

In-Office Medication Dispensing Policy

The information provided in this document is for general informational purposes only and is not intended as, nor should it be construed as, legal advice. This policy is limited to noncontrolled medications. Any practice that intends to implement an in-office dispensing program should have the policy and related procedures reviewed by its own legal counsel and office manager/compliance officer prior to implementation to ensure compliance with applicable federal, state, and local laws and regulations.

1. **Purpose.** In Pennsylvania, physicians are generally permitted to dispense medications to patients under their care so long as they comply with State and Federal requirements. In-office medication dispensing benefits patients by ensuring timely, same-day access to prescribed treatments. This policy outlines some of the requirements and best practices that apply to physicians participating in an in-office medication (noncontrolled) dispensing program. This policy does not cover certified registered nurse practitioners and physician assistants.
2. **Prescribing and Dispensing New Prescriptions.** All physicians prescribing, administering or dispensing drugs for new prescriptions must adhere to the following procedures:
 - **Conduct Medical History and Physical Exam.** A duly licensed medical practitioner may dispense, compound or otherwise give any drug to his own patients after diagnosis or treatment of said patient, if such compounding, preparing and dispensing is done by said licensee himself (63 P.S. § 390-8).
 - **Check for Drug Interactions.** Ensure that there are no allergies or drug interactions for the drug to be prescribed, administered, or dispensed.
 - **Counsel the Patient.** Counsel the patient regarding the condition diagnosed and the drug dispensed. Patients should be counseled about the following:
 - Dosage levels;
 - Instructions for use;
 - Frequency and duration of use; and
 - Possible side effects.
 - **Update the Patient's Medical Record with Medication Information.** Document the evaluation and care received by the patient in the patient's medical record. The medical record should include the following:



- A specification of the symptoms observed by the licensed health care provider and reported by the patient.
- The diagnosis of the condition for which the medication is being given.
- The directions given to the patient for the use of the medication.
- The name, strength and quantity of the medication and the date on which the medication was dispensed.
- **Price the Medication.** Provide patient with price of medication prescribed.
- **Enter Prescription into Pharmacy Software.** Prescribe medication in Electronic Health Record (EHR)/Pharmacy Software.
 - Physician enters prescription request through EHR software.
- **Print label for prescription from EHR/Pharmacy Software.** Label should include the following:
 - Name of medication (use abbreviations if necessary);
 - National Drug Code (NDC) number;
 - Quantity;
 - Name of the manufacturer if the drug is a generic drug;
 - Date dispensed;
 - Name and address of practitioner;
 - Patient's name;
 - Patient's date of birth;
 - Dosing instructions;
 - Lot number;
 - Expiration date of medication dispensed; and
 - Directions for use of the drug by patient.
- **Provide Package Insert.** Provide patient prescription drug package insert developed by EHR/Pharmacy for dispensed prescription.
- **Record NDC and Order Quantity.** Ensure that EHR/Pharmacy software records NDC number, lot number, expiration date, and quantity of medication dispensed. If EHR/pharmacy software is not available, documentation is still required.
- **Dispense Medication.**
- **Apply label to prescription container.** Apply label safety closure packaging to be given to patient ([49 Pa. Code § 16.93](#)).
- **Warning and Precautions Information.** Please include a warning label and a description of clinically significant adverse reactions or risks with the medicine.
 - Numerical estimate or rate of adverse reactions or risks



- Outcomes
 - Known risk factors
 - Information, when known, on how to prevent, mitigate, or monitor adverse reactions or risks
 - **Inspect and approve prescription.** Physician should inspect matching stock bottle of medication with dispensed bottle of medication via name of med, dose, quantity, NDC, lot number and expiration date.
 - **Obtain Patient Signature on duplicate label for confirmation.** Have the patient sign a duplicate label containing the following information to confirm receipt of the medication:
 - Name of medication (use abbreviations if necessary);
 - NDC number;
 - Quantity;
 - Name of the manufacturer if the drug is a generic drug;
 - Date dispensed;
 - Name and address of practitioner;
 - Patient's name;
 - Patient's date of birth;
 - Dosing instructions;
 - Lot number;
 - Expiration date of medication dispensed; and
 - Directions for use of the drug by patient.
 - **Maintain record of prescription.** Place signed duplicate label(s) into record book and make sure prescription (name, quantity, etc.) is documented in patient's medical record.
 - **Other.** Certain medications may be subject to additional requirements or procedures that are specific to the medication and are not addressed in this policy. Please consult your attorney for guidance regarding any applicable medication-specific requirements.
3. **Prescribing and Dispensing Refills.** All physicians prescribing, administering or dispensing drugs for refills must adhere to the following procedures:
- **Corroborate the refill request.** Check the patient's chart to ensure medication requested is refillable and consistent with the name of med/dose/frequency already listed in patient's medication list.
 - **Check for Drug Interactions.** Ensure that there are no allergies or drug interactions for the drug to be prescribed, administered, or dispensed.



Counsel the Patient. Counsel the patient regarding the condition diagnosed and the drug dispensed. Patient should be counseled about the following:

- Dosage levels;
- Instructions for use;
- Frequency and duration of use; and
- Possible side effects.
- **Update the Patient's Medical Record with Medication Information.** Document the evaluation and care received by the patient in the patient's medical record. The medical record should include the following:
 - A specification of the symptoms observed by the licensed health care provider and reported by the patient.
 - The diagnosis of the condition for which the medication is being given.
 - The directions given to the patient for the use of the medication.
 - The name, strength and quantity of the medication and the date on which the medication was dispensed.
- **Price the Medication.** Provide patient with price of medication prescribed.
- **Enter Prescription into Pharmacy Software.** Prescribe medication in Electronic Health Record (EHR)/Pharmacy Software.
 - Physician enters prescription request through EHR software.
- **Print label for prescription from EHR/Pharmacy Software.** Label should include the following:
 - Name of medication (use abbreviations if necessary);
 - NDC number;
 - Quantity;
 - Name of the manufacturer if the drug is a generic drug;
 - Date dispensed;
 - Name and address of practitioner;
 - Patient's name;
 - Patient's date of birth;
 - Dosing instructions;
 - Lot number;
 - Expiration date of medication dispensed; and
 - Directions for use of the drug by patient.
- **Provide Package Insert.** Provide patient prescription drug package insert developed by EHR/Pharmacy for dispensed prescription.



- **Record NDC and Order Quantity.** Ensure that EHR/Pharmacy software records NDC number, lot number, expiration date, and quantity of medication dispensed. If EHR/pharmacy software is not available, documentation is still required.
- **Dispense Medication.**
- **Apply label to prescription container.** Apply label safety closure packaging to be given to patient ([49 Pa. Code § 16.93](#)).
- **Warning and Precautions Information.** Please include a warning label and a description of clinically significant adverse reactions or risks with the medicine.
 - Numerical estimate or rate of adverse reactions or risks
 - Outcomes
 - Known risk factors
 - Information, when known, on how to prevent, mitigate, or monitor adverse reactions or risks
- **Inspect and approve prescription.** Physician should inspect matching stock bottle of medication with dispensed bottle of medication via name of med, dose, quantity, NDC, lot number and expiration date.
- **Obtain Patient Signature on duplicate label for confirmation.** Have the patient sign a duplicate label containing the following information to confirm receipt of the medication:
 - Name of medication (use abbreviations if necessary);
 - NDC number;
 - Quantity;
 - Name of the manufacturer if the drug is a generic drug;
 - Date dispensed;
 - Name and address of practitioner;
 - Patient's name;
 - Patient's date of birth;
 - Dosing instructions;
 - Lot number;
 - Expiration date of medication dispensed; and
 - Directions for use of the drug by patient.
- **Maintain record of prescription.** Place signed duplicate label(s) into record book and make sure prescription (name, quantity, etc.) is documented in patient's medical record.



- **Other.** Certain medications may be subject to additional requirements or procedures that are specific to the medication and are not addressed in this policy. Please consult your attorney for guidance regarding any applicable medication-specific requirements.

4. **Pennsylvania State Labeling Requirements for Dispensed Drugs.** The label on a dispensed drug container shall include ([49 Pa. Code § 16.94](#); [28 Pa. Code § 25.93](#); and [28 Pa. Code § 25.95](#)):

- Name of the drug, using abbreviations if necessary;
- Quantity;
- Name of the manufacturer if the drug is a generic drug;
- Name and address of practitioner;
- Date dispensed;
- Name of patient; and
- Directions for use of the drug by patient.

If a practitioner specifically indicates that the name of the drug may not appear on the label, the recognized NDC number shall be placed on the label if the number is available for the product.

Drugs which, at the time of their dispensing, have full potency for less than 1 year, as determined by the expiration date placed on the original label by the manufacturer, may only be dispensed with a label that indicates the expiration date. The label shall include the statement, "Do not use after manufacturer's expiration date," or similar wording ([49 Pa. Code § 16.94](#) and [28 Pa. Code § 25.94](#)).

5. **Security Controls/Storage.** Medication should be stored securely in a locked space with restricted access under proper conditions of sanitation, temperature, moisture, and light, and in accordance with any State or Federal requirements. Requirements may vary by medication type and quantity. Practices should implement written policies on storage, security and access to medication.
6. **Adverse Event Reporting.** Practices should implement and maintain written reporting policies on, including but not limited to, the following:
- Medication errors
 - Adverse drug reactions



- Diversion concerns
- Theft or loss of medications

7. Auditing and Monitoring. Practices should have written audit and monitoring procedures. They should conduct periodic audits and document any findings and corrective actions, including the following:

- Dispensing records
- Inventory reconciliation
- Labeling compliance
- PDMP compliance
- Disposing of expired drugs

8. Registrations/Licenses.

- **Medical License.** Maintain your medical (M.D. or D.O.) license by completing biennial renewal requirements, including continuing education requirements.
- **Other.** Reach out to the State Boards of Medicine or Osteopathic Medicine, State Board of Pharmacy, and Department of Health to discuss any other requirements needed to dispense medication.
 - **State Board of Medicine:** [Medicine | Department of State | Commonwealth of Pennsylvania](#)
 - **State Board of Osteopathic Medicine:** [Osteopathic Medicine | Department of State | Commonwealth of Pennsylvania](#)
 - **State Board of Pharmacy:** [Pharmacy | Department of State | Commonwealth of Pennsylvania](#)

9. Resources.

- [Pharmacy | Department of State | Commonwealth of Pennsylvania](#)
- [49 Pa. Code Subchapter F. Minimum Standards of Practice](#)
- [Frequently Asked Questions about Labeling for Prescription Medicines | FDA](#)
- [U.S. Food and Drug Administration](#)