CMS released an updated LTC facility regulation on October 4, 2016. Some sections (Phase I) of the rule took effect on November 28, 2016. Since the release of this rule, one pharmacy-related question that has been received from providers and surveyors pertains to whether or not the medical director must act upon each report by the pharmacist.

The pharmacy services section in the updated rule was changed to require that the pharmacist report be provided to the medical director. Regulations specific to drug regimen review were updated in the new rule and are listed below:

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
(2) This review must include a review of the resident’s medical chart.
   Wis. Stat. § 483.45(c)(2) will be implemented beginning November 28, 2017 (Phase II).
(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. (continued)
(4) The pharmacist must report any irregularities to the attending physician and the facility’s medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility’s medical director and director of nursing and lists, at a minimum, the resident’s name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident’s medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident’s medical record.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

For Phase I, effective November 28, 2016, the changes include:

- Pharmacist report is to be documented as a separate, written report with resident’s name, relevant drug(s) and irregularity.
- The pharmacist’s report must be provided to the medical director.
- The attending physician must document in the medical record that the report was reviewed and what action was taken.
- If attending physician refuses recommendation, they should document rationale in medical record.
- Facility needs to develop and implement policies and procedures for drug regimen review.

CMS has not provided updated guidance for these rules; however, there is guidance that still exists, which may pertain.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report without providing some basis for disagreeing.

If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility’s medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those
recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

Until different guidance is provided by CMS, the bolded sections above support the following position: If the medical director is also the attending physician for a particular resident, the medical director is expected to document that the report was reviewed and what action was taken.

If the medical director is not the attending physician, facility policies should address when the pharmacist and facility will contact the medical director for guidance and possible intervention.

BEYOND USE DATES

Most pharmacy items come from the manufacturer with a lot number and an expiration date. However, after pharmacy items are opened, prepared, repackaged, or compounded, some of these items have shorter expiration dates or what is referred to as the “beyond use date.”

Many of you are familiar with multi-dose vials; insulin being the most common. Sterile products in multi-dose vials once opened have a default beyond use date of 28 days. Some insulin products have longer beyond use dates. A chart for insulin can be found at: https://www.dhs.wisconsin.gov/publications/p01904.pdf

Recently a question has come up about pharmacy/lab items and what the beyond use or expiration date may be. Once opened, blood glucose meter test strips may have a shorter beyond use date. Typically, beyond use dates for test strips are 90 days or longer, extending all the way to the stamp expiration date on the test strip. Most test strips come in quantities of 50 so someone testing only once a day will always use the current supply in less than 50 days. In some settings, there may also be testing solutions available with point of care testing devices or other testing equipment; once these testing solutions are opened, they may have shorter beyond use dates than the test strips.

Facilities need to have policies in place to ensure that items like test strips and testing solutions are not expired. Procedures may include writing a “date opened” on the container, assigning a new beyond use date, or even replacement of all strips or solutions on a given date. Surveyors can review these procedures and observe whether or not the facility procedures are being implemented appropriately.

CONSULTANT CORNER by Doug Englebert, R.Ph.

During a survey at a CBRF where there is no nurse, we observed the drug Letairis, not in unit dose packaging. The facility told us that the pill cannot be bubble packed. They were unable or unwilling to explain why, but insisted that it is a medication that cannot be bubble packed. Can you shed some light as to why this medication cannot be bubble packed?

There are a handful of drugs that cannot be packaged in unit of use. For example, nitroglycerin sublingual tablets are not stable and must remain in the manufacturer’s container. When there are stability concerns about medications or delivery limitations (all inhalers, nitroglycerin tablets) pharmacies may not be able to package in unit of use. When medications cannot be packaged in unit of use, the requirements for unit dose packaging for those CBRFs without a nurse cannot be met. When this occurs, staff need to be trained how to give this medication with the packaging provided. In addition, the facility should have documentation from the pharmacy as to why the medication cannot
be packaged in unit of use. Please note that, in some cases, pharmacies can contact the manufacturer to obtain other packaging information or, like Laitaris, bubble-type packaging may be available from the manufacturer.

In most cases, package restrictions are due to product stability or how the drug is delivered/administered. However, Laitaris has major birth defects associated with it so it is possible that repackaging puts pharmacy staff and/or pharmacy equipment at risk and the manufacturer relays that information in their labeling. In addition, the Laitaris manufacturer already provides this drug in bubble packs. Due to the birth defect risk, staff should be aware of this risk and administer the medication with precaution.

In a CBRF, is Nudexta a psychotropic medication? We need to know if it should be included in a facility's psychotropic review.

Wisconsin Admin. Code § DHS 83.02 Definitions states:

(41) “Psychotropic medication” means a prescription drug, as given in s. 450.01(20), Stats., that is used to treat or manage a psychiatric symptom or challenging behavior.

If a drug is used for a challenging behavior, it meets the definition above. Nudexta may be administered for a challenging behavior of Pseudobulbar Affect (PBA). If so, it would be considered a psychotropic medication per the DHS 83 definition and would need to be included in the quarterly review.