National Coordinating Council for Medication Error Reporting and Prevention

Council Recommendations

Print

Recommendations for Avoiding Medication Errors With Drug Samples

---

Drug samples of medications are available to patients through healthcare sites such as practitioners' offices, clinics, hospital emergency departments, and pharmacies. Drug samples provide a vital service to patients whose pharmacotherapeutic regimen is not well established, are poor, uninsured, underinsured, or in need of medications when pharmacies are closed. However, systems for distributing samples are often inadequate or unsafe for patients due to insufficient control, poor documentation, improper storage, inadequate instruction for use, lack of written instruction, poor labeling or packaging, and the dispensing of expired medications.

The Council is issuing the following recommendations to highlight the risk of medication errors with the use of drug samples and to provide guidance for a standardized approach to distribution of drug samples in all practice settings.

Recommendations:

General Use

1. Drug samples should be provided only by licensed practitioners in accordance with state laws and regulations.
2. In practice settings where drug samples are routinely distributed professional staff should develop policies and procedures that address their procurement, storage, access, and distribution/dispensing, and proper disposal of drug samples. All providers and appropriate employees should be trained on and have access to the policies and procedures.
3. Drug samples usually should not be given for long-term use or maintenance therapy, unless they are part of a program that includes pharmacy dispensing and traditional safety checks that are provided by a pharmacist.
4. In institutions with on-site pharmacies, the pharmacy should be responsible for the procurement, distribution, and control of all drugs, including drug samples used in the institution.

Manufacturer Packaging and Labeling

5. Manufacturers are urged to provide drug samples in patient-friendly, child-

resistant packaging that includes the following:

- only one dosage unit per blister, when blister packaging is used;
- lot number and expiration date;
- manufacturer-provided information as required by the FDA (e.g., medication guide); and
- an open space where the provider of the drug sample can either affix a label with the patient name and specific instructions for use, or be able to write this information for the patient.

6. Multiple doses should be packaged in a manner that preserves labeling for each dose (e.g., the label or backing of each dose should contain the drug's name, strength of medication, lot number, and expiration date).
7. Unique National Drug Code (NDC) numbers should be assigned to each drug sample to facilitate electronic documentation and tracing of products.

Storage and Handling

8. Drug sample should be safely stored and in accordance with the manufacturers' labeling. The following should never be placed in drug storage areas;
   - drug delivery devices used for patient education and/or demonstration;
   - placebo drugs;
   - food;
   - hazardous chemicals; and/or
   - potential adulterants.
9. All expired, damaged, or deteriorated drug samples should be immediately removed and disposed of properly.
10. All drug sample storage areas should comply with safe storage practices, and be evaluated and inspected by appropriately trained staff for the potential for medication errors due to similar drug names, packaging or labeling.

Instructions for Use

11. Patient–specific information (e.g., medical record) should be readily available to the practitioner at the time that sample medications are provided to patients for the purpose of checking for interactions/contraindications.
12. For each drug sample, the patient instructions should be written in language appropriate for the patient. At a minimum, a drug sample should be labeled to include:
    - the name of the patient;
    - the brand and/or generic name of the drug;
    - the strength of the drug per dosage unit;
    - clear directions for use by the patient; and
    - any necessary cautionary statements or use instructions such as, 'May cause drowsiness' or 'Take with food'.

This information should be affixed so as not to cover the drug name, drug strength, lot number, expiration date, or other critical information, such as storage instructions. Each drug sample should have a separate set of directions. Multiple units of the same drug can be placed in a single bag or box with an appropriate label affixed.

13. Education of the patient and/or caregiver as to the safe and proper use of drug samples should be provided and should include any manufacturer-produced ancillary material intended for the patient.
14. Patients should include any drug samples they are taking on medication lists or in interviews with their healthcare providers.

Monitoring and Record Keeping

15. Whoever provides the drug sample should check the expiration date and visually examine the product's integrity before giving it to the patient.
16. Patients taking drug samples should be monitored for therapeutic effect and adverse events. As with any medication, adverse events with drug samples should be collected, recorded in the medical record and, when appropriate, reported to FDA's MedWatch program.
17. Prescribers should document in the patient's medical record drug samples given to patients as they would any other medication.
18. Drug samples should be included in any list of medications that is communicated to another provider or care setting.

These Recommendations apply to healthcare providers in the following settings: adult day care, ambulatory care, assisted living facilities, home health care, behavioral health facilities, hospitals, physicians' offices, and long-term care facilities.

Definitions:

Drug Samples are prescription medications packaged as one or more dosage units by a manufacturer or distributor in accordance with Federal and State statutes. Drug samples are provided by a pharmaceutical company to a licensed practitioner free of charge. A drug sample is not intended to be sold and is intended to promote the eventual sale of the drug. A drug sample may be a packet, card, blister pack, bottle, container, or other single package that is provided to a patient in an unbroken or unopened condition. Drug samples include dose titration packages and starter kits.

Related Recommendations: Recommendations to Reduce Medication Errors in Non–Health Care Settings

Adopted: February 5, 2008
