

CBD: Could be Dope?
Plus Bonus Round:
LB 997: Out-of-Network Emergency
Medical Care Act

Nebraska Chapter of HFMA
Winter Program
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Federal Agriculture Improvement Act of 2018

- Federal law was amended in 2018 to remove Hemp from the list of controlled substances
 - Effective January 1, 2019
 - Hemp is a substance with less than .3% THC
 - CBD is processed from hemp
 - Legalized the sale of hemp, subject to state regulation of the substance

Food and Drug Administration (FDA)

- Still has authority over hemp
- FDA has prohibited the sale of CBD in any unapproved health products, dietary supplements or food
- The only approved use of hemp as a health product is the drug Epidiolex

FDA Loophole

- FDA does not have authority if the CBD producer and seller do not
 - Make any health claims about the CBD products; or
 - Put it in food or dietary supplements

FDA Hearing

- FDA published a notice of public hearing and proposed rule on April 3, 2019.
- Goal was to obtain additional scientific data and other info related to cannabis and cannabis derived compounds, both from botanical and synthetic sources, to inform regulatory oversight of these products.

FDA Action

- In July, 2020, FDA issued draft guidance on “Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry”
 - Aimed at individuals considering clinical research in this area
- No regulations or other actions.

Drug Enforcement Administration

- The DEA has advised that it will leave hemp enforcement to the FDA
 - Since the adoption of the 2018 Farm Act
 - Demoting hemp from controlled substance status

State Regulation of CBD

- Nebraska, for example
- Unicameral adopted the Nebraska Hemp Farming Act (L.B. 657)
 - Effective May 30, 2019
 - Removed hemp from the Nebraska list of controlled substances
 - Set up a licensure system for "processor-handlers" of hemp

Nebraska Hemp Farming Act

- Hemp licensure authority appears to include the sale of CBD as the "marketing" of hemp
- Due to the complexities of the Act, transportation of hemp across state lines may be illegal under some circumstances
- So Nebraska residents would be well-advised to purchase their CBD products in Nebraska

CBD in Licensed Facilities

- Any need for physician order?
- Any need to examine as a “home med”?
- Any need to confirm purchase in Nebraska?
- Any need to confirm no health claims on the packaging?

CDB in Licensed Facilities

- Nebraska Nursing Facilities, for example
- A Nursing Facility must have appropriate policies and procedures for "accurate acquiring, receiving, and administering of all medications to meet the needs of each resident." 175 NAC 12-006.12A
- If the Nursing Facility does not have a policy allowing residents to bring medications from home, it should adopt one, with reasonable safeguards

Nebraska Nursing Facility

- If a Nursing Facility anticipates multiple requests for use of CBD, it should probably adopt a policy specifically on that substance
- NE regs require pharmacist review of each resident's drug regimen, at least monthly

Nebraska Nursing Facility

- The drug regimen review must conclude with the pharmacist signing and dating a statement reporting any irregularities to the Director of Nursing and the primary medical practitioner
- The pharmacist's statement should say one of:
 - No potential problems were found;
 - A problem was found but it was deemed not significant;
or
 - A significant problem was found

Nebraska Nursing Facility

- The pharmacist's statement must include a description of the situation and the information that was communicated to the individual with the authority to correct it, usually the medical practitioner
- 175 NAC 12-006.12B

Iowa Laws on CBD

- Iowa Hemp Act signed into law on May 13, 2019.
- Approved by the USDA to allow licensed farmers to grow up to 40 acres of industrial hemp.
- This program does not legalize the use of CBD for human consumption, extraction or processing in Iowa.

LB 997: Nebraska Surprise; Out-of-Network Emergency Medical Care Act

Bonus Round

LB 997; Effective 1/1/2021

- Nebraska law
- Signed by governor in July, 2020
- Out-of-Network Emergency Medical Care Act
- Purpose is to prohibit providers from billing insureds for emergency services in excess of copayments applicable to in-network services pursuant to the health plan

Some Familiar Faces

- LB 997 relies largely on language used in the Emergency Medical Treatment and Active Labor Act.
- But no specific application to OB (other than in an emergency)
- Medical necessity standard applies
- No application to ambulance services

Similar to “No Surprises Act”

- Federal law
- Enacted within the past month or so
- Same theory as the Nebraska law, but with different language.
- Applies to air ambulances.
- Effective 1/1/2022
- Regulations expected 10/1/2021

Surprise is Right!

- There's a mistake in LB 997.
- Definition of Health Care Facility names general acute hospital, ASC and satellite emergency department.
- LB 997 doesn't apply to CAHs.
- Apparently, this was not known by legislators.

To-Do's for PPS Hospitals

- Warn hospital-based physician groups; it does apply to them.
- Discuss with billing team its current practice with claims as out-of-network provider
- Consider whether team can continue that without violating LB 997
- What is a [dispute]?

Resolution of Disputes

- Under LB 997, if an OON provider considers a claim or payment unreasonable:
 - It must return the payment
 - Parties have 30 days to negotiate
 - If no settlement, mediation
 - Cost of mediation split evenly

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