

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Best Practice Recommendations To Promote Optimum Pharmaceutical Care In the Commonwealth of Massachusetts

In 2000, in response to medication error rates and medication distribution issues, the Massachusetts Board of Registration in Pharmacy (Board) convened an advisory committee to make recommendations to the Board regarding continuing quality improvement (CQI) initiatives that could be implemented in all pharmacy practice settings to promote optimum pharmaceutical care. Participants in the Board's CQI Advisory Committee included Board members, representatives from institutional and retail pharmacy settings, professional associations, colleges of pharmacy, the Massachusetts Coalition for the Prevention of Medical Errors, the Department of Public Health and related regulatory agencies.

The CQI Advisory Committee developed a set of **Best Practice Recommendations** (Recommendations) that could be implemented by the various pharmacy settings according to the particular needs, available resources, and community served by the pharmacy. The Recommendations developed by the CQI Advisory Committee were based on a review of current literature on medication dispensing systems and recent research on the incidence and causes of medication errors, as presented by the Board's Quality Assurance Surveyor and CQI Advisory Committee Chairman (a member of the Board). The CQI Advisory Committee provided comment and direction regarding the Recommendations and forwarded the proposed Recommendations to the Board for adoption.

The Board adopted these Best Practice Recommendations on September 25, 2001 (amended on various dates thereafter) as recommended standards of professional practice to be considered for implementation as appropriate by pharmacies to promote optimum pharmaceutical care outcomes in the Commonwealth.

The Recommendations cover most pharmacy settings and include a variety of measures that can be implemented immediately and other processes that involve technological and training topics that can be instituted over a longer period of time to improve medication delivery systems. This list is **not** exclusive of other improvements that may be necessary to a particular pharmacy setting and may be supplemented by the Board from time to time.

The Board urges all pharmacies to make review of these recommendations a high priority and to consider implementation of those measures that are appropriate to the particular pharmacy setting. 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 in general.

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- 1. Develop policies and procedures providing that incident reports will be completed and submitted to a national database, such as the ISMP Medication Errors Reporting Program (MERP), for each quality-related event (QRE) occurrence. A QRE is defined as any departure from the appropriate dispensing of a prescribed medication that is not corrected prior to the delivery of the medication.**

The term “quality-related event” includes variations from the specifications of a prescription, such as wrong drug, wrong strength, wrong directions, and wrong dosage form. The term also includes packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient’s drug therapy.

- **Recommended Actions**

- ✓ Create a system for reporting medication errors to a national database to promote analysis of the occurrence of the QRE and prevent similar events from recurring.
- ✓ Promote a non-punitive atmosphere for the reporting of medication errors.
- ✓ Voluntarily report QRE to the ISMP Medication Error Reporting Program.

- 2. Institute a system to review incident reports generated at the pharmacy on a quarterly basis. Perform root cause analysis and include information from such review in quality improvement programs. Reviewers should include pharmacists, pharmacy technicians, and appropriate management personnel.**

- **Recommended Actions**

- ✓ Evaluate the QREs that occurred in the pharmacy on a quarterly basis and identify the root cause of the QREs.
- ✓ Implement improvements/interventions based on the information gathered as part of the root cause analysis.
- ✓ Publicize changes to pharmacy staff.

- 3. Develop and implement an effective workflow plan that is evaluated periodically to maximize effective use of space, equipment and staff.**

- **Recommended Actions**

- ✓ Develop policies and procedures to ensure that the appropriate individuals are completing appropriate tasks.
- ✓ Consider the use of automated devices to aid staff.
- ✓ Explore ways to optimize patient care services (i.e. providing separate area for confidentiality when counseling patients).
- ✓ Evaluate the size of the pharmacy to determine optimum dispensing area.

4. **Routinely survey customers regarding quality of care and satisfaction with service.**
 - **Recommended Actions**
 - ✓ Develop a customer-focused survey to identify areas of improvement.
 - ✓ Review the findings of the survey with pharmacy staff to develop solutions to improve patient satisfaction.

5. **Develop and implement a comprehensive technician-training program that requires pharmacy technician trainees to demonstrate competence in functioning as pharmacy technicians and to qualify for registration as pharmacy technicians.**
 - **Recommended Actions**
 - ✓ Develop a comprehensive pharmacy technician training program and provide a copy of the technician training program to the Board's Technician Training committee for Board approval.
 - ✓ Encourage pharmacy technicians registered by the Board to meet and maintain certification requirements.
 - ✓ Provide continuing education opportunities for pharmacy technicians.

6. **Implement a policy requiring that counseling be offered to every patient receiving a prescription, regardless of whether the prescription is new or a refill. During patient counseling, the pharmacist should verify that the patient understands the purpose, proper use and expected outcomes of their drug therapy. Counseling should also include information as to the safe and accurate use of prescribed medications. Educating patients about the safe and effective use of medications promotes patient involvement in their own care and is an important component of any medication error reduction strategy. Patient counseling may have a beneficial impact by reducing the incidence of quality-related events.**
 - **Recommended Actions**
 - ✓ Dispense or recommend proper measuring devices (e.g. oral dosing spoon) with all liquid medications. Instruct patients or caregivers on how to use the measuring device.
 - ✓ Provide written patient drug information materials with all new outpatient prescriptions dispensed.
 - ✓ Develop standard counseling procedures that include checks for the following:
 - Right patient
 - Right drug
 - Right drug for this patient
 - Appropriate dosing schedule
 - Appropriate route of administration
 - Correct route of administration for this patient
 - Verification that the patient understands why they are taking the drug
 - Verification that the patient understands how to use the drug

7. Develop policies and procedures that insure patient profiles are periodically updated for drug allergies, patient weight, adverse reactions, over-the-counter (OTC) medication usage, and alternative medication/herbal remedy usage.

▪ **Recommended Actions**

- ✓ Develop a policy that requires that allergy information be updated when filling or refilling a prescription.
- ✓ Require all new prescriptions include allergy information.
- ✓ Develop a policy of updating patients weight periodically
- ✓ Ask patients about their use of OTC medications and herbal remedies and document responses in the patient profile.
- ✓ Update patient profiles periodically. Updates should include information on newly developed allergies even if patient is not filling a new prescription.

8. Utilize available age and weight adjusted dosing guidelines when appropriate.

▪ **Recommended Actions**

- ✓ Verify pediatric dosing to ensure proper dose.
- ✓ Develop pediatric and geriatric specific guidelines for age and weight adjusted dosing.
- ✓ Consider acquiring or utilizing reference materials, textbooks and/or computer software that directly address pediatric and geriatric dosing.
- ✓ When appropriate and necessary, verify that doses are appropriate for the patient.

9. Provide adequate and easy access to appropriate reference materials.

▪ **Recommended Actions**

- ✓ Provide Internet access to pharmacists to research clinical information.
- ✓ Establish a clinical department to serve as a resource for dispensing pharmacists.
- ✓ In addition to required reference texts, provide additional reference materials, such as computer software programs, relevant to particular practice setting.

10. When necessary and appropriate, question adherence to prescriber directions when a medication intended for chronic use is filled more than three days late or when the medication is reordered earlier than expected.

▪ **Recommended Actions**

- ✓ Monitor prescription drug usage among patients with chronic disease states to ensure compliance.
- ✓ Ask the patient if a drug therapy change has occurred and, if needed, contact the prescriber to obtain updated information.
- ✓ Ask patients how they are feeling, paying attention to improvements in the patient's condition as well as adverse effects.

11. Develop written policies and procedures to assure that outdated stock or stock with an expiration date that does not allow sufficient time for dispensing by the pharmacy or use by the patient is segregated from other stock and either prepared for return to the manufacturer or destroyed and documented.

▪ **Recommended Actions**

- ✓ Periodically inspect the expiration date on the medication stock bottles.
- ✓ Periodically inspect the expiration date on the medication containers in the refrigerator or freezer.
- ✓ Identify short dated items with a colored label indicating expiration date.
- ✓ Check expiration dates on all products prior to completing the filling and dispensing of medication.

12. Adopt written policies and procedures pertaining to the handling of filled prescription orders waiting for pick-up by a patient or patient representative.

▪ **Recommended Actions**

- ✓ Verify the patient's name, address, and date of birth when prescription orders are picked up.

13. Adopt written policies and procedures relating to the return of unclaimed prescriptions to stock.

▪ **Recommended Actions**

- ✓ Adopt a policy that only a pharmacist may return medication to the stock with appropriate checks.

14. Develop procedures to ensure drug recalls are acted upon in a timely manner.

▪ **Recommended Actions**

- ✓ Adopt procedure that personnel receiving recall notice are required to immediately bring the recall notification to the pharmacist's attention.

15. Explore the reasons for out of stock items.

▪ **Recommended Actions**

- ✓ Collect data and analyze trends related to out of stock items.
- ✓ Utilize a computer program employing maximum/ minimum strategy to determine inventory.
- ✓ Consider auto replenishment technology.
- ✓ Refer to the FDA shortage list

16. Adopt a policy allowing for continuation of therapy for out of stock or unavailable items.

▪ **Recommended Actions**

- ✓ Inform patient or caregiver that the medication is out of stock or unavailable.
- ✓ If known, inform patient or caregiver when the medication would be available.

- ✓ Offer to make arrangements for the patient or caregiver to pick up the medication at another location.
- ✓ If the availability from manufacturer will result in interruption of therapy, offer to call the physician to discuss a change in therapy.

17. Adopt a policy allowing pharmacists up to a thirty-minute lunch break when they work six or more hours in a day.

- **Recommended Actions**
- ✓ Develop policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods in accordance with policies of the Board of Registration in Pharmacy.
- ✓ Develop policies and procedures detailing the authorized duties of ancillary staff during temporary absences of the pharmacist, the pharmacist's responsibilities for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy.

18. Develop policies and procedures regarding proper staffing.

- **Recommended Actions**
- ✓ Periodically review staffing requirements to assure adequate availability of professional, technical and clerical staff.
- ✓ Ensure that available and competent staff is available during periods of high activity.

19. Utilize interpreters as necessary.

- **Recommended Actions**
- ✓ Employ individuals who can speak a second language.
- ✓ Learn a second language.
- ✓ Engage an interpreter service (such as AT&T).

20. Develop policies and procedures, which continually improve pharmacy practice by incorporating strategies to optimize therapeutic outcomes.

- **Recommended Actions**
- ✓ Consider disease state management programs and certification programs to enhance delivery of pharmaceutical care.
- ✓ Initiate a program to monitor HbA1C levels of diabetic patients.
- ✓ Counsel patients with diabetes regarding proper injection techniques and the proper use of glucose monitoring equipment, insulin, syringes, and insulin pens.
- ✓ Implement a program to encourage high-risk patients to have cholesterol levels evaluated.
- ✓ Encourage patients with asthma to demonstrate proper use of Metered Dose Inhalers (MDIs), spacers, and peak-flow meters.
- ✓ Institute and promote procedures to determine if patients utilizing chronic care medications are adhering to prescribed medical regimens.

- ✓ Develop a plan for the acquisition of adherence software within an acceptable time frame.
- ✓ Provide counseling and conduct activities to help increase immunization rates for patients at high risk for pneumonia and influenza.

21. Develop policies and procedures, which continually insure the integrity of Biologicals and Pharmaceuticals.

▪ **Recommended Action**

- ✓ Consider maintaining a daily temperature log on file to insure proper storage of biologicals and refrigerated pharmaceuticals

22. Develop and implement written policies and procedures that enhance anti-counterfeiting measures regarding the receipt, storage and security of controlled substances.

▪ **Recommended Action**

- ✓ Visually examine all deliveries promptly on receipt to identify contents and determine if any contaminated, damaged, misbranded, expired and or suspected counterfeit drugs or devices are included in the shipment.
- ✓ Quarantine any drugs or devices found to be unacceptable for further examination and determination.
- ✓ Inspect medication during final verification to assure product accuracy and integrity.
- ✓ Request wholesalers to certify that all medications delivered to the pharmacy, not accompanied by a pedigree, are purchased directly from the manufacturer.
- ✓ Report suspected counterfeit medications to **MedWatch** (the FDA Safety Information and Adverse Event Reporting Program), the Board and appropriate law enforcement authorities within three business days.
- ✓ Educate consumers about the risks of counterfeit medications.
- ✓ Encourage consumers to promptly consult with health care professionals if they suspect that their medication is counterfeit.
- ✓ Remind consumers to be aware of noticeable differences in their medications or packaging and the occurrence of any adverse events.
- ✓ Alert consumers to the important role pharmacists play in identifying, reporting and responding to counterfeit drug events.
- ✓ Advise consumers to make online medication purchases from pharmacies that have obtained the Verified Internet Pharmacy Practice Site (VIPPS) seal from the National Association of Boards of Pharmacy (NABP).
- ✓ Maintain records of counterfeit reports from manufacturers and other sources for a minimum three-year period.
- ✓ Consult NABP's "National Specified List of Susceptible Drug Products" available for reference at www.nabp.org and the Board's website under "Board News" at www.mass.gov/reg/boards/ph.

23. Develop and implement written policies and procedures regarding the identification of medication when requested by a consumer/patient or medical professional.

Resources for Non-Emergency Product Identification Requests
[If emergency call poison control center at 1-800-222-1222]

▪ **Recommended Actions**

1. When a prescription is associated with the medication to be identified.

- a. Verify the prescription content with the original copy of the prescription dispensed making sure that the markings on the unidentified medication match the prescription medication dispensed and is identified from the original prescription.
- b. If unidentified medication can not be verified then refer to procedure #2.

2. Identification of a medication with manufacturer's code and/or NDC code or other marking(s) on the product.

- a. Utilize available resources and references (Reference/Resource) to identify medication by manufacturers' identification codes, NDC code, or drug name.
- b. If medication cannot be identified then refer to procedure #3.

3. Identification of a medication that has no markings and/or is a formulation (liquid) that is not positively identifiable.

- a. Call the poison control center and describe medication and indication for use if known. (EMERGENCY SITUATION)
- b. In non-emergency situations, obtain services for laboratory product analysis, <http://www.bostonanalytical.com> or <http://www.bio-concept.com>

References/Resources

Online resources for identifying prescription and non-prescription drugs:

- <http://www.drugdigest.org> click on to Drug library then pill images.*
- <http://www.drugs.com/> identifies by, name, codes and/or description.*
- <http://www.rxlist.com/interact.htm> identifies by code, drug name, or Manufacturer.*
- <http://www.drugs.com/manufacturers.html> links to Medication manufacturers.*
- *PDRhealth*, The Drug Information Directory.*
- Prescription drugs
http://www.pdrhealth.com/drug_info/rxdrugprofiles/alphaindexa.shtml*
- OTC drugs
http://www.pdrhealth.com/drug_info/otcdrugprofiles/alphaindexa.shtml*
- www.mcphs.edu/altmed Center for Complementary and Alternative Pharmacotherapy.*
- <http://www.micromedex.com/> Micromedex

- <http://www.cp.gsm.com/> *Clinical Pharmacology* Product Identification
- <http://www.identadrug.com/> by Pharmacist Newsletter
- * Information accessed without charge

Books for identifying drugs may be available at your local public or university library:

- *Ident-A-Drug Reference*; identifies drugs by the numbers, letters and images.
- *Mosby's DrugConsul*
- *Physicians' Desk Reference (PDR)*
- *Facts and Comparisons*

24. Develop policies and procedures to document pharmacist initiated interventions to provide a record of accountability that can be retrieved, reviewed or acted upon at a future date. Properly documented interventions can be utilized to change unsafe practices, correct repetitive faults in the prescription fulfillment process and/or change the outcome of a patient's treatment.

- **Recommended Actions**
- ✓ Create a system (manual or electronic) for documenting pharmacist initiated interventions.
- ✓ Provide necessary training and resources to promote a pharmacist initiated intervention program.
- ✓ Implement improvements based on information gathered from an intervention program.

References/Resources

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- *Annals of Internal Medicine* 15 May 2007 | Volume 146 Issue 10 | Pages 714-725
- Pharmacy interventions can reduce clinical errors - Part I of findings from ISMP survey: June 26, 2002 issue ISMP Newsletter
- *Drug Benefit Trends* 11(1):41-46, 1999. © 1999 Cliggott Publishing, Division of SCP Communications
- Clinical pharmacy interventions by community pharmacists during the dispensing process. *Br J Clin Pharmacol.* 1999 June; 47(6): 695–700.
- <http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/>

25. Develop a policy and procedure providing for immediate notification of patient or patient's representative upon discovery of significant QRE (medication error) and effective communication of seriousness of the event and verification of completion of pharmacy personnel training related to such policy and procedure.

- **Recommended Actions**
- ✓ Create a system for a pharmacist to notify, upon discovery of a significant QRE (medication error), the patient or patient's representative of remedial action to avert ingestion or potential harm.

- ✓ Provide necessary training and resources to the pharmacist on the proper methods of immediate patient notification to prevent adverse medication events.
- ✓ Document communication (manual or electronic) based on information gathered from the incident.

References/Resources

- Communicating Critical Test Results: Safe Practice Recommendations. *Joint Commission Journal on Quality and Patient Safety*. 2005 February; 31(2): 68-80. Available at: <http://www.macoalition.org/Initiatives/docs/CTRgriswold.pdf>.
- Medication Error Council Promotes Error Prevention Recommendations. 1996 September. Available at: <http://www.ismp.org>.
- Culture Change: Prevention, Not Punishment. VA's Approach to Patient Safety. Available at: <http://www.patientsafety.gov/vision.html>.
- <http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/>

26. Develop policies and procedures to ensure the proper storage of refrigerated and frozen medications. Provide ongoing education on the importance of proper storage of medications requiring refrigeration.

Recommended Actions

Educate pharmacists and other pharmacy personnel regarding the importance of proper storage of refrigerated and frozen medications.

- Review the Board's Policy No. 2011-01: Proper Storage of Refrigerated and Frozen Medications in a Pharmacy.
- Review current refrigeration standards established by Centers of Disease Control and Prevention, USP and the Massachusetts Department of Public Health, Division of Epidemiology and Immunization.

References/Resources

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3. <http://www.cshp.org/index.php?mact=News,cntnt01,print,0&cntnt01articleid=315&cntnt01showtemplate=false&cntnt01returnid=155>

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All websites listed were accessed August 2001 (Nos. 1 - 20). Other websites accessed on amended dates noted below.

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2. Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (MERP). Available at: <https://www.ismp.org/orderforms/reporterrortoism.asp>
 3. Lesar TS. Recommendations for reducing medication errors. *Medscape Pharmacists*, 2000. Available at: <http://www.medscape.com/Medscape/pharmacists/journal>.
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Available at: <http://www.state.ma.us/reg/boards/ph/pol00003.htm>.
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Available at: <http://human-factors.arc.nasa.gov/ihs/activities/ASRS.gif>.
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Available at: http://mhalink.org/mcpme/mha_best_practice_recommendation.htm.
 16. American Pharmaceutical Association. Quality Improvement in Pharmacy: Report Cards, Continuous Quality Improvement, and Peer Review.
Available at: www.aphanet.org/govt/policycomm2000/qualityassessbackground.html.
 17. Veterans Administration (VA) National Center for Patient Safety. VA NCPS root cause analysis. Available at: <http://www.va.gov/ncps/tools.html>.
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