Cannabis Forum for Certifying Providers

Cannabis Use During Pregnancy and While Nursing

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UPDATE

Rescheduling of Cannabis
On August 29, 2023, the Department of Health and Human Services (HHS) recommended to the Drug Enforcement Agency (DEA) that cannabis be rescheduled from Schedule I to Schedule III under the Controlled Substances Act (CSA).

- Schedule I – heroin, LSD, MDMA, peyote
- Schedule III – ketamine, Tylenol with codeine, anabolic steroids
  - Schedule III substances have an accepted medical use and may lawfully be dispensed by prescription

**DEA enforces drug laws – FDA enforces drug standards**
Proposal – Schedule I to Schedule III

• Recognize the medical uses of cannabis.
• Acknowledge cannabis has less potential for abuse than some other substances.

• Currently 38 states, three territories, and the District of Columbia allow the medical use of cannabis.*
• Currently 24 states, two territories, and the District of Columbia allow cannabis for adult recreational use.*

*National Conference of State Legislatures – April 09, 2024*
https://www.ncsl.org/civil-and-criminal-justice/cannabis-overview
Federal Implications

• Legal Status
  • Rescheduling would not make all medical and recreational cannabis legal at the federal level.
  • Products such as flower, edibles, vape products, suppositories, and topicals would still be illegal...until FDA approved.

• Production and Sales
  • Those who manufacture, distribute, dispense and possess medical cannabis may now be able to do so lawfully under the CSA.
  • Cannabis producers and retailers would be able to deduct the costs of selling their product for the purposes of federal income tax filing.
  • Easier access to banking services for cannabis businesses.
Federal Implications (continued)

• Agencies
  • Will VA patients and IHS patients now have access to providers who will certify them to use medical cannabis?

• Research
  • Less strict regulatory control as a Schedule III would promote greater research.
  • Will improved access cause pharmaceutical companies to pursue the development of additional cannabis drugs that can pass FDA muster?
  • Will FDA approved cannabis drugs be sold at pharmacies?
State Implications

• Current “state-legal” cannabis markets are not designed for a Schedule III drug. State and federal laws would still be in conflict.
  • Currently over 1,000 dispensaries in New Mexico with a myriad of different products.

• Will the FDA fully enforce regulations on cannabis products as it does for all other Schedule III drugs?
  • Could the rescheduling actually be regressive for those states that currently have a medical and adult-use program?
  • Will there be a specific carve-out for cannabis products currently in the market?
Patient Implications

• Those who use medical cannabis lawfully may benefit in the following ways:
  • Improved access to public housing
  • Obtain immigrant and nonimmigrant visas
  • Purchase and possess firearms
  • Face fewer barriers for federal employment
  • Eligible to serve in the military
  • Reduced penalties for federal cannabis crimes
Provider Implications

• Will medical providers be required to “prescribe” only those cannabis products that have met FDA regulatory standards?
• Will medical providers have to write an actual prescription specific dose and administration details?
• Will the insurance industry compensate providers for the time and energy spent evaluating and educating patients about medical cannabis?
Next Steps

• Proposal was reviewed by the White House Office of Management and Budget and moved forward.*

• May 16, 2024*
  • Notice of Proposed Rulemaking was submitted to the Federal Registrar by the Attorney General - initiating the formal rulemaking process.

• Public-comment period now open! – (ends July 22, 2024)*
  • Federal Register :: Schedules of Controlled Substances: Rescheduling of Marijuana
Next Steps

• Review from an administrative judge

• Likely some litigation!

• DEA would publish the final rule confirming the rescheduling

  **Expect at least 12 to 18 months for full rescheduling**

  HCPs – 9 years       Epidiolex – 3 months
Cannabis Use During Pregnancy and While Nursing
Background

• THC is lipid soluble
• THC can cross the placenta.¹
• THC can diffuse into the blood stream of the fetus.²
• THC can cross the blood brain barrier and bind to endocannabinoid receptors in the fetal brain.³
  • (Receptors present as early as 5 to 6 weeks)⁴
• THC can accumulate in the breastmilk and be released slowly over days to weeks.⁵
Trends

• Cannabis use amongst pregnant women is growing.\textsuperscript{6}
  • (3.4\% to 7\%)

• Use is greatest in the first trimester.\textsuperscript{6}
  • (5.7\% to 12.1\%)

• Use is greatest in the young\textsuperscript{6}
  • (<18 y/o = 22\%, 18 to 24 y/o = 19\%)

• Use is typically misrepresented
  • Twice as likely to screen positive than what was self reported\textsuperscript{7}
  • Self reported use = 7\%\textsuperscript{6} / Tested umbilical cords = 22.4\%\textsuperscript{8}
Trends

• Women in states with legalized recreational were more likely to consume during preconception.\(^9\)
  • Preconception = 1.52 times more likely to use
  • Pregnancy = 2.21 times more likely to use
  • Postpartum = 1.73 times more likely to use

• Met criteria for cannabis abuse and/or dependence (18.1\%)\(^{10}\)
Mode of use

• Smoking (91%)
• Eating (12.1%)
• Vaporizing (7.1%)
• Dabbing (4.5%)
• Drinking (0.5%)
• Other (0.5%)
Reasons for use

• Nausea and vomiting of pregnancy (77.8%, 77%)\textsuperscript{11,12}
• Stress/Anxiety (81.5%, 75%)\textsuperscript{11,12}
• Pain (55.1%, 83%)\textsuperscript{11,12}
• Sleep disorders (74%)\textsuperscript{12}
• Improve appetite (70%)\textsuperscript{12}
• Recreationally or for fun (45.7%)\textsuperscript{11}
Information Sources

• Family and friends\textsuperscript{13}
• Internet and Social media\textsuperscript{14,15}
• Dispensary/Budtenders\textsuperscript{16}
• Labels\textsuperscript{17}
• Healthcare providers
Dispensary/Budtenders

• “Mystery Caller” study

  • 36% of budtenders blatantly stated cannabis use is safe in pregnancy
  • 69% recommended cannabis products specifically for morning sickness
  • 65% based their recommendations on personal or secondhand experiences rather than research or clinical recommendations
  • Often expressed animosity and distrust of physicians
  • “If cannabis is safe for cancer, it must be safe in pregnancy”
Dispensary/Budtenders

- USA - no oversight board or regulation that holds budtenders accountable for spreading misinformation to customers.
- States - no individual state has requirements regarding what medical information budtenders are allowed to recommend.
  - Cannabis Regulatory Advisory Committee (C-RAC) – Cannabis Server
  - "A New Mexico public post-secondary educational institution may offer a practical or academic curriculum designed to prepare students for participation in the cannabis industry. The institution shall register its cannabis training and education program with the division, which shall include the information about the program on its website."
Labels

- Cannabis Regulation Fact Sheet 2022\textsuperscript{17}

  - 15/17 jurisdictions required labels on cannabis products to include a warning about the dangers of using the product while pregnant or breastfeeding.

  - Oregon and Washington had no such warning on labels.

  - New Mexico does have a warning, but not required on principal display panel, only on information panel or accessed through QR code.
Perceptions of use

• Perceive as low risk to fetus\textsuperscript{18}
• Cannabis is not addictive\textsuperscript{18}
• Aware of risks, but perceived cannabis use as safer than prescribed medications because it is a “natural plant”\textsuperscript{19}
• Medical cannabis is safer than recreational marijuana
• A lack of communication by medical providers reinforced the idea that cannabis use may be harmless or risk insignificant.\textsuperscript{20}
What is the message we should give?

• ACOG recommends that anyone who is pregnant, planning to get pregnant, or breast feeding - not use cannabis.

Marijuana and Pregnancy

If you use marijuana during pregnancy, you may be putting your health and your fetus's health at risk.

Possible Effects on Your Fetus
- Disruption of brain development before birth
- Smaller size at birth
- Higher risk of stillbirth
- Higher chance of being born too early, especially when you use both marijuana and cigarettes during pregnancy
- Harm from secondhand marijuana smoke
- Behavioral problems in childhood and trouble paying attention in school

Possible Effects on You
- Permanent lung injury from smoking marijuana
- Dizziness, putting you at risk of falls
- Impaired judgment, putting you at risk of injury
- Lower levels of oxygen in the body, which can lead to breathing problems

Did you know?
- Medical marijuana is not safer than recreational marijuana. Recreational and medical marijuana may be legal in some states, but both are illegal under federal law.
- There's no evidence that marijuana helps morning sickness. Ask your obstetrician-gynecologist (ob-gyn) about safer treatments.
- You should also avoid marijuana before pregnancy and while breastfeeding.
Some hard numbers

• Mother using cannabis during pregnancy 2.6 times more likely to have baby with low birthrate.\textsuperscript{21}

• 1.7 times more likely to spontaneously deliver their newborn prematurely.\textsuperscript{21}

• Mother using cannabis during pregnancy 1.5 times more likely to have a child with autism.\textsuperscript{22}

• Infants born to mothers were 2.5 times a likely to need to be admitted for intensive care.\textsuperscript{21}
Impact of Prenatal Cannabis Exposure (PCE) on growth parameters²³

• Cannabis use through gestation resulted in significant deficits in birth weight and head circumference.

• The longer the exposure time resulted in a greater impact on the fetus.

• Recommendation: Cannabis use should be discontinued as early as possible during the pregnancy!
Impact of Decreased Birth Weight & Head Circumference\textsuperscript{24-27}

• Neurological issues
  • Cognitive delay
  • ADHD

• Psychological issues
  • Depression
  • Social dysfunction
  • Somatic symptoms

• Health Complications in childhood
  • Childhood hypertension
  • Obesity in Adolescence

• Non-communicable diseases in adulthood
Prenatal Cannabis Exposure (PCE) and structural birth defects²⁸

• Mixed and inconclusive association
• Lack of results should not be interpreted that cannabis use during pregnancy is safe
• Highlights the need for greater research
Effects to Mother

• Lung injury if smoking
• Dizziness leading to falls risk
• Impaired judgement leading to injury
• Lower levels of oxygen leading to breathing problems
Why are we seeing this data now?

- Increased number of users
- Increased number of states who have legalized use
- Increased potency of product
- Continued distribution of misinformation
Recommendations

• Follow ACOG Recommendations

• Ensure that women who use cannabis during pregnancy are treated in a neutral, non-stigmatizing way and are supported to make decisions based on evidence, rather than ideology.

• Women who are unable to abstain from cannabis use are advised not to breastfeed within 1 Hour of inhaling or consuming cannabis to reduce the infant’s exposure to the highest concentration of cannabis in breast milk.

• Avoid pitting the rights of the mother and fetus against each other or threaten punitive measure in cases of substance misuse.


References


References


Any Questions?

- Website: [www.nmhealth.org/go/mcp](http://www.nmhealth.org/go/mcp)
- Email: [medical.cannabis@doh.nm.gov](mailto:medical.cannabis@doh.nm.gov)
- Phone: (505) 827-2321