

## MEDICAL MARIJUANA: USE IN HEALTHCARE FACILITIES

Medical Marijuana

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<u>Initiated Measure 26</u> was passed by South Dakota voters in November 2020, legalizing medical marijuana in South Dakota effective July 1, 2021. South Dakota Codified Law (SDCL) <u>Chapter 34-20G</u> contains the statutes legalizing medical cannabis under Initiated Measure 26.

## **Federal Law**

Marijuana is classified as a Schedule I drug under the Controlled Substances Act of 1970 (CSA). This means that the cultivation, manufacture, sale distribution, possession and use of medical cannabis violates the CSA and constitutes a federal felony.

#### **Medicare Conditions of Participation**

To participate in Medicare and Medicaid, healthcare facilities must comply with applicable regulations. Most facilities, with the exception of Assisted Livings, have a broad requirement to comply with all federal laws, which would include compliance with the CSA as it relates to marijuana. It is unclear as of the writing of this document how the South Dakota Department of Health will view patient use of medical marijuana in a healthcare facility in state survey. The following table summarizes applicable regulations for various healthcare facilities:

Provider	Regulation	
Hospitals	42 CFR § 482.11	The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.
	42 CFR § 482.25	In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.
Critical Access Hospitals	42 CFR § 485.608	The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.
Nursing Facilities	42 CFR § 483.70	The facility must operate and provide <u>services</u> in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing <u>services</u> in such a facility.
Assisted Livings	None Listed	
Home Health Agencies	42 CFR § 484.100	The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients.
Hospice	42 CFR § 418.116	The <u>hospice</u> and its staff must operate and furnish services in compliance with all applicable Federal, <u>State</u> , and local laws and regulations related to the health and safety of patients.
FQHCs & RHCs	42 CFR § 491.4	The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

Facilities should also be aware of requirements for Schedule I drugs related to Drug Enforcement Agency



(DEA) licensure and certification both for providers and facilities. Under DEA licensure requirements, all drugs listed in Schedule I may not be prescribed, administered, or dispensed for medical use. It is unclear if written certification could be construed as a "prescribing" under federal regulation. If certification is construed as the equivalent to prescribing medical marijuana, the DEA may have grounds to revoke the controlled substance license of any practitioner certifying patients. Suspension of revocation of a DEA license is grounds for revocation of enrollment in Medicare and Medicaid.

#### **Department of Justice Enforcement Guidance**

As the legalization of medical marijuana has expanded across the country, the Department of Justice has issued guidance related to enforcement priorities. Currently, two documents describe federal enforcement priorities. Neither document states a priority for federal enforcement of the CSA related to legal medical marijuana use in healthcare facilities.

- <u>2009 Memo Investigations and Prosecutions in States Authorizing the Medical Use of</u> <u>Marijuana</u>: In this memo, the Department of Justice (DOJ) advised federal prosecutors to focus on core federal enforcement priorities, such as the "prosecution of significant traffickers of illegal drugs, including marijuana, and the disruption of illegal drug manufacturing and trafficking networks" and that resources should be directed toward those objectives. It further explains that federal resources should not be utilized on "individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana."
- <u>2013 Memo Guidance Regarding Marijuana Enforcement</u>: This memo also advises federal prosecutors to exercise prosecutorial discretion. However, it also stated that there is not a guarantee, safe harbor, or immunity of any kind that federal authorities will not prosecute marijuana offenses. Like the previous memo, this memo also details federal enforcement priorities. No federal enforcement priorities include the use of medical cannabis legal under state law. This memo expects state governments to "implement strong and effective regulatory and enforcement systems."</u>

## State Law

SDCL <u>Chapter 34-20G</u> does not directly address patient use of medical cannabis in healthcare facilities, including assistance in administration by licensed and unlicensed staff in healthcare facilities. It is unclear if current regulations offer protections to healthcare facilities for permitting patient use:

- <u>SDCL § 34-20G-7</u> appears to allow some protections for facilities and staff related to the use of medical marijuana in a health care facility. This rule prohibits disciplinary action or penalty of any kind by any professional licensing board for allowing the use of personal property for legal medical cannabis use and assisting registered qualifying patients with the act of using or administered cannabis.
  - It is unclear if this would require state survey to disregard medical cannabis use in healthcare facilities.
- <u>SDCL § 34-20G-16</u> prohibits law enforcement officers employed by agencies receiving state or local government funds to expend time to conduct any investigations related to a violation of the federal Controlled Substances Act if there is reason to believe that use is in compliance with SDCL <u>Chapter 34-20G</u>.
  - Again, it is unclear if this statute would require state survey to disregard medical cannabis



use in healthcare facilities, as the term "law enforcement officer" is not defined, but could be construed to encompass state survey staff.

• Other sections of <u>Chapter 34-20G</u><sup>1,2</sup> allow the prohibition of medical cannabis use when use would violate federal law or regulations or cause the loss of licensing-related benefits under federal law. However, patient use in a healthcare facility is not mentioned and remains ambiguous.

State law under <u>SDCL § 34-20G-20</u> prohibits using a registered qualifying patient's use of medical cannabis to disqualify a patient from medical care such as organ or tissue transplants. However, <u>SDCL §</u> <u>34-20G-23</u> allows for an exception if it conflicts with obligations under federal law or would disqualify the organization from a monetary or licensing-related benefit under federal law or regulation.

## Policy Considerations and Example Policies for Healthcare Facilities

South Dakota statute, federal law, and accrediting organization's requirements do not clearly align related to the use of medical cannabis by patients. Currently, South Dakota statute does not clearly address patient use in healthcare facilities. There is not a common standard for all South Dakota healthcare facilities. Each facility should customize their policy approach based on patient needs, staff considerations, and legal analysis. A facility may choose not to adopt new policies specific to medical cannabis and may instead rely on existing policies already in place.

Folicy considerations		
1.	What is the facility's current policy for medications brought into the facility by the patient?	
2.	What is the facility's intake procedure, and how does it address medical marijuana use?	
3.	What is the facility's controlled substance diversion prevention protocol?	
4.	Does the institution receive federal funding that could be impacted by permitting the use of medical marijuana?	
5.	Does the facility treat a population or particular demographic with a higher rate of medical marijuana use?	
6.	Does the facility specialize in treating patients with qualifying conditions?	
7.	Are there patient conditions that warrant an exception to a non-use policy?	
8.	Does the facility or patient participate in FDA approved compassionate use/expanded access programs or clinical trials related to Medical Cannabis?	

#### **Policy Considerations**

SDAHO has reviewed relevant resources from other states<sup>3,4</sup> and has made available three example policy templates as an appendix to this brief. The three policies can be summarized as:

- 1. The healthcare facility will not allow medical cannabis.
- 2. The healthcare facility will allow inpatients to continue use while inpatient in the healthcare

<sup>&</sup>lt;sup>4</sup> Washington Health Care Association. *Sample Medical Marijuana Policy*. Retrieved April 8, 2021, from <u>https://www.whca.org/files/2013/04/sample-medical-marijuana-policy.pdf</u>.



<sup>&</sup>lt;sup>1</sup> Initiated Measure 26, South Dakota Codified Law § 34-20G-19 (2021).

<sup>&</sup>lt;sup>2</sup> Initiated Measure 26, South Dakota Codified Law § 34-20G-23 (2021).

<sup>&</sup>lt;sup>3</sup> Minnesota Hospital Association. *Medical Cannabis*. Retrieved April 8, 2021, from <u>https://www.mnhospitals.org/quality-patient-safety/quality-patient-safety/medical-cannabis</u>

facility and medical cannabis will be treated as self-administered home therapy.

3. The healthcare facility will allow inpatients to continue use while inpatient in the healthcare facility I and medical cannabis will be treated as a medication and integrated within the healthcare facility medical workflows.

#### **Quick Answers**

- Do healthcare facilities have to allow patients to access medical cannabis in their facility? South Dakota statute is unclear. It appears facilities may ban the use of medical cannabis in their facilities at their discretion.
- Will allowing use of medical cannabis negatively affect a facility's Medicare certification? It is unclear how the South Dakota Department of Health will view medical cannabis use in healthcare facilities.
- **Do facilities need a special policy for medical cannabis?** Facilities should review their current policies to determine if they fully encompass the facility's stance on medical cannabis use. SDAHO has provided three policy templates for additional consideration by facilities.
- **Can medical cannabis use disqualify a patient for certain procedures?** State law is ambiguous in this area, both providing protections for medical cannabis users and also an exception to the protection for conflicts with federal regulation. Facilities should review cases on an individual basis.

### **Additional Resources**

This brief is one of a series related to Medical Marijuana Implementation in South Dakota. Please visit <u>https://sdaho.org/marijuana/</u> to view additional resources.

## **Future Statute Changes**

SDAHO will aggregate issues related to the implementation of this statute in preparation for future legislation. Please contact Sarah Aker with examples of the impact on your organization or healthcare facility and recommended changes to the statute.

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## **Template 1: Will not Allow Medical Cannabis in Healthcare Facility**

**POLICY STATEMENT:** XXX healthcare facility recognizes that while South Dakota codified law permits Medical Cannabis for registered patients with a qualifying condition, medical cannabis will not be permitted in XXX healthcare facility.

**SCOPE:** This policy is applicable to all adults and minors in XXX healthcare facilities. Use will not be allowed in areas covered under the healthcare facility license including XXX settings.

#### **PROCEDURES:**

#### Use or Possession of Medical Cannabis by Patients

- 1. Medical cannabis use or possession is not permitted on the premises of XXX healthcare facility.
- 2. If staff of XXX healthcare facility determines that a patient possesses medical cannabis, staff should determine whether the individual is permitted to possess the medical cannabis.
- 3. If the patient is identified as a registered cardholder, staff will ask the patient to remove the medical cannabis from the facility premises immediately. If it is not possible for the patient to remove the medical cannabis from the premises immediately, it will be secured with patient's other belongings.
- 4. If the patient is not a registered cardholder, facility staff should handle the medical cannabis in accordance with the facility's policy on disposal of illegal drugs brought to the facility.
- 5. The provider will document registry participation on the problem list in the medical record, or in medical record as defined in facility policy.
- 6. If the patient was admitted due to an adverse event thought related to medical cannabis (and the cannabis is not continued), the event will be reported internally and the certifying provider will be notified for potential reporting to the South Dakota Department of Health.

#### **Other Considerations:**

- Patient population
- Exceptions for rare/unique situations based on patient's condition
- Controlled substance diversion prevention policy
- FDA approved compassionate use/expanded access programs or clinical trials related to Medical Cannabis



## Template 2: Continuation of Medical Cannabis by Patients as Self-Directed Therapy

#### POLICY STATEMENT:

- XXX healthcare facility will permit the use of medical cannabis in a manner consistent with South Dakota Codified Law Chapter 34-20.
- XXX healthcare facility has exempted medical cannabis from its medication use policies and procedures.
- The policy provides guidance on the continuation of medical cannabis within XXX healthcare facility.
- Only patients that are registered cardholders with the South Dakota Department of Health will be permitted to use medical cannabis pursuant to this policy.
- Nothing in this policy should be interpreted to require health care practitioner to certify a patient as eligible for the registry program or to continue medical cannabis use as inpatient.

**SCOPE:** This policy is applicable to all adults and minors in XXX healthcare facility.

#### Patient Eligibility Criteria for Continuation of Medical Cannabis:

The health care practitioner may only continue medical cannabis as a patient's home therapy if:

- The patient has their own supply.
- The patient's condition warrants continuation of medical cannabis.
- The reason for admission is not due to an adverse event from medical cannabis.
- The health care practitioner and designated healthcare facility personnel are able to verify that the patient is currently registered with the South Dakota Department of Health and the supply is from a South Dakota registered medical cannabis establishment.

#### **PROCEDURE:**

#### Medical Cannabis Identification

- 1. Patients must be a registered cardholder with the South Dakota Department of Health. Registration or cannabis from another state will not be allowed. Proof of registration must be substantiated by the patient or parent/legal guardian or designated caregiver.
- 2. Proof of medical cannabis registration may be validated by the designated healthcare facility personnel.
- 3. Medical cannabis will not be accepted if the expiration date has lapsed (typically one year).
- 4. In no case will medical cannabis nor medical cannabis product be supplied by the healthcare facility.
- 5. Vaporized or smokable medical cannabis is not allowed according to XXX healthcare facility policy on Tobacco-free Premises.
- 6. Forms of cannabis, other than medical cannabis approved by the South Dakota Department of Health, will be handled according to XXX healthcare facility policy for securing unauthorized drugs.
  - Note: Medical cannabis from states other than South Dakota is considered contraband and should follow the same site security policies for securing unauthorized drugs.
- 7. If medical cannabis will not be continued upon admission to the healthcare facility, the patient or designated caregiver will be asked to remove the medical cannabis product immediately from the premises.



- 8. If a patient does not have a designated caregiver that is available to remove the medical cannabis, the product will be stored with the patient's personal possessions using the local policy and procedure governing patient valuables.
- 9. If the patient was admitted due to an adverse event thought related to medical cannabis (and the cannabis is not continued), the event will be reported internally and the certifying provider will be notified for potential reporting to the South Dakota Department of Health.

#### Documentation, Administration and Storage

- 1. The provider will determine if medical cannabis is medically necessary to continue use while receiving services in the facility and authorize continuation of self-directed therapy.
- 2. Questions or concerns with medical cannabis therapy should be directed to the medical cannabis establishment.
- 3. Medical cannabis will be administered by the patient or designated caregiver per labeled instructions by the medical cannabis establishment.
- 4. Medical cannabis will not be left unsecured at any time. The medical cannabis will be stored securely in the patient's room or other designated area defined by the health care facility via XXX (specify for your site locked box/safe/etc.) or with the registered designated caregiver (on their person).
- 5. Nurses and other health care professionals will not retrieve medical cannabis from storage or administer/observe administration of medical cannabis.
- 6. Documentation of medical cannabis administration will not be required in the medical record.

#### **Discharge**

- 1. Upon discharge, all remaining medical cannabis will be removed by the patient or designated caregiver.
- 2. The health care facility is not obligated to address the ongoing use of medical cannabis at the time of discharge.

#### **Other Considerations:**

- Exclusion of medical cannabis as a medication from home and self-administered medication policies
- Patient population
- Exceptions for rare/unique situations based on patient's condition
- Controlled substance diversion prevention policy
- Determine if Medical Cannabis will be included in medication reconciliation policies and procedures
- Determine if and where the healthcare facility will document medical cannabis use and registration
- Determine if and where the healthcare facility will document medical cannabis administration
- Determine if the patient or designated caregiver are able to self-administer/administer to patient
- Consider patient or designated caregiver signing an acknowledgment/waiver indicating agreement accepting full responsibility for storage and administration of the medical cannabis while hospitalized. The form will also include documentation by the patient of the initial amount of product brought into the hospital. Other elements to consider:
  - The product has not been altered and is reflective of what the labeling states.
  - The medical cannabis is being used by the patient as a continuation of self-directed therapy.
  - The healthcare facility assumes no responsibility for vetting the substance
  - $\circ$  The patient assumes the responsibility for any adverse effects of the product.
- FDA approved compassionate use/expanded access programs or clinical trials related to Medical Cannabis



# Template 3: Continuation of Medical Cannabis by Patients Incorporated into Medication Process

#### POLICY STATEMENT:

- XXX healthcare facility will permit the use of medical cannabis in a manner consistent with South Dakota Codified Law Chapter 34-20G.
- The policy provides guidance on the continuation of medical cannabis within XXX healthcare facility.
- Only patients that are registered cardholders with the South Dakota Department of Health will be permitted to use medical cannabis pursuant to this policy.
- Nothing in this policy should be interpreted to require health care practitioner to certify a patient as eligible for the registry program or to continue medical cannabis use as inpatient.

**SCOPE:** This policy is applicable to all adults and minors in XXX hospital.

#### Patient Eligibility Criteria for Continuation of Medical Cannabis:

The health care practitioner may only continue medical cannabis as a patient's home medication if:

- The patient has their own supply.
- The patient's condition warrants continuation of medical cannabis.
- The reason for admission is not due to an adverse event from medical cannabis.
- The health care practitioner and designated healthcare facility personnel are able to verify that the patient is currently registered with the South Dakota Department of Health and the supply is from a South Dakota registered medical cannabis establishment.

#### Procedure:

#### Product Identification and Waiver

- 1. Patients must be a registered cardholder with the South Dakota Department of Health. Registration or cannabis from another state will not be allowed. Proof of registration must be substantiated by the patient or parent/legal guardian or designated caregiver.
- 2. Proof of medical cannabis registration may be validated by the designated healthcare facility personnel.
- 3. Medical cannabis will not be accepted if the expiration date has lapsed (typically one year).
- 4. In no case will medical cannabis nor medical cannabis product be supplied by the healthcare facility.
- 5. Vaporized or smokable medical cannabis is not allowed according to XXX healthcare facility policy on Tobacco-free Premises.
- 6. Forms of cannabis, other than medical cannabis approved by the South Dakota Department of Health, will be handled according to XXX healthcare facility policy for securing unauthorized drugs.

Note: Medical cannabis from states other than South Dakota is considered contraband and should follow the same site security policies for securing unauthorized drugs.

#### Ordering, Labeling and Administration

- 1. Medical cannabis will be included in medication reconciliation policies and procedures.
- 2. The provider will determine if medical cannabis is medically necessary to continue use while receiving services in the healthcare facility and authorize continuation and use of patient's own supply.



- 3. If a decision has been made to continue medical cannabis, the healthcare facility's healthcare professionals may not change the dose or frequency of cannabinoids beyond holding doses or discontinuing use during the stay.
- 4. Medical cannabis will appear as a continuation of therapy order within the electronic medical record (EMR). The order is not intended to be a medication order. Medical cannabis will be listed on the medication administration record (MAR) as "Medical Cannabis (Patient's Own Supply)."
- 5. Medical cannabis will be stored securely by placing the manufacturer's package in an automated dispensing cabinet (ADC) or in locked storage area as designated by the healthcare facility within a plastic self-sealing bag and a manual perpetual inventory log. Record the initial count to the extent possible. The storage decision may be driven in part by the patient's self-report of medical cannabis dosing regimen.
- 6. A nurse will administer and document medical cannabis on the MAR per the facilities medication administration policies, including bar-code scan on administration where applicable.
- 7. If medical cannabis will not be continued upon admission to the hospital, the patient or designated caregiver will be asked to remove the medical cannabis product immediately from the premises.
- 8. If a patient does not have a designated caregiver that is available to remove the medical cannabis, the product will be stored with the patient's personal possessions using the local policy and procedure governing patient valuables.
- 9. If the patient was admitted due to an adverse event thought related to medical cannabis (and the cannabis is not continued), the event will be reported internally and the certifying provider will be notified for potential reporting to the South Dakota Department of Health.

#### **Discharge**

- 1. The healthcare facility is not obligated to address the ongoing use of medical cannabis at the time of discharge, beyond the medication reconciliation process.
- 2. Upon discharge, the patient's medical cannabis will be returned to either the registered patient or designated caregiver.
- 3. The designated caregiver will perform discharge medical cannabis inventory reconciliation ensuring the ending count matches the beginning count, less doses administered. This task may be completed by designated healthcare facility personnel or bedside caregiver depending on the storage process employed.

#### **Other Considerations:**

- Patient population
- Excluding medical cannabis from medications from home policy.
- Controlled substance diversion prevention policy
- If adding a bar-code label: Upon completion of the order, place the EMR bar-coded label over the manufacturer bar-code label. In this manner, the EMR label is an order-specific bar-code to be scanned by the nurse during administration.
- Consider incorporating acknowledgment/waiver elements listed in Template 2
- FDA approved compassionate use/expanded access programs or clinical trials related to Medical Cannabis

