CBRF Inspection from a Pharmacist

For those of you who are charged with inspecting community-based residential facilities (CBRF), the following is a report from a pharmacist who conducted an annual CBRF inspection.

Today (November 2017), I completed an annual medication inspection for a 20-bed CBRF. Below is a quick summary of what I found.

1. A 13” X 9” plastic bin in the bottom drawer of med cart full of unlabeled over-the-counters. When asked what they were for, I was told by staff and administrator, “Oh, we just give those to them if they need them.” No doctor orders were found to match these over-the-counters. Looking at the medications, over half were expired. Bin was removed from cart.

2. Topicals, ointments, eye drops, and ear drops were all mixed together with no physical separation.

3. A bag of lorazepam liquid syringes properly labeled by pharmacy (for hospice) in the refrigerator with a clear expiration date of 90 days that was dispensed in Feb 2017 and good through May 2017. So, by November the Lorazepam was six months expired.

4. Three bags (filled by pharmacy July, August, and October) with scheduled insulin pens in them for the same resident. Not one insulin pen in the whole refrigerator was dated with “date opened.” When I asked the staff how they knew which insulin pen they had just used, they said, “We just pick one, use it, and put it back in one of the bags in the refrigerator.” They had no idea which pens had been used and which were new. No one had contacted pharmacy to let them know they did not need more insulin at this time.

(continued)
For CBRF surveyors, this review highlights some areas of concern.

1. To avoid wasting medications (and money), facilities may save medications (for example, over-the-counter drugs) in anticipation that they may be used again. These may be forgotten and will expire over time. Be aware of saved medication.

2. Medications used internally need to be separated from those used externally. Another good practice is to separate medications by route so that ear drops and eye drops do not get mixed up.

3. Medications that are prepared by pharmacy, such as oral syringes, often have shorter beyond-use dates or expiration dates. When inspecting a facility, pay close attention to items mixed or prepared by the pharmacy.

4. Carefully inspect insulin pens for expiration dates and resident labeling. Insulin pens are to be used only for one person and once put into use will have a shorter expiration, ranging from 14 days to 4-6 weeks. Facilities should have a process in place to know when these expire. Often they will put a “date open” on the pen.

Ancillary Services in Hospital and Pharmacy Services

Many services in a hospital may incorporate use of pharmaceuticals for procedures. For example, in radiology departments, the use of various contrast media (considered a drug) are injected or orally administered for various scans. In maternity departments medications are administered to induce labor. In respiratory therapy and in ear, nose, and throat (ENT) departments, medications are inhaled for various conditions.

The Conditions for Participation for Pharmaceutical Services requires a pharmacist to be responsible for developing, supervising, and coordinating all activities of pharmacy services. In some cases in the departments noted above, the pharmacy is supplying medications but may have lost sight of how these medications are being prepared, stored, administered, and destroyed. When there are issues of how medications are utilized in these ancillary departments, the requirements for pharmacist oversight should be evaluated.

For example, surveyors have identified ENT departments where medications are mixed and placed in atomizers (creating inhaled medications from injectable medications). In some cases these medications may not be labeled and may not have beyond-use dates on them. This practice does not follow standards of practice and should be considered a violation.

Another example is a physical therapy department where sterile, injectable medications are being used for topical applications. In some cases the medications are prepared in a manner causing the injectable medications to no longer be sterile, but are maintained in containers that indicate the medications are sterile. Again, this does not follow standards of practice and should be considered for a violation.

When medications are used in various departments, procedures must be reviewed by a pharmacist to ensure that medications are stored, labeled, and disposed of properly. When this does not occur, surveyors should evaluate the condition for participation for pharmacy services.

Consultant Corner

On November 28, 2017, a new survey process and new regulations took effect for skilled nursing facilities (SNF). The following is a list of the frequently asked questions relating to the pharmacy regulations.

Q: Regulation F329: Unnecessary Drugs specifies requirements for psychotropic medications that are PRN and Gradual Dose Reductions (GDRs) for these medications. Does Compazine (which is an antipsychotic drug according to some medication resources) taken for nausea and vomiting on a PRN basis expire every 14 days and have to be reevaluated and renewed every 14 days?

A: (By CMS): Compazine, or prochlorperazine, is considered an antipsychotic, though it can be used to treat nausea and vomiting. Therefore, according to federal requirements, a PRN order for Compazine would be limited to 14 days. A new PRN order cannot be renewed unless the attending physician or prescribing practitioner first evaluates the resident to determine if entering a new order for the PRN medication is appropriate.
Q: **PRN antipsychotic medications (specifically haloperidol)** have become routinely prescribed by hospice physicians. I see no exception to this type of order in the requirements of participation or supporting materials in Appendix PP. The hospice PRN order may go unused for a period of 14 days, necessitating an in-person reevaluation by the physician, despite the desire of the physician to have the medication available to assist with potential symptoms of dying, particularly delirium associated with hyperactivity at the end of life or for its potent antiemetic properties. Good hospice care, honoring resident’s choices and person-centered care, and hospice clinical best practices all seem to be in conflict with the 14-day limit of PRN orders for antipsychotic medications for persons receiving hospice services.

Is there an opportunity, if the medical record indicates the PRN order for haloperidol is being used to manage end-of-life symptoms for a patient on hospice care, for an exception to this requirement? These issues were all raised during the comment period, with little to no response.

A (By CMS) We understand your concerns and appreciate the importance of promptly addressing the needs of all residents, especially those residents who receive end-of-life or hospice care. There is no exception to the PRN antipsychotic requirement in the regulations. The intent of this requirement is to address the concern that use of an antipsychotic medication, on a PRN basis beyond 14 days without physician evaluation of the resident, could be detrimental to the resident. We are aware that the current Medicare Hospice requirement under 42 CFR 418.54 requires the comprehensive assessment be updated every 15 days or more frequently, as needed.

Q: **Is melatonin considered a hypnotic to be reduced every 90 days?**

A (By CMS): Melatonin does not fall under the requirement for psychotropic medications. Melatonin is a natural hormone that is classified as a dietary supplement by the Food and Drug Administration and, therefore, is not subject to the requirements of hypnotics under the new psychotropic medication category at 483.45(c)(3). However, residents taking melatonin should still be monitored with regard to benefits, risks, and potential adverse consequences.

**Hospice, Nursing Home, PRN Psychotropics, and PRN Antipsychotics**

As noted in the FAQ’s above, there are no exceptions for residents receiving hospice services in nursing home settings as it relates to PRN antipsychotics or PRN psychotropics. Hospice providers and nursing home providers will need to specifically address the use of PRN antipsychotics and PRN psychotropics.

A common issue upon admission of a resident on hospice services is that the resident may be prescribed a comfort pack that contains PRN lorazepam, which is a psychotropic medication. When this is done within the first 14 days of admission, a practitioner must provide rationale as to why the psychotropic is needed beyond 14 days and document duration of use of the PRN lorazepam. For example, if the lorazepam is for terminal restlessness, expected to occur throughout the balance of the resident’s hospice care, that can be the rationale and the duration can be until the resident passes away.

For antipsychotic medications, such as haloperidol, the PRN orders can only be 14 days in length. Each time a PRN antipsychotic is reordered there must be a practitioner evaluation. The rule does not require the hospice practitioner to always conduct the evaluation; they can be coordinated between hospice prescribing practitioners and nursing home facility practitioners.