PHARMACY NEWSCAPSULE

DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

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APP For That!

TurboScan™: document scanner can turn your phone into a powerful scanner.

This app can help surveyors with everything from expense reporting to record keeping.

Ask your supervisor to complete a Cherwell ticket request to have the app distributed to your phone.

CBD Update

Recently there have been many questions coming in from providers about cannabidiol (CBD) and something called **delta-8**. Providers are asking can residents, patients, or clients in our facility or program use these items? Can staff at the facility administer them? Can the facility store them?

To ensure that surveyors have the same information that providers have, the following is a summary of the status of CBD, delta-8 and other cannabis or hemp-derived products.

Regulatory language:
The following comes from Wis. Stat. ch. 961.

Wis. Stat. § 961.32(2m)(b) *An individual may possess a cannabidiol product if the individual has certification stating that the individual possesses a cannabidiol product to treat a medical condition, if the certification has an issue date that is no more than one year prior to the possession, and if any expiration date provided by the physician in the certification has not passed.* ***A certification is not required to possess hemp, as defined in s. 94.55 (1), or a prescription drug product that has been approved by the U.S. food and drug administration.***

CBD cont.

The following comes from Wis. Stat. ch. 94 which regulates the plant industry.

Wis. Stat. § 94.55(1)
In this section, " hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis or the maximum concentration allowed under federal law up to 1 percent, whichever is greater, as tested using post-decarboxylation or other similarly reliable methods. "Hemp" does not include a prescription drug product that has been approved by the U.S. food and drug administration.

CBD or delta-8 that meets the definition of hemp does not require a certification as stated in Wis. Stat. § 961.32(2m)(3b) for a resident, patient, or client to possess and use.

Facilities or programs have a set of regulations where they need to balance resident, patient or client rights, provide safe care, follow various laws, and protect their own liability and staff. Currently products like CBD or delta-8 are not standardized. However, CBD and delta-8, along with other extracts from hemp, are not always benign. These products can interact with medications individuals may be taking. The doses used of the hemp products may lead to adverse events. Lastly, the hemp-derived products may contain levels of delta-9-tetrahydrocannabinol that make the product illegal or may contain contaminants or higher levels of CBD or delta-8 than what appears on any labeling.

Facilities may implement a range of policies about hemp-derived products in their facilities or programs to balance rights, safety, and liability. Those policies may include:

- Notifying staff that these products will be self-administered by patients and documenting the usage in patients' care plans.
- Allowing staff to administer these products only under certain circumstances, such as with products that have a certificate of analysis to show the product is un-contaminated, legal, and has a consistent dose.
- Applying limits on smoking hemp-derived products similar to policies for tobacco-based products.
- Allowing these products to be used only if they do not interfere with other care plan interventions, such as causing a significant drug interaction.
- Allowing these products to be used on a trial basis. . For example, restricting hemp-derived products if a resident's sharing of a hemp-based product leads to negative outcomes for other residents.

These are just some of the policies facilities may be adopting that surveyors may run into. Some of these policies may lead to complaints about rights of residents, patients, or clients. As in many resident right issues, the investigation will hinge on did the facility or program notify individuals of the policy? Think of smoking policies and the balance of resident, patient, or client rights with procedures facilities or programs put in place.

CBD cont.

For some surveyors there are some specific regulations that will apply when CBD, delta-8 or other hemp-derived products are used. Specifically, surveyors who survey Community Based Residential Facilities (CBRFs) have the following provisions to consider:

Wis. Admin. Code § DHS 83.37(1)(a)
There shall be a written practitioner's order in the resident's record for any prescription medication, over-the-counter medication or dietary supplements administered to a resident.

Wis. Admin. Code § DHS 83.02(20) *"Dietary supplement" means a product taken by mouth that contains a dietary ingredient such as vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites*

Since dietary supplement is broadly defined, hemp products would require a practitioner's order when facility staff administer the product.

In summary, consider the potential concerns and unknowns about cannabis-derived products from the Food and Drug Administration:

- CBD has the potential to harm you, and harm can happen even before you become aware of it.
  - CBD can cause liver injury.
  - CBD can affect how other drugs you are taking work, potentially causing serious side effects.
  - Use of CBD with alcohol or other drugs that slow brain activity, such as those used to treat anxiety, panic, stress, or sleep disorders, increases the risk of sedation and drowsiness, which can lead to injuries.
  - Male reproductive toxicity, or damage to fertility in males or male offspring of women who have been exposed, has been reported in studies of animals exposed to CBD.
- CBD can cause side effects that you might notice. These side effects should improve when CBD is stopped or when the amount used is reduced.
  - Changes in alertness, most commonly experienced as somnolence (drowsiness or sleepiness).
  - Gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite.
  - Changes in mood, most commonly experienced as irritability and agitation.
- There are many important aspects about CBD that we just don't know, such as:
  - What happens if you take CBD daily for sustained periods of time?
  - What level of intake triggers the known risks associated with CBD?
  - How do different methods of consumption affect intake (e.g., oral consumption, topical, smoking or vaping)?
  - What is the effect of CBD on the developing brain (such as on children who take CBD)?
  - What are the effects of CBD on the developing fetus or breastfed newborn?
  - Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?

COVID-19 Antivirals

As surveyors in various settings, you may be seeing two oral antivirals being used: PAXLOVID® and Molnupiravir.

- These are for treatment of lab-confirmed mild-moderate COVID-19.
- These are not for prophylaxis or exposure to COVID-19.
- Treatment must begin with 5 days of symptom onset.

The following are some of the facts you should know which may help you with your survey activities.

PAXLOVID®

- Can be used in those aged 12 and up.
- This is a combination of two drugs: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for 5 days, can be taken with or without food.
- Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.
- PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 mL/min).
- The tablets should be swallowed whole and not chewed, broken, or crushed.
- Drug Interactions: See the FDA fact sheet for a complete list of drug interactions.

Molnupiravir

- Can be used in those aged 18 and up.
- Dosing is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food.
- Not recommended for use during pregnancy because may cause fetal harm . Authorized for use in pregnancy only if benefits would outweigh risks for the individual patient; documentation requirements apply.
    - Females of childbearing potential should be advised of potential risk to a fetus and should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.
    - Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- There are no known drug interactions.

The U.S. Department of Health & Human Services offers a side-by-side comparison of these two oral antivirals.