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News

Massachusetts Board of Registration in Pharmacy

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Labeling

There are several content and print size labeling requirements for a pharmacist filling controlled substance (CS) prescriptions. They can be found in Massachusetts General Laws Chapter 94C, Section 21, the United States Pharmacopeia (USP) standards, as well as federal regulations. Once they are in effect, the Massachusetts Board of Registration in Pharmacy's draft regulations at 247 Code of Massachusetts Regulations 9.00 will also contain additional labeling requirements.

Elderly persons or visually impaired persons can request a larger print size on their prescription labels. To meet this request, the directions on the label must be typed in a print size not allowing more than 10 characters per inch. There are no language stipulations, so you may label a filled prescription in the patient's preferred language if you have the capacity to do so. Although not required, it would also be helpful to provide a physical description of the drug.

In general, prescription labels affixed to the container must include the following:

- Pharmacy name and address
- Pharmacy phone number if a sterile or complex nonsterile compounding pharmacy
- Serial number of the prescription
- Name of the patient, unless it is a veterinary prescription
- Name of prescriber
- Filling pharmacist's initials
- Date of fill
- Name of CS, including strength or concentration
- When a less expensive product is substituted, the phrase: "Interchange (or IC): Generic name of less expensive drug plus manufacturer name"
- Directions for use
- Quantity
- Cautionary statements, if any
- Expiration date from the manufacturer's container or one year from the date the drug is dispensed, whichever is earlier (USP <7>)
- Beyond-use-date of a compounded preparation
- If the prescription was compounded by the pharmacy, a statement that the drug is either a sterile or nonsterile compounded drug preparation
- For a Schedule II, III, or IV drug, the words: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

License Status During the COVID-19 Emergency Period

Governor Charlie Baker has issued an order for licensing allowances and extensions during the emergency period. Below is information on license statuses, reactivation of expired and retired licenses, and emergency reciprocity.

- If the license expiration date is **prior** to March 10, 2020, the license is expired.
- If the license expiration date is **between** March 10, 2020, and June 30, 2021, the license remains current under the governor's order but will expire on June 30, 2021.
- If the license expiration date is **on or after** June 30, 2021, the license is current and will expire on the stated date.

For licenses that expired prior to March 10, 2020, but less than two years after the expiration date, you can apply for late renewal, using one of the following two actions:

1. Submit a paper renewal application for the coronavirus disease 2019 (COVID-19) state of emergency only. This temporary renewal has no fee, no renewal requirements, and will expire 90 days after the termination of the state of emergency.
2. Log in to the Massachusetts Department of Public Health Online Licensing portal and complete a late

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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renewal. The late fee will be waived; however, the regular license renewal fee must be paid, and continuing education (CE) requirements must be met. This renewed license will expire in ordinary course.

For licenses that expired or retired more than two years ago but less than 10 years after the expiration date, you can apply for reactivation using one of the following two actions:

1. Submit a reactivation application for the COVID-19 state of emergency only. This reactivation has no fee, no reactivation requirements, and will expire 90 days after the termination of the state of emergency.
2. Submit a routine reactivation application. The regular license renewal fee must be paid, but any required back-cycle fees and late fees will be waived. CE and other requirements must be met. This reactivated license will expire in ordinary course.

During the COVID-19 state of emergency, a pharmacist or pharmacy technician who is licensed to practice in another state may receive emergency authorization to practice on behalf of a Massachusetts-licensed pharmacy or health care facility. To do so, the pharmacist or pharmacy technician must:

1. submit a completed application to the Board;
2. sign up for an NABP Passport via the National Association of Boards of Pharmacy® (NABP®);
3. receive written authorization from the Board prior to engaging in practice; and
4. comply with all Massachusetts laws and regulations.

Impaired Operation of Vehicles

The National Transportation Safety Board (NTSB) conducted a study about the relationship between pilot fatalities and increased use of potentially impairing drugs among pilots. This study brings attention to the fact that the increase in potentially impairing drug use among pilots is indicative of a similar trend in the general population, and that the risk of transportation accidents **is not limited to pilots but extends to individuals operating other types of vehicles such as boats, trains, trucks, or cars.** In addition, the study found the most common potentially impairing drug used by pilots was diphenhydramine, the sedating antihistamine used in many non-prescription medications such as Benadryl® and Unisom®.

Accordingly, the Massachusetts Boards of Registration in Dentistry, Nursing, Pharmacy, and Physician Assistants (Boards) join the NTSB in strongly recommending that health care providers discuss with patients the effect that medical conditions, and any prescribed, dispensed, or recommended medications, may have on **patients' ability to safely operate a vehicle in any mode of transportation.**

While the NTSB alert highlights this particular, important concern, the Boards remind health care providers that the recommended conversation should be a part of a broader discussion with patients concerning the effects of their medical conditions and medications.

Getting to Know Your Board Members – Carly Jean-Francois

Carly Jean-Francois is the nurse member of the Board and has worked as a pediatric nurse for about 20 years. Approximately five years ago, she decided to obtain her nurse practitioner degree because she enjoys working with children and their families and wanted a new opportunity to make a difference in their lives. Even while growing up, she knew that she wanted to work with children in some capacity and had considered becoming a schoolteacher. However, having come from a family of nurses, Carly pursued a career in pediatric nursing.

While exploring volunteer opportunities, Carly followed a friend's suggestion to serve on a licensing board and has been part of the pharmacy Board for about three years. Pharmacists serving on the Board have specialized knowledge, experience, and training in pharmacy as well as the laws regulating it, and Carly has found that this is the only real difference between pharmacist members and nurse members. The common dedication to public service and the mission of the Board are the same. As a nurse who understands the important role that pharmacists and the pharmaceutical industry play in the health and well-being of patients, Carly can offer different perspectives and ideas with her nursing background and pharmacy experiences.

Never having served on a board, Carly did not know what to expect. At first, she found it difficult to navigate the terminology and laws regulating pharmacy. However, with the "assistance and guidance of my fellow Board members as well as my dedication to reviewing and learning all the materials that were presented to me, I have been able to overcome some of the challenges and continue to grow in my knowledge of the pharmacy field." Serving on the Board with the other "dedicated and hardworking professionals" has not only given Carly a renewed appreciation for pharmacists and the hard work that they do, it has also strengthened her commitment to public service. Carly feels that serving the public is a great responsibility, but she also enjoys the in-person meetings and the camaraderie of having lunch with fellow Board members. Now that COVID-19 has changed the meetings to twice monthly virtual events, she misses those interactions, but appreciates the opportunity to stay safely at home.

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Carly's advice to the pharmacy Board's licensees "would be to be mindful at all times that every decision that you make as a pharmacist, intern, or technician has the potential of impacting someone's life in a positive or negative way. As long as it's within your control, always strive for a positive impact. The only way to do that is to keep up with your education, stay abreast of the changing laws and regulations in the field, and exercise due diligence and caution in the work that you do to ensure public safety at all times."

Did You Know?

- Even though e-prescribing is now required, a pharmacist receiving an otherwise valid written or oral prescription may dispense it without having to verify that a waiver has been granted or that an exception applies. Essentially, there has been no change to this aspect of pharmacy practice!
- Paper reminder notices regarding license renewal will no longer be provided. The Board will move to email reminders in 2022, so please keep your email address up to date.

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