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Wyoming State Board of Pharmacy News

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Notice of Intent to Amend Rules

The Wyoming State Board of Pharmacy proposes to amend Chapter 16: Immunization Regulations of the Wyoming Pharmacy Act (WPA) Rules and Regulations in order to include the coronavirus disease 2019 (COVID-19) vaccines, ease requirements for administering vaccines, and to update the incorporated Centers for Disease Control and Prevention (CDC)-recommended vaccination schedules.

Chapter 16: Immunization Regulations

- Vaccines for COVID-19 are being added to the vaccines that are allowed to be prescribed and administered to healthy adults or healthy minors, or that may be administered by a prescription of a physician to a high-risk adult or high-risk minor.
- The incorporation by reference is being updated to include the current (2021) CDC-recommended vaccine schedules.
- The definition of "private space" and the requirement for individuals receiving vaccinations while seated in a chair with back support is being removed. This is being done to ease the requirements for pharmacists and interns to administer vaccines, which allows patients to receive vaccines in a less restrictive environment.
- The basic life-support requirement is being amended to basic CPR.

Requests for copies of the proposed amendments may be addressed to the Board executive director at 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002. The proposed amended rules and new chapters are posted on the Wyoming Secretary of State website. Comments may be submitted to the Board address above by mail or to bop@wyo.gov on or before April 26, 2021, at 5 PM MDT.

The University of Wyoming School of Pharmacy Is Now an Accredited Provider of Continuing Professional Education

The University of Wyoming School of Pharmacy was accredited by the Accreditation Council for Pharmacy Education as an accredited provider of continuing professional education. The mission of the University of Wyoming School of Pharmacy Continuing Education Group is to develop, conduct, and evaluate educational programs to meet the continuing professional development needs, tools, and resources for pharmacy professionals and pharmacy technicians to better care for the patients and communities they serve. The group will employ a variety of delivery methodologies using both live and distance learning techniques for providing educational content/materials to the targeted audience.

The first course is titled "Pharmacy and Pandemic Preparedness Policies." This program examines the impact of pandemics on society with a focus on pharmacy. A grant from the Wyoming Health and Bioscience Fund is covering registration for all pharmacists and pharmacy technicians who are working in Wyoming. Information on the number of participants who complete the program will be shared with the funding source; however, no personal information will be shared. If you are a pharmacist or technician outside of Wyoming and would like to take this course, there will be a fee of $75 to receive credit.

If you are interested, you may visit *https://pharmacyshare.catalog.instructure.com/courses/pharmacy-and-pandemic-preparedness-policies* to register. Future CE opportunities may be found at *http://www.uwyo.edu/pharmacy/resources/continuing-education.html.*

Collaborative Practice Agreement

By Samantha Coppola, PharmD Candidate

Collaborative practice agreements (CPAs) provide a unique opportunity for pharmacists to work with physicians in caring for certain patients. Pharmacists have long been thought of as only dealing with the medication aspect of patient care. With this agreement, pharmacists can practice outside their usual scope and work directly with the patient in managing chronic disease states. Pharmacists are in the unique position to assist a multidisciplinary team in the treatment and management of chronic disease states (eg, diabetes, hypertension, dyslipidemia) based on their expert knowledge in medication management, as well as their high level of accessibility to the public. CPAs may allow pharmacist prescriptive authority as laid out and agreed upon with the physician. They also give the pharmacist the ability to prioritize more time on the patient to manage chronic disease states more effectively and efficiently. This team-based approach may be particularly beneficial in Wyoming, as residents are more dispersed and access to pharmacists is often greater compared to providers. Services offered within CPAs may include, but are not limited to, initiation and modification of medication therapy.

The WPA Rules Chapter 20 outlines the requirements for CPAs in Wyoming. The Collaborative Practice Advisory Committee is composed of two pharmacists licensed in Wyoming by the Board, one of whom is a current member of the Board; two physicians

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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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licensed by the Wyoming State Board of Medicine; and the Board of Pharmacy executive director. The advisory committee meets two times per year to review CPAs.

It is important to note that in Wyoming, CPAs are not required for Clinical Laboratory Improvement Amendments (CLIA)-waived point-of-care testing. The WPA Rules Chapter 2, Section 4(z)(xi)(B) states that medication therapy management (MTM) services may be performed without a CPA, and includes CLIA-waived laboratory assessments as one of the many services classified under MTM.

The steps for creating a CPA are as follows:

- The physician and the pharmacist create a CPA outlining the terms and conditions about what the pharmacist can and cannot do regarding patient disease management.
- The CPA is submitted to the Board to be reviewed by the committee.
- The committee will either accept or deny the agreement. Denied agreements may contain notes that the physician and pharmacist can review. If denied, they may choose to resubmit a revised agreement for the next committee meeting.
- An approved CPA must be reviewed and renewed annually.

This formal partnership between patient, provider, and pharmacist allows pharmacists to work at the top of their license, within the scope of the agreement, to provide the best possible care to the patient. CPAs can greatly benefit patients with complicated disease states who need more one-on-one attention to maximize treatment and outcomes.

340B Prescription Discount Program and Insulin/Epinephrine Pricing

By Meghan O'Brien, PharmD Candidate

340B is a federal drug discount program first established in 1992 for the purpose of reducing scarce resources and expanding services to vulnerable populations in an outpatient setting. In 2010, the Patient Protection and Affordable Care Act (PPACA) restructured the program to better fit the needs of patients, allowing prescriptions to be filled at contracted pharmacies and increasing care in hospitals. The PPACA also expanded Medicaid eligibility, therefore increasing the registrar pool of other health care practices. Since then, the program has grown with additional services and organizations involved (eg, hospitals, pharmacies, and other health care facilities). A well-managed 340B program can have a significant impact on hospitals and pharmacies, allowing them to receive additional revenue to establish a more profitable business. While companies receive additional revenue, patients experience increased access to resources, services, and drug discounts ranging from 30%-50%. 340B gives patients access to affordable lifesaving medications and care services while helping companies subsidize budgets and/or provide additional services. Recently, epinephrine and insulin are among some of the lifesaving medications that have an executive order with federally qualified health centers (FQHCs) to receive discounted prices in the 340B Drug Discount Program.

The program requires drug manufacturers to offer discounted drugs to wholesalers. Contract pharmacies are then able to purchase the discounted 340B drugs. The Health Resources and Services Administration (HRSA) is a major stakeholder that provides oversight to the program, enforcing contract negotiation and other value-added services. HRSA also regulates entity registration information online annually. Patients are also major stakeholders within the program, and it is essential to understand that "an individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug."

Over the last few years, epinephrine and insulin prices have increased significantly. For example, a pack of two epinephrine auto-injectors (EpiPen 2-Pak®) has an out-of-pocket price of $365.17. Manufacturers have been exceeding the statutory limit when selling covered outpatient drugs to 340B covered entities, which is known as the "340B ceiling price." If a 340B ceiling price is exceeded, then a penny pricing policy mandates the manufacturer to charge covered entities $0.01 per unit. The average manufacturer price minus the unit rebate amount equals the 340B ceiling price. If the 340B ceiling price is zero, then the covered entity is charged $0.01 per unit. When an FQHC purchases these medications at low prices from penny pricing penalties, they do not always sell the medications at low prices for low-income consumers. This provision ensures continued access to discounted prescription drugs.

The 340B Drug Discount Program is an available option for low-income consumers that has been expanding since 1992. It is a beneficial program for health care facilities, pharmacies, and most of all, patients. As the executive order takes effect in the coming years, consumers may experience a change in the cost of epinephrine and insulin.

Best Wishes to Patrick Johnson

The Board would like to thank Patrick Johnson for his hard work and service while at the Board. Patrick joined the office staff as an inspector/compliance officer in March 2019. Patrick has accepted a position as a pharmacist consultant with the Wyoming Department of Health and Wyoming Medicaid. The Board wishes him well in his new position!

Best Wishes to Kristina Carroll

The Board would like to thank Kristina Carroll for her hard work and service while at the Board office. Kristina joined the office staff in July 2019. The Board wishes her well as she pursues her bachelor's degree in wildlife conservation!

Recent Disciplinary Action

C.G., Pharmacy Technician License #T2279: Revocation of license for diversion of controlled substances from employer, tampering with perpetual inventory, and providing false or misleading information to the Board.

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