with benzodiazepines (alprazolam XANAX, diazepam VALIUM, etc) or with alcohol or some seizure medications, some blood thinning medications and more.
12. Patients with debilitating anxiety may need more time than other patients on their very first visit to the dispensary.
13. Patients may not realize that their loved one is not allowed inside the dispensary with them until that moment/upon arrival and this may increase anxiety for them.
14. Patients may have already tried several products over the course of years. Using the information about these trials can be useful to determine what to do next and a medical professional is more inclined to approach this safely where a non-medical person may simply offer a different product to try. We have many patients with a closet full of products that "didn't work" because this is a common issue. Medical professionals can work with patients and what they have already purchased to guide them to determine ways to optimize the regimen.

When our program began in PA in 2018, a medical professional was required to be physically inside the dispensary during hours of operation in PA.

During COVID, our temporary regulations included an option for pharmacists to provide telephone consultations to prevent exposure to COVID in our patients that did not feel comfortable to enter the dispensary to get their medicine or see the medical professional for consultation in-person. The temporary regulations included a curb-side aspect for patients as well (similar to most retail or restaurant settings). Some dispensary locations were able to operate a drive-thru window system (instead of curbside). These options are great for our advanced age patients or patients with pain/injuries that may have some mobility issues (e.g., use a cane, walker, electric scooter or wheelchair).

The real question being asked by the dispensary owners in PA is: Do I need to pay one medical professional salary for all of my locations to operate ---or do I need to pay one medical professional salary (or more) for each location to operate according to the regulation?

So far, each answer to this question has included a list of which medical professional type can be located where. Unfortunately, this is not addressing the point of the question, which is: How many medical professionals need to be in-person in each individual dispensary location?

While we can appreciate the appeal of paying one medical professional salary for operating six or more locations and let them virtually cover the locations regardless of if there is anyone in-person at all. However, the patients are not getting the level of care that they did when we had pharmacists/medical professionals inside all of the dispensaries during the hours of operation (pre-COVID).

In addition to patient care activities, the medical professional inside the dispensary is a valuable source of information for education of our patients, caregivers, staff members and medical professionals in other settings. Sometimes we may be called on to serve as a liaison to other medical professionals involved in the care of our patients.

If a medical professional is only focused on being successful with verifying patient certifications, he/she may be not accessible to answer clinical or patient care questions because there is potential disruption to the workflow of the patients coming in to purchase while you are speaking with a patient inside.

This means that even in some dispensary locations where there are pharmacists/medical professionals inside the dispensary, the focus may be on the non-clinical work. Ideally until the certifications can be verified in an automated way, we would have a second pharmacist/medical professional inside the dispensary to answer the patient questions and provide the education as needed.

There is a significant difference in the impact that a pharmacist has on patient care and education by being INSIDE the dispensary versus a pharmacist that is available for telemedicine and covering multiple locations remotely.

Telemedicine and remote pharmacist coverage can lead to issues when the pharmacist is not physically there to make sure the patient gets the correct product. Miscommunications happen and my patients received the wrong cannabis medicines despite all of my efforts to prevent that from happening when I was working remotely to cover dispensary locations. This resulted in frustration since the products cannot be returned to the

dispensary and the patients were upset that they wasted time, energy and money purchasing the wrong medicine.

Telemedicine is not for everyone. Advanced-age patients are not always served best in this fashion. Many of these people do not have their own computer or smartphone and rely on family members to assist them with technology. Offering only a virtual model creates a barrier to care for this fragile and high-risk patient population.

The advanced age patients often need extra information to calm their concerns and select products that meet their needs. This is especially true if they have a complicated health history or extensive list of prescription medications in their regimen.

Our younger patients and medically complex patients may also need a different level of care than a pharmacist may typically be able to provide remotely.

The recommendations and cannabis product information I have overheard in various dispensaries is not always accurate. The pharmacists can help to decrease the sharing of misinformation in the dispensary. However, pharmacists can only help if we are inside the dispensary to hear the misinformation and speak up.

The pharmacist understands how to read the labels of the products in a way that most people do not.

The tinctures (and solutions) are challenging and expression of concentration varies across all the grower processors. This is currently a source of great confusion for most of the dispensary staff. Patients need this information to know what their dose is in milligrams to allow them to use new products safely. If patients use the recommended "dose volume" listed on the cartons and containers of the cannabis tinctures/solutions, he/she may be taking more than the smallest effective dose. The pharmacist will assist the patient to not take more of the medicine than the patient needs, despite the dose information listed on the carton. Often the actual concentration is stronger than the estimated concentration listed on the carton and this increases the risk for taking too much as well.

Having a virtual or remote pharmacist to assist patients is not the best option for many patients that need individualized assistance and education to optimize their regimens. Inside the dispensary we use demo products to show the patients how to use things and allow them to practice, see and touch the devices before they purchase anything. For example, if a patient does not have the dexterity to press the button on the battery five times quickly (on/off), we may suggest he/she use a breath-activated battery instead of the button battery.

The importance of the pharmacist's role inside the dispensary must not be overlooked for the safe use of cannabis medicines by our patients. Please see the attached publication from 2021 in support of improving and enhancing the role of the pharmacist/medical professional inside the dispensary. Megan K. Reed, Erin L. Kelly, Beth Wagner, Emily Hajjar, Greg Garber & Brooke Worster (2021): A Failure to Guide: Patient Experiences within a State-Run Cannabis Program in Pennsylvania, United States, Substance Use & Misuse, DOI: 10.1080/10826084.2021.2019780

Thank you for your consideration.

Sincerely,

Marci Lee, PharmD, FISMP

Clinical Cannabis Pharmacist

PA Department of Health Pharmacist Advisory Board Volunteer since November 2019