PHARMACY NEWSCAPSULE

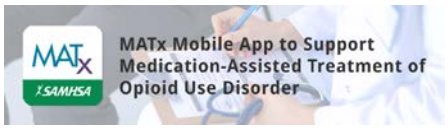
DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

March / April 2018

Douglas Englebert, R. Ph. ● 608-266-5388 ● douglas.englebert@dhs.wisconsin.gov

In This Issue

App for That!



MATx Mobile App

This app provides effective, evidence-based care for opioid use disorders. This free app supports practitioners who currently provide medication-assisted treatment (MAT), as well as those who plan to do so in the future.

Cannabidiol (CBD)

Facilities and surveyors alike have seen CBD products administered or taken by patients and residents in the facilities, agencies, and programs that the Division of Quality Assurance regulates. Questions as to whether or not residents or patients can have this product and whether we should apply pharmacy regulations to them have been raised by surveyors and providers alike.

On April 27, 2018, the Wisconsin Statewide Intelligence Center (WSIC) issued an unclassified Analytical Note to draw awareness to the illegality of the possession and sale of CBD products in the state of Wisconsin. Surveyors should be aware of the following highlights:

- "Cannabidiol (CBD) is an active cannabinoid chemical found in the marijuana plant. Unlike the main psychoactive cannabinoid in marijuana, tetrahydrocannabinol (THC), CBD does not produce intoxication. CBD frequently takes the form of CBD oil, capsules, sprays, lotions, balms, "edibles," or 'vapes' and has been sold in stores nationwide and online."
- "Interest in the potential therapeutic effects of CBD has been growing rapidly, partially in response to media attention surrounding the use of CBD oil in young children with intractable seizure disorders, including Dravet syndrome and Lennox-Gastaut syndrome. Additionally, preclinical research has shown CBD to

have a range of effects that may be therapeutically useful, including anti-seizure, antioxidant, neuroprotective, anti-inflammatory, analgesic, antitumor, antipsychotic, and antianxiety properties. While there are promising preliminary data, rigorous clinical studies are still needed to evaluate the clinical potential of CBD for specific conditions."

- "Second, an individual may possess CBD (without THC) if they also possess a certification issued by a physician. This certification must include : (1) a date of issue no more than one year before the date of possession, (2) the name, address, and telephone number of the physician, (3) the name, address, and phone number of the patient, and (4) a certification that the patient possesses the CBD to treat a medical condition. See Wis. Stat. § 961.32."

Based on this information, surveyors may see patients or residents who have CBD available to them and have the certification as outlined in Wis. Stat. § 961.32. CBD with the certification is legal for patients or residents.

Currently, the CBD products that most surveyors have seen involve products that are not classified as medications. Since many of the regulations DQA enforces apply only to medication, surveyors may not have a specific medication regulation to apply. In other cases, like in a community-based residential facility (CBRF), there are regulations that apply to dietary supplements that may apply to many of the CBD products. The dietary supplement requirements in a CBRF, per DHS 83.37(1)(a), pertain to having a written order; in the case of CBD, the certification may include the written order.

Facility staff may ask surveyors many other questions regarding their liability with CBD. Facilities should be directed to review the WSIC Analytic Note and consult the facility's legal counsel for guidance.

Training Review Lesson 2

This is a review related to the observation of herbal products and other dietary supplements during the medication pass task, completed on a nursing home survey.

Nutritional and Dietary Supplements

Nutritional supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna, and Promote).

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement rather than a medication.

For clinical purposes, it is important to document a resident's intake of such substances in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate. The exception to this would be vitamins and minerals, which are generally considered a category of dietary supplements. Medication errors involving vitamins and/or minerals should be documented at F759 and counted towards the error rate calculation. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criterion at F760 is also met.

The following tool provides additional guidance to help surveyors evaluate if a product should be included in the sample when conducting the medication pass task.
https://www.dhs.wisconsin.gov/publications/p01864.pdf

Consultant Corner

Q: Can an RN in a skilled nursing facility (SNF) "re-package" medications from one bubble pack card to another self-sealing bubble pack card within the facility?

A: No. For an explanation, see Wis. Admin. Code § DHS 132.65(6)(b)2 at https://docs.legis.wisconsin.gov/code/admin_code/dhs/110/132/VI/65

Q: Is this statement true or false: We do not have to do a gradual dose reduction (GDR) for over-the-counter medication, even if it is being used as a psychotropic (e.g., diphenhydramine for sleep).

A: False. Federal regulations do not distinguish between over-the-counter (OTC) and non-OTC medications. If a medication is necessary, a psychotropic, and requires a gradual dose reduction (GDR), it does not matter if it is prescription or OTC.

> *Wisconsin Stat. § 483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:*
>
> *(i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic*
>
> *Wisconsin Stat. § 483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:*
>
> *(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;*
>
> *(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs*

Q: We understand that nutraceuticals, such as melatonin, do not need a GDR. However, do they still need patient/guardian consent if being indicated for use as a psychotropic?

A: Melatonin is not a drug, so the federal rules specific to drugs do not apply. However, if someone is diagnosed with insomnia and a facility decides to use melatonin for an intervention, the facility needs to monitor melatonin and change the sleep care plan, which may require dosage and timing changes of the melatonin. If the facility does not do that, they risk a care planning/assessment citation.

All drugs and care interventions need consent. Residents have the right to be informed of their care and decide if they agree and wish to participate. For some individuals a written consent is required. Per the definition in Wis. Stat. § 50.08, melatonin is not a psychotropic; however, also per Wis. Stat. § 50.08, if the person has degenerative brain disorder and the drug is psychotropic and the drug has a black box warning, written consent is required. If the person has a developmental disorder or mental illness, Wis. Admin. Code ch. DHS 94 for psychotropic drugs would apply and a written consent is required. In theory, Melatonin could (under DHS 94), require written consent; however, this scenario is unlikely in a nursing home.

Q: Is there any guidance on how epi-pens should be handled in CBRFs? Locking them up doesn't make the best sense. Would providers simply follow manufacturer instructions?

A: It depends. If following the CBRF rules as spelled out in Wis. Admin. Code § DHS 83.37, the answer depends on the situation. A resident who will be self-administering the epi pen could keep it unsecured on their person or in their room as they are managing their own medications.

If the facility has epinephrine as a general first aid kit item without specific resident orders, then they should have a policy on use and access to the first aid kit; this is probably rare in a CBRF.

If the facility has a resident with an order for epinephrine and staff are to administer it in an emergency, then that should be stored locked. However, this may not be the best way to store the epinephrine for immediate access and the facility should consider requesting a waiver to store epinephrine unlocked, e.g., at bedside. In addition, the facility may need to request a waiver to the requirement for a nurse to delegate injections.

Q: I am surveying a facility that is packaging medications for residents to take home, taking them from large facility pill bottles and putting them in small plastic pill packages. Can the facility do this?

A: No. This is dispensing. A pharmacist, physician, nurse practitioner, and veterinarian are able to dispense prescription drugs in Wisconsin. Physicians can also delegate the practice of dispensing medications. Those individuals who dispense medication need to have a prescription order on file, label the container correctly, and provide counseling. In addition, facility-specific regulations may apply. Facility regulations may limit further who can dispense medication and how dispensing prescription medications must be done.

Illustration Attribution

Millspaugh, Charles Frederick, *American Medicinal Plants: An Illustrated and Descriptive Guide to the American Plants Used as Homeopathic Remedies; Their History, Preparation, Chemistry, and Physiological Effects,* Boericke & Tafel, New York, Philadelphia, 1887.