PHARMACY NEWSCAPSULE

WISCONSIN DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

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APP for That!

Google Authenticator

As more of DQA begin using the iQIES system you do have the option through your HARP account to receive the two-step authentication number through google authenticator in addition to receiving the code via email. Check it out!

Clozapine Monitoring

As surveyors, many of the programs we are tasked with inspecting we may have come to expect extensive monitoring with clozapine has been used. In some cases, the stringent requirements for monitoring have led to the medication being stopped inappropriately when the monitoring was missed when scheduled.

Earlier this year the Food and Drug Administration (FDA) issued the following:

The FDA does not expect prescribers, pharmacies, and patients to participate in the risk evaluation and mitigation strategies (REMS) program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. Information about severe neutropenia will remain in the prescribing information for all clozapine medicines, including in the existing Boxed Warnings.

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Clozapine Monitoring (cont.)

Although the risk of severe neutropenia with clozapine still exists, FDA has determined that the REMS program for clozapine is no longer necessary to ensure the benefits of the medicine outweigh that risk. Eliminating the REMS is expected to decrease the burden on the health care delivery system and improve access to clozapine. FDA has notified the manufacturers that the clozapine REMS must be eliminated. FDA has instructed the clozapine manufacturers to formally submit a modification to eliminate the Clozapine REMS and to update the prescribing information, including removing mandatory reporting of ANC blood tests to the REMS program.

What does this mean? The stringent REMS programs will no longer be used. You will still see monitoring of ANCs by blood test but hopefully the flexibility allows for more individual care and lessen situations where the medication is discontinued inappropriately. As surveyors if you have come to expect all the REMS paperwork you may no longer see that.

Internal/External Medication Separation

Some DQA-regulated facilities and programs are required to store internal and external medications separately.

The typical regulation language may read: "...physically separate medications for internal consumption from medications for external application." However, many of these regulations often lack definitions leading to questions about items such as eye drops, ear drops, nose sprays, and medications inhaled into the lungs. Historically these requirements have been interpreted using pharmacy-based terms of external medications being topicals and internal being everything else. For example, eye drops, ear drops and creams or ointments are considered topical/external and should be separated from oral medications.

Some facilities may implement more restrictive policies by separating medications by route of administration (such as separating ear drops from eye drops) to reduce medication errors. Examples of compliant separation may include using different drawers or bins in medication carts or placing each medication in a labeled individual bag.

DQA Mailbag

1. Who can administer injectable medications in a community based residential facility (CBRF)?
    - Residents can self-administer their own injectables.
    - Licensed professionals (nurses, physicians, pharmacists) may administer injectables.
    - Trained staff may administer injectables if delegated by an RN.

2. Can a CBRF borrow medications from an attached skilled nursing facility (SNF)?

    No. The SNF's emergency kit belongs to the pharmacy and is intended only for SNF residents. Borrowing from this supply violates several rules in Wis. Admin. Code ch. DHS 83, including Wis. Admin. Code § DHS 83.37(1)(b).

3. When is written informed consent required for medications in nursing homes?

   Informed consent is always required, but written consent is specifically required under Wis. Stat. § 50.08 in certain cases:

   - For residents with dementia or other degenerative brain disorders.
   - When psychotropic drugs with black box warnings are prescribed.
   - The reason for prescribing (not just the drug's FDA approved use) determines the need for written consent.
     - If the drug is on the list on the publication and in BOLD you would need written consent.
   - Additional written consent requirements may apply under Wis. Stat. chs. 51 and 55 placements or Wis. Admin. Code ch. DHS 94 rules for residents placed under mental health statutes.

   Helpful reference regarding informed consent requirements in nursing homes:
   Informed Consent Requirement in Nursing Homes

4. Can a facility use different strengths of the same medication to make the dose needed?

   Yes. For example, 175 mg of sertraline may be given using a 100 mg tablet, a 50 mg table and a 25 mg tablet combination. Labeling and medication administration records (MARs) may vary by pharmacy or facility, but as long as the correct dose is administered, it is acceptable.