

The Commonwealth of Massachusetts

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Board of Registration in Pharmacy

Best Practice Recommendations

The Board of Registration in Pharmacy (Board) offers these Best Practice Recommendations in order to promote optimal pharmaceutical care outcomes. The Board believes that adoption and institution of these practices will result in improved performance, increased patient safety, a reduction in medication errors, and enhanced pharmacy medication delivery systems. These recommendations should be used in a complementary manner with federal and state laws and regulations.

Be aware that there may be mandatory requirements associated with some of these recommendations (i.e. mandated reporting).

Quality Related Events (QRE)

- ✓ Create a system for a pharmacist to immediately notify, upon discovery of a QRE, the patient (or representative) and prescriber (if necessary) of remedial action. Take responsibility for the error with the patient and fully address patient concerns directly.
- ✓ Properly review and verify prescriptions that had been placed "on-hold" before dispensing to prevent future filling errors.
- ✓ Promote a non-punitive atmosphere for reporting.
- ✓ Document and track QRE's as part of the facility's continuous quality improvement (CQI) program and document all communications (manually or electronically).
- ✓ Perform root cause analysis and include information from such reviews in CQI programs.
- ✓ QRE reviewers should include pharmacists, interns, technicians, and appropriate management personnel.
- ✓ Implement improvements / interventions based on the information gathered during the root cause analysis.
- ✓ Evaluate QRE's on a quarterly basis and inform pharmacy staff of changes and follow up to continually improve processes.
- ✓ Use documented interventions to change unsafe practices and correct repetitive faults in the prescription fulfillment process.
- ✓ Report <u>Serious Adverse Drug Events</u> (SADEs) as required.

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Workflow

- ✓ Develop policies and procedures to ensure that the appropriate individuals are completing job-appropriate duties.
- ✓ Consider the use of automated devices and verification technology (i.e. barcode scanning).
- ✓ Evaluate size and equipment to determine optimal dispensing area.
- ✓ Maximize effective use of space, equipment, and staff.
- ✓ Explore ways to optimize patient care services (i.e. providing separate counseling area for confidentiality).
- ✓ Designate a clean, private area for immunization activities.
- ✓ Train all pharmacy personnel on LEAN concepts.
- ✓ Phone messages should be returned within 2 hours.

Pharmacy Technician Training

- ✓ Develop a comprehensive pharmacy technician training program.
- ✓ Encourage licensed technicians to become nationally certified and remind the certified technicians to maintain certification requirements.
- ✓ Provide continuing education opportunities.

Compounding

- ✓ Sterile compounders must comply with all provisions of USP, especially <797> and <800>, as applicable. Refer to draft regulations at 247 CMR 17.00 for further guidance. See the Board's compounding documents.
- ✓ Non-sterile compounders must comply with all provisions of USP, especially <795> and <800>, as applicable. Refer to draft regulations at 247 CMR 18.00 for further guidance. See Non-Sterile Compounding Policy.
- ✓ Ensure all personnel who physically compound or directly supervise compounding are properly trained and qualified in the type of compounding conducted before being allowed to compound or supervise compounding.
- ✓ Perform a gap analysis within the facility to determine any areas of improvement with regards to compliance with current compounding standards.
- ✓ A pharmacy participating in compounding is required to maintain formal, written Quality Assurance and Quality Control Programs in accordance with USP.

Counseling

- ✓ Patient education promotes patient involvement in their care and is an important component of any medication error reduction strategy.
- ✓ Ensure counseling is offered to every patient regardless of whether the prescription is new or a refill.
- ✓ Question medication usage of patients with chronic disease states to ensure compliance as well as to identify adverse effects.

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- ✓ Counsel patient if the absence of manufacturer allergens cannot be guaranteed, such as in the case of a gluten allergy.
- ✓ Ask the patient if a drug therapy change has occurred and, if needed, contact the prescriber to obtain updated information.
- ✓ Dispense or recommend proper measuring devices (i.e. oral syringe or dosing spoon) with all liquid medications and provide instruction on their use.
- ✓ If dispensing a stock bottle, counsel on the removal of desiccants, seals, or cotton present within the bottle.
- ✓ Verify patient understanding by using the "teach-back" method.
- ✓ Provide written information regarding the safe and accurate use of the medications.
- ✓ Provide written information regarding compounded products, especially hazardous ones. Include such information as proper use, possible side effects, beyond-use-dates (BUDs), storage, handling, and disposal.
- ✓ Review the <u>ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling</u> for further information.

Pharmacy Practice Improvements

- ✓ Initiate a program to monitor HbA1C levels of diabetic patients.
- ✓ Counsel diabetic patients regarding proper injection techniques and use of insulin, syringes, insulin pens, and glucose monitoring equipment.
- ✓ Counsel asthmatic patients on the proper technique when using Metered Dose Inhalers (MDIs), spacers, and peak-flow meters.
- ✓ Offer immunizations especially for patients at high risk for pneumonia, COVID, and influenza.

Reference Materials

- ✓ Provide internet access to clinical information as well as current laws and regulations.
- ✓ Provide updated reference materials for pediatric and geriatric dosing, as well as veterinary references, if applicable.
- ✓ Establish a clinical department or subject matter expert to serve as a resource.

Outdated and Soon-to-Expire Stock

- ✓ Check expiration dates on all products prior to filling and dispensing a medication.
- ✓ Periodically inspect expiration dates on stock medications including those in the refrigerator and freezer.
- ✓ Identify short-dated items with a colored label indicating expiration date.
- ✓ Rotate stock to ensure products with the soonest expiration dates are in front to be used first.
- ✓ Segregate expired meds from active inventory and prepare for return or destruction.

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✓ Expired/damaged Schedule II drugs must be counted in the perpetual inventory until reverse distributed.

Prescription Processing

- ✓ Verify the name, address, and birthdate when prescriptions are dropped off and picked up.
- ✓ Obtain updated allergy and disease state information as well as any other adverse reactions to medications or their excipients (e.g., gluten, red dye, etc.) with each prescription.
- ✓ Document use of any OTC medications and herbal remedies.
- ✓ Verify at drop-off and / or pick-up the preference for non-childproof caps.
- ✓ Maintain security of prescriptions awaiting pick-up.
- ✓ Review the DEA Pharmacist's Guide to Prescription Fraud.
- ✓ Consider contacting the prescriber to consolidate medications to decrease pill burden.

Compliance Packaging

- ✓ Offer different packaging options for patients who are not at goal with medication adherence.
- ✓ Ensure the filling area is uncluttered.
- ✓ Fill one drug at a time into unit-of-use packages.
- ✓ Avoid skin contact with any medications by donning gloves.
- ✓ Review the Board's regulations and policy.

Unclaimed Prescriptions

- ✓ Consider a policy to allow only certified pharmacy technicians to return medication to stock.
- ✓ Ensure patient-specific information, including the prescription number, is redacted from all containers when returning to stock.
- ✓ Reverse any insurance billing.
- ✓ Maintain documentation in the patient's profile that the medication was not picked up and was returned to stock.

Drug Recalls

- ✓ Recall notices should be brought to the pharmacist's attention immediately.
- ✓ Check frequently for recalled drug products by reviewing the FDA's <u>website</u> or by signing up for the FDA's *Recalls, Market Withdrawals, & Safety Alerts* email alerts.
- ✓ Identify, segregate, and clearly label any recalled, withdrawn, or otherwise affected drug products or substances from active inventory.
- ✓ Contact patients as soon as possible with any next steps.

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Out-of-Stock Items

- ✓ Collect data and analyze trends related to out-of-stock items.
- ✓ Optimize computer inventory management systems to effectively maintain inventory.
- ✓ Consider auto replenishment technology.
- ✓ Consult the FDA shortage list.
- ✓ Inform the patient or caregiver that the medication is out-of-stock or unavailable before they arrive to pick it up. If known, inform them as to when the medication will be available.
- ✓ Offer pick-up at another location.
- ✓ Create contingency plans for out-of-stock and recalled medications.
- ✓ Contact the prescriber if necessary.

Proper Staffing Levels

- ✓ Regularly review staffing needs to ensure adequate availability of professional staff.
- ✓ Create a schedule in accordance with staffing ratios.

<u>Interpreters</u>

- ✓ Based on the pharmacy's needs, consider employment of personnel who can speak
 a second language.
- ✓ Engage an interpreter service.
- ✓ Ask the patient to come in with a trusted individual to translate.

Anti-Counterfeiting Measures

- ✓ Examine all deliveries promptly to determine if any contaminated, damaged, misbranded, expired and / or suspected counterfeit drugs or devices were included.
- ✓ Quarantine any unacceptable drugs or devices.
- ✓ Report suspected counterfeit medications to FDA MedWatch and appropriate law enforcement authorities.
- ✓ Advise consumers to make online medication purchases from Accredited Digital Pharmacies verified by the National Association of Boards of Pharmacy (NABP).

Document Pharmacist Interventions

- ✓ Document all interventions related to changes in a patient's medication therapy.
- ✓ Provide a record of accountability that can be retrieved, reviewed, or acted upon at a future date.
- ✓ Create an electronic documentation system.
- ✓ Provide necessary training and resources to promote an intervention program.
- ✓ Implement improvements based on the gathered information.

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Veterinary Prescriptions

- ✓ Veterinarians do not have NPI numbers since NPI numbers are only for human health care providers.
- ✓ DEA numbers are not required for Schedule VI prescriptions.
- ✓ Only the Massachusetts Controlled Substances Registration ("MCSR") number is required for Schedule VI prescriptions.
- ✓ Contact your IT Department / Help Desk / software vendor for the data entry process without an NPI or DEA number and be sure to educate all staff members.

Identification ("ID") Requirements for Dispensing and Delivering

✓ Review procedures in the <u>PMP Data Submission Dispenser Guide</u> for dispensing PMP drugs when the patient does not have an ID.

Please direct any questions to: Pharmacy.Admin@mass.gov

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