

Medication: Dispensing

What's the Risk?

Medications dispensed in an ambulatory care setting are particularly susceptible to error because a crucial safety net – pharmacist review and check of medications – is eliminated.¹ Eliminating pharmacists from the dispensing process increases the chance of error, especially when unlicensed healthcare personnel are utilized to dispense medication, including samples, to patients.

One of the most common types of medication error-related claims reflected in Coverys data pertains to patients with a known drug allergy being prescribed a derivative or otherwise related medication. This error may be caught by a pharmacist prior to dispensing; however, it may be less likely to be caught prior to dispensing a medication in the office.

Other risks associated with dispensing medications include:

- Improper labeling.
- Inadequate patient counseling, especially when patient education is delegated to unlicensed healthcare personnel with insufficient knowledge of the medication.
- Improper medication storage, resulting in unlocked medications being stolen by employees and/or members of a contracted service with after-hours access; for example, cleaning staff.
- Inadequate checks for expired medications, resulting in a patient taking an expired medication.
- Inadequate documentation of the medication dispensed.
- Inadequate policies and procedures for dispensing medications or removing recalled medication from stock.

When Is This Risk an Issue?

Physician offices may dispense medications to increase patient convenience and improve patient compliance with the medication regimen. While the FDA has approved the practice of dispensing medications out of a physician's office, it is typically regulated by the state and is often restricted to dispensing sample medications.¹ State regulations may address exactly when a medication may be dispensed, by whom, and how. For example, a state's regulations may require sample medications to be labeled in a particular manner. In some states, a licensed person may delegate their dispensing privileges to an unlicensed staff member. In general, however, unlicensed personnel may not dispense medications, including over-the-counter drugs.

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Automated Dispensing Cabinets (ADCs)

ADCs or similar devices are increasingly being used in outpatient settings as a primary method of drug delivery. When such devices and the systems that support them are used inappropriately, patient safety is compromised. The complexity of the devices, design and function variations, a lack of proper maintenance and/or education/training, and other factors can result in medication errors.

For-Profit Dispensing

A potential conflict of interest may exist when the prescriber is the same person who is dispensing and potentially receiving a profit. In Opinion 9.6.6: [Prescribing and Dispensing Drugs and Devices](#), the American Medical Association (AMA) advises prescribers to “avoid direct or indirect influence of financial interests.”

Drug Recalls

The Food and Drug Administration (FDA) produces a weekly [Enforcement Report](#) that identifies product recalls and classifies each recall as a Class I, II, or III action. Each recall class is defined in [FDA Recalls, Corrections and Removals \(Devices\)](#).

It is important to have a process in place to review the FDA’s weekly Enforcement Report; determine whether the practice maintains any of the drugs on the recall list; check the existing stock of medications, including samples, and remove those that have been recalled; determine whether replacement medicines need to be obtained; and take appropriate action to notify patients who received a recalled medication. For this process to occur, the practice needs to have a tracking mechanism in place to identify which sample medications have been dispensed in the office and to whom. See the [Sample Medication Log](#).

Patient Education

Educating patients on the correct use of medications is crucial to avoiding adverse drug events. An accurate, plain language medication information sheet is a useful way to educate the patient and family members. For an example, view ConsumerMedSafety.org’s [High-Alert Medication Learning Guides](#).

Labeling Medication

Medications, including samples, must be labeled prior to dispensing. A well-designed medication label ideally helps the patient take medication appropriately, thereby reducing the risk of a medication error. Many states regulate the information that must appear on the label.

While state regulations must be followed, the Institute for Safe Medication Practices (ISMP) recommends that the following information should be on the label when a physician office dispenses a medication:

- Prescribing practitioner’s name and telephone number.

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- Patient's name.
- Medication name.
- Strength.
- Dose that should be taken.
- Route of administration.
- Frequency of taking the medication.
- Reason for taking the medication.
- Special precautions; for example, may cause drowsiness, take with food, fast for a specified period of time.
- Expiration date.¹

See sample [Medication Label](#).

Expired Medication

Medications are considered “expired” on the first day of the month/year following the month/year indicated on the package. Expired medications and supplies are not suitable for patients or charitable donation and **should be discarded** according to local, state, and federal environmental regulations. In states that require samples to be returned to the manufacturer or distributor, practices should have a system in place for drug representatives to sign in and list which sample medications are given to the office, so that expired sample medications can later be returned to the proper entity.

Donation of Sample Medications

Practices sometimes donate or send sample medications for medical missions. The World Health Organization (WHO) issued [Guidelines for Medicine Donations](#), in part, to protect recipient countries from inappropriate donations.² According to WHO:

Donating returned medicines (unused medicines returned to a pharmacy for safe disposal, or free samples given to health professionals) is an example of a double standard because in most countries their use would not be permitted owing to regulations on quality control. Such donations also frustrate management efforts to administer medicine stocks in a rational way. Prescribers are confronted with many different medicines and brands in ever-changing dosages, while patients on long-term treatment suffer because the same medicine may not be available in the future. For these reasons, this type of donation is forbidden in an increasing number of countries and is discouraged elsewhere.²

Disposal of Expired or Unwanted Medications

Some healthcare facilities use toilets or sinks to dispose of unwanted medication. However, some pharmaceuticals are regulated as hazardous waste, and strict rules are in place for

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disposal. The United States Environmental Protection Agency provides [resources for managing hazardous waste pharmaceuticals](#).

How Can I Reduce Risk?

Use the following strategies to reduce risks when dispensing medications, including samples.

Develop a Sample Medication Policy and Procedures

Develop sample medication policy and procedures

- Develop a policy and procedures for sample medications that addresses procuring, storing, dispensing, maintaining, discarding sample medications, and managing related recalls. See the [Sample Medications Policy and Procedures](#).

Educate staff

- Ensure that staff members are familiar with and have ready access to the policy and procedures. Educate staff members about changes as they occur.

Develop ADC Policies and Procedures

Develop ADC policies

- Develop policies that address the use of ADCs, including placement, security, medication withdrawal, system overrides, restocking, and employee competency.

Place ADCs in secure location

- Ensure that ADCs are placed in locations that are secure when cabinets are not being used.

Develop downtime procedures

- Ensure that well-designed downtime procedures are in place for software or hardware malfunctions, drawer failures, or unexpected loss of power to ADCs.

Prevent diversion

- Establish security processes to provide adequate control over medications outside of the pharmacy and to reduce the potential for medication diversion. For more information on diversion, see [Medication: Diversion](#).

Restock safely

- Establish safe ADC restocking processes, including with regard to placing medications in the correct location within the device.

Ensure accurate medication withdrawal

- Develop procedures to ensure the accurate withdrawal of medications from the ADC. Recognize that the types of medications, volumes, concentrations, and configurations play an important

Develop ADC Policies and Procedures

- role in the safe selection and removal of the medications.
- Establish override criteria**
 - Establish criteria for ADC system overrides.
- Provide education**
 - Provide staff members with education and validate their competency.
- Seek additional information**
 - For more information on ADCs, see the Institute for Safe Medication Practices' (ISMP's) [Guidelines for the Safe Use of Automated Dispensing Cabinets](#).

Develop For-Profit Dispensing Policies and Procedures

- Develop for-profit dispensing policies**
 - Develop a written policy and procedures that address dispensing repackaged and prelabeled full prescription size containers directly to patients at the point-of-care. Be sure to comply with federal and state-specific regulations. Adhere to recordkeeping requirements that licensed pharmacists must follow.
 - Address the following in the policy:
 - Specifying those persons in the office who may access and dispense the medications, in accordance with state-specific dispensing requirements.
 - Procedures for appropriately identifying both the medication and the patient.
 - Properly safeguarding medications by placing them in the proper location, such as locked cart, locked room, medication refrigerator, and/or controlled drug inventory area. For more information on controlled drug storage, see [Medication: Diversion](#).
 - Using a storage system that separates drugs with names that look alike or sound alike, as well as the same drug in different dosages. For more information on medication storage, see [Medication: Safety](#).
 - Ensuring that a written, legible, and complete physician order is in place prior to dispensing.
 - Including all practice-approved, medication-specific protocols for laboratory reports and other

Develop For-Profit Dispensing Policies and Procedures

- clinical measurements when generating physician order sheets.
- Implementing a system for review for possible drug interactions and allergies.
- Using a double-check system for drug, dosage, route of administration, and concentration, including comparing the manufacturer's label with the physician's order.
- Providing an individual medication information sheet that includes therapeutic use, side effects, and adverse consequences.
- Providing precautionary instructions and parameters for use on the medical label.
- Labeling the drug container or packaging so it is legible and identifies the following:
 - Name, address, and telephone of the clinic from which the drug was dispensed.
 - Name of the patient.
 - Name of the prescriber.
 - Name(s) of the active ingredient(s), strength, and manufacturer.
 - Instructions for use.
 - Date the drug was dispensed.
 - Quantity dispensed.
 - Expiration date, when appropriate.
- Complying with established practice protocols for timely, safe delivery and receipt of medication.
- Requiring the patient's signature upon receipt of medication and handouts.
- Complying with documentation requirements.

Store and Log Sample Medications Appropriately

Establish and implement a system for sample medications

- Establish a system for storing, securing, and dispensing sample medications, as well as for monitoring expiration dates and drug recalls.

Store and Log Sample Medications Appropriately

Log all sample medications received by the practice

- Log all medication samples received in the practice and keep the medication log in a locked drawer. Ensure that the log includes the name, strength, lot number, quantity, source (company and representative), date received, and, as applicable, date returned. Include the name or initials of the person(s) receiving and returning the samples.
- Log out all expired medications when they are discarded.

Log all sample medications dispensed to patients

- Maintain a sample medications log to record all sample medications that are dispensed. Include the patient's name, medication dispensed, strength, quantity, lot number, expiration date, and date dispensed.
- Maintain a separate medication log for each type of medication dispensed so that in the event of a recall or problem with a particular medication, it is easy to identify the patients who received the medication. See the sample [Medication Log](#).

Secure sample medications

- Store and secure sample medications in a locked room or closet at all times.

Store medications appropriately

- For more information on proper medication storage, see [Medication: Safety](#).

Dispense Medications Safely

Check regulations

- Check federal and state laws and regulations for any requirements pertaining to dispensing medications, including samples. Comply with all applicable federal and state laws and regulations.

Identify who may dispense medications

- If your state permits dispensing medications, make sure that your medication policy and procedures identify those persons within the practice who are authorized to access and dispense medications, in accordance with state-specific dispensing requirements.

Dispense safely

- Ensure that medications, including samples, are safely dispensed to patients by following consistent processes and practices, such as:

Dispense Medications Safely

- Ensuring that only authorized personnel dispense medications.
- Identifying the patient.
- Requiring a legible prescribing practitioner order.
- Verifying medication allergies.
- Verifying drug-drug interactions.
- Verifying pregnancy status, as applicable.
- Dispensing the right medication at the right dose with the right quantity and right label to the right patient.

Label sample medications

- Review state regulations to determine if any labeling requirements exist.
- Recognize that poorly designed labels may lead to medication errors.
- Label all sample medications dispensed to a patient with information similar to that which would be on the label if the patient was to obtain the medication from a retail pharmacy. In general, include the following information on all sample medication labels:
 - Prescriber's name and telephone.
 - Patient's name.
 - Patient's date of birth.
 - Medication name, strength, and dosage form.
 - Date medication is dispensed.
 - Quantity dispensed.
 - Administration route in plain language (for example, by mouth rather than oral).
 - Administration frequency.
 - Reason for taking the medication.
 - Special precautions (for example, may cause drowsiness, take with food or after fasting for a specified period of time).
 - Expiration date.

Dispense Medications Safely

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| Document the patient's medical record | <ul style="list-style-type: none">• Document the patient's medical record to reflect the medications dispensed to the patient. Include the following:<ul style="list-style-type: none">○ Prescribing practitioner's order.○ Medication name.○ Lot number.○ Expiration date.○ Strength.○ Dosage.○ Quantity.○ Instructions given to the patient.• Enter all medications, including samples and over-the-counter medications, dispensed to a patient into the medication list maintained in the patient's medical record. |
| Monitor and document the patient's response | <ul style="list-style-type: none">• Monitor and document the patient's response, both positive and negative, to all dispensed medications. |

Educate Patients

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| Provide medication information and instructions | <ul style="list-style-type: none">• Ensure that patients receive the following information for every medication given, as appropriate:<ul style="list-style-type: none">○ Name, dosage, frequency, and timing of administration.○ Expected effects of the medication.○ Possible side effects.○ When to notify the practice if the medication is ineffective or if there is a serious side effect.○ Other medications (prescription and over-the-counter) that are contraindicated.○ Contraindications related to alcohol and food.○ How long to continue the medication or when to use it if it is ordered as needed (PRN).○ How to use aerosols, suppositories, sublingual medications, etc. |
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Educate Patients

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| Provide written instructions | <ul style="list-style-type: none">• Provide written instructions to patients for all dispensed medications, including samples. Use approved sources when providing written or verbal instructions to the patient. |
| Document education | <ul style="list-style-type: none">• Document patient instructions and the education provided in the patient's medical record. |

Develop a Drug Recall Process

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| Assign responsibility | <ul style="list-style-type: none">• Assign responsibility for reviewing the FDA's weekly Enforcement Reports and notifying staff members of pertinent findings. |
| Determine appropriate steps | <ul style="list-style-type: none">• Identify whether the drug recall is Class I, II, or III. Have prescribing practitioners determine whether patient notification is necessary and/or if a replacement medication needs to be issued. |
| Review medication logs | <ul style="list-style-type: none">• If patient notification is necessary, review medication logs to determine if a recalled medication was dispensed. |
| Confirm patient identity | <ul style="list-style-type: none">• Confirm patient identification from the medication log and patient medical records. Ensure that both the log and the medical record contain the patient's name, medical record number, medication, strength, quantity, and lot number. |
| Notify patients | <ul style="list-style-type: none">• When notification is necessary:<ul style="list-style-type: none">○ Call or send a letter to patients who received a recalled medication. If the provider determines that a replacement medication is necessary, make arrangements to provide the replacement medication.• Document the recalled medication and its replacement, as applicable, in the medical record of each pertinent patient. |
| Remove recalled medications | <ul style="list-style-type: none">• Remove recalled medications from stock and discard them in accordance with the recall notice. |

Develop a Process to Identify and Properly Discard Expired Medications

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| Check expiration dates monthly | <ul style="list-style-type: none">• Check all medication expiration dates on a monthly basis. Separate expired medications from the medication inventory and discard them according to the applicable regulations. |
| Check regulations | <ul style="list-style-type: none">• Recognize that state laws may vary and that some states require that expired medications, including samples, be returned to the manufacturer or distributor. |
| Return to pharmaceutical sales representative, when possible | <ul style="list-style-type: none">• When it is necessary to return medications to the manufacturer, follow the manufacturer's guidelines for returning the medications. This may include returning the medications to the appropriate pharmaceutical sales representative.• Make a notation in the log about the number and kind of medication (including lot number) returned. |
| Consider using a hazardous waste company | <ul style="list-style-type: none">• Recognize that a hazardous waste company may be necessary to properly dispose of expired or unwanted medications.• Retain any waste disposal slips for three years (or longer, if required by state law). Ensure that the disposal slips indicate which medications were removed from the premises by a hazardous waste company. |
| Develop processes that help ensure the timely use of unexpired medications | <ul style="list-style-type: none">• Rotate medications so that those with an earlier expiration date are dispensed first.• Accept only drugs you know you will use.• Accept drugs with a shelf life longer than one year. |
| Do NOT flush expired medications | <ul style="list-style-type: none">• Recognize that discarding medications by flushing them down a toilet or sink represents an environmental hazard. |

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References:

1. Institute for Safe Medication Practices. Good intention, uncertain outcome ... our take on physician dispensing in offices and clinics. ISMP Medication *Safety Alert!* March 8, 2012. <https://www.ismp.org/resources/good-intention-uncertain-outcome-our-take-physician-dispensing-offices-and-clinics>. Accessed June 11, 2021.
2. World Health Organization. *Guidelines for Medicine Donations*. http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf?ua=1. Revised 2010.