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News

Alabama State Board of Pharmacy

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2020 – A Year in Review

2020 was an unusual and busy year for everyone, particularly those involved in health care. The Alabama State Board of Pharmacy is no exception. In addition to licensing and regulating every individual and entity involved in the chain of custody of prescription medications and devices, the year 2020 presented the Board with several challenges.

While the Board office continued to perform normal and essential functions, the Board was also vigilant and proactive to address the needs of the state during the coronavirus disease 2019 (COVID-19) pandemic.

To address potential exposure, the Board sent out guidance to limit contact for pharmacy staff and patients. This guidance reflected Centers for Disease Control and Prevention information, as well as best practices that were in place in Alabama and other states. The Board shared information on proper compounding of hand sanitizer utilizing United States Pharmacopeia guidelines.

The Board partnered with Drug Enforcement Administration (DEA) to assist pharmacists with questions about emergency guidance issued by DEA. In addition, the Board worked closely with DEA to expedite controlled substance orders, particularly with wholesalers where a previous relationship had not existed, to ensure that medications required for ventilated patients were received by institutions.

The Board worked in conjunction with DEA to aid in facilitation of the spread of inventory between hospitals when supply allowed.

Partnering with the Alabama Board of Medical Examiners, the Board of Pharmacy authored a joint statement to address DEA temporary exceptions regarding the issuance of oral Schedule II prescriptions in light of the nationwide public health emergency. The joint statement detailed DEA's temporary exceptions and the processes and documentation required by pharmacists and physicians to be compliant with DEA guidance.

The Board contacted wholesalers in an effort to increase order size and delivery of needed ventilator medications. The Board communicated with wholesalers to stay abreast of impending shortages, hoping to identify other supply opportunities.

The Board worked with Governor Kay Ivey's office, pursuant to a proclamation, to write emergency rules to provide temporary pharmacist and pharmacy permits to those meeting certain requirements and qualifications.

An emergency rule to allow institutional facilities to dispense metered dose inhalers to aid in respiratory distress was implemented.

In order to prioritize patient care, the Board extended the deadline for the technician training requirement completion to December 31, 2020, or six months from initial registration, whichever was the later date.

During this trying time, the Board worked diligently to provide communication and information for pharmacists, technicians, and pharmacy staff in this state to facilitate the best care for the citizens of Alabama. Communication of these actions is available on the Board website.

The Board continued to perform its usual day-to-day activities while addressing COVID-19 issues. These activities included conducting monthly hearings and Board meetings compliant with COVID-19 protocols and the Open Meeting Act.

In addition, one of the more important actions by the Board is the rulemaking process. In 2020, the Board amended or authored 11 rules, not including six emergency rules related to COVID-19. The 11 changes or additions are:

680-X-2-.04 Prescription Department Technical Equipment

Amended to remove requirements for antiquated equipment.

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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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680-X-2-.08 Pharmacist Consultants of Pharmaceutical Services

Proposed amendment to align consultant requirements with renewal cycle and amend continuing education hours requirements.

680-X-2-.09 Training for Preceptors

Amended to align preceptor requirements with renewal cycle.

680-X-2-.14 The Role of Technicians in Pharmacies in Alabama

Amended to ensure accurate communication of requirements for each renewal cycle and to include background checks for technician reinstatement.

680-X-2-.19 Parenteral Sterile Therapy

Amended to ensure the public's safety by requiring ongoing proficiency of parenteral standards.

680-X-2-.23 Drug Manufacturers; Wholesale Distributors, Repackagers, Third-Party Logistics, 503B Outsource

Amended to add language consistent with federal requirements and provide clarity for new categories and facilities.

680-X-2-.25 Drug Manufacturers; Wholesale Drug Distributors; Private Label Distributors, Repackager, Third Party Logistics, 503B Outsourcer; Reverse Distributor Permit Fees

Amended to correct clerical error and provide clarity.

680-X-2-.37 Continuing Education for Pharmacy Technicians

Amended to update technician continuing education requirement timelines to align with renewal cycle.

680-X-2-.39 Pharmacy Off Site Order Entry

Amended to provide clearer guidelines to ensure public's safety.

680-X-2-.45 Noncontrolled Prescription Requirements

Added to provide clarity of requirements for prescription documents.

680-X-3-.03 Time and Method of Payment; Renewal and Non-Disciplinary Penalty For Late Renewal of Controlled Substances Permit

Amended to allow for non-disciplinary penalty for one late renewal occurrence when in compliance with all other rules.

The Board safeguards the public health by ensuring and regulating the licensing of pharmacy practitioners and entities such as pharmacists, retail pharmacies, institutional/hospital pharmacies, nuclear pharmacies, manufacturers, distributors, and many others totaling over 28,000 licensees. This responsibility entails the oversight of every drug, every individual associated with medications dispensed, and every drug distributor in the state of Alabama, including nonresident entities.

However, that is just a portion of the responsibilities and actions by the Board. By enforcing regulatory compliance, the Board functions as an extension and partner of many different state and federal agencies, including DEA, the Federal Bureau of Investigation, the Alabama Attorney General's Office, the US Office of the Attorney General, the US Postal Inspection Service, Food and Drug Administration (FDA), the Office of Inspector General, other state boards of pharmacy, and state and local law enforcement.

The Board has investigated, charged, and shut down operations involved in hundreds of millions of dollars in health care fraud (including one pharmacy with ties to Russia) and an entity whose operations produced sterile eye injectables that killed one, blinded one, and caused numerous other long-term negative effects.

The Board initiated and/or aided in numerous other fraud investigations that resulted in guilty pleas in federal courts as well as the Board taking appropriate action against the pharmacies involved. The Board has initiated conversations with the Alabama Attorney General and other state law enforcement to identify a means to get these cases addressed in state court so that Alabama may recoup the money so egregiously taken from Alabama residents.

However, these cases only touch the surface of the volume of cases in which the Board investigates. Examples of cases include pharmacists and pharmacies performing compounding and other pharmacy functions that are noncompliant with FDA and state regulations and endanger the public health, violations of the Alabama Pharmacy Practice Act and Controlled Substances Act, and numerous others.

While the Board is charged with regulating the practice of pharmacy and safeguarding the public health for the state of Alabama, it also endeavors to educate and facilitate the safe practice of pharmacy by all practitioners. An update from the executive secretary is available via email monthly. To enroll to receive these updates, select "Monthly Board Updates" from the menu on the left side of the Board website.

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