

PHARMACY NEWS CAPSULE

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Medication Shortages By Doug Englebort, R.Ph.

Medication shortages are occurring more frequently than they have in the past. This is happening for various reasons. For example, medication shortages may occur because the Food and Drug Administration requires a manufacturer to stop production following violations at their production plant. Or, manufacturers --- lacking a market --- may stop medication production on their own. Additional medication shortages may occur when there is an insufficient supply of ingredients, a medication recall, or a spike in demand.

What is the impact of medication shortages? Shortages of medication mean that providers need to plan for alternatives when such shortages occur. Some patients or residents may be switched to other equivalent medications. In other instances, treatment alternatives can be attempted or a medication shortage may be used as an opportunity to taper a medication and to determine if it is still needed.

The possibility of such shortages should be addressed and a plan of action should be developed. Allowing a resident or patient to run out of medication without having a plan does not meet a resident's or patient's needs.

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New Medications

Brand Name	Generic Name	Use
Uloric	febuxostat	A medication for the treatment of chronic gout.
Edlua	zolpidem	Sublingual formulation of sleep medication.
Gelnique	Oxybutynin	Topical gel for overactive bladder.
Kapidex	Dexlansoprazole	A proton pump inhibitor for treating esophagitis and gastrointestinal reflux disease.

Nursing Home F Tag Review By Doug Englebert, R.Ph.

Investigation of Self-Administration --- F176

A resident of a nursing home has the right to self-administer medications if the interdisciplinary team has determined that this practice is safe. Surveyors who observe medication errors occurring with residents who self-administer should not count those errors as part of the facility medication error rate. However, if medication errors occur with residents who self-administer medications, surveyors should investigate the interdisciplinary team evaluation of self-administration and, if appropriate, cite F176.

The following factors should be considered when investigating F176:

- **Does the care plan reflect self-administration of medications?**
- **Does the interdisciplinary team assessment address medication administration components?**

Specifically, does the assessment address medication storage, responsibility for documentation of the medication administration record, requirements for staff observation, dosage selection by the resident, resident ability to manipulate devices, etc.?

- **Does the interdisciplinary team assessment consider resident outcomes?**

Residents who request self-administration of medications are often attempting to maintain at least a little control of their medications. And, as is often the case, they may want to administer only one or two medications, such as an inhaler, eye drops, or oral medications. In many instances, these residents refuse to take their medications at all if they are not allowed to self-administer.

The interdisciplinary assessment of these cases may determine, for example, that the resident does not use appropriate technique in administering an inhaler. However, if the resident's condition is being controlled and the resident is not suffering side effects, the interdisciplinary team may appropriately decide to allow the resident to self-administer the medication and may continue to work with training and guidance. The interdisciplinary team may determine that this is a better option than having the resident refuse the medication. The interdisciplinary team must also determine the safest process for the resident. In some situations, the resident's imperfect self-administration technique may be preferable to the resident's complete refusal of the medication.

Surveyors who observe or have concerns regarding the occurrence of medication errors during self-administration should investigate the interdisciplinary team assessment under F176. When investigating, it is important to consider the big picture and to look at the resident's outcome, on-going training, the implementation of facility interventions, and alternatives that the interdisciplinary team has considered.

If a facility fails to consider a resident's request to self-administer medications or fails to assess the resident and provide the safest environment for self-administration, the survey team may decide to cite F176.

Medication Labeling Q&A By Doug Englebert, R.Ph.

One area of medication labeling that tends to be a problem is the labeling of items such as inhalers, eye drops, and tubes of ointments. In some cases, a pharmacy will only label the outer box or other outer container of a medication. This is often done because the eye medication

bottle, inhaler, or tube is too small for a label. In other cases, the outside container is labeled to protect the integrity of the medication. A problem arises when, at the facility, the box or outside container with the pharmacy label is opened, put aside, and separated from the medication.

Ideally, the label needs to stay with the medication to assure that the medication is used for the appropriate patient or resident. Proper medication labeling helps avoid medication errors, concerns with infection control, and medication waste.

There are ways to ensure that a label stays with its medication. For instance, the outer box/container with the label can be retained and the medication can be replaced in the box/container after use. Another method is to place the label and all related items in another common package, such as a plastic bag. Facilities should work with their pharmacist to develop a method to maintain medication labeling that works for the facility.

Consultant Corner By Doug Englebert, R.Ph.

1. What are the requirements for dose reductions in an ICF/MR?

In an intermediate care facility for the mentally retarded (ICF/MR), the facility must work with the physician to gradually reduce medications used for behaviors. There is no requirement to withdraw other medications. There is, however, a requirement for the pharmacist to review all medications quarterly and to report irregularities. The ICF/MR guidance directs surveyors to follow Appendix N, which provides pharmacy guidance that identifies some general medication monitoring parameters.

However, the Centers for Medicare and Medicaid Services withdrew Appendix N shortly before the new pharmacy guidance was issued in Appendix PP for nursing homes. Since Appendix PP identifies potential medication related problems that are based on standards of practice, it would make sense for a consultant pharmacist to use the Appendix PP pharmacy section to address irregularities or medication related problems. Some irregularities or medication related problems may suggest dose reductions of medications that are used for issues other than behaviors. Although regulations do not require dose reductions, they may make clinical sense and it would be appropriate for a consultant pharmacist to recommend medication changes to optimize medication therapy.

2. How do we evaluate situations where a patient/resident does not rinse their mouth after using an inhaler?

This question is raised when observing medication administration and when determining if a medication error has occurred. Rinsing the mouth of medications after using some inhalers is done to avoid adverse effects such as local mouth infections. Since the purpose of rinsing the mouth does not affect the dose of the medication, not rinsing is not considered a medication error. However, instances of not rinsing may be investigated for standards of practice or pharmacy practice, especially if adverse mouth infections are occurring.

3. How should rural health clinics address sample medications?

When a rural health clinic gives drug samples and other medications to patients to administer at home, it is considered physician dispensing. Physician dispensing is regulated by Med 17. Sample medications are prescription drugs and, although they may be exempt from packaging requirements, record keeping of samples must still occur.

Excerpts of Med 17 include:

Med 17.04 Labeling. (1) A prescription drug dispensed by a practitioner shall contain a legible label affixed to the immediate container disclosing:

(a) The name and address of the facility from which the prescribed drug is dispensed; (b) The date on which the prescription is dispensed; (c) The name of the practitioner who prescribed the drug or device; (d) The full name of the patient; (e) The generic name and strength of the prescription drug dispensed unless the prescribing practitioner requests omission of the name and strength of the drug dispensed; and, (f) Directions for use of the prescribed drug and cautionary statements, if any, contained in the prescription or required by law.

(2) **NONAPPLICATION OF LABELING REQUIREMENTS.** The labeling requirement specified in sub. (1) does not apply to complimentary samples dispensed by a practitioner in original containers or packaging supplied to the practitioner by a pharmaceutical manufacturer or distributor.

Med 17.05 Recordkeeping. (1) **PRESCRIPTION DRUGS.** (a) A practitioner shall maintain complete and accurate records of each prescription drug received, dispensed or disposed of in any other manner. (b) All prescription drugs dispensed by a practitioner shall be recorded in the patient record.

Typically, issues with sample medications involve recordkeeping. An effective method to meet Med 17.05 would be to keep a log of samples brought to the facility, samples used, and samples destroyed. The record keeping should create a system that can, at anytime, determine what has happened to specific prescription medication samples.