

# Experimental Drugs, Marijuana, and Alternative and Complementary Medication Use in Long Term Care Settings - Risks and Best Practices

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## Complementary and Alternative Medicine

- CAM is defined by the NIH's National Center for Complementary and Alternative Medicine (NCCAM) as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine."
- CAM embraces holistic healing that recognizes a mind, body connection.

## Examples of Complementary and Alternative Medicines

- The NCCAM identifies four domains:
  - Biologically-based practices;
  - Energy therapies;
  - Manipulative and body-based methods; and
  - Mind-body medicine.
- Examples of CAM include: Acupuncture, Massage, Reiki, herbal and nutritional products and other supplements, Homeopathy, hypnosis, naturopathy, electrotherapy, art therapy, aromatherapy and chiropractic services.

## Laws Regulating CAM

- The Food and Drug Administration regulates some types of CAM.
  - Federal Food, Drug, and Cosmetic Act
  - Public Health Service Act
- State laws regulate more CAM modalities, but the laws vary widely.

## Complementary and Alternative Medicine in LTC

- The use of CAM therapies continues to increase for adults 65 and older.
- Chiropractic services, herbal remedies, massage, and spiritual healing are some of the most common CAM therapies sought by older adults.
  - Common conditions treated by CAM are back pain and arthritis.

## Complementary and Alternative Medicine in LTC (cont.)

- Very few studies on CAM utilization in LTC settings.
- Varying studies suggest that 45-80% of nursing home residents have pain that causes functional impairment, but pain is usually only treated with drugs.

## Legal Considerations

- Legal considerations when evaluating the clinical integration of CAM into conventional care: (1) credentialing and licensure; (2) scope of practice; (3) malpractice liability; (4) food and drug laws; (5) reimbursement; and (6) rules governing health care fraud.

## Best Practices and Other Considerations

- Resident's right to participate in his or her own care.
- Staff tolerance of CAM treatments.
- Possible CAM providers on staff or under contract with LTC facility.

## Investigational Drugs

- An investigational new drug means a new drug or biological drug that is used in a clinical investigation.
- Individuals can typically only use investigational drugs when they are participating in a clinical study.

## Expanded Access A.K.A. Compassionate Use

- Sometimes called “compassionate use,” expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.
- Two methods for obtaining access to investigational drugs:
  - **Expanded access programs (EAPs)**
  - **Right to Try**

## Expanded Access Programs (EAPs)

- Three types: (1) widespread (large-scale) use EAPs; (2) intermediate (medium-size) use EAPs; (3) **individual use EAPs**.
- In general, EAPs are for patients who meet all of these conditions:
  - Have a serious and life-threatening condition;
  - Are not eligible for any current clinical trial that's using the drug;
  - Have no other comparable treatment options; and
  - Are likely to have benefits that outweigh the risks involved.

## Right to Try Act of 2017

- Intended to provide an alternative pathway to the expanded-access policies of the FDA and allows patients to work directly with pharmaceutical sponsors without direct FDA oversight.
- "Right to Try" does not actually give patients the right to try any unapproved drug they wish to try. Instead, it gives them the right to request access to an unapproved drug from the company that makes it, without having to go through the FDA.
- Bypassing the FDA does not necessarily mean that such access will be granted. There are a number of reasons access may be denied, including:
  - If the patient does not meet the criteria spelled out in the law.
  - If the drug company refuses to provide the drug, or if they are not able to make enough of it for all of the people requesting it.

## "Right to Try"

- To be eligible for "Right to Try," a person must:
  - Be diagnosed with a life-threatening disease or condition;
  - Have tried all approved treatment options for the disease or condition;
  - Be certified by a doctor that they are unable to participate in a clinical trial for the investigational drug; and
  - Give written informed consent that they understand the risks of taking the investigational drug.
- In addition, the drug itself must have already been through a phase I clinical trial. (This is the earliest phase of clinical trials, which is generally intended to begin evaluating the safety of the drug and proper dosage.)

## Best Practices and Other Considerations

- Self-administration of drugs by a resident.
- Drug interactions.
- Legal liability for LTC facility if a compassionate use drug is obtained by a resident.
- Physicians have a responsibility to ensure that patients are only given treatments that the physician believes can help the patient.

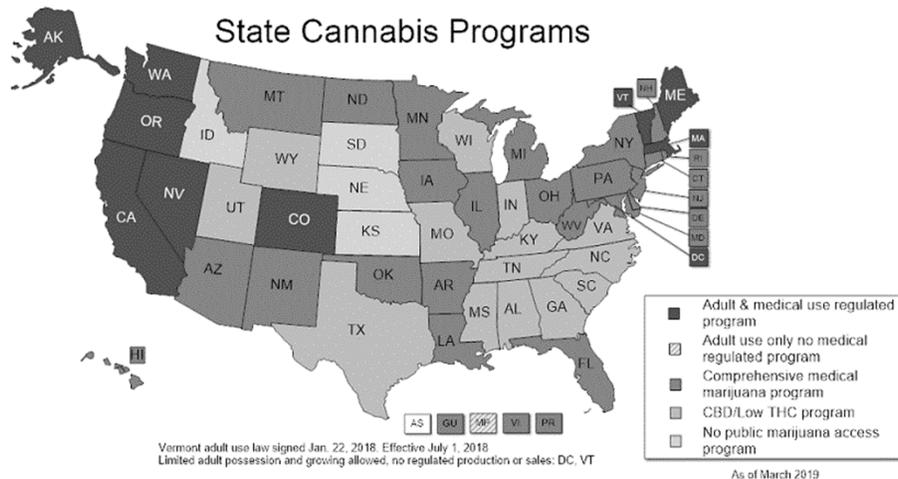
## Marijuana

- Marijuana is defined as “all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.” 21 U.S.C. § 802(16) (1971).

## Marijuana

- The laws surrounding the use and possession of cannabis are changing rapidly.
- AK, CA, CO, DC, MA, ME, MI, NV, OR, VT and WA allow for the recreational use of cannabis for adults over age 21.
- Thirty-three states have legalized medical marijuana in some form.

# NCSL State Cannabis Program Map



## Marijuana Laws - Federal

- **Federal:** Marijuana classified as a Schedule 1 Drug (i.e. controlled substance) under the Controlled Substances Act (CSA), 21 U.S.C. §1308.11 (1971).
- Marijuana shares Schedule I classification with other well-known drugs such as heroin and LSD.
- Under the CSA, it is unlawful for any person knowingly or intentionally—
  - (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or
  - (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance. 21 U.S.C. §841(a)(1971).

## Marijuana Laws - Federal (cont.)

- The U.S. Department of Justice (DOJ) has issued prosecutorial guidance on federal enforcement of marijuana in light of state laws.
- The DOJ will not prosecute individual use, possession, or cultivation of marijuana where permitted under state law and will leave enforcement up to the state and local authorities to address enforcement of their drug laws so long as states have a strong and effective regulatory system such that federal priorities are not jeopardized.
- However, the guidance also clearly explains that the stated priorities do not legalize medical marijuana and that compliance with state law does not create a legal defense to a CSA violation.
- Keep in mind that this is mere guidance and could potentially change from one administration to another.

## Marijuana Regulation

- **Drug Enforcement Agency (DEA):** “[t]he clear weight of the currently available evidence supports [the] classification [as a controlled substance], including evidence that smoked marijuana has a high potential for abuse, has no accepted medicinal value in treatment in the United States, and evidence that there is a general lack of accepted safety for its use even under medical supervision.”
- **U.S. Department of Housing and Urban Development (HUD):** Federal nondiscrimination laws do not require allowing the use of medical marijuana as a reasonable accommodation.
  - The Americans with Disabilities Act and Section 504 of the Rehabilitation Act disqualify illegal drug users from protection.
  - Under the Fair Housing Act, permitting the use of medical marijuana would constitute a fundamental alteration of a public housing authority’s or owner’s operation.
- **U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS)** have been silent on the issue of medical marijuana.

## Marijuana Uses

- The Institute of Medicine (IOM) issued a report in 1999 finding that “scientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation.”
- The IOM also found that the “psychological effects of cannabinoids, such as anxiety reduction, sedation, and euphoria can influence their potential therapeutic value. Those effects are potentially undesirable for certain patients and situations and beneficial for others. In addition, psychological effects can complicate the interpretation of other aspects of the drug's effect.”
- Further studies have found that marijuana is effective in relieving some symptoms for people with cancer, epilepsy, Multiple Sclerosis, Glaucoma, and HIV/AIDS.

## Providers’ Conundrum: Resident Rights v. Federal & State Law

- Medical marijuana use among the populations occupying health care facilities is increasing:
  - Medical marijuana use among the elderly population is growing.
  - Several states have specifically identified Alzheimer’s disease, which afflicts many nursing home residents, as a condition that qualifies for the legal use of marijuana.
- **42 C.F.R. § 483.10 Resident Rights:** Includes the rights of accommodation of needs, freedom of choice, and self-administration of medications.
- **CMS F309 §483.25 Quality of Care:** Each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

## Liability Associated with Marijuana use in Health Care Facilities

- Social Security Act (SSA) requires that any individual or entity that has been convicted of a felony offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance be excluded from participation in any federal health care programs.
- Due to accreditation through the Centers for Medicare & Medicaid Services, hospitals and nursing homes/operators can face penalties, lose federal funding, and/or be excluded from participation by allowing patients to use medical marijuana.
- For Medicaid beneficiaries, providers must certify they are in compliance with all state and federal law when billing for services.
- Compliance with state law does not create a legal defense to a CSA violation.

## Liability Associated with Marijuana use in Health Care Facilities (cont.)

- Liability appears to be shrinking, but absent guidance from the DOJ or the HHS that providers compliant with state law will not be prosecuted, the remote possibility of exclusion exists.
- Mandatory exclusion under the SSA is required only after a felony conviction relating to the “unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.” This does not seem to include facilitating or allowing use.
- The DOJ would be the agency that would have to charge providers. Although its guidance does not address enforcement priorities with respect to institutional providers or caregivers, there have been no reported attempts by the DOJ to charge them with a CSA violation.
- There are no reported cases of exclusion or threats of exclusion of any provider.
- The 2015 Omnibus spending bill signed on December 16, 2014, prohibits the DOJ and the DEA from using any funding to prevent states that currently permit medical marijuana from implementing their laws.
- While the risk of exclusion may be low, providers should still be cautious as they could be violating federal law even if they are not convicted and excluded.

## Marijuana Policy

- **Non-Medical and Non-Recreational Use**  
**Marijuana States:** unless a very clear exception applies, do not permit the use of medical marijuana in facilities.

## Marijuana Policy (cont.)

- **Medical/Recreational Marijuana States:**
  - Because medical marijuana is not accessed in the same way as traditionally prescribed drugs, it is foreseeable that the facility could be a passive participant in the process by merely providing the resident a place in which to use medical marijuana.
  - The facility could require that, in compliance with state law, a family member or outside caregiver obtain, deliver, and assist the resident with administration.
  - While this model may seem attractive because providing a place to use the drug does not appear to rise to the level of unlawfully manufacturing, distributing, prescribing, or dispensing a controlled substance, there is no guarantee that the government would adopt that interpretation.

## State Marijuana Policy

- Missouri became the 33rd state to legalize medical marijuana in 2018. However, Missouri Veterans Commission Executive Director, Grace Link, said that it will prohibit the use of medical marijuana in the seven nursing homes for veterans in order to stay in compliance with the U.S. Department of Veterans Affairs, which still considers marijuana an illegal drug.
- Minnesota’s medical cannabis statute extends state law protections and immunities to employees of hospitals and clinics when providing care to a patient on the Minnesota medical cannabis patient registry. The statute also allows health care facilities to reasonably restrict the use of medical cannabis by patients.

## State Marijuana Policy (cont.)

- The Massachusetts Department of Public Health which oversees the Massachusetts medical marijuana program permits staff members at LTCFs to act as “personal caregivers,” meaning someone, other than a nursing home resident’s personal physician, “who has agreed to assist with a registered qualifying patient’s medical use of marijuana.”
  - “An employee of a hospice provider, nursing, or medical facility... may serve as a personal caregiver.”
  - Personal caregivers are authorized to:
    - Purchase Cannabis from marijuana dispensaries to bring to patients.
    - Prepare marijuana for use by the patient/administer Cannabis to the patient.
    - Transport patients to and from dispensaries.

## Sample Marijuana Policy Resources

- Sample Assisted Living Facility Policy by Washington Health Care Association for Medical Marijuana Use in a Medical/Recreational Marijuana State.
- Three sample Hospital Medical Marijuana Policies (Minnesota Hospitals Association).

## Other Risk-Management Issues

- Drug diversion.
- The marijuana forms that will be permitted (smoke, vaporized, edible, pill).
- Revision of no-smoking policies if necessary.
- Interventions to protect impaired residents.
- Protecting the rights of other residents.
- Limitations and restrictions on use.
- Ensure a facility has a well developed policy on employee use of marijuana.

## Resources and Best Practices

- State LTC Ombudsman.
- State survey agency.
- State Departments of Health and DEA.
- Obtain consent from a resident, POA or guardian.
- Review guidance from professional organizations.
- Develop and implement appropriate policies and procedures.
- Adopt (and periodically review) appropriate guidelines.
- Involve compliance and ethics programs as well as QAPI Committee.
- CONSULT COMPETENT LEGAL COUNSEL.

## Questions?

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