MEDICATION SAMPLES IN THE OFFICE: UNDERSTAND THE RISKS TO THE PATIENT AND TO THE PSYCHIATRIST

Medication samples can be beneficial for many purposes such as starting new prescriptions and assisting patients with financial problems. There are, however, important safety concerns associated with the use of samples. Risks to patient safety include poor instructions, inadequate labeling, and expired samples. Medication samples should not be treated casually – they must be treated with the same formality as any other prescription (e.g., not to be dispensed outside of a treatment relationship). In fact, there are additional requirements put on physicians who choose to add the role of dispenser on top of the role of prescriber.

"Distribution of free samples to patients bypasses the pharmacist and thus skips a crucial safety checkpoint."

Cutrona SL, Woolhandler S, Lasser KE, Bor DH, Himmelstein DU, Shrank WH, LeLeiko NS. Free drug samples in the United States: characteristics of pediatric recipients and safety concerns. *Pediatrics* 2008;122(4):736-742.

UNDERSTAND THE LEGAL REQUIREMENTS FOR DISPENSING SAMPLES

The legal rules governing dispensing of medication samples vary depending on the medication and on the physician's practice setting. In addition to federal law, many states have enacted their own laws regarding physicians and samples.

Federal law: The distribution of medication samples is governed by FDA regulations (21 CFR 203) promulgated under the Prescription Drug Marketing Act of 1987. These regulations cover the physician's written request, receipt, and other record-keeping requirements for the physician to receive samples from the manufacturer. For those physicians utilizing samples of controlled substances, there are additional regulations from the Drug Enforcement Agency. These regulations include requirements for secure storage, qualification of employees having access to the samples, theft reporting, record keeping, inventory, and disposal. More information can be found in the DEA's *Practitioner's Manual*, available online at www.deadiversion.usdoj.gov/pubs/manuals/index.html.

State law: State boards of medicine and/or boards of pharmacy may have regulations, rules, and policies governing dispensing of medication samples. Boards may also have additional requirements for samples of controlled substances. Physicians should contact the medical board and pharmacy board in the state(s) where the physician practices to determine state-specific requirements for dispensing medication samples.

RISK MANAGEMENT RECOMMENDATIONS

In addition to complying with all applicable state and federal laws, the risk management advice related to medication samples is to develop and follow policies and procedures for storing, dispensing, and disposing of medication samples. These policies and procedures should address at least the following:

Securely storing medication samples

- Maintain a log to track incoming samples. Consider including the following information:
  - Date samples received
  - Drug name and strength
  - Lot numbers
  - Quantity
  - Expiration date
  - Monthly inventory review – date and initials
- Store samples in a secured location – in a *locked* medication cabinet or storage room
- Access to samples should be limited to authorized staff only. Employees should not have access to samples for personal use
- Medications with similar names or similar packages should be separated in storage
- Store the samples in accordance with the manufacturers' recommendations, such as those related to light and temperature
- Follow any specific legal requirements, such as those related to samples of controlled substances
- Perform a monthly inventory of samples
  - Expired samples should be removed from inventory and disposed of properly (see section below on sample disposal)
  - Recalled medications should be removed from inventory and disposed of properly. To track drug recalls, visit www.fda.gov/Safety/Recalls/EnforcementReports/default.htm
  - Document when samples have been inventoried

Safely dispensing medication samples

- As with any other prescription:
  - Only dispense medication samples within a bona fide treatment relationship
  - Obtain the patient's informed consent to use of the medication
  - Review the patient's drug allergies
  - Review patient's other medications, supplements, and complementary and alternative substances for potential interactions and contraindications
- Only physicians and others with prescribing authority should dispense the samples
- Check the sample's expiration date

- Document the samples dispensed in a dispensing log. Consider including the following information:
    - Date dispensed
    - Patient name (and possibly another identifier, such as date of birth)
    - Drug name and strength
    - Lot number
    - Quantity dispensed
    - Expiration date
    - Prescriber
    - Dispenser (if different)
- Ensure the patient understands exactly how to take the medication, including dosage and any special instructions
- Ensure samples are adequately labeled, including at least the following:
    - Patient name
    - Medication name, strength, and quantity
    - Lot number
    - Expiration date
    - Date dispensed
    - How often to take
    - Directions, such as take with food
    - Precautions
- Provide written instructions to the patient. Patients are typically given verbal instructions on the use of samples, but often the medication is not properly labeled and written patient instructions are not provided, thus creating a patient safety issue. Patient-specific written instructions should include the following:
    - Physician's name and contact information
    - Patient's name
    - Date medication dispensed
    - Name and strength of medication
    - Quantity given
    - Lot number(s)
    - Patient instructions
    - Possible side effects
    - Other patient information provided, such as medication information sheets
    - Other relevant information
- The instruction sheet should be signed by the patient and a copy of the sheet should be retained in the patient record
- Extra caution should be exercised when providing medication samples for use by children
    - Sample packages may not be child-proof
    - Preprinted dosing instructions may not be appropriate for children

Documenting dispensed samples

- Record-keeping is an important key in managing the risk associated with providing medication samples
- The following logs related to samples should be maintained (see Appendix for specific information to consider including on these logs):
    - Log of inventory
    - Log of dispensed samples
    - Log of destroyed samples
- Documentation for the sample label is discussed in the dispensing section above
- In terms of documentation in the patient record that samples were dispensed:
    - A copy of the written instructions provided to the patient with the samples (see dispensing section above) should be retained in the patient's chart
    - Sample medications should be included on the patient's medication list

Monitoring

- As with any medication prescribed, physicians must:
    - Monitor the patient for medication effectiveness and safety
    - Stay current with safety information related to the particular medication prescribed. Sources for medication safety information include:
        - FDA's MedWatch – www.fda.gov/safety/MedWatch/
- Additionally, any medication dispensed which is subsequently recalled must be appropriately disposed of and the patient must be notified.
    - See storage section above for recall resources
    - Patients with recalled medications samples should be advised regarding stopping the medication and asked to return unused samples to the physician
    - The patient's chart should reflect this communication with the patient

Disposing of medication samples

- Expired and recalled samples must be disposed of in accordance with applicable federal, state, and local laws. Resources for determining these laws include:
    - Federal Environmental Protection Agency –
        - http://www.epa.gov/ppcp/basic2.html
        - http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm
    - State environmental protection agency – www.epa.gov/epawaste/wyl/stateprograms.htm
    - State pharmacy board

- Document the disposal of samples in the log of destroyed samples. Consider including the following information:
    - Date
    - Name and strength of medication
    - Quantity
    - Signature
    - Additional information that may be required for controlled substances, such as a second signature

DISPENSING SAMPLES: IT IS A TWO-STEP PROCESS

Step 1: The first step in dispensing samples is doing what would be done when writing a prescription for any medication, including:

- Only prescribing in the context of a physician-patient treatment relationship, and not dispensing samples casually to family, friends, and employees
- Checking for drug allergies and drug interactions
- Obtaining and documenting informed consent
- Providing patient education
- Monitoring the effectiveness of the medication

Step 2: The second step in dispensing samples is doing what would normally be done by a pharmacist, as a safety check, including:

- Checking (again) for drug interactions
- Providing written instructions on how to take the medication, safety warnings, etc.; also keep in mind that many medications have patient medication guides that are to be provided to patients when the medication is dispensed
- Monitoring for recalled medications that have been dispensed

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