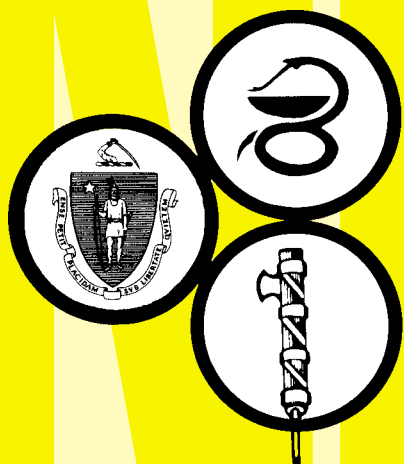


June 2001



# Massachusetts Board of Registration in Pharmacy

100 Cambridge St., Rm. 1514  
Boston, MA 02202

Published to promote voluntary compliance of pharmacy and drug law.

## **Recent Board Policies**

For a complete list of all Massachusetts Board of Registration in Pharmacy policies visit our Web site at [www.state.ma.us/reg/boards/ph/default.htm](http://www.state.ma.us/reg/boards/ph/default.htm).

### **Policy No. 2000-01**

Policy on Disease State Management Guidelines – Rescinded – Refer to NABP Guidelines at [www.nabp.net](http://www.nabp.net).

### **Policy No. 2000-02**

#### **Policy on Canadian Graduates**

Canadian graduates of approved colleges of pharmacy are exempted from taking the Foreign Pharmacy Graduate Equivalency Examination.<sup>TM</sup> Under certain conditions, however, the examination is now an electronic version given throughout the year, so there is not as great an accommodation to these candidates as in the past. Please refer to the Web site for complete details.

### **Policy No. 2000-03**

#### **Policy on Pharmacy Operations During the Temporary Absence of a Pharmacist**

Board Regulations at 247 CMR § 6.02(9)(a) state: “A registered pharmacist shall be on duty and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy department.”

To ensure that a pharmacist may take necessary and appropriate breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open, the requirements of 247 CMR s. 6.02(9) a) shall be interpreted by the Board as allowing the temporary absence of a pharmacist from the pharmacy department for such breaks and meal periods, provided the following requirements are strictly observed during such absences.

In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the prescription drugs and devices will be maintained in the pharmacist’s absence.

**If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during the pharmacist’s absence.**

(a) During the pharmacist’s temporary absence, **no prescription medication may be provided to a patient or to a patient’s agent unless the prescription medication is a refill medication** that the pharmacist has checked and determined does not require the consultation of a pharmacist prior to being released to the patient.

A new prescription which has been previously prepared, visibly checked by a pharmacist, and had a drug utilization performed by a pharmacist, may be picked up by a patient during such temporary absence of a pharmacist, provided that a log of all such transactions, including the patient’s phone number, is kept. The pharmacist, upon return from break or meal period, shall contact the patient within a reasonable time to review any pertinent counseling deemed appropriate.

(b) During such times that the pharmacist is temporarily absent from the pharmacy, the pharmacy technical support staff may continue to perform the nondiscretionary duties authorized to them by pharmacy law and regulation. However, any duty performed by any ancillary staff member shall be reviewed by the pharmacist upon return to the pharmacy.

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- (c) Pharmacist managers, at their discretion, may develop a written policy for allowing Pharmacy Technician Certification Board (PTCB) and/or Board-approved certified technicians and pharmacy interns to receive telephone prescription orders from practitioners, unless otherwise prohibited by law or regulation.
- (d) In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not without a pharmacist for a temporary period.
- (e) The temporary absence authorized hereunder shall not exceed 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period; however, the pharmacist shall be required to remain on the premises. The total temporary absence shall not exceed more than 30 minutes during any work period of at least six consecutive hours.
- (f) The pharmacy shall have written policies and procedures regarding the operation and closure of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff; the pharmacist's responsibilities for checking all work performed by ancillary staff; and the pharmacist's responsibility for maintaining the security of the pharmacy. These policies and procedures shall be available for inspection by the Board or its designee at all times during business hours.

## **Policy 2000-04**

### **Policy and Guidelines for Confidentiality and Compliance Programs**

The Board of Registration in Pharmacy adopted the following guidelines regarding patient confidentiality, compliance programs, and the requirements of Board Regulations at 247 CMR § 9.01 (19), which states:

A pharmacist shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information that is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

## **Guidelines**

### **Section 1: Confidentiality of Health Care Information**

Patient Compliance and Patient Intervention Programs shall be conducted in a manner to ensure the confidentiality of confidential health care information. The unauthorized release or disclosure of confidential health care information may constitute a violation of Massachusetts pharmacy practice acts or rules and/or other state and federal laws or regulations.

The following minimal safeguards shall be in place for patient compliance and patient intervention programs:

- a) Confidential health care information shall be maintained in a manner to protect against the unauthorized release of such information;
- b) Confidential health care information shall be accessed only by the pharmacist or by individuals under the direct supervision of the pharmacist and may be released or disclosed to an external entity with authorization of the patient or caregiver;
- c) Confidential health care information used to implement a patient compliance or patient intervention program shall not be released or disclosed to any external entity other than the external entity implementing the program with, or on behalf of, the pharmacy;
- d) All personnel with access to confidential health care information shall sign and their employer shall retain on file current confidentiality and non-disclosure agreements;
- e) Representative copies of all form correspondence and lists of individual patients to whom such correspondence has been sent shall be maintained by the pharmacist/pharmacy and external entity for a reasonable period of time. Records of specific patient interventions or compliance initiatives shall be traceable and easily accessible;
- f) If the Patient Compliance or Patient Intervention Program information is mailed, delivery systems that: 1) ensure the information will be delivered to the designated patient or caregiver and will remain confidential; and 2) allow for the return of the information if not deliverable, shall be utilized. For example, if the contact is via the US Postal Service, the information should be mailed first class in a sealed security envelope;
- g) Methods to access, transmit, store, analyze, or purge confidential health care information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience;
- h) External entities maintaining confidential health care information outside the pharmacy's internal system shall adhere to the same security requirements adhered to by the pharmacy in regard to its internal system, including

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but not limited to, those requirements addressing information access, storage, auditability, and release;

- i) Procedures shall be in place to ensure that purged confidential health care information cannot be misused or placed into active operation without appropriate authorization; and
- j) Internet connectivity or remote access tied directly to systems containing confidential health care information must be secure.

## **Section 2: Patient Participation**

Patient Compliance and Patient Intervention Programs shall be conducted in the best interest of the patient and shall inform patients about the program's purpose and use of confidential health care information. The patient shall have the option to participate in ("opt in") or withdraw from ("opt out") any such program at any time. Patients electing to participate in such programs shall be provided with the following information:

- ◆ A description of the Patient Compliance or Patient Intervention Program;
- ◆ Benefits of the program to the patient;
- ◆ Nature of participation;
- ◆ How the program works and the potential contacts that will be made; and
- ◆ The name of the person making the contacts.

Programs designed to change a patient's medication or medication therapy solely for economic or financial gains or incentives without the consent of the patient and prescribing practitioner are contrary to these guidelines and may violate the state pharmacy practice acts in Massachusetts and rules and/or other state and federal laws or regulations.

Nothing in these guidelines supercedes existing state drug product selection laws or procedures for drug recalls, nor prevents access to nonconfidential health care information for research purposes.

## **Section 3: Pharmacist Participation**

A pharmacist shall oversee and approve all Patient Compliance and Patient Intervention Programs and shall be responsible for:

- 1) maintaining an accurate list of participating patients; and
- 2) the accuracy and appropriateness of the information being presented to the patients.

Pharmacists involved in Patient Compliance and Patient Intervention Program, whether through contact with patients or caregivers or through the design, implementation, management, and analysis of the program, shall be educated about such programs and their objectives. Results of the programs shall be communicated to all participating pharmacists.

## **Section 4: Utilization of Nonconfidential and Confidential Health Care Information for Research Purposes**

Notwithstanding any other provision of law, nothing in these guidelines shall be interpreted to prohibit the release of:

- a) Confidential health care information for research that is subject to the requirements of federal laws and regulations protecting the rights and welfare of research participants; and
- b) Non-confidential health care information for research purposes or analysis.

## **Section 5: Measurement and Analysis of Program**

Patient compliance and patient intervention programs may include methodologies to measure the outcomes of the program in relation to patient care and the performance of the pharmacy/pharmacist. The following minimum guidelines shall be observed when measuring and analyzing the program outcomes:

- a) Analysis and aggregate data reports shall not contain confidential health care information;
- b) Study design, measurement, and analysis shall adhere to accepted research and study designs; and
- c) Reports prepared or published shall provide accurate and statistically correct information.

### ***Policy No. 2000-05***

#### **Policy on Approved Programs**

This policy provides that the Board will recognize continuing education credit by any NABP Board of Pharmacy member in the US and its territories.

### ***Policy No. 2000-06***

#### **Policy on Quality Related Event Reporting (Medication Errors)**

Requires as a follow up to all complaints appearing before the Board involving medication errors that the pharmacist Manager of Record submit a Medwatch report, including corrective measures taken to reduce recurrence. This root cause analysis of the medication error and subsequent follow-up corrective action may be shared with other pharmacies, resulting in possible prevention plans. NABP defines Quality Related Event as:

**Quality-Related Event** means 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 stan-

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dards, 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.

### **Policy No. 2001-01**

#### **Board Interpretation of USP Beyond-Use Date Requirement**

Policy allows under very strict conditions, a one-year beyond-use date on certain repackaged single unit or unit dose containers. Please refer to complete text on Web site or request a copy from Board.

### **Policy No. 2001-02**

#### **Board Guidelines for Pilot Project Approval**

Policy sets the conditions and outlines the procedures for applying for a pilot project approval. Requires that the proposed pilot project enhance pharmaceutical care services which contribute to positive patient outcomes.

### **Proposed Technician Regulations for Registration of Technicians**

The Board has drafted proposed technician regulations which will create three levels of support assistance for pharmacists. According to the proposed regulations, a **Technician Trainee, who is** required to be at least 16 years old and pursuing a high school diploma or equivalent, will be allowed to work up to 1,000 hours prior to being required to register with the Board as a pharmacy technician, unless granted a waiver. A **Registered Pharmacy Technician** will be required to work at least 500 hours as a technician trainee, complete a Board-approved Technician Training course, and take a Board-approved company administered competency assessment test (and pass with a score of at least 75%). The examination must cover the following knowledge-based areas:

- i. Practice settings;
- ii. Duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel;
- iii. Laws and regulations regarding the practice of pharmacy and patient confidentiality;
- iv. Medical abbreviations and symbols;
- v. Common dosage calculations; and
- vi. Identification of drugs, dosages, routes of administration and storage requirements

After meeting these requirements, a registered Pharmacy Technician will be required to register and pay a registration fee.

A third category of supportive personnel will be the **Certified Pharmacy Technician** (CPhT) who is a Registered Pharmacy Technician who has successfully passed the Pharmacy Technician Certification Board (PTCB) examination and holds

a **current** PTCB certificate. Should the certificate expire, or should the CPhT **not** meet the requirements for renewal of the PTCB Certificate, then the Certified Pharmacy Technician would be required to practice as a Registered Pharmacy Technician and follow the ratios and practice requirements accordingly.

### **Proposed Ratios**

- (a) 1:4 – One pharmacist for a maximum of four supportive personnel; provided at least one of four is a Certified Pharmacy Technician and one is an intern; or at least two are Certified Pharmacy Technicians.
- (b) 1:3 – One pharmacist for a maximum of three support personnel; provided at least one of the three is a pharmacy intern or a Certified Pharmacy Technician.

### **Regulatory Requirements**

- ◆ A Technician Trainee will be required to function under **direct** supervision at all times and cannot take telephone prescriptions or refill authorizations.
- ◆ A Registered Pharmacy Technician will be allowed to take a renewal request from a practitioner or agent, provided the therapy has been unchanged and provided further that the pharmacist on duty authorizes the Registered Pharmacy Technician to perform this function.
- ◆ A Certified Pharmacy Technician, with approval of the pharmacist on duty, may be allowed to receive new prescriptions over the phone and receive refill requests from a practitioner or agent.
- ◆ All technician personnel will be required to wear name tags with job titles.

The **proposed regulations** are currently being reviewed by the Office of Consumer Affairs (OCA) and the Executive Office of Administration and Finance (A and F). Following OCA and A and F review, a public hearing and comment period will be scheduled by the Board. Check the Board's Web site for notice of such hearing.

### **Continuing Education Audits**

The Board recently sent out a continuing education (CEU) audit request to a group of pharmacists to determine compliance with Board Regulations at **247 CMR § 4.04 et seq.** Audited pharmacists are required to submit original certificates of completion for a two-year period to the Board. Following review by the Board, penalty hours will be required of deficient licensees and, in some cases, complaints will be filed against non-compliant licensees.

**Notice:** When a registered pharmacist signs a license renewal form "under the pains and penalties of perjury," without first verifying continuing education credits are in compliance, disciplinary action may result where the licensee is found to be deficient in CEUs. **Please** store continuing education credits in a safe place and confirm that you have met requisite requirements **each year** before year-end. The Board strongly recom-

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mends that pharmacists participate in programs directly related to their practice setting to ensure continued competence in their respective areas of specialization. The Board is currently reviewing a policy which will result in disciplinary proceedings being initiated in the event a pharmacist is audited and found deficient in CEUs as set forth below:

**First Offense**

1. Should the audited pharmacist be deficient by five (0.5 CEUs) or more hours of continuing education during the preceding two-year period, the pharmacist will be requested to immediately surrender their licenses pending the fulfillment of additional CEUs.
2. **An additional** three contact hours for each contact hour of credit deficient, **and in addition** audit of continuing education credits for the next three years, and such other terms and conditions as the Board determines.

**Second Offense**

A complaint may be issued and action initiated by the Board to suspend the license for at least a two-week period and such other terms and conditions as the Board shall see fit.

Licensee should be aware disciplinary actions are reported to the National Association of Boards of Pharmacy (NABP) and Healthcare Integrity and Protection Data Bank.

**Board Member List**

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- Donna Horn, RPh ..... Secretary  
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- Dan Sullivan, RPh ..... Member
- Karen Ryle, RPh ..... Member
- James DeVita, RPh ..... Member
- Robert Paone, RPh, PharmD ..... Member
- Marilyn Barron, MSW ..... Public Member

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- Susan Manning, Esq ..... Administrative Counsel
- Fred Frankhauser, RPh ..... Quality Assurance Surveyor
- Lau Kwan ..... Administrative Assistant
- Carolyn Reid ..... Administrative Assistant

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- Daniel Warren, RPh ..... 617/727-6388
- James Emory, CPhT ..... 617/727-1803
- Alan Van Tassel ..... 413/784-1151

**Committees and Task Forces**

1. In response to the Institute of Medicine Report “To Err is Human-Building a Safer Health Care System,” published in 1999, the Board has voted to consider implementation of continuing quality improvement standards for pharmacists employed in health systems regulated by the Board. The Board has established an advisory committee chaired by Board Member Robert Paone and Board Quality Assurance Surveyor Fred Frankhauser to study the issues, review the research, and make recommendations to the Board. The task force is comprised of representatives from retail (chain and independent), hospital, managed care, chain drug council, Department of Public Health, colleges of pharmacy, and professional associations.
2. The Board has established a Strategic Planning Committee to set the future direction of the Board in drafting its regulatory priorities. Board member Donna Horn is Chair of the Committee along with Board members Karen Ryle and James DeVita. The Board hopes to have a strategic planning meeting sometime in May or June.
3. The Board continues to participate in and support the DPH/Board/MPHA pilot project involving pharmacist administration of influenza vaccine. To date, more than 1,000 high-risk patients have been immunized by a pharmacist as part of the pilot project and preliminary review of customer survey returns indicate a high degree of satisfaction by consumers. The participating pharmacists have completed a formal APhA Immunization Training Course and were required to be CPR Certified. The second phase of the pilot project will involve a larger number of pharmacies and pharmacists. Congratulations to these dedicated pharmacists and pharmacies for their commitment to expanded pharmaceutical care practices.

**Disciplinary Actions**

In fiscal year 2000, the Board investigated 150 Priority 1 and 2 complaints; 85 Priority 3 and 4 complaints and 200 pre-complaint Special Assignments. Complaints are prioritized according to the nature of the allegations, with priority 1 and 2 complaints primarily involved in medication errors resulting in actual ingestion of the prescribed prescription drug product and injury resulting. Drug diversion and substance abuse would also be included in these high priority investigations. Limited space in this *Newsletter* does not permit the publishing of each of the cases, but future newsletters may be devoted to this issue.

**Continuing Education Program Update**

During the past year, the Board and staff have participated in more than 25 CE programs as part of outreach efforts to reach licensees. With resources very limited over the past sev-

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eral years, it has been difficult to publish newsletters and conduct compliance inspections. As a result, some Board members have taken time out of their busy schedules to speak before pharmacy groups. Board President Harold Sparr has taken the lead in this initiative, and Members Jim Devita, Bob Paone, and Karen Ryle, as well as staff members Chuck Young, JD Coffey, and Fred Frankhauser have also contributed in this effort. Board members and staff are prohibited from accepting an honorarium for public speaking so the time devoted to these efforts is strictly voluntary and represent an ongoing commitment to the practice of pharmacy. Please make every effort to attend programs involving the Board.

### Question/Answer of the Month

*Question: I have patients traveling to Europe for the summer who have a prescription for Ritalin that they would like me to mail to them while they extend their stay. Am I permitted to do so?*

*Answer:* According to Drug Enforcement Administration, controlled substances that are dispensed pursuant to a legitimate prescription **may not** be delivered or shipped to individuals in another country without proper authorization. Any such delivery or shipment is an export under the Controlled Substances Act (CSA) and cannot be conducted unless the person sending the controlled substances has:

1. Registered as an “exporter” (see 21 CFR 1301); and,
2. Obtained the necessary permit(s), or submitted the necessary declaration(s) for export as outlined in 21 CFR 1312.

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