February 2021

News

Massachusetts Board of Registration in Pharmacy

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Vaccination Updates

Revisions have been made to the Massachusetts Board of Registration in Pharmacy's immunization policy in response to the United States Department of Health and Human Services declaration under the Public Readiness and Emergency Preparedness Act (PREP Act). The revised policy allows pharmacists and interns to immunize children as young as three years old. Going forward, immunization training must be Accreditation Council for Pharmacy Education (ACPE) approved. For any pharmacists and interns who may have received non-ACPE-accredited training in the past, it is recommended to only administer vaccines to persons nine years of age and above until ACPE-approved training is completed. Current CPR certification is now also a requirement.

Also, the Board has approved an exciting new policy allowing qualified pharmacy technicians to vaccinate patients during the coronavirus disease 2019 (COVID-19) emergency period. A qualified pharmacy technician is defined as a licensed certified pharmacy technician or a licensed pharmacy technician with at least 500 hours of practice. Qualified pharmacy technicians must also complete an ACPE-approved vaccination administration training course and may administer vaccines that are on the Advisory Committee on Immunization Practices (ACIP) list for persons ages three through 18 years, or as otherwise authorized by the PREP Act.

Technicians may only prepare and administer vaccines and emergency medications for adverse reactions under the direct, on-site supervision of a pharmacist.

Pharmacists, interns, and qualified pharmacy technicians are all authorized to administer any Food and Drug Administration (FDA)-licensed or FDA-authorized COVID-19 vaccines, whether or not they appear on the ACIP list, for patients aged three years and older.

As pharmacies update their vaccine standing orders to include qualified pharmacy technicians, be sure that appropriate epinephrine doses for children under 33 lbs are addressed. Many available epinephrine devices are not suitable for patients under this weight.

COVID-19 Testing

A policy has been issued that provides details for pharmacists and pharmacy interns to order, administer, process, read, and report the results of FDA-authorized COVID-19 tests. It also authorizes qualified pharmacy technicians to administer and process the tests. The document also includes requirements for pharmacies that wish to become participating sites.

Reporting Reminders

Each individual pharmacist manager of record (MOR) must notify the Board in writing (via email) within 10 working days after leaving an MOR position. This will ensure that the Board is aware that the individual is no longer responsible for the pharmacy. The new MOR is responsible for ensuring that the change of manager paperwork is submitted to the Board. The Board must always know who is responsible for each pharmacy.

Naloxone dispensing reports are due annually by January 15. If your pharmacy's information has not yet been reported for 2020, please do so as soon as possible.

Retail pharmacies must report any serious adverse drug event that occurs as a result of a dispensed, compounded preparation (sterile or nonsterile) or an "improper" dispensing of a prescription drug that results in serious injury or death. Notification to the Board must occur within seven business days.

Any Massachusetts-licensed pharmacy that has dispensed a defective sterile or complex nonsterile compounded drug preparation into or from Massachusetts must report the details to the Board within seven days.

Sterile Compounding Environment Contamination Levels

Policy 2019-08: Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results outlines the requirements of a Board-licensed pharmacy in the event of an above action level finding. An above action level environmental monitoring (EM) result is one that exceeds the US Pharmacopeia (USP) Chapter <797> criteria for nonviable, viable, air, and surface contamination. Any EM findings that are not within USP Chapter <797> action limits in an ISO-classified environment must be reported to the Board and properly remediated.

In the event of a significant loss of control in an ISO Class 5 area (eg, hood), a recall of any products within their beyond-use date (BUD) must occur. A significant loss of control is defined by the recovery of >15 CFU after EM. Prescribers must be contacted, adverse event surveillance must be performed, and an infection control professional must be consulted.

To consider resuming sterile compounding during the remediation period, the pharmacy must have assessed the above action

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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.

DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (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 Food and Drug Administration (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.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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level EM results, developed and implemented a remediation plan, and scheduled repeat monitoring.

The risk to any products made during remediation must be considered as well as having an appropriate risk mitigation plan in place.

BUD limitations for all compounded sterile products are required should the pharmacy decide to compound during remediation.

For ISO Class 7 areas, BUDs must be limited to 24 hours room temperature or three days refrigerated.

For ISO Class 8 areas, BUDs must be limited to (a) 24 hours room temperature or three days refrigerated if prepared from any nonsterile starting component(s); or (b) 30 hours room temperature or nine days refrigerated if prepared from only sterile starting component(s).

A contaminated **ISO Class 5 hood** may not be used until remediation is proven by repeat testing.

Getting to Know Your Board Members – Timothy Fensky

This quarter, the Board would like to highlight Timothy D. "Tim" Fensky, RPh, DPh, FACA, who currently holds the sterile compounding seat on the Board.

Tim initially aspired to be a pediatrician, but his interest in chemistry led him to pharmacy at Northeastern University. His jobs as bouncer and bartender did not prepare him for his career, but Northeastern University's pharmacy program placed him at the Jamaica Plain VA Medical Center and Sullivan's Pharmacy and Medical Supply, Inc, to provide him with valuable pharmacy experience as well as his future position.

During his 27 years at Sullivan's Pharmacy, Tim has had the opportunity to develop and oversee pharmacy operations in retail, assisted living, long-term care, hospice, compounding (sterile and nonsterile), and hospital operations at a local institution with a focus on mental health and substance use disorders. He currently holds the chief pharmacy officer position.

Tim has been a part of several professional organizations including the American College of Apothecaries, Massachusetts Independent Pharmacists Association, Massachusetts Pharmacists Association, and the National Association of Boards of Pharmacy® (NABP®). With his experiences of serving as a member of the Massachusetts Board of Registration in Pharmacy, volunteering for various NABP task forces and committees, and serving as a member of the NABP Executive Committee for District 1, Tim had been elected as the 2020-2021 NABP president.

"The experience to be involved with NABP has been amazing. The collaboration with other board of pharmacy members and staff and the relationships I have gained are invaluable. The work done by the member boards and NABP, in collaboration with other associations like ACPE and the American Association of Colleges of Pharmacy, to protect public health has been among the proudest moments of my career.

"If I have any advice for pharmacy students it is to **get involved.** Do not wait for others to shape your profession. Don't just join associations, **get involved** in committees, work groups, or task forces of these associations and voice your thoughts. Lastly, **get involved** with local and federal governing bodies to ensure your voice is heard. Many times, as pharmacists we get engrossed in the clinical aspects of pharmacy and lose sight of who and what is shaping and developing the future of pharmacy."

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 is 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 updated.
- Did not complete your continuing education on time last year? Send an email to self-disclose this to the Board, and the Board will work with you to remediate it.
- Under certain circumstances, Massachusetts General Laws, Chapter 118E, Section 10K allows for a 12-month supply of birth control pills to be dispensed at once. Please contact the patient's insurer for details.
- As a reminder, any remodeling or expansions of Board-licensed pharmacies must have prior approval of the Board. Please use the Board's application found here.
- Board-licensed pharmacies must follow instructions in the Board's policy in order to participate in any research studies.

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