



# Tennessee Pharmacists Association

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October 24, 2017

To: Chairman Rusty Crowe  
Senator Richard Briggs, MD  
Joint Ad Hoc Committee on Medical Cannabis

From: Micah Cost, PharmD, MS  
Executive Director  
Tennessee Pharmacists Association

## **Chairman Crowe and Senator Briggs:**

On behalf of the Board of Directors of the Tennessee Pharmacists Association (TPA), I want to thank you both for your ongoing support for pharmacists and the practice of pharmacy, and I greatly appreciate this opportunity to provide insight and recommendations, from the perspective of practicing pharmacists in Tennessee, regarding the state's consideration of legalization to permit the medical use of marijuana (including medical cannabis). As the only 501(c)6 state pharmacy organization in Tennessee representing approximately 3,000 pharmacists, student pharmacists, pharmacy technicians, and associate members in all pharmacy practice areas, TPA's mission is to advance, protect, and promote high-quality pharmacist-provided patient care in Tennessee.

This response has been reviewed and approved by the TPA Board of Directors. This response should not be considered as TPA's official position on any specific legislative proposal and is intended to provide members of the Joint Ad Hoc Committee on Medical Cannabis with greater insight on this issue from the perspective of pharmacists. TPA reserves any formal determination regarding its official position on specific legislative proposals until such legislation has been properly vetted by the TPA Legislative and Regulatory Policy Committee and TPA members.

## **The TPA Board of Directors strongly advocates for resolution of regulatory conflicts surrounding the legal status of medical cannabis at the federal level**

The TPA Board of Directors urges lawmakers in Tennessee to formally petition the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) to update the list of approved indications for medical cannabis and to reschedule medical cannabis as a schedule II controlled substance. Such actions taken by these federal agencies will resolve regulatory conflicts and minimize any risks related to pharmacists' involvement in the prescribing, dispensing, and use of medical cannabis by patients in Tennessee.

The Food and Drug Administration (FDA) utilizes a rigorous process of checks and balances to weigh the clinical benefits versus the risks of approving new drug products. Per the Food and Drug Administration (FDA), "the FDA has not approved cannabis as a safe and effective drug for any indication. The agency has, however, approved two drugs containing a synthetic version of a

substance that is present in the cannabis plant and one other drug containing a synthetic substance that acts similarly to compounds from cannabis but is not present in cannabis. Although the FDA has not approved any drug product containing or derived from botanical cannabis, the FDA has acknowledged that there is considerable interest in its use to attempt to treat a number of medical conditions, including, for example, glaucoma, AIDS wasting syndrome, neuropathic pain, cancer, multiple sclerosis, chemotherapy-induced nausea, and certain seizure disorders.” It is important to recognize that there are currently available medications which contain either a synthetic version of substances that are present in the cannabis plant or that act similarly to compounds from cannabis. TPA further acknowledges that (FDA) approval of indications is the ideal and preferred method to authorize the use of medical cannabis, but is cognizant of the reality that medical cannabis is now legal in the majority of states without having FDA approval.

Additionally, medical cannabis and medical cannabis are currently classified as schedule I controlled substances by the Drug Enforcement Administration (DEA). The DEA maintains five schedules of controlled substances (I-V), whereby Schedule I is the most restrictive. According to the DEA, schedule I drugs are classified as such based on the following findings:

- A. The drug or other substance has a high potential for abuse.
- B. The drug or other substance has no currently accepted medical use in treatment in the United States.
- C. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Under optimal conditions, the DEA would reschedule medical cannabis as a schedule II controlled substance, which would permit licensed physicians to prescribe and permit licensed pharmacists to store, manage, and dispense these drugs in pharmacies. If these products were rescheduled as schedule II drugs by the DEA, pharmacies would be the most ideal locations to manage medical cannabis products, including the storage, distribution, dispensing, and management. However, because the DEA has consistently rejected any attempt to reschedule medical cannabis as a schedule II controlled substance, physicians and pharmacists are placed in a difficult position which prevents them from actively participating in the prescribing or dispensing of medical cannabis. Their participation could place their federal DEA registration at risk for adverse legal and regulatory action, including but not limited to suspension or revocation. Suspension or revocation of their DEA registration would jeopardize their ability to practice and limit access to care and services for all their patients, including those who do not use medical cannabis.

### **The TPA Board of Directors supports regulatory changes which ease restrictions on structured research to appropriately evaluate the clinical safety, efficacy, and quality of medical cannabis**

As the medication experts on the health care team, pharmacists work daily to maintain a high level of patient safety, to ensure the effectiveness of medication therapies, and to advocate for optimal standards regarding the quality of medications. Pharmacists accomplish these patient-focused goals using evidence-based guidelines, standards of care, and ongoing clinical evaluation and management of patients. Published studies for medical cannabis have produced variable and often conflicting statistical, clinical, and practical endpoints related to the benefits of medical cannabis, patient populations which may benefit, and appropriate therapeutic uses for such products. Without sufficient evidence-based clinical guidelines and standards of care related to the

prescribing and dispensing of these products, as well as potential variations in quality and consistency within the manufacturing process, pharmacists and other providers are left with anecdotal evidence based on individual patient experiences to guide treatment. Easing restrictions to allow for appropriately-designed clinical research studies which evaluate clinical safety, efficacy, dosing, drug interactions, side effects, adverse events, and quality of medical cannabis would provide pharmacists with needed evidence-based guidelines and clinical tools to ensure that patients have access to safe and effective medical cannabis products.

**If state legislation authorizes the use of medical cannabis by patients in Tennessee, the TPA Board of Directors advocates that each dispensing practice site should be required to retain a pharmacist consultant**

Pharmacists are extensively trained and uniquely positioned to work with patients in the evaluation and management of their medication therapies to promote a high level of safety and quality, to ensure optimal clinical efficacy, and to help patients achieve optimal health outcomes. Pharmacists apply skills and knowledge daily to monitor patients for drug interactions, side effects, adverse events, clinical outcomes, and to ensure that patients' medication use is consistent with evidence-based clinical guidelines, best practices, and standards of care. Involving pharmacists in the development and implementation of standards for use of medical cannabis ensures that patients receive clinical medication management services. Pharmacists are essential to maintaining an environment where patients using medical cannabis can achieve optimal health outcomes and avoid unwanted adverse events through education and information, as well as the creation evidence-based clinical guidelines, best practices, and standards for care.

The TPA Board of Directors opposes the storage and dispensing of controlled substances outside of licensed pharmacies but is sensitive to the current conflicts between state and federal law placing pharmacists and pharmacies at risk. If, in the future, the DEA decides to reschedule marijuana and/or cannabis as schedule II controlled substances, then these medications should be stored and dispensed through licensed pharmacies just as all other controlled substances are today. If Tennessee chooses to reschedule cannabis and treat it as a medicine, the TPA Board of Directors recommends that pharmacists be involved in the education, training, evaluation, and monitoring of medical cannabis to ensure that patients in Tennessee achieve optimal health benefits and avoid unwanted medication-related adverse events. Further, the TPA Board of Directors recommends that any state legislative proposal for the legalization of medical cannabis require pharmacist involvement in the management of patients using medical cannabis through ongoing medication therapy management reviews, as well as through consultation with dispensing practice sites similar to the approach taken by the Arkansas legislature during their 2017 legislative session. In Arkansas, HB 2190 requires that each medical cannabis dispensing facility in Arkansas appoint a pharmacist consultant. Roles for pharmacist consultants within medical cannabis dispensing practice sites in Tennessee should include, at a minimum:

- 1) Development and implementation of annual training and education for medical cannabis dispensary agents, patients, and providers regarding the use of medical cannabis in Tennessee;
- 2) Creation and provision of oversight of clinical and therapeutic guidelines related to the use of medical cannabis in Tennessee; and,

- 3) Oversight and monitoring for adverse events, side effects, drug interactions, and other medication-related issues associated with the use of medical cannabis in Tennessee.
- 4) Delivery of pharmacist-provided medication therapy management services to patients upon initial dispensing of medical cannabis and annually thereafter, at a minimum.

**If cannabis is rescheduled to a lesser schedule than schedule I in Tennessee, the TPA Board of Directors recommends that state legislation should limit rescheduling cannabis to only a schedule II controlled substance**

Per the DEA, schedule I controlled substances, like marijuana and cannabis, are defined as substances with no accepted medical use. Rescheduling cannabis to a schedule II controlled substance in Tennessee acknowledges that there are accepted medical uses. Further, schedule II controlled substances are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Limiting state legislative proposals to rescheduling medical cannabis to a schedule II controlled substance would permit access for patients with legitimate medical needs while also ensuring that the Tennessee Department of Health and respective licensing Boards retains the authority to require adequate safety and quality standards and provide proper oversight and monitoring consistent with other schedule II controlled substances. The TPA Board of Directors also recommends that any state legislative proposal should remove criminal penalties for possession of paraphernalia used as delivery devices for medical cannabis if the patient has a legitimate prescription for medical cannabis.

**If cannabis is rescheduled to a schedule II controlled substance in Tennessee, the TPA Board of Directors advocates that state legislation authorizing medical cannabis should include explicit protections from liability and penalty for pharmacists and other health care providers**

Pharmacists and other health care providers who voluntarily participate in any part of the development, production, distribution, consultation, and/or management of patients using medical cannabis should be protected from liability and should not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including civil penalty or disciplinary action, by the Tennessee Department of Health or by any other business, occupational, or professional licensing board or bureau, solely for performing their duties in accordance with state law.

**If cannabis is rescheduled to a schedule II controlled substance in Tennessee, the TPA Board of Directors recommends that state legislation legalizing medical cannabis should establish an advisory board or committee to establish a narrow and specific list of indications for use**

Medical cannabis has been shown in some published studies to have benefits in certain health conditions, while other studies have demonstrated marginal or limited clinical efficacy in other health conditions. Any legislation permitting medical cannabis use should authorize an advisory board or committee consisting of health care providers, including pharmacists, to guide decisions and develop a narrow and specific list of clinical indications for use of medical cannabis in Tennessee to assist providers in evaluating risk versus benefit for their patients.

**If cannabis is rescheduled to a schedule II controlled substance in Tennessee, the TPA Board of Directors recommends that state legislation legalizing medical cannabis include monitoring through a state-facilitated patient registry or database**

The Tennessee Controlled Substance Monitoring Database (CSMD) remains one of the most important and useful patient care tools for health care providers to utilize to ensure that their patients receive the highest level of care possible which results in optimal patient health outcomes. The TPA Board of Directors acknowledges the existing issues with the FDA and DEA, and is cognizant of the challenges that may come with including a federally-designated schedule I controlled substance in the CSMD. For this reason, the state should create and implement a state-facilitated patient registry or database similar to the CSMD to track patient use of medical cannabis. This information would provide health care providers with a more complete medication history which will assist them in providing the best care possible to their patients.

**The TPA Board of Directors opposes any state legislation which legalizes cannabis for recreational use and further opposes any pharmacist involvement in furnishing cannabis for recreational use**

Tennessee faces ongoing challenges related to substance abuse, including the abuse of legally obtained substances such as alcohol and tobacco, FDA-approved prescription drugs such as opioids, and illegally distributed heroin and fentanyl-containing products. TPA believes that approving cannabis for recreational use, with no restrictions or limitations on use, would likely increase these challenges by adding another drug to the list of potentially abusable substances in Tennessee. State legislation should be restricted to legalization of cannabis for medical purposes only.

In conclusion, the TPA Board of Directors appreciates this invitation to provide comments. This is a very important and challenging public health issue which affects many Tennesseans. Please feel free to reach out if you have any additional questions or need further clarification.

Sincerely,



Micah Cost, PharmD, MS  
Executive Director  
Tennessee Pharmacists Association