November 2019

News

Massachusetts Board of Registration in Pharmacy

Published to promote compliance of pharmacy and drug law

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Scales/Balances

The scales (balances) in pharmacies that are used for pharmaceutical compounding and/or counting medications are very important pieces of equipment in pharmacy practice. As such, all scales used in Massachusetts pharmacies are required to meet stringent requirements for accuracy and performance and must be suitable for the intended pharmacy application. According to the Commonwealth of Massachusetts Division of Standards, scales used in pharmacies must meet Class II designation and have specific values for both readability and sensitivity approved by the National Type Evaluation Program (NTEP). All scales must have an NTEP Certificate of Conformance (CC) number that will be indicated on the scale's identification plate/label, and the corresponding certificate must indicate under the "Application" heading that the scales may be used for a specific purpose (eg, prescription weighing, prescription counting, pharmacy use). The National Conference on Weights and Measures issues an NTEP CC following successful completion of an evaluation of a device, which indicates that the device described in the certificate is capable of meeting all applicable requirements of NIST Handbook 44 and is **"legal for trade."**

The Massachusetts Board of Registration in Pharmacy's proposed regulations at 247 Code of Massachusetts Regulations (CMR) 9.00, Professional Practice Standards, require Board-licensed pharmacies to have a balance capable of accurately weighing quantities as small as 10 mg, which is required to be tested and sealed by the state or local sealer of weights and measures **at least once during each calendar year.** For example, if a pharmacy scale was sealed in January 2019, the seal remains **valid** until December 31, 2020. The weights and measures official will punch the seals for the month and year that the scales were tested and sealed. As a note, seals issued in odd years are always red and white and those issued in even years are always green and white. If a pharmacy has a scale that is due for reinspection and the end of the year is nearing, the municipality (city or town) should be contacted by phone or email 60 to 90 days before the end of the year to request a scale inspection to be performed by the appropriate weights and measures authorities. Scales that do not meet sensitivity and suitability standards or otherwise fail inspection are required to be taken out of service immediately and must not be used for counting medications or compounding until repaired or replaced, then reinspected and placed back into service by the weights and measures official. New or repaired scales cannot be used until they are duly inspected and sealed. Please also note that in accordance with the Board's draft regulations, all new balances purchased by the pharmacy shall have the NTEP CC number on the ID plate/label to indicate that the device is in fact **legal for trade.** Upon inspection of Board-licensed pharmacies, Board inspectors will check to see if a pharmacy's scale has been sealed and is valid for the designated time period.

Finally, with many pharmacies moving from the traditional mechanical torsion balances to digital versions, it is important that these scales be handled carefully and not moved around in the pharmacy. Since they are delicate instruments and can easily lose their accuracy, it is recommended that pharmacies using digital scales purchase a Class I or Class II certified weight and place it on the scale at frequent intervals to verify weighing accuracy. Pharmacies should have a policy and procedure in place for routine scale calibration, cleaning, and maintenance.

PMP Clinical Platform

The Massachusetts Prescription Monitoring Program (PMP) is excited to announce a soon-to-be available new clinical platform named the Visano Opioid Stewardship platform from Appriss Health. Thanks to funding from the Centers for Disease Control and Prevention, Massachusetts will be providing a one-year pilot of Visano. This system is the next generation substance use disorder (SUD)

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

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platform designed to provide a more comprehensive approach to addressing SUD and to help prescribers and pharmacists make better-informed decisions by providing expanded functionality and intelligence within the PMP. This platform will aggregate pharmacy prescription data and present it in a visually interactive format comprised of graphs, additional risk indicators, full prescription details, provider resources, and more.

Visano will be available to all those prescribers and dispensers registered for the Massachusetts Prescription Awareness Tool (MassPAT). It will be accessible via the MassPAT web portal or through an integrated system.

A release date has not yet been finalized, but more information can be found here and additional resources will be available on the MassPAT website in the coming weeks.

Technician Requirements and Duties

Pharmacy technicians (PTs) are individuals who assist in filling prescriptions under the direct supervision of a pharmacist. They fall into one of three categories: PT trainee (PTT), PT, and certified PT. Every technician must be properly licensed in accordance with 247 CMR 8.00 Pharmacy Interns and Technicians, but the requirements and scope of practice for each category vary.

Technicians may not administer medications or vaccines, perform drug utilization review, conduct clinical conflict resolution, contact prescribers concerning therapy clarification or therapy modification, provide patient counseling, or perform final patient dispensing process validation.

Pharmacy Technician Trainees

- Must maintain a valid PTT license from the Board.
- May relay the pharmacist's offer to counsel.
- May not take prescriptions over the phone.
- May assist in the transport of Schedule II controlled substances (CS).
- May not work more than 1,500 hours or more than one year, whichever period is shorter, unless:
  - ◊ the Board grants an extension;
  - ◊ the individual has not yet reached 18 years of age; or
  - ◊ the individual has not yet completed at least 500 hours of employment as a PTT.

Pharmacy Technicians

- Must maintain a valid PT license from the Board.
- May relay the pharmacist's offer to counsel.
- May accept authorization of refills provided that no information has changed from the previous prescription.
- May assist in the transport of Schedule II CS.

Certified Pharmacy Technicians

- Must maintain a valid PT license from the Board, as well as a current certification from a Board-approved certifying body, eg, the Pharmacy Technician Certification Board's Certified Pharmacy Technician (CPhT) program.
- May relay the pharmacist's offer to counsel.
- After identifying himself or herself as a certified PT, may request refill authorizations.
- May receive new or omitted prescription information.
- May perform prescription transfers for Schedule VI CS.
- May assist in the transporting and handling of Schedule II CS.
- If certification lapses, the individual is required to function as a PT until certification is current.

Did You Know?

- Our newest Board member, Richard Lopez, MD, was welcomed at the September 2019 Board meeting.
- Retail pharmacies must report drug losses in accordance with Board policy. View the policy here for a refresher!

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