PHARMACY NEWSCAPSULE

WISCONSIN DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

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IN THIS ISSUE

APP for That!

MS Teams is being used more in our daily work. If you need help, check out the resource page, as well as quick how-to videos.

Refrigerators and Medications

Select medications need to be stored at refrigerated temperatures. Typically, those temperatures are between 36- and 46-degrees Fahrenheit. However, how should temperatures be monitored and what type of refrigerator should be used?

The process for monitoring temperatures depends on the medications stored and the outcome the facility will implement for medications found at risk. For example, if medications stored in a refrigerator become at risk once the medication reaches 46 degrees for more than four hours, refrigerator temperatures need to be looked at on intervals of four hours to ensure the medication did not go above 46 degrees for the allowed interval. If medications are at risk after 24 hours, check daily.

Monitoring may be done manually or with devices that are set up with alarms. In some cases, alarms may be centralized so that there is someone to intervene and manage the medications to avoid disposal of medications that have been exposed to inappropriate temperatures.

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Refrigerators and Medications cont.

What about refrigerator What about refrigerator type? Some studies have indicated that certain refrigerators are problematic, especially dormitory style refrigerators with the small freezer inside the refrigerator. Temperatures within the dormitory style refrigerator/freezer may have extreme variations and have led to products becoming frozen. For this reason, some contracted programs, such as the Vaccine for Children program, mandate that the dormitory style freezer/refrigerator combination not be used.

As surveyors, you should see facilities adopt practices that match the needs or requirements of the medications, refrigerator, and thermometer device.

Medications and Bare Hands Handling by Caregivers

Recently, surveyors have observed staff administering medications by punching or pouring out pills or capsules into their bare hands prior to putting the medications into a medication cup to administer to a patient or resident.

In most cases, the staff person had washed their hands with soap and water or had used hand sanitizers. Obviously, if no hand washing was done this activity would violate various standards of practice related to hand hygiene. However, even with hand washing, this practice of touching pills and capsules with bare hands is problematic.

First, bare hands are touching something that will be consumed by another person. This action is generally not accepted for food items, and it makes sense that it would not be accepted for medications. Second, some medications may be affected by moisture and residue from hand sanitizer (alcohol if hands are not dry). This may adversely affect the medication and, in turn, the resident or patient. Lastly, touching medications with bare hands may put the staff member at risk. Some medications carry risks of birth defects and, therefore, women of childbearing age should be cautious in handling these medications.

Surveyors who observe bare hand handling of medications should investigate this practice. Often, if this behavior is routine practice, there will be a violation involved related to infection control, pharmacy, or nursing standards.

Sample Medications

In various clinics, including Rural Health Clinics and Outpatient Mental Health programs which DQA surveyors visit, distribution of sample medications raises questions about proper management of these medications.

Everyone must remember that sample medications are still prescription drugs. The act of providing sample medications to patients is dispensing. A pharmacist or a practitioner or their agent (a practitioner is someone allowed by law to write prescription orders) can only dispense prescription medications. As a result, pharmacy and/or medical dispensing regulations affect sample prescription medications.

First, the regulations indicate record keeping must be done in the patient's record. Second, although the regulations are not clear on this, sample medication security is a must. Unsecure sample medications have been a target, in some cases, for staff to self-medicate without a prescription. Third, like all prescription drugs, there are occasional recalls of these medications for product that should not be used. In these cases, clinics need to have a procedure to remove these products from use. Sample medications may have a role for some clinics, but the clinics need to remember that sample medications are prescription drugs that require an adherence to regulations outside of the clinic requirements.

Medical Assistants

In regulating various health care entities in Wisconsin, questions arise as to who is authorized to perform specific functions and what training is required. One specific group of individuals includes medical assistants; questions routinely come from surveyors and providers in nursing homes, assisted living facilities, rural health clinics, hospices, home health and hospitals related to the scope of practice for medical assistants.

To summarize, medical assistants are not licensed, registered, or certified by the State of Wisconsin. Any licensure, registration, or certification that a medical assistant possesses has been issued by some other organization or state. Therefore, a medical assistant working in a licensed facility in Wisconsin (nursing home, home health agency, hospital, assisted living, etc.) is recognized as an unlicensed person.

Specific facility licensure regulations dictate what an unlicensed person can do and identify the training that is required. For example, to perform some tasks in a nursing home you may need to be a nurse aide if you are not licensed as a nurse. A medical assistant who is not licensed would need to become a nurse aide to do some tasks. The same would apply in assisted living facilities where specific training is required. Exemptions are not provided for medical assistants, so additional training would be required.

The bottom line is that all medical assistants working in licensed facilities are treated as unlicensed staff.

Health Alert: Tianeptine Containing Products

Below is a repeat of a recent health alert issued by DHS. From a DQA perspective, surveyors in all facilities may run into this issue. Those in assisted living and those who survey substance use disorder treatment entities may run into products containing tianeptine. As surveyors it's important to be aware of the ease to access these products, what the adverse events are for these products and what we may see providers do to respond when these products are used inappropriately.

Key points

- Adverse health effects, including seizures, loss of consciousness, and death, have been reported after use of Neptune's Fix and other products containing tianeptine.
- Tianeptine is not approved by the U.S. Food and Drug Administration (FDA) for any use and FDA has warned consumers not to purchase or use any tianeptine-containing products.
- The company responsible for Neptune's Fix is voluntarily recalling its products; however, there are other tianeptine products available, especially online.

Background

- On January 11, 2024, the FDA sent a letter to gas stations, convenience stores, and other retailers urging them to stop selling Neptune's Fix and other tianeptine-containing products.
- On January 23, 2024, the FDA issued a warning to consumers not to purchase or use Neptune's Fix or any tianeptine product due to serious health risks.
- On January 28, 2024, the company responsible for Neptune's Fix products issued a voluntary nationwide recall of all Neptune's Fix products.
- Tianeptine is an atypical tricyclic drug that has not been approved by the FDA for medical use. Neptune's Fix is sold as an elixir or in tablets and tianeptine is sold in tablet or powder form.
- Neptune's Fix and other tianeptine-containing products have been sold at gas stations, convenience stores, and other retailers, including online.
- The adverse health effects of tianeptine products may be exacerbated by alcohol use and by interactions with other medications, especially certain antidepressants (monoamine oxidase inhibitors (MAOIs).
- With use of tianeptine, there is a risk of suicidal ideation or behavior in children, adolescents, and young adults 25 and under.

DHS Health Alert cont.

Information for health care providers

- Providers should be aware of the potential health risks of tianeptine products. A wide range of adverse health effects have been associated with tianeptine (alone or with other drugs) including agitation, drowsiness, sweating, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.
- Those with opioid use disorder may be at risk of using or abusing tianeptine. Clinical effects of tianeptine abuse and withdrawal may mimic opioid toxicity and withdrawal.
- Providers can contact their local poison center for clinical guidance as needed (contact information below).