

IHCA's Regulatory & Legal Team Work Group

March 2019

### **OVERVIEW**

Iowa law legalizes medicinal marijuana under specific limited conditions. The medical cannabidiol program, which allows for the production and sale of marijuana derivatives, went into effect in December 2018 and included the opening of five dispensaries in Iowa. For purposes of this memorandum, all medicinal marijuana including cannabidiol (CBD) will be referred to as marijuana derivatives except for those limited products that have received FDA approval and are re-classified as Schedule V drugs (see below).

The law was written in a way that allows for certain persons certified with one of the eligible conditions for medicinal marijuana-derivative treatment or their designated caregivers to obtain, store and take marijuana derivatives. Based on interpretation of the current law by IDPH and IBP, only a patient certified with one of the eligible conditions for marijuana-derivative treatment or their designated caregiver would be protected from prosecution by Iowa law for administering and storing the medication.

There are currently no provisions in state or federal law for regulated care facilities or providers to store or administer marijuana derivatives.

IHCA's Regulatory & Legal Work Group prepared this article to offer key considerations for IHCA members (nursing facilities, assisted living, and home care agencies) related to medicinal marijuana use in these settings. The Work Group collaborated with IHCA General Counsel Ken Watkins, Iowa Department of Inspections and Appeals (IDIA), Iowa Department of Public Health (IDPH) and Iowa Board of Pharmacy (IBP) to address questions regarding the administration, handling and storage of medical marijuanaderivatives in long-term care settings. The Work Group also sought guidance from CMS, but have received no specific information from that agency to assist in our analysis, other than a statement that CMS expects nursing facilities to comply with federal certification guidelines and federal law.

IDPH also offers additional information about Iowa's medical cannabidiol program on its website at: https://idph.iowa.gov/cbd.

# **NURSING FACILITIES**

IHCA's concern is that current federal laws and regulations effectively prohibit allowing marijuana-derivative products in nursing facilities and skilled nursing facilities.

Marijuana and its derivatives, including CBD oils, continue to be classified as Schedule I drugs. A Schedule I drug, under federal law, may not be prescribed, administered, or dispensed even for medical use.

The only exception to this law relates to FDA-approved medications such as Epidiolex, which contains purified CBD used to treat epilepsy and has been re-classified as a Schedule V drug. All other marijuana and CBD products, including medications sold in Iowa's approved dispensaries, continue to fall under the category of a Schedule I drug, which may not be prescribed, administered, or dispensed for medical use.

Current Medicaid/Medicare certification guidelines mandate that the indication for use for any medication must be ordered by a physician or physician extender for a resident of a nursing facility, with such order identified and documented in the resident's record, whether prescription or OTC.

Since federal law does not allow Schedule I drugs to be prescribed by a doctor, and because doctors are understandably reluctant to an issue an order prescribing a marijuana derivative such as CBD, it is unclear whether nursing facilities will be able obtain the required physician order for marijuana-derived medications.

Under Iowa's medicinal marijuana law, physicians merely issue a written certification that their patient suffers from at least one of the conditions for which medical marijuana has been approved in the state. This certification allows patients to participate in the state's patient registry and obtain marijuana derivatives from a licensed marijuana dispensary or supplier.

Specifically, Iowa's law provides that a licensed physician does not prescribe, recommend or set dosing recommendations. Only a licensed physician (not a nurse practitioner or physician's assistant) does the following:

- Certify that he/she has relationship with the patient and is involved in the patient's care;
- Certify that patient has a qualifying debilitating condition;
- Provide educational material to the patient as provided by the department;
- Agree to recertify the patient annually to ensure that program criteria are met;

This certification required by state law <u>does not</u> satisfy the requirements under federal regulations for a written order issued by the attending physician.

In addition, since Schedule I drugs under federal laws, cannot be administered, or dispensed for medical use, nursing facilities and individual nurses or medication aides run the risk of violating federal law simply by storing and administering marijuana derivatives.

The legalization of medicinal marijuana in Iowa does not override or supersede federal law which continues to designate marijuana or its derivatives as an illegal Schedule I drug.

The Board of Nursing has not yet provided guidance associated with issue regarding nurses' involvement on the administration of medical marijuana.

Based on analysis of the federal laws as well as the certification regulations applicable for NF/SNFs, including other potential issues relating to reimbursement issues regarding medicinal marijuana, IHCA is advising its members not to allow for any medicinal marijuana to be stored or administered in a nursing facility.

# **ASSISTED LIVING PROGRAMS**

Where assisted living programs participate in the Medicaid Elderly Waiver program, it is unclear whether the program can follow the protocols set forth below, as an elderly waiver participant must comply with all applicable federal laws. <u>Until further clarification is received, ICAL recommends that assisted living programs with Elderly Waiver tenants not allow for the administration of marijuana-derivative medications.</u>

For non-Elderly Waiver tenants, since ALP regulations are set by Iowa Code and Iowa administrative rules, ICAL recommends that the following protocols be established which will allow for the storage and administration of medicinal marijuana in certain circumstances, where the tenant is able to self-administer medications. Unlike nursing facilities, self-administration by assisted living tenants does not require physician order.

In order to comply with existing state law, medicinal marijuana-derivatives can be allowed only if each and all of the following steps are followed:

1. Tenant must receive an approved Medical Cannabidiol Registration Card from the Iowa Department of Public Health.

- 2. The Tenant or Primary Caregiver<sup>1</sup> are responsible for procuring the medical marijuana from one of the state-approved dispensaries. Under no circumstances will program staff assist in transporting or holding, medicinal marijuana derivates.
- 3. Marijuana derivates obtained from another source (mail order CBD, or families who obtain marijuana-derivatives from states where medical or recreational marijuana is legal) will not be allowed in an ALP program, as this is a violation of current Iowa law if not supplied by an approved dispensary.
- 4. Based on Iowa's no-smoking law, only oils or other forms of the medication approved by the Medical Cannabidiol Board are allowed to be self-administered.
- 5. All marijuana-derivative products must be stored by the Tenant in a lock box located in the tenant's apartment.
- 6. The tenant must be able to self-administer the marijuana-derivative or receive assistance from a primary caregiver. Under no circumstances will program staff be allowed to administer marijuana derivative medications.
- 7. If a tenant becomes unable to self-administer medications and cannot arrange for a primary caregiver to assist with administration, staff <u>cannot</u> assist in the storage or administration of any marijuana derivates.
- 8. If a tenant fails to follow these protocols, medicinal marijuana-derivatives will not be allowed to be maintained by the tenant in the assisted living program.

### **HOME HEALTH & HOME CARE**

For private home health care agencies, similar protocols for assisted living apply.

1. Patient must receive an approved Medical Cannabidiol Registration Card from the Iowa Department of Public Health.

<sup>&</sup>lt;sup>1</sup> Primary caregiver is a patient's parent or legal guardian, or another individual who has been designated by a patient's health care practitioner as a necessary caretaker for managing the wellbeing of the patient with respect to the use of medical cannabidiol.

- 2. The Patient or Primary Caregiver<sup>2</sup> who has been granted approval of a Medical Cannabidiol Registration Card will be responsible for procuring the medical marijuana from one of the state-approved dispensaries. Under no circumstances will a home health care employee assist in transporting or holding, medicinal marijuana derivates.
- 3. Marijuana derivates obtained from another source (mail order CBD, or families who obtain marijuana-derivatives from states where medical or recreational marijuana is legal) will not be allowed in an ALP program, as this is a violation of current Iowa law if not supplied by an approved dispensary.
- 4. A home health patient must be able to self-administer the marijuana-derivative, or receive assistance from a Primary Caregiver. Under no circumstances will a home health employee be allowed to administer marijuana derivative medications.
- 5. If a patient becomes unable to self-administer medications and cannot arrange for a primary caregiver to assist with administration, home health employees <u>cannot</u> assist in the administration of any marijuana derivates.

For Medicare certified home health care agencies, it is unclear whether the agency can follow the protocols set forth above as certified agencies must comply with all applicable federal laws. Federal regulations applicable to home health care agencies, require the treating physician to issue an order for all medications, which as noted above places the physician in a position of violating federal law by prescribing a marijuana-derivative. IHCA recommends that home health care workers should not assist in the procurement or administration of any marijuana-derivates, however it is permissible to allow the patient to self-administer such medications.

IHCA, based on information currently known, believes that home health care agencies can allow tenants to self-administer marijuana-derivatives as long the protocols set forth above are strictly followed. These protocols also apply to Medicare certified agencies, only if the treating physician has issued an order for the marijuana derivative.

## **QUESTIONS**

For questions, contact IHCA at 515.978.2204.

<sup>&</sup>lt;sup>2</sup> Primary caregiver is a patient's parent or legal guardian, or another individual who has been designated by a patient's health care practitioner as a necessary caretaker for managing the wellbeing of the patient with respect to the use of medical cannabidiol.