



Massachusetts Board of Registration in Pharmacy

Published to promote compliance of pharmacy and drug law

239 Causeway Street, 5th Floor • Boston, MA 02114 • www.mass.gov/dph/boards/pharmacy

Newsletter Returns . . . by Popular Demand!

The Massachusetts Board of Registration in Pharmacy welcomes you to the first issue of its *Newsletter*. For those of you with extensive pharmacy experience, you may remember receiving this as a printed, mailed version in the past.

The Board hopes to promote compliance of pharmacy law and best practices by educating its licensees on both state and national pharmacy news topics. You can receive this *Newsletter* every quarter electronically by using the subscribe link on the National Association of Boards of Pharmacy® website at www.nabp.pharmacy/boards-of-pharmacy/massachusetts or asking to be added to the Board's distribution list by emailing Pharmacy.Admin@MassMail.State.MA.US. The distribution list periodically sends out information related to new Board advisories, policies, and regulations and is a great way to stay up to date on Massachusetts pharmacy practice. The Board welcomes your suggestions for any topics you would like to see addressed.

Gabapentin and MassPAT

The Massachusetts Prescription Awareness Tool (MassPAT) is an online tool utilized by authorized providers that supports safe prescribing and dispensing of Schedule II-V controlled substances (CS). It is part of the Massachusetts Prescription Monitoring Program and requires pharmacies to report prescribing and dispensing information for all drugs in Schedules II-V and those drugs in Schedule VI that have been designated as "additional drugs." This information is then used to provide more complete information to prescribers, dispensers, and regulatory agencies in order to identify prescribing and dispensing trends, detect drug abuse and diversion, and facilitate communication between health care providers based on a patient's prescription fill history.

Because of its abuse potential, gabapentin has been classified as an "additional drug" and must be reported to MassPAT as of August 1, 2017.

More information about MassPAT and its use may be found at www.mass.gov/dph/dcp/pmp.

Out-of-State Prescriptions

Schedule III-VI prescriptions can be issued by any authorized practitioner from any state but must be filled within 30 days of the date written. Pharmacists must request and record that a written prescription be forwarded within seven days for any out-of-state Schedule III-V oral prescriptions.

Nonnarcotic Schedule II prescriptions can only be issued by authorized physicians (no other practitioners) from any state. These prescriptions must be filled within five days of the date written.

Finally, **narcotic Schedule II** prescriptions can only be issued by authorized physicians (no other practitioners) who are properly licensed and registered in Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, or Vermont. These prescriptions must be filled within five days of the date written.

For more information, visit <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C/Section18>.

Regulatory Update

The Board continues its review of existing regulations, as well as drafting new ones for compounding, hazardous drugs, and fines.

A public hearing for regulations 247 Code of Massachusetts Regulations 5.00, 6.00, 9.00, 12.00, 15.00, and 20.00 was held on June 29, 2017. After all comments are collated, they will be presented to the Board members for possible inclusion and final approval.

To view comments that have been submitted, visit www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/public-hearings.html.

Vaccination Update

Regulations have been recently revised to allow qualified pharmacists and pharmacy interns to administer

WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

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certain vaccines to individuals nine years of age and older. Only vaccines included in the latest immunization schedule as approved by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention are permitted to be administered.

Of note, since the ACIP does not currently recommend the zoster vaccine (ie, Zostavax®) for adults ages 50 through 59, pharmacists and pharmacy interns are **not** permitted to administer the zoster vaccine to this age group.

Revised regulations may be viewed at www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr700.pdf. The Board's vaccine policy may be viewed at www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/pharmacy-regs/policies.

Pharmacy Intern Supervision

Supervising a pharmacy intern can be a rewarding and educational process for both the preceptor and student. Bear in mind that a pharmacist preceptor may not directly supervise more than two pharmacy interns at one time during dispensing functions or patient care activities.

There are settings where a pharmacy intern may work in an office or similar setting without patient or provider contact, doing research or working on projects; in these situations, no direct supervision is required.

It is important to note that a licensed pharmacist must be present at all times when any intern participates in patient or practitioner consultations or recommendations, or perform any other duty in which an intern's error could have a negative impact on patient safety.

The Board encourages its licensees to read the advisory addressing supervisory ratios, among other topics, on the Massachusetts Executive Office of Health and Human Services website at www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/alerts/pharmacy-board-advisories.html.

Did You Know?

- ◆ You can email the Board with practice inquiries at Pharmacy.Admin@MassMail.State.MA.US.
- ◆ In order to participate in a research study, whether with commercially available approved drugs or not, a study-specific CS registration is required from the Massachusetts Drug Control Program.
- ◆ Pharmacies may **not** provide "stock supply" medications to any office or facility. This includes such products as vaccines and naloxone.

Technician Training

In order to standardize technician training throughout the Commonwealth of Massachusetts, the Board has adopted new guidelines for approval. Policy 2017-01 details

the requirements for obtaining approval for pharmacy technician exams and training programs. For details, visit www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/policy-2017-01.pdf.

Reporting Lost Controlled Substances

The number of CS a pharmacy handles in one day can be astounding. If at some point a loss of CS occurs, it is important to report it properly. Only those pharmacies that hold a license with the Board are required to report, in the manner outlined below.

Within one business day of a suspected reportable loss, a pharmacy must report Section A of the Report of Loss of Controlled Substances (RLCS) form to the Board. Within 30 days of submission of Section A, the pharmacy must submit Section B of the RLCS form, including investigation results, police reports (if applicable), and any other related documentation. The RLCS form can be downloaded online at www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/borp-report-loss-controlled-substance.pdf.

Pharmacies are still required to submit a Drug Enforcement Administration (DEA) Form 106 to DEA, state police, and local police, as well as to the Board if there is a significant theft or loss of federally controlled substances. Please review DEA's definition of "significant loss" at https://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0812.htm.

The Board approved this procedure in late 2016 to allow pharmacies enough time to conduct a thorough internal investigation. In many cases, the increased investigative time proved helpful in loss reconciliation.

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