May 2018

News

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*

Electronic Versus Faxed Prescriptions

Electronic prescriptions for Schedules II–VI are acceptable only if **both** the prescriber and pharmacy computer systems and software meet Drug Enforcement Administration (DEA) verification and authentication requirements. The transmission is considered secure since the data is being electronically exchanged between the prescriber and pharmacy computer systems.

If the prescriber's software converts an electronically signed, computer-generated prescription into a computer-generated fax, this would **not** be considered an electronic prescription. Similarly, electronically generated prescriptions that have been printed are considered "paper-based" and require a manual, handwritten signature.

Regardless of how the script was generated, if it arrives to the pharmacy as a fax, it is subject to the faxed prescription rules.

A pharmacy may accept **faxed prescriptions** for Schedule III-VI medications, provided that the prescription was manually signed prior to faxing. If it was not manually signed, it should be treated as an oral prescription, thereby requiring the pharmacist to verify with the prescriber before dispensing.

As always, traditional paper prescriptions require manual, handwritten signatures.

Please visit the following links for more information:

- *www.mass.gov/eohhs/docs/dph/regs/105cmr721.pdf*
- *https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm#9*
- *https://www.uspharmacist.com/CMSImagesContent/2011/9/Tech-RxT1.gif*

Substance Use Disorder Assistance

A new program is now available for pharmacists, pharmacy interns, and pharmacy technicians afflicted with substance use disorder (SUD) involving alcohol or drugs. The Pharmacy Substance Use Disorder (PSUD) Program was established as a result of a new law that allows the Massachusetts Board of Registration in Pharmacy to establish a voluntary, confidential, non-disciplinary rehabilitation program to assist its licensees.

Individuals in the pharmacy profession and health care in general are at higher risk for an SUD. Studies published in the *Journal of the American Pharmacists Association* in 2017 have estimated that 7-25% of pharmacists are affected by this disorder. Currently, 46 states offer programs for pharmacy licensees, with anecdotal success rates of 80-85%.

The program offered by the Board typically involves a five-year monitoring program coordinated by PSUD Program Supervisor Ed Taglieri, MSM, NHA, RPh, with oversight and direction from the Rehabilitation Evaluation Committee (REC). The program components include: abstinence from controlled substances (CS) and alcohol, random testing, individual treatment, peer support, restricted and/or monitored practice, and regular self-help meetings. Periodic meetings with the REC are also part of the treatment program. Participation in the PSUD Program is confidential and non-disciplinary so long as the licensee complies with the terms of the rehabilitation program. Please note, however, that failure to comply with the requirements of the rehabilitation program may result in disciplinary action (including suspension) against the licensee.

Admissions and referrals can be made voluntarily or as a result of disciplinary concerns resulting from SUD in the workplace. For more information, contact Ed Taglieri at the Board at 617/973-0908 or edmund.taglieri@state.ma.us.

Technician Trainee Licensure

Recently revised regulation 247 Code of Massachusetts Regulation (CMR) 8.03 now **requires all pharmacy technician trainees to be licensed by the Board.** Effective April 6, 2018, no individual may work as a technician trainee without holding a valid pharmacy technician trainee license.

Continued on page 4

National Pharmacy Compliance News

May 2018

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.

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

Continued from page 1

Those technician trainees who are currently employed must have received a Board-approved license by July 6, 2018, in order to continue work in this capacity.

Pharmacy technician trainees hired on or after April 6, 2018, must obtain a pharmacy technician training license before beginning work in a pharmacy.

The application form may be found at *https://www.mass.gov/pharmacy-technician-licensing.* **No application fee is required.**

It is not necessary to receive the physical card before beginning work as a technician trainee.

License status may be verified at the Massachusetts Health Professions License Verification Site.

Waivers

With the recent update to 247 CMR 14.00 Petition for Waiver, waivers now expire five years after original Board approval.

All waivers granted by the Board on or before June 30, 2013, will expire on June 30, 2018. If the waiver continues to be necessary, the pharmacist manager of record must submit an updated waiver request prior to June 30, 2018, for reconsideration.

All waivers granted after June 30, 2013, will expire five years after the date the waiver was initially granted. Without additional approval by the Board, a pharmacy must comply with all Board regulations after the waiver expires.

Waivers may be approved for any length of time up to a maximum of five years.

Petitions for waiver forms may be found at *https://www.mass.gov/how-to/petition-for-a-waiver-of-the-provisions-of-247-cmr.*

All documentation of granted waivers must be readily retrievable during Board inspections.

MPJE Study Materials

As a requirement of state licensure, pharmacists must pass a law exam. Massachusetts participates in the Multistate Pharmacy Jurisprudence Examination® (MPJE®) developed by the National Association of Boards of Pharmacy® (NABP®). The exam consists of 120 multiple-choice questions with a content blueprint that is the same across all participating states. The blueprint, along with a breakdown of competencies, is available in the *NAPLEX/MPJE Application Bulletin* on the NABP website.

All applicants for licensure as pharmacists are advised to review all relevant and current Board regulations and policies, Massachusetts Department of Public Health regulations, and Massachusetts General Laws to prepare for the MPJE. A helpful reference document with related website links is available on the Board's website.

Renovation/Expansion

Pharmacies that are intending to expand or renovate must complete and submit an application prior to the commencement of any work. The application may be found at *https://www.mass.gov/files/documents/2018/02/27/pharmacy-renovation-expansion-request.pdf.*

Compounding pharmacies may complete some minor repairs or service without filing this application. Please review the advisory at the following link to help make this determination: *https://www.mass.gov/files/documents/2018/02/16/repairs-compounding-facilities.pdf.*

Reporting Loss of CS – What Is 'Significant'?

In Massachusetts, all prescription drugs (Schedules II-VI) are categorized as CS. **Policy 2016-02: Requirements and Procedures for Reporting Theft or Loss of Controlled Substances** provides guidelines and procedures for reporting losses or thefts.

The Board follows DEA's definition of **"significant loss"** for all CS, including Schedule VI. DEA explains that there can be no universal measure as to what quantifies a "significant loss." What may be significant to one pharmacy may not be significant to another (eg, a small community pharmacy versus a busy chain pharmacy). DEA provides details at *https://www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0812.htm.*

What to Report to the Board – 'Reportable Losses'

- **All losses of any Scheduled II-VI drugs** must be reported to the Board when the loss is related to **employee pilferage/diversion.**
- **All significant losses of Schedule II-V drugs** due to break-in, lost in transit, customer theft, armed robbery, or other known or unknown losses must be reported to the Board in addition to DEA.
- **All significant losses of Schedule VI drugs** that are required to be reported to the Massachusetts Prescription Awareness Tool (MassPAT), an online tool that is part of the Massachusetts Prescription Monitoring Program, must be reported to the Board when the loss is due to break-in, lost in transit, customer theft, armed robbery, or other known or unknown losses. At this time, gabapentin is the only Schedule VI drug that must be reported to MassPAT.

If a pharmacy has an **unreportable** loss, **document it on site** in the pharmacy (ie, logbook, electronic log) and track for adverse trending. If an adverse trend (eg, three losses of the same drug in a 90-day period) is discovered, report it to the Board.

Sterile Compounding Resources

The Board has several advisories and guidance documents to assist sterile compounders with their responsibilities.

The **Advisory on Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments** provides guidance regarding proper response and remediation of high-efficiency particulate air (HEPA) filter failures in ISO-classified environments. The advisory provides remediation steps and encourages pharmacies to perform risk assessments of the products that were compounded during the time of failure. It also provides guidance on how to proceed with continuation of compounding during the remediation period.

The **Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding** provides guidance and examples of when such facilities may conduct repairs and/or service without having to submit an **Application for Remodeling, Change in Configuration, or Change in Square Footage (Renovation/Expansion).**

Repairs and services that fall outside of the scope of the advisory require submission of an Application for Remodeling, Change in Configuration, or Change in Square Footage (Renovation/Expansion).

The Board advises suspension of compounding activities during and/or after any service or construction until environmental monitoring reports demonstrate levels within acceptable United States Pharmacopeia Chapter <797> levels. As with failed HEPA filters, the pharmacy is responsible for ensuring continuity of care for patients in the event of suspended compounding services and should utilize a risk assessment to determine when it is safe to resume compounding.

If compounding activity is not suspended, the Board advises limited beyond-use dates and not freezing or batching any compounded sterile preparations.

While any service or work is in progress, the facility must have a written strategy to mitigate the effects of the work (eg, excess dust and particulates) and explain how quality assurance will be maintained during the work period. All reports and documentation related to the repair or service event must be maintained in the pharmacy's records and available for Board inspection.

In addition to these advisories, the Board has also provided guidance documents such as **Recommended Pharmacy Response to Above Action Level Environmental Monitoring Results** and **Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results.** These tools can help pharmacies ascertain the root cause of an above action level result as well as how to proceed with a plan to remediate.

Did You Know?

- All pharmacies that compound, including those that only prepare simple nonsterile preparations, must maintain a **defective drug preparation log.** Defective drug preparations are those that demonstrate any out of specification result such as potency, purity, quality, stability, improper composition, contamination, mislabeling, or sterility. Please review the advisory at the following link for details: *https://www.mass.gov/advisory/advisory-on-pharmacy-requirement-to-maintain-defective-drug-preparation-log.*
- You can perform a self-inspection of your pharmacy using the same tools the pharmacy inspectors use. These tools may all be found under "Inspection Templates" at *https://www.mass.gov/lists/pharmacy-practice-resources.*

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