IF3: FDA RISK EVALUATION AND MEDICATION SAFETY (REMS) MEDICATION GUIDES

Policy

The FDA requires the pharmacy to provide patient package inserts (PPIs) to patients for some classes of medications, such as estrogens, with each new prescription and with each prescription refill order. When a resident self-medicates, the FDA requires the pharmacy to provide medication guides to patients for some medications. FDA-required Medication Guides explain the benefits and risks associated with use of a medication or medication class.

Procedures

A. At least one copy of each PPI or Medication Guide is kept at each nursing station for applicable medications used in the facility.

B. When a medication provided by the pharmacy requires a Patient Package Insert, the facility staff should assure the resident and/or responsible party is offered a copy or offered an explanation of the information contained in the PPI.

C. When a medication provided by the pharmacy requires a FDA-approved Medication Guide, the facility staff should assure the self-medicating resident and/or responsible party is offered a copy or offered an explanation of the information provided in the medication guide.

D. The provision of the PPI or Medication Guide for each applicable medication or estrogen or the offer to provide, if declined, is documented in the resident's medical record.

E. Facility staff should retain readily retrievable copies of applicable PPIs and Medication guides for each resident's current medications at the nursing station.

NOTE:

- Regarding the applicability of Medication Guides in the nursing facility setting, TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, SUBCHAPTER C--DRUGS: GENERAL, PART 208: MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS, Subpart A--General Provisions, Section 208.1 states: "It (*the Medication Guide requirement)* applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional."
- Regarding the applicability of Patient Package Inserts in the nursing facility setting, 21CFR 310.515 states: "Patient package inserts for estrogens dispensed in acute-care hospitals or long-term care facilities will be considered to have been provided in accordance with this section if provided to the patient before administration of the first estrogen and every 30 days thereafter, as long as the therapy continues."