



North Carolina Board of Pharmacy

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Item 2415 – Southeastern District Board Member Election Under Way

The North Carolina Board of Pharmacy is holding an election to fill the Southeastern District seat. The election period coincides with the licensure renewal period – November 1, 2020 through March 1, 2021. All actively licensed pharmacists who were living in North Carolina as of November 1, 2020, are eligible to vote. Log in through the Board's Licensure Gateway and click on the election tile to cast your vote. **Note:** Voting and license renewal may be done at the same time, or at different times during separate login sessions.

Seven pharmacists from the Southeastern District submitted petitions to appear on the ballot:

- ◆ J. Andrew “Andy” Bowman
- ◆ Wesley Hickman
- ◆ Eric Lee
- ◆ Bronson Lowery
- ◆ Robert “Joey” McLaughlin
- ◆ Justin Sparrow
- ◆ Irving Trust

Candidate biographies are located here: www.ncbop.org/election2020SoutheasternDistrictCandidates.html.

Item 2416 – Board Welcomes Input on Signing FDA's Final MOU Addressing Interstate Distribution of Compounded Human Drug Products

On October 27, 2020, Food and Drug Administration (FDA) published the final version of its “Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration” in the *Federal Register*. State boards of pharmacy have until October 26, 2021, to sign the memorandum of understanding (MOU), after which compounding pharmacies in states that opt not to sign will be subject to the Drug Quality and Security Act's

5% limitation on the interstate distribution of compounded human drugs. A detailed description of the MOU can be found in the [Federal Register notice](#).

In the coming months, the Board will decide whether to sign the MOU. The Board welcomes input from pharmacists and pharmacies on that decision.

Board staff asks that commenters specifically consider the following when providing input:

1. The terms of the MOU are final and were fixed after two rounds of public comment in 2015 and 2018 (the Board provided comments each time). Accordingly, suggestions for changes in the terms of the MOU cannot be acted upon. Please provide input on the MOU as it is written.
2. In Q1 2021, the National Association of Boards of Pharmacy® (NABP®) Information Sharing Network can be used by state boards of pharmacy to satisfy compounding data collection and reporting requirements under the MOU. More information can be found on the NABP [website](#). If the Board signs the MOU, it is strongly considering joining this network.
3. If the Board signs the MOU, to fulfill the requirements that allow compounding pharmacies to distribute more than 5% of their compounded products interstate, it will need to promulgate a rule requiring reporting of compounding data through the network (or any other system the Board selects).

The Board would like to hear any thoughts by February 1, 2021, so that it can make a timely decision. All comments should be submitted via email to mou@ncbop.org.

Item 2417 – HHS Issues Additional Declarations Authorizing Pharmacists to Order and Administer Pediatric Vaccines and COVID-19 Vaccines

As reported in the October 2020 [Newsletter](#), on August 19, 2020, the United States Department of Health and Human Services (HHS) issued a declaration authorizing pharmacists to order and administer, and a supervised pharmacy intern to administer certain vaccines to patients

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National Pharmacy Compliance News

January 2021



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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 vinCRISTine sulfate injection. Importantly, they have removed wording from the vinCRISTine package insert that described direct intravenous (IV) injection of vinCRISTine 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, vinCRISTine 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 vinCRISTine 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 vinCRISTine. 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 vinCRISTine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vinCRISTine 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 2014¹. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vinCRISTine labeling.²

ISMP has frequently referred to wrong route administration of vinCRISTine 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 vinCRISTine 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 vinCRISTine 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 vinCRISTine 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](https://www.fda.gov/biosimilars)
- ◆ [purplebooksearch.fda.gov](https://www.purplebooksearch.fda.gov)
- ◆ [fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act)
- ◆ [fda.gov/media/135340/download](https://www.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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ages three to 18 during the federally declared coronavirus disease 2019 (COVID-19) public health emergency. More detail about that grant of authority and its intersection with North Carolina law is available [here](#).

HHS has since issued two additional declarations. One authorizes pharmacists to order and administer, and a supervised pharmacy intern to administer FDA-approved COVID-19 vaccines, when available, to patients ages three years or older during the federally declared public health emergency. This update describes the conditions under which pharmacists and pharmacy interns may exercise that authority, and how these conditions differ from existing [North Carolina law](#).

The other declaration authorizes “qualified pharmacy technicians” to administer Advisory Committee on Immunization Practices-recommended vaccines to patients ages three to 18 and FDA-approved COVID-19 vaccines to patients ages three years or older under the supervision of a qualified pharmacist. Board guidance on implementing this declaration is located [here](#).

Board staff have received questions about the immunizing pharmacist continuing education (CE) requirements under the federal authorization versus CE requirements under North Carolina law. Under the HHS declarations, the licensed pharmacist must complete a minimum of two hours of Accreditation Council for Pharmacy Education-approved, immunization-related continuing pharmacy education during each state licensing period (annually in North Carolina). This CE requirement differs somewhat from North Carolina law. North Carolina law requires an immunizing pharmacist to maintain “documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration” (North Carolina General Statutes §90-85.3(i)(3)). Any pharmacist exercising authority granted by HHS must slightly

increase his or her immunization-related CE and acquire two hours each year.

Board staff have been asked whether, under the HHS declaration, a qualified pharmacy technician may only administer a vaccine that a qualified pharmacist has ordered. The answer is no. The HHS declaration permits a qualified pharmacy technician to administer these vaccines under the supervision of a qualified pharmacist. The authority is not conditioned on the identity of the health care provider who ordered or prescribed the vaccine. So long as a valid order for the vaccine exists – by way of pharmacist order, physician order, state-authorized standing order, or other legal order – and the qualified technician is supervised by a pharmacist, the technician may administer the vaccine.

Please continue to monitor the Board website – www.ncbop.org – for frequent updates on the COVID-19 vaccination effort.

Item 2418 – DEA Issues Updated Version of Its Pharmacist’s Manual

US Drug Enforcement Administration (DEA) has released a new version of its [Pharmacist’s Manual](#). The manual is an extremely valuable resource for pharmacists. In addition to the new version of the manual, DEA’s Diversion Control Division [website](#) remains a rich resource for information and guidance on the federal Controlled Substances Act.

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