

High Times: Recreational and Medical Marijuana and the Changing Landscape for Healthcare Providers and Hospital Administrators

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Jennifer Disner and/or Andrew Efaw do not have any real or apparent conflict(s) of interests or vested interest(s) that may have a direct bearing on the subject matter of the continuing education activity.

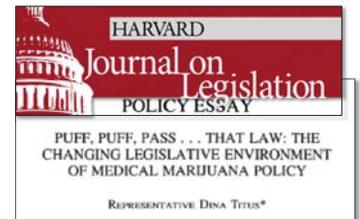
Learning Objectives

This presentation will enable participants to:

- Summarize the current trends and law relating to medical marijuana and the impact on health systems.
- Analyze risk and liability issues relating to inpatients with medical marijuana prescriptions.
- Identify the requirements for providers to recommend medical marijuana, the risks of declining to do so, and the risk of employed or privileged physicians making recommendations.
- Propose changes to informed consent and other policies.

“In Limbo”

- Rep. Dina Titus (D-Nev.)
 - “[T]he legal status of state medical marijuana laws remains ambiguous, which leaves many doctors, patients and businesses in limbo.



Dina Titus, Puff, Puff, Pass . . . That Law: The Changing Legislative Environment of Medical Marijuana Policy, 53 Harv. J. Legis. 39, (2016)

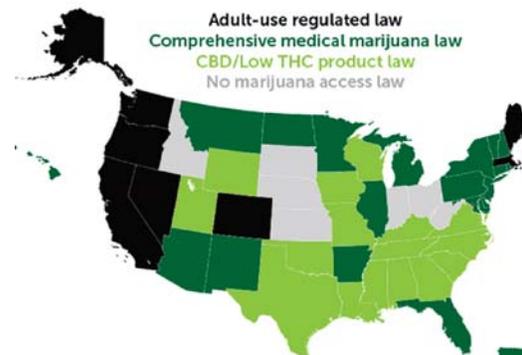
“In Limbo”

- Rep. Dina Titus (D-Nev.)
 - “[T]he discretionary restraint by the federal government coupled with its lack of enforcement resources has created a temporary environment of stability, but this offers little reassurance to the burgeoning medical marijuana industry and its growing market of users.”



Dina Titus, Puff, Puff, Pass . . . That Law: The Changing Legislative Environment of Medical Marijuana Policy, 53 Harv. J. Legis. 39, (2016)

Only 7 States with No Marijuana Access Laws



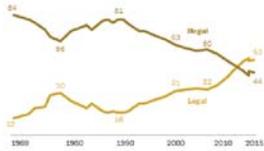
+ Ohio comp. medical marijuana law signed on June 8, 2016

<http://www.ncsl.org/bookstore/state-legislatures-magazine/marijuana-deep-dive.aspx>

61% Favor Legalization

March 2015

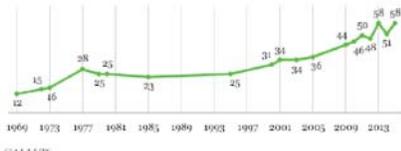
Slim Majority Supports Marijuana Legalization
% saying the use of marijuana should be...



Survey conducted March 25-26, 2015.
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PEW RESEARCH CENTER

October 2015

Do you think the use of marijuana should be made legal, or not?



GALLUP

February 2016

	AP-NORC 2/11-14/2016
Yes, should be legal	61
No, should not be legal	39
DON'T KNOW	-
SKIP/REFUSED	*
N	1,047

<http://www.people-press.org/2015/04/14/in-debate-over-legalizing-marijuana-disagreement-over-drugs-dangers/current-opinion-on-legalizing-marijuana>
<http://www.gallup.com/poll/186260/back-legal-marijuana.aspx>
<http://www.apnorc.org/PDFs/Drugs/AP-NORC%20Drugs%20Report%20Topline.pdf>

69% Believe Alcohol Is More Harmful to Health

Alcohol Seen as Bigger Danger than Marijuana

Which is more harmful to ...

	People's health	Society*
	%	%
Alcohol	69	63
Marijuana	15	23
Both/Neither (Vol.)	14	11
Don't know	3	2
	100	100

Survey conducted Feb. 14-23, 2014.
*Question asked which would be more harmful if marijuana were as widely available as alcohol.

PEW RESEARCH CENTER

<http://www.people-press.org/2014/04/02/americas-new-drug-policy-landscape/4-2-14-3/>

Recreational Use

- Pre-2016 - Legalized in 4 States & DC
 - Colorado & Washington (2012)
 - Alaska, Oregon, and Washington, D.C. (2014)
- 2016 Election Results – 4 More States
 - California (56% support)
 - Maine (50.26% support)
 - Massachusetts (54% support)
 - Nevada (54% support)
- The Only Loser in 2016
 - Arizona (48.68 Yes v. 51.32% No)



https://ballotpedia.org/Marijuana_on_the_ballot#tab=By_year
<http://statesandcapitol.blogspot.in/new.com/2016/05/12/new-poll-shows-55-percent-support-for-marijuana-legalization/>
<http://www1.wme.edu/collegiate/this/article/news/2016-spring-marijuana-charter-schools.cfm>
<http://kstar.com/story/1262722/poll-shows-slight-approval-edge-for-legalized-marijuana-in-arizona/>
<http://www.ktrv.com/news/political/mtv-mussen-poll-voters-favor-legalizing-recreational-pot-plan-to-reorganize-school-district>

21 States With Decriminalization Measures

- Minnesota* (1976)
- Mississippi, New York, & North Carolina* (1977)
- Nebraska (1978)
- Nevada (2001)
- Massachusetts (2008)
- Maine (2009, 1976)
- California (2010, 1976)
- Colorado (2010, 1975)
- Connecticut (2011)
- Rhode Island (2012)
- Ohio* (1975, 2012) & Washington (2012)
- Vermont (2013)
- Alaska (2014), Maryland (2014), Missouri* (2014) & Oregon (2014, 1973)
- Delaware (2015)
- Illinois (2016)

* These states still classify marijuana possession offenses as criminal misdemeanors for first offense, but the offenses do not carry any threat of jail time.
<https://www.mpp.org/issues/decriminalization/state-laws-with-alternatives-to-incarceration-for-marijuana-possession/>

Board Support for Medical Marijuana



- 89% of Americans support medical marijuana



- 71% of Texans support medical marijuana



- 72% of Utahns support medical marijuana

<http://www.qu.edu/news-and-events/quinnipiac-university-poll-national-release-detail/ReleaseID%2354>
<http://extract.suntimes.com/news/1015316620/poll-71-percent-texans-support-expanding-medical-marijuana-access>
<http://libertasutah.org/survey-public-opinion-poll-do-utahns-support-legalizing-medical-cannabis/>

Even Hillary & Trump Agreed – WAIT, Maybe not

FORTUNE

If There's One Issue Hillary Clinton and Donald Trump Agree On, It's This

by Chauncy L. Alcom JULY 12, 2016, 9:31 PM EDT



<http://fortune.com/2016/07/12/hillary-clinton-donald-trump-marijuana/>



- "I won't commit to never enforcing federal law."
- "We need grown-ups in charge in Washington to say marijuana is not the kind of thing that ought to be legalized... that it is, in fact, a very real danger."

Expansion of Medical Marijuana into 25 States

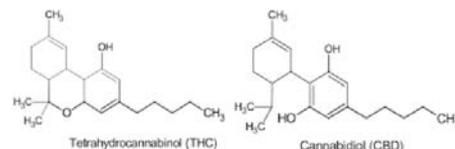


Medical Use in 25 States + DC, Gaum & Puerto Rico

- California (1996)
- Alaska, Oregon & Washington (1998)
- Maine (1999)
- Colorado, Hawaii & Nevada (2000)
- Montana & Vermont (2004)
- Rhode Island (2006)
- New Mexico (2007)
- Michigan (2008)
- Arizona, New Jersey, and Washington, D.C. (2010)
- Connecticut (2012),
- Delaware (2011),
- Massachusetts (2012),
- Illinois & New Hampshire (2013)
- Maryland, Minnesota, New York & Guam (2014)
- Puerto Rico (Jan. 2016),
- Pennsylvania (Apr. 17, 2016),
- Ohio (June 8, 2016)

CBD Laws in 17 States

- Cannabidiol (CBD) or "low THC" Laws
 - Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, Wisconsin (2014)
 - Delaware, Georgia, Louisiana*, Oklahoma, Texas, Virginia (2015)



What is CBD?

- The two major neuroactive components in cannabis are the psychoactive tetrahydrocannabinol (THC) and the non-psychoactive cannabidiol (CBD)
 - Unlike THC, CBD does not activate CB₁ and CB₂ receptors
 - As a result, CBD does not produce psychotropic effects or a "high"

THE DENVER POST

Medicinal marijuana advocates speak with NFLPA officials

Push for CBD research gains notice from NFL



Medical Use on the Ballot

- On the Ballot in 2016 – 4 States
 - Arkansas
 - Florida
 - Montana
 - North Dakota



Tampa Bay Times

Poll: Medical marijuana at 77-percent support

Current Research Critiquing Medical Use

The Washington Post

In Theory | Opinion

5 reasons marijuana is not medicine

1. The drug's chemistry must be known and reproducible.
2. There must be adequate safety studies.
3. There must be adequate and well-controlled studies providing efficacy.
4. The drug must be accepted by well-qualified experts.
5. Scientific evidence must be widely available.

https://www.washingtonpost.com/news/in-theory/wp/2016/04/29/5-reasons-marijuana-is-not-medicine/?hpid=hp_hp-top-table-main-marijuana-opinion%3Ahomepage%2Fstory&utm_term=.64c75c4287ad

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The Controlled Substances Act

• Schedule I

- “[D]rugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence.”
- Heroin, LSD, **marijuana**, MDMA/ecstasy, methaqualone (Quaalude), and peyote



<https://www.dea.gov/druginfo/ds.shtml>

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The Controlled Substances Act

• Schedule II

- “[D]rugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.
- Hydrocodone (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin



<https://www.dea.gov/druginfo/ds.shtml>

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The Problem

- The Schedule I Classification creates significant roadblocks for research.
 - Researcher Dr. Sue Sisley is leading the first placebo-controlled trial that uses raw marijuana for PTSD.
 - Government approval for the study took over **4 years**.

The New York Times

Medical Marijuana Research Hits Wall of U.S. Law

The Washington Post

The government is stifling medical marijuana research, major think tank declares

<http://www.nytimes.com/2014/08/10/us/politics/medical-marijuana-research-hits-wall-of-federal-law.html>

<https://www.washingtonpost.com/news/health/wp/2015/10/20/the-federal-government-is-stifling-medical-research-major-think-tank-declares/>

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The Problem

- The National Institute on Drug Abuse (“NIDA”) contracts exclusively with the University of Mississippi to grow marijuana for research purposes.
 - Significant delays to deliver plants for Dr. Sisley’s trial.
 - NIDA also failed to achieve the phenotype and potency requested.

The Washington Post

Marijuana research hampered by access from government and politics, scientists say



<http://www.nytimes.com/2014/08/10/us/politics/medical-marijuana-research-hits-wall-of-federal-law.html>

<https://www.washingtonpost.com/news/health/wp/2015/10/20/the-federal-government-is-stifling-medical-research-major-think-tank-declares/>

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The Problem

- Medical and recreational marijuana business cannot use banks and have to operate in all-cash, which creates security and regulatory concerns.

THE PEW CHARITABLE TRUSTS

Why Marijuana Businesses Still Can't Get Bank Accounts

BUSINESS INSIDER

This could be the No. 1 problem facing legal weed businesses in America

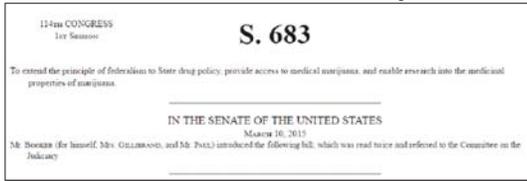
<http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/03/22/why-marijuana-businesses-still-cant-get-bank-accounts>

<http://www.businessinsider.com/americas-marijuana-companies-cant-put-money-in-banks-2015-11>

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Reclassification to Schedule II?

- March 10, 2015 – Compassionate Access, Research Expansion, and Respect States Act
 - Move marijuana from Schedule I to Schedule II;
 - Amend the CSA to prevent prosecution of individuals acting in compliance with state medical marijuana laws
- Referred to Committee on the Judiciary; no further action



Compassionate Access, Research Expansion, and Respect States Act of 2015, S. 683, 114th Cong. (2015), <http://perma.cc/9VFN-S6VR>
 Actions: S. 683-114th Congress (2015-2016): Compassionate Access, Research Expansion, & Respect States Act of 2015, Library of Cong., <http://perma.cc/9VFN-S6VR>

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Reclassification to Schedule II?

- July 8, 2015 – Credible Research on Medical Efficacy of Marijuana Amendment to the 21st Century Cures Act
 - encourage the NIH and the DEA to collaborate on research regarding the medical risks and benefits;
 - create a new federal sub-classification within Schedule I, “Schedule 1R,” to make research easier
- Denied opportunity for full vote on the floor

The Washington Post

House Republicans say no to allowing federal studies of medical marijuana

Press Release, Congressman Sam Farr, Bipartisan Medical Efficacy Of Marijuana Amendment Introduced In House (July 8, 2015), <http://perma.cc/C46D-2V19>; Final Vote Results for Roll Call 283, Office of the Clerk, U.S. House of Representatives, <http://perma.cc/23V9-W5C9>; Final Vote Results for Roll Call 258, Office of the Clerk, U.S. House of Representatives, <http://perma.cc/T74G-UN7X>; https://www.washingtonpost.com/politics/house-republicans-say-no-to-allowing-federal-studies-of-medical-marijuana/2015/07/09/01029cda-262d-11e5-b77f-e013a215f93_story.html

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The DEA's Response

- April 4, 2016
 - “DEA understands the widespread interest in the prompt resolution of these petitions and hopes to release its determination [on CSA classification] in the first half of 2016.”
- August 12, 2016

THE DENVER POST

DEA declines to reschedule marijuana, saying drug has no accepted medical use

DENIED

https://www.washingtonpost.com/blogs/workblog/files/2016/04/Response.pdf?hpid=hp_hp-top-table-main-med-marijuana-20160811-dea-not-rescheduling-marijuana_

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The DEA's Response

- Aug. 11, 2016 – DEA Administrator Chuck Rosenberg
 - “As detailed in the HHS evaluation, the drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.”

npr

DEA Rejects Attempt To Loosen Federal Restrictions On Marijuana



<http://www.denverpost.com/2016/08/11/dea-not-rescheduling-marijuana/>

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Catch-22

- Dan Riffle, Director of Federal Policies at the Marijuana Policy Project
 - “The biggest obstacle, at least historically, to doing research on marijuana to prove its medical benefit is that it’s in Schedule I.”
 - “So you had that Catch-22, where marijuana is a Schedule I drug because there’s no evidence, and there’s no evidence because marijuana is a Schedule I drug.”

Newsweek

WHY IT'S HARD TO DO MARIJUANA RESEARCH

<http://www.forbes.com/sites/jacobsumlin/2014/02/07/more-than-zero-reclassifying-marijuana-would-have-a-significant-impact-on-drug-policy/#207a20181625>
<http://www.newsweek.com/why-its-hard-do-marijuana-research-69753>

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DEA Easing Research Restrictions

- DEA easing restrictions on research
 - Allowing more facilities to grow marijuana for research
- Aug. 11, 2016 – DEA Spokesperson Russell Baer
 - “We’re really excited about some of these studies that are coming out. . . . They’re promising, they’re preliminary, but they’re inadequate.”
- DEA Administrator Chuck Rosenberg
 - “We are not changing our enforcement priorities.”

POPULAR SCIENCE

DEA LOOSENS RESTRICTIONS ON MARIJUANA RESEARCH, BUT NOT USE

<http://www.thecannabist.co/2016/08/11/dea-reschedule-marijuana-rules-federal-register/60777/>
<https://www.washingtonpost.com/news/your-health/wp/2016/08/10/u-s-affirms-its-prohibition-on-medical-marijuana/>

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Medical Marijuana & Inpatient Care

- Supreme Court has concluded that only states have the right to regulate medicine within their boundaries.
- However . . .
- Hospitals and practitioners are subject to federal law regarding illegal substances.
- So, what about our admitted patient with a medical marijuana “prescription”?



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When a Patient Has a Prescription to Use MMJ

- The patient is admitted in your facility.
- A physician has recommended CBD oil every 4 to 6 hours prn.
- The state allows medical marijuana use.
- The patient has been using CBD oil for some time.



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Medical Marijuana in the Facility

Is it reasonable to look at the product, verify the substance, and approve it for use in the facility?



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Handling & Administering a Schedule I Substance

Risks of handling and administering a Schedule I substance in a pharmacy or hospital without an approved protocol:

- A Federal offense
- Puts the pharmacy’s DEA license at risk
- Puts the hospital’s federal Medicare reimbursement at risk
- Refer to the Approved Protocol

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Handling & Administering a Schedule I Substance

What is an “approved protocol”?



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Policies for MMJ

Few hospitals have policies regarding the use of medical marijuana and cannabis . . .

- A survey of 25 well-known health care institutions revealed none has a medical marijuana protocol
- Creating a policy can be difficult
- A hospital must discuss the policy with their insurance company



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Guideline Questions



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Prescribing MMJ



Don'ts and Recommendations

Medical Marijuana is a Schedule I Substance, a physician cannot prescribe cannabis. A physician can recommend the use of cannabis.

Physicians can only certify that a patient has a qualifying condition and the potential benefits outweigh the health risks.

There must be a physician-patient relationship or a doctor is not allowed to sign a cannabis recommendation.

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1st Amendment Right to Discuss Treatment Options

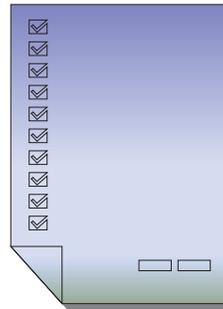


Courts recognize physicians' right to discuss medical marijuana with their patients

- Must be honest in discussion of benefits and risks
- Must make available clinical trial information
- Must obtain appropriate informed consent – use a written form

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Consent Form

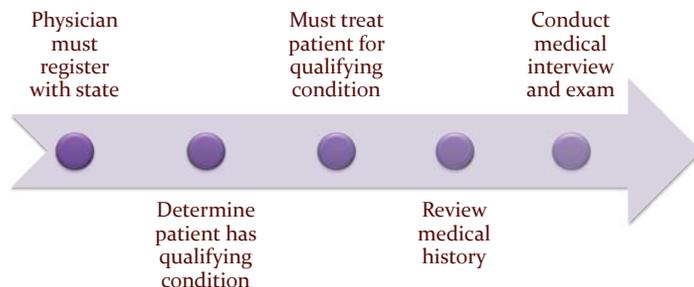


Written Form to Include:

- Addiction and other risks
- Confirmation of qualifying condition
- Direction of type of cannabis
- Note that marijuana is given in reliance of patient's statement of condition, diagnosis, and need for relief
- **Signed by patient**

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Requirements to Recommend



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1st Amendment Right to Discuss Treat Options

Are physicians, who don't support the use of marijuana, obligated to discuss the option with their patients?



- No legal obligation
- However, must meet the standard of care for treatment

Currently, there is no widely accepted standard practice for the prescription or use of medical marijuana.

Medical marijuana is not listed in the Physician Desk Reference.

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Standard of Care

- A physician presented with a patient request for medical marijuana faces a dilemma because medical marijuana use in many states is still in its infancy.
 - “Simply acceding to patient demands for a treatment on the basis of popular advocacy, without comprehensive knowledge of an agent, does not adhere to the ethical standards of medical practice. . . . [And] any recommended therapy requires proof of concept by sound scientific study that attests to both efficacy and safety.”

Pharmacist Role in Medical Marijuana



- Have a greater liability risk related to marijuana prescriptions and use
- Medical marijuana is outside the pharmacist scope of practice

Pharmacist Role in Managing Patients Taking MMJ

What role should/can a pharmacist play in managing a patient who requests to ingest medical marijuana?

- May communicate the legal status of marijuana in their state
- May discuss known risks and benefits of the treatment
- Should consult with risk or legal department regarding any requests

Are you Covered?

Does malpractice insurance cover claims related to medical marijuana?

As of today, malpractice insurance covers claims related to the prescription and administration of FDA-approved medications and treatments.

Since medical marijuana is recommended, not prescribed, it may be covered in states where it is legal to recommend.

Notify your carrier.

Some carriers, captives, and RRGs are looking at writing malpractice policies that cover medical marijuana related claims.

MMJ in SNF Facilities

- Aug. 19, 2009, Randall K. Brooks, Assistant Regional Counsel, CMS, regarding the use of MMJ in skilled nursing facilities (“SNF”):
 - “[F]ederal law prohibits a SNF from dispensing medical marijuana. As the court held [in *Gonzales v. Raich*], ‘even if respondents are correct that marijuana does have accepted medical uses and thus should be redesignated as a lesser schedule drug, the CSA would still impose controls beyond what is required by California law. . . . [T]he dispensing of new drugs, even when doctors approve their use, must await federal approval.’” (emphasis added).

MMJ in SNF Facilities

- Maine
 - Permits nursing homes and inpatient hospice workers to act as registered MMJ caregivers for patients.
- Michigan, Oregon & Rhode Island
 - Include “agitation of Alzheimer’s Disease” as a qualifying condition for legal use of MMJ
- Montana
 - Does not permit smoking in any health care facility, but cannabis may be used in other forms
- New Mexico
 - Allows MMJ in SNF facilities

MMJ in SNF Facilities

- Sample MMJ use policy for SNF facilities, developed by the Washington Health Care Association:
 - Suggests that marijuana be brought to a qualifying patient by a designated patient representative and promptly removed by the patient's representative after use.
 - All marijuana must be in edible form only, no marijuana should be grown or stored on site, and the medical provider staff should not assist the patient with the medical marijuana in any manner.



David F. Beach & Kristyn S. Appleby, Complex and Developing Liability Issues: Legal Implications of Medical Marijuana, 57 No. 8 DRI For Def. 42 (Aug. 2015)
Washington Health Care Ass'n, Document Library, Skilled Nursing Sample Medical Marijuana Policy, <http://www.whca.org/files/2013/04/samplemedical-marijuana-policy.pdf> (providing the policy "for informational purposes only" and cautioning that it should not be used "without first reviewing them with your clinical/operational team and, if necessary, obtaining the advice of competent regulatory counsel.")

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Talking Points

- Should hospitals allow their physicians to "recommend" MMJ?
- Without more empirical data on the efficacy of MMJ, does it violate the standard of care to recommend MMJ to patients?
- On the other hand, with the state of current research and wide ranging reports of medical benefit, does it violate the standard of care to NOT recommend MMJ to patients?

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Questions?



Thank you!

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