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April 1, 2021

John J. Collins, Director, Office of Medical Marijuana
Department of Health
Room 628, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

RE: Regulation #10-219-Medical Marijuana

Dear Director Collins:

On behalf of the Pennsylvania Medical Society (PAMED), I am writing to provide the following comments and questions regarding the Department's publication of proposed permanent regulations relating to the Commonwealth's medical marijuana program.

1. General Comments. The terms "practitioner" and "physician" appear to be used interchangeably throughout these regulations. While in certain sections this may be permissible, PAMED would note that the term "practitioner" is defined in the Medical Marijuana Act (Act) as a "physician who is registered with the department under section 401." Section 401 relates to practitioners who seek registration with the Department to certify patients for medical marijuana. The term "physician," on the other hand, could include physicians who are not registered with the Department to certify patients but rather physicians that work in dispensaries, as an example. Specifically, §401 of the Act is entitled "practitioner registration" but §1181a.24 of the proposed regulations is entitled "physician registration." PAMED is requesting that the Department review these regulations to ensure that the proper term is used in the relevant sections.
2. Definitions relating to continuing care, §1141a.21. Regarding patient certification consultations, the definition of "continuing care" is proposed to be revised to mirror the definition in §103 of the Act by adding "including an in-person consultation with the patient." The definition of "continuing care" incorporated in the regulations reads in full: "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 an in-person consultation with the patient."

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References to in-person examinations are included in other parts of the regulations as well, such as in the definition of “patient consultation,” which is defined as a “complete in-person examination of a patient and the patient’s health care records at the time a patient certification is issued by a practitioner.” As a result of the COVID-19 pandemic, the usage of telehealth has expanded greatly. Waivers and relaxation of regulatory requirements have allowed patients to be certified and re-certified for medical marijuana via remote consultation utilizing telehealth technologies. PAMED asks whether this inclusion of “in-person consultation” into the proposed regulations signifies that telehealth may no longer be utilized in Pennsylvania’s medical marijuana program?

3. Definitions relating to serious medical conditions, §1141a.21. The definition of “serious medical condition” has been revised from the temporary regulations to include “any other condition recommended by the Medical Marijuana Advisory Board and approved by the Secretary.”

Pursuant to §1201(j)(4) of the Act, the Medical Marijuana Advisory Board (Board) was charged with issuing a final report within two years after the effective date of §1202 (approximately May 17, 2018). As part of this report, the Board was to recommend whether to “change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act.” *See* §1201(j)(5)(ii). The Board’s final report recommended that a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis, which the Secretary approved. Subsequently, the Secretary approved additional medical conditions that would qualify as serious medical conditions.

Section 1202 states that after receiving *the* report of the advisory board under section 1201(j)(4) (*emphasis added*), at the discretion of the Secretary, the Department may promulgate regulations to effectuate recommendations made by the advisory board.

We respectfully request more information regarding the Department’s assertion that it may continue to add medical conditions through the Board without going through the legislative or regulatory processes? Under what authority is the Department asserting, after the initial report by the Board, that it may continue to add medical conditions outside of the legislative and rulemaking processes?

4. Relating to records subject to disclosure, §1141a.22(f). The newly proposed subsection (f) of §1141a.22 provides that the Department may release de-identified data for research purposes that are subject to approval and oversight by the Department and an IRB. Such a release of data is not enumerated in §302 of the Act. PAMED requests that additional information be provided clarifying what type of information and data the Department anticipates releasing for these purposes.
5. Relating to practitioners generally, §1181a.22(a). This section states that “...the qualifications that a physician shall meet to be registered with the Department and approved as a practitioner are continuing qualifications.” This provision is unclear, as it is assumed that §1181a.22(a) is intended to indicate that the qualifications needed for a physician to *remain* in the registry are continuing qualifications. If this is indeed the intent of the §1181a.22(a), please clarify the proposed language accordingly.
6. Relating to medical professionals generally, §1181a.23(a). This section states that “...the qualifications that a medical professional shall meet to be employed at a dispensary are continuing qualifications.” This provision is unclear. Like the comment provided above, it is assumed that §1181a.23(a) is intended to indicate that the qualifications needed for a medical professional to *remain* employed at a dispensary are continuing qualifications. If this is indeed the intent of the §1181a.23(a), please clarify the proposed language accordingly.

7. Relating to physician registration §1181a.24(b)(2). This section requires the physician to include his or her education, specialty, training, experience and supporting documentation where available on the application for registration. PAMED is seeking more specificity to make it clear that this information is directed towards a physician's qualifications to treat one of the serious medical conditions as denoted in §401(a)(2) of the Act (relating to practitioner registration).
8. Relating to denial, revocation, or suspension of a practitioner registration, §1181a.26(d)(3). This section prohibits a physician who has been removed from the practitioner registry from providing a copy of an existing patient certification to any person... "except in accordance with applicable law." PAMED requests that the Department provide clarification on what applicable laws this section references to provide guidance to physicians.
9. Relating to issuing patient certifications, §1181a.27(c)(1). This section provides that the patient certification shall include, at a minimum, "the patient's name, home address, telephone number, date of birth and email address, if available." However, §403(b)(1) of the Act specifically requires only the patient's name, date of birth and address. Given the limitations set forth in the Act and privacy concerns, how can the Department require information other than what is specifically contained in the Act?
10. Relating to issuing patient certifications, §1181a.27(c)(2). This section provides that the patient certification shall include, at a minimum, "the practitioner's name, business address, telephone numbers, professional email address, medical license number, area of specialty, if any, and signature." However, §403(b)(5) of the Act specifically requires "the name, address, telephone number and signature of the practitioner." Again, given the limitations set forth in the Act and privacy concerns, how can the Department require information other than what is specifically contained in the Act?
11. Relating to patient certifications, §1181a.27(c)(7)(ii). This section permits a practitioner, rather than including the form of medical marijuana on the patient's certification, to recommend to the patient the he or she discuss the form of medical marijuana with the physician or pharmacist at the dispensary. PAMED has several concerns related to this option. Section 403 of the Act details the requirements for issuance of a certification to a patient. Section 403(a) provides specific requirements that must be met for a physician to issue a certification to a patient, including continuing care of that patient, a serious medical condition, and a determination of therapeutic or palliative benefits of medical marijuana for the patient. Section 403(b) provides requirements for what must be included in the certification itself. Specifically, subsection (b)(6) requires the certification to include "any requirement or limitation concerning the appropriate form of medical marijuana and limitation on the duration of use, if applicable, including whether the patient is terminally ill." This section appears to require the physician certifying the patient to document the form of medical marijuana that should be dispensed to the patient. PAMED requests clarification from the Department on this issue.

Second, the Act permits a caregiver to go to a dispensary and obtain medical marijuana on behalf of the patient. (See §801 of the Act). Under the parameters set forth in the Act and the proposed regulations, a practitioner could recommend to a patient that he or she discuss the form of medical marijuana with the physician or pharmacist at the dispensary. However, what happens when a caregiver, who is authorized under the Act to obtain medical marijuana on behalf of a patient, goes to the dispensary? How is a physician or pharmacist at the dispensary supposed to adequately discuss the form of medical marijuana with the caregiver when it is likely that the caregiver will be unable to provide necessary

information to the physician or pharmacist for that physician or pharmacist to be able to determine what form of medical marijuana to dispense?

Third, §801(g) of the Act requires that “medical marijuana dispensed to a patient or caregiver by a dispensary shall conform to any requirement or limitation set by the practitioner as to the form of medical marijuana for the patient.” This section seems to indicate that the form, including limitations, must be set by the practitioner (who is defined in the Act as a physician who is registered with the department to certify patients for medical marijuana) and not by a physician or pharmacist at the dispensary. PAMED requests clarification from the Department on this issue.

Fourth, the Act authorizes certified registered nurse practitioners or physician assistants to be present at other locations owned by the dispensary in lieu of a physician or pharmacist. (See §801(b)). If a patient or caregiver goes to one of these alternate locations, it appears the Department’s proposed regulations will prohibit the patient from obtaining medical marijuana since the certifying physician did not dictate the form of medical marijuana and a physician or pharmacist is not present at the dispensary. PAMED requests clarification from the Department on this issue.

Finally, §1181a.27(c)(10) of the proposed regulations requires the certifying physician to include a statement, if applicable, that the patient is homebound or an inpatient and is unable to visit the dispensary to obtain medical marijuana. Like our concerns regarding caregivers, how can a physician or pharmacist at a dispensary adequately determine the form of medical marijuana to be dispensed when the patient is unable to visit the dispensary?

12. Relating to modifying a patient certification, §1181a.28(a). PAMED is requesting clarification on why the Department is requiring notice if a practitioner modifies the form of medical marijuana within a 30-day period? Where specifically in the law does it prohibit a practitioner from modifying the form unless notice is given to the Department? In addition, PAMED is requesting clarification on how this requirement will work if a practitioner defers the determination of the form of medical marijuana to the physician or pharmacist working at the dispensary?

Finally, PAMED is requesting clarification on how a certifying physician modifies the certification? Will there be a specific form that must be completed? Will the certification form include a caption denoting that it is a “modified certification”?

13. Relating to revocation of a patient certification, §1181a.29(c). As this section permits a physician to withdraw the issuance of a patient certification at any time by notifying both the Department and the patient in writing, is there immunity from suit or disciplinary sanctions for a physician that chooses to withdraw the issuance of the patient certification? Has the Department discussed this issue with the Department of State relating to continuity of care as required under the requisite medical practice acts?
14. Relating to practitioner prohibitions, §1181.a31(g). The newly added subsection (g) of §1181.a31 provides that “a practitioner may not excessively charge a patient for any expense related to the certification and follow-up process.” The Department states it is proposing the change due to patient complaints of practitioners taking advantage of the certification process by charging excessive lab testing, follow-up, or other fees not initially disclosed. However, the proposed regulations do not define “excessively charge” nor do the proposed regulations provide any guidance regarding how charges will be determined to be excessive. PAMED respectfully requests that the Department provide a definition and clarification explaining how whether a practitioner has excessively charged a patient will be determined.

15. Relating to training, §1181a.32. PAMED is concerned that the training requirements are open-ended and could result in programs that are too different in scope. Specifically, PAMED is seeking clarification or further guidance on the following:

- a. General information about medical marijuana under Federal and State law. This requirement does not provide direction to a continuing education provider as to what is acceptable and how much information must be provided.
- b. The latest scientific research on medical marijuana, including its risks and benefits. How recent must the research be, what organizations are acceptable to the Department for a continuing education provider to use that research, and how much research must be provided to participants of the course?
- c. Best practices for recommendation of the form of medical marijuana. What constitutes “best practices” and what entities are recognized as being able to provide information on these best practices?
- d. Can any entity provide this training, such as entities that have a direct interest in medical marijuana (medical marijuana organizations, dispensaries, etc.), or must they be eligible CME providers?
- e. Has the Department considered, or will it consider, prohibiting “commercial interests,” as defined by the Accreditation Council for Continuing Medical Education (ACCME), from providing the required training courses? Under the ACCME, commercial interests are defined as “any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.” The ACCME does not consider providers of clinical services directly to patients to be commercial interests - unless the provider of clinical services is owned, or controlled by, an ACCME-defined commercial interest. A commercial interest is not eligible for ACCME accreditation and thus cannot be accredited providers or joint providers.

In addition, the proposed regulations do not provide information on how courses are to be submitted to the Department for approval (or whether pre-approval is even required), where to send them, timeframes for approval, and other information to give continuing education providers adequate notice as to what they can expect throughout this process.

PAMED thanks you for the opportunity to provide comments on these important regulations. PAMED stands ready to assist the Department in any way that it can.

Sincerely,



Edward Balaban, DO, FACP, FASCO, FCPP
Chair, Board of Trustees
Pennsylvania Medical Society