REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-I-19

Subject:	Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals (Resolution 414-A-19)
Presented by:	Michael M. Miller, MD, Chair
Referred to:	Reference Committee K

Resolution 414-A-19, introduced by the Oklahoma Delegation and referred by the House of Delegates asks:

> That our American Medical Association offer guidance to medical staffs regarding patient use of non-US Food and Drug Administration approved medical marijuana and cannabinoids on hospital property, including product use, storage in patient rooms, nursing areas and/or pharmacy, with report back to the House of Delegates at the 2019 Interim Meeting.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2009 to August 2019 using the search terms: “hospital policies” and cannabis; “hospital policies” and marijuana. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and applicable professional organizations, including hospital associations, were reviewed for relevant information.

The Council on Science and Public Health acknowledges that the use of non-FDA approved cannabis and cannabinoid products presents challenges in health care facilities beyond hospitals (e.g., long-term care facilities, mental health and addiction facilities) and patients (e.g., visitors and employees), but those issues were deemed outside of the scope of this report.

CURRENT AMA POLICY

The AMA believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use. Furthermore, cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process. The AMA also supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws and believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions (D-95.969, “Cannabis Legalization for Medicinal Use”).

The AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-

based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product (H-95.952, "Cannabis and Cannabinoid Research").

STATUS OF CANNABIS UNDER FEDERAL LAW

Under the U.S. Controlled Substances Act (CSA) of 1970, cannabis is classified as a Schedule I controlled substance, meaning it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.[1] This means that the cultivation, manufacture, sale distribution, and use of medical cannabis violates the CSA and constitutes a federal felony.

Cannabis is not FDA-approved as a safe and effective drug for any indication. However, the agency has approved three drug products containing synthetic versions of the main psychoactive ingredient of cannabis, delta-9 tetrahydrocannabinol (THC). Marinol® and Syndros™, which include the active ingredient dronabinol, are indicated for nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS.[3] Cesamet®, which contains the active ingredient nabilone, is also indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy.[2]

The Agriculture Improvement Act of 2018 (Farm Bill) removed hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.[2] However, the law explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds.[2] The FDA has approved one cannabis-derived product, Epidiolex®, which contains a purified form of the drug substance cannabidiol (CBD) for the treatment of seizures associated with Lennox-Gastaut or Dravet syndrome.[3] The FDA has expressed concern at the proliferation of products asserting to contain CBD that are being marketed for therapeutic or medical uses that have not been approved by FDA.[3] Since CBD has been studied as a new drug, it cannot be legally included in foods or dietary supplements. The FDA is currently considering potential regulatory frameworks for CBD.

STATUS OF CANNABIS UNDER STATE LAW

At the state level, trends in law have moved from decriminalization, to the legalization of medical use of cannabis, to cannabis regulated for adult use.[4] California was the first jurisdiction in the United States to legalize the medical use of cannabis. Today, 33 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have legalized the medical use of cannabis through either the legislative process or ballot measures. These laws vary greatly by jurisdiction, from how patients access the product (home cultivated or dispensary), to qualifying conditions, product safety and testing requirements, packaging and labeling requirements, and consumption method (some states prohibit smoking the product). In jurisdictions that have legalized cannabis for medicinal use, physicians can "certify" or "recommend" a qualifying patient for the medicinal use of cannabis, but physicians cannot prescribe cannabis for medical purposes because it is illegal under federal law. In recent years, an additional 17 states have enacted laws allowing access to low THC/high CBD products for children with epilepsy.

In 2012, Colorado and Washington were the first U.S. jurisdictions to legalize the adult use of cannabis for recreational purposes. Today, a total of 11 states and the District of Columbia have legalized cannabis for adult use. Most of these jurisdictions have created for-profit, commercial cannabis production and distribution markets where the product is sold and taxed.

DISCUSSION

The AMA does not approve of state-based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. Hospitals are being encouraged to accommodate patient use of cannabis.[5] The primary argument for allowing patients to use cannabis in hospitals is focused on continuity of care. If patients have had success using cannabis for medicinal purposes, ending that treatment due to a hospital admission disrupts treatment and could lead to worse outcomes.[5]

Risks to Hospitals in Allowing Patient Use of Cannabis Products

Hospitals are subject to federal law because they receive reimbursement from federal programs. Since cannabis is a Schedule 1 controlled substance, its manufacture, distribution, or possession is a criminal offense. Hospitals that allow patient use of cannabis are at risk of violating federal law, losing their deemed status from Centers for Medicare and Medicaid Services (CMS), exposing themselves to possible penalties or sanctions, and losing federal funding.[6-8]

Physicians who maintain DEA licensure are also subject to federal law and are not permitted to prescribe a Schedule I substance. In addition to the prohibition on prescribing, the DEA also prohibits a practitioner from administering a Schedule I substance, which means that physicians and other clinicians with DEA licenses cannot administer cannabis. Doing so may jeopardize a clinician's federal DEA registration and their ability to prescribe controlled substances.

In addition to federal law, hospitals must also meet standards for pharmacies and medication management such as those established by hospital accreditation bodies.[8] For example, The Joint Commission Standard MM.03.01.05 on Medication Management requires that: "[t]he hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners."[8,9]

This standard includes the following elements of performance:

- The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.[9]
- Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.[9]
- The hospital informs the prescriber and patient if the medication brought into the hospital by patients, their families, or licensed independent practitioners is not permitted.[9]

One of the biggest challenges for hospitals in meeting this standard for cannabis would likely be identifying the medication and visually evaluating the medication's integrity.[8] Depending on state law, the patient may be enrolled in the state's cannabis for "medicinal use" program and have their own supply from a state licensed manufacturer. However, the hospital would likely not want to assume responsibility for vetting the substance or any adverse effects the patient experiences as a result of the product.

Hospitals would also have to address medication storage concerns, particularly if cannabis products should be stored with the pharmacy department and treated as a controlled substance, by security personnel, or with the patient.[10] There are also complicated logistics for self-administration of cannabis by the patient or caregiver. Many hospitals have policies on self-administration of

medicines that permit patients to use their own medications only after identification and labeling by pharmacy personnel.

Since many hospitals have policies prohibiting smoking on facility grounds, hospitals would have to determine what preparations of cannabis would be allowed (e.g., oils or edibles).[8] Hospitals should also be prepared to provide information to their medical staffs on cannabis withdrawal symptoms as well as possible cannabis or cannabinoid contraindications, drug interactions, or possible adverse effects.

State Laws Addressing Cannabis Use in Hospitals

Some states have tried to address cannabis use in hospital facilities by amending their state laws. Connecticut and Maine permit the use of cannabis by hospitalized patients and give some state-level legal protection for clinicians who administer it. Connecticut law provides that a nurse shall not be subject to arrest or prosecution, or penalized in any manner for administering cannabis to a qualifying patient or research program subject in a hospital or health care facility licensed by the Department of Public Health.[11]

Maine has enacted protection for hospitals and long-term care facilities for use of edible cannabis products, tinctures, and salves by an admitted patient who has been certified for use of cannabis products under state law.[12] The law provides that hospitals and long-term care facilities are not subject to prosecution, search, seizure or penalty in any manner, including but not limited to a civil penalty or disciplinary action by an occupational or professional licensing board or entity, and may not be denied any license, registration, right or privilege solely because the admitted patient lawfully engages in conduct involving the medical use of cannabis.[12] These protections also apply to officers or directors, employees or agents of a hospital or long-term care facility.[12]

Minnesota law provides that hospitals may adopt reasonable restrictions on use and storage of cannabis.[13] The restrictions may include a provision that the provider will not store or maintain the patient's supply of cannabis, that the provider is not responsible for providing cannabis for patients, and that cannabis be used only in a place specified by the provider.[13] Under Minnesota state law, employees of these facilities are not subject to violations under the statutes for possession while carrying out employment duties, such as providing or supervising care to a registered patient, or distribution of cannabis to a registered patient.[14]

The Minnesota Hospital Association (MHA) convened a broad group of stakeholders to discuss the impact of the state's cannabis law on hospital workflows as well as policies and procedures.[15] The group produced template polices on cannabis for MHA members. The policies can be summarized as follows: (1) the hospital will not allow patient use of cannabis, (2) the hospital will allow inpatients to continue use while inpatient in the hospital and cannabis will be treated as self-administered home therapy, and (3) the hospital will allow inpatients to continue while inpatient in the hospital and cannabis will be treated as a medication and integrated within the hospital medical workflows.[15] The templates provide hospitals with a helpful list of issues for consideration.

CONCLUSION

It is the AMA's position that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use. The AMA does not believe cannabis for medicinal use should be legalized through the state legislative, ballot initiative, or referendum process. Given the growing number of states that have legalized cannabis use, hospitals

are increasingly likely to encounter patients who are taking cannabis or cannabis-related products. It has been argued that patients should be allowed to use non-FDA approved cannabis-related products to ensure continuity of care if they are admitted to the hospital. However, hospitals and physicians face legal risks in doing so given cannabis' status as a Schedule I controlled substance. Hospitals should consider the risks associated with allowing the use of non-FDA approved cannabis or cannabis-derived products by patients and develop policies to address this issue so patients and clinicians have clarity on what is permitted. Hospitals that decide to allow the use of non-FDA approved cannabis or cannabis-derived products should provide information to their medical staffs on cannabis withdrawal symptoms as well as possible cannabis or cannabinoid contraindications, drug interactions, or possible adverse effects.

RECOMMENDATIONS

The Council recommends that the following recommendation be adopted in lieu of Resolution 414-A-19, and the remainder of the report be filed.

> The AMA encourages hospitals and health systems to: (1) engage stakeholders, including, but not limited to physicians, nurses, pharmacists, legal counsel, experts in controlled substance diversion prevention, as well as relevant state and federal agencies in developing policies for addressing patient use of non-FDA approved cannabis or cannabis-derived products for use within their facilities and (2) communicate their policy on patient use of non-FDA approved cannabis or cannabis-derived products within their facilities, to ensure clinicians are prepared to treat patients in accordance with policy. (New HOD Policy)

Fiscal Note: less than $500

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