PHARMACY NEWSCAPSULE

DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

July / August 2018

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In This Issue

App for That!

Breathe2Relax

Breathe2Relax is an app that assists in stress management. The app provides education about stress and teaches you breathing exercises to manage stressful situations.

Black Box Warning Medications and Skilled Nursing Facilities

In the last issue of the Pharmacy Newscapsule, written consent was addressed. In this issue, consent for "black box warnings" is addressed.

Surveyors and nursing facilities have submitted numerous questions regarding requirements pertaining to written consent for psychotropic medications; most notably, when consent is required for medications with back box warnings.

"Black box warning" is a designation given by the Food and Drug Administration (FDA). As the term suggests, in FDA-approved package labeling, this warning on the manufacturer's label is surrounded/boxed with a black border. It is the strongest warning that the FDA requires. More importantly, this warning is designed to call attention to serious risks and often life-threatening adverse reactions related to use of the medication. Typically, when medications with black box warnings are being used in the facility and there are serious potential risks for adverse or serious side effects, the resident should be informed and a discussion regarding the benefits vs. the risks should occur. When the benefits do not outweigh the risks, the medication should not be used.

In Wisconsin, nursing facility use of antipsychotic medications with black box warnings has received much attention due to the administration of these medications to residents with dementia behaviors.

However, there are many other medications with black box warnings that are commonly used. For example, ciprofloxacin and other fluoroquinolones carry the following black box warning. (For full prescribing information regarding black box warnings, see *FDA Drug Safety Communication: FDA advises restricting fluoroquinolone antibiotic use ….)*

> WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS
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> Fluoroquinolones, including CIPRO®, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects.
>
> Discontinue CIPRO immediately and avoid the use of fluoroquinolones, including CIPRO, in patients who experience any of these serious adverse reactions.
>
> Fluoroquinolones, including CIPRO, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid CIPRO in patients with known history of myasthenia gravis.
>
> Because fluoroquinolones, including CIPRO, have been associated with serious adverse reactions, reserve CIPRO for use in patients who have no alternative treatment options for the following indications: acute exacerbation of chronic bronchitis, acute uncomplicated cystitis, acute sinusitis.

There are instances within nursing facilities where ciprofloxacin and other fluoroquinolones are being used inappropriately for unconfirmed infections; putting residents at risk for these serious adverse effects. Most recently, in July 2018, the FDA again indicated that labeling for fluoroquinolones be updated to reflect risks of mental health side effects and serious blood sugar disturbances. These latest warnings were not a black box warning; however, these risks should also be considered when using these medications.

Surveyors in other states have cited facilities for the inappropriate use of black box warning medications. For example:

> A facility in another state was cited for immediate jeopardy when the facility gave two residents unsafe drug combinations—the proton-pump inhibitor omeprazole (Prilosec/Prilosec OTC) and the blood thinner clopidogrel (Plavix) (excerpted from Docket No. C-16-13, Decision No. CR4947). This combination was unsafe, particularly since these residents were at risk for heart attacks or strokes. The judge in the case noted that on November 18, 2009, the FDA issued a black box warning against using Plavix and Prilosec at the same time.
>
> The FDA later reiterated these warnings in drug safety communications and the facility's own written policies "echo the warning." The facility administered the unsafe combination of drugs to Resident M for more than three years and to Resident N for seven months. The facility violated federal requirements by administering fentanyl patches without determining resident tolerance, as required by the FDA black box warning. The nurse supervisor told surveyors that staff would administer the drug so long as they had a physician order, without regard to whether the resident was opioid-tolerant.

If a medication does have a black box warning, it does not mean it cannot be used by a particular resident. Additionally, if a medication with a black box warning is used by a resident who is at risk, it does not mean that the situation is automatically a citation and immediate jeopardy. In some cases, there may have been discussions with the resident about the risk and potential benefits, monitoring may

be in place, and discontinuing the medication when/if the medication no longer works may also be planned. All of these interventions are examples where citations and immediate jeopardy may no longer exist. As a surveyor reviewing medications, if you are aware of a medication that has a black box warning that could directly affect the resident, you should evaluate if there was a discussion about the risk, what the monitoring plan may be to minimize the risk, and what interventions may be implemented should adverse events occur.

Medication Management: RCAC

In a residential care apartment complex (RCAC) residents can receive a range of services. A service many residents may opt to receive is medication management. What is medication management? The administrative code defines it as oversight by a nurse, pharmacist, or other health care professional to minimize risks associated with use of medications. Medication management includes proper storage of medications; preparation of a medication organization or reminder system; assessment of the effectiveness of medications; monitoring for side effects, negative reactions, and drug interactions; and, delegation and supervision of medication administration.

To meet this definition many facilities will create policies that ensure this level of management occurs and works in their environment. Sometimes those policies and procedures may not match the practices you see in other settings like hospitals and nursing homes. However, just because an RCAC is not using bar code technology when administering medications does not mean the practice the RCAC is using is not following the standard of care.

There are existing standards for medication management. For example, the National Coordinating Council for Medication Error Reporting and Prevention (an independent association comprised of 27 other national associations) has standards related to medication administration. One of those standards states:

> Healthcare professionals only administer medications that are properly labeled, and labels should be read during the following 3 steps in the administration process:
>
> - When reaching for or preparing the medication
> - Immediately before administering the medication
> - When discarding the container or replacing unused medication back into its storage location

Although this standard exists, the packaging of medications by a resident and an RCAC, and the procedures related to medication administration, may look different from one facility to the next. Facilities often have very similar practices that we are accustomed to seeing in these settings and, as a surveyor observing such differences, one may question those practices. However, it is important to focus on the outcomes to determine if the facility is managing the medications rather than on the fact that the system is different from what is normally seen. If medication errors are occurring, medications are not available, or if residents are experiencing adverse events, this is evidence that the facility is not managing medications according to the definition above. And, failure to manage the medications may result in citations.

Consultant Corner

Q: A CBRF pharmacy began sending "e-scripts" for every medication prescribed for residents. The CBRF already has a copy of the physician's orders. This is extra paper for them. The provider has "heard" it is "the state" that is requiring the e-scripts.

A: In a CBRF, a written physician order is required for medications per Wis. Admin. Code § DHS 83.37. DQA publication P-01905, Physician Orders and Medications, provides guidance as to what constitutes a written order. Electronic prescriptions (e-scripts) can meet those requirements. The copy that the pharmacy has is what was directly obtained from the physician, which could, in some cases, be different then the order the physician provided to the CBRF.

Q: Are there regulations or concerns around using either scheduled or PRN Tylenol PM?

A: Tylenol PM usually contains diphenhydramine or Benadryl. Diphenhydramine is highly anticholinergic, causing drying out of secretions, which is highly problematic in the elderly and is generally not recommended for use. If residents are using it, providers should have justification and monitoring plans for side effects, some of which include falls, confusion, constipation, and trouble swallowing. For more information please consult with a pharmacist and review American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults.

Q: We observed a needleless adaptor on 30 ml vials of dexamethasone injectable medication in the physical therapy department. The facility keeps this device on and draws doses over the 30 days they used the vial. Are there any standards of practice that you know of for this situation?

A: The U.S. Pharmacopeial Convention (USP) has a standard, USP 797, which would indicate that multidose injectable vials have a beyond use date of 28 days after opening unless the manufacturer labeling has other requirements. There are no general standards indicating whether you can or cannot use transfer devices or what the beyond use date would be going forward.

There are a wide range of transfer devices. The manufacturer of the transfer devices should have information that the facility should consider when creating policies as to when transfer devices can be used and as to the length of time a multidose vial can be punctured and used. If the facility did not have policies on multidose vials using a transfer device, that would be a concern and should be investigated. Was the pharmacy consulted on the policy? What information was considered when creating the policy? If facilities have not reviewed manufacturer requirements and developed a policy related to multidose vials and transfer devices, this may be a citation related to pharmacy services.

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.