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Minnesota Board of Pharmacy News

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Board disciplinary actions can be found on the Board's website under the "Resources/FAQs" menu item.

Pharmacy Technicians

Registration

Pharmacy technician registration renewals were due on December 1, 2020. Technicians were then given the month of December as a "grace period." The registrations of technicians who failed to renew by December 31, 2020, have expired. Individuals cannot continue working as technicians if their registrations have expired. Pharmacists-in-charge (PICs) are encouraged to verify that technicians working under their supervision have current registrations. That can be done by using the license verification feature on the Board's website. If an unregistered individual performs duties that require a technician registration, the Board can take disciplinary action against that individual, the PIC, and the pharmacy.

Allowed Duties Clarification

The Board's October 2020 *Newsletter* included the following information: Minnesota Rules 6800.3100 specifically reserves the receipt of verbal orders to pharmacists and pharmacist interns. That includes both new orders and clarification of orders. That rule also reserves verification of the validity and propriety of all prescription drug orders to pharmacists and interns. In addition, the Board considers clarification of orders to require the professional judgment of a pharmacist. Consequently, technicians may not contact long-term care facilities (LTCFs), clinics, or prescribers to clarify nursing home orders or outpatient prescriptions. Technicians can fax a clarification request, but only if a pharmacist or pharmacist intern has prepared the request.

As clarification of the rule, technicians cannot contact LTCFs, clinics, or prescribers to clarify information when the professional judgment of a pharmacist would be necessary. Technicians can clarify information not requiring professional judgment, such as demographic information, obtaining the quantity to be dispensed if quantity was omitted, or confirming the name of the prescriber. For questions that do require the professional judgment of a pharmacist – and when it is appropriate for a fax to be sent for clarification – the technician can prepare the fax, but the pharmacist must review it before it is sent. A technician can also call LTCFs, clinics, or prescribers to leave a message indicating that the pharmacist needs to talk with the prescriber or a nurse about a prescription.

Pharmacist License Renewals

Pharmacists who want to renew their license for the license period that starts on March 1, 2021, may do so at this time. Renewal reminders are emailed out to all licensed pharmacists, and the Board encourages pharmacists to make sure that the email address on their record is one that is currently used. The Board encourages licensees to take advantage of the online renewal option for faster processing.

To renew your license, visit the Board's website and select the "Login to My Account" item from the "How Do I" tab in the upper right-hand corner of the page. This will take you to the sign-in page. Click on the appropriate links and follow the prompts. The renewal screen will also allow you to change your address, update your employment, or change your license status. If you have any questions, you may call the Board during normal business hours for assistance at 651/201-2825, and one of its staff members will assist you.

If you would rather submit a paper renewal, follow the directions in the paragraph above. Use the appropriate links on your account page to make any address and employment

continued on page 4

National Pharmacy Compliance News

January 2021

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.

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.

continued from page 1

changes. Once you have made any necessary changes to your addresses and employment, instead of clicking on "Renewal-In-Progress," click on "Print Pharmacist Renewal Invoice" at the bottom of the page. Print the invoice, sign and date it, and send it to the Board office with your payment. If you do not have an internet connection, contact the Board office at 651/201-2825, and the Board will print a renewal and mail it to you.

The renewal period for pharmacists opened in mid-December, and the deadline for completing the renewal process is **February 1,** not February 28 or 29, as many people mistakenly believe. The month of February is a grace period during which no late fees are assessed for pharmacists who have missed the February 1 deadline. If your completed application and required fee are not received by the Board office prior to March 1, 2021, your license will expire and the late fee will be imposed. You will not be allowed to practice pharmacy in the state of Minnesota until the Board receives the completed application and fees.

MN PMP AWARxE RxManagement Tool

Dispensers (pharmacies) licensed by the Board must report daily all Minnesota Schedule II-V controlled substance (CS), butalbital, and gabapentin prescriptions to the Minnesota Prescription Monitoring Program (MN PMP), when dispensed within or into the state. Pharmacies are required by law to report error-free prescription records. Prescription records that are not error-free must be resolved within seven days of the initial erroneous submission. File Status Reports containing errors are electronically distributed to the pharmacy or its data submitter (eg, software vendor, corporate uploader) based on the pharmacy's prescription monitoring program (PMP) Clearinghouse account. Failure to correct prescription errors within the allowed seven days may result in a referral to the Board's executive director, who may initiate a complaint against the pharmacy.

Within the MN PMP AWARxE system, a new feature, called RxManagement, can be made available to pharmacist account holders for resolving errors in both the PMP Clearinghouse and the AWARxE database. The PIC can request the enablement of RxManagement for himself or herself, and for additional staff pharmacists by visiting *http://bit.ly/RxMgmt* and submitting the request. Access to RxManagement is only made available to pharmacists who are responsible for correcting and maintaining prescription information in the PMP for their employer's Drug Enforcement Administration (DEA) registration. When the pharmacist is no longer responsible for maintaining prescription information in the PMP for said employer, he or she must notify PMP staff to remove the employer's DEA registration from his or her PMP account (an email noting this to minnesota.pmp@state.mn.us will suffice). Please note, access to RxManagement is only made available to pharmacist account holders (not delegates), and pharmacist employment information will be verified against the Board's records. Using this tool may supplement or improve upon the pharmacy's existing process for error resolution.

DEA Publishes Updated Pharmacist's Manual

The Diversion Control Division of United States DEA recently published an updated version of *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act.* This is an important and useful resource for pharmacists and pharmacies. With few exceptions, Minnesota CS statutes and rules either defer to federal statutes and regulations or are written in a manner that closely follows the federal language.

Many significant changes have been made to federal CS statutes, regulations, and policies since the *Pharmacist's Manual* was last updated in 2010. The Board has provided information about those changes in its *Newsletter,* and in frequently asked questions on its FAQ page. However, the publication of the new edition of the *Pharmacist's Manual* is a good opportunity for pharmacists to review those changes. A review of the *Pharmacist's Manual* would also benefit pharmacist licensure applicants who need to pass the Multistate Pharmacy Jurisprudence Examination®.

Revised MPCA Guidance for Pharmaceutical Waste

To ensure safe management of pharmaceutical wastes from the health care industry while reducing unnecessary regulatory burdens, the Minnesota Pollution Control Agency (MPCA) has revised its guidance for annual reporting and on-site documentation of wastes managed through pharmaceutical reverse distribution. A summary of major recent and upcoming changes to pharmaceutical waste management in Minnesota, including these revisions to reverse distribution expectations, may be found in the updated MPCA fact sheet "Changes in pharmaceutical waste management," available on the MPCA website by visiting *www.pca.state.mn.us/sites/default/files/w-hw3-33.pdf.*

More detailed discussion of specific pharmaceutical reverse distribution requirements may be found in the updated MPCA fact sheet "Pharmaceutical reverse distribution," available on the MPCA website by visiting *www.pca.state.mn.us/sites/default/files/w-hw3-36b.pdf.*

Medication Repository

The Board has selected RoundtableRx to be the vendor that will administer the Minnesota Medication Repository Program, through which certain donors may donate a drug or medical supply for use by an individual who meets the eligibility criteria specified in Minnesota Statutes §151.555. Currently, RoundtableRx has a facility that is licensed as a drug wholesaler and that can accept donations. It will be working to establish a network of local repositories at which donated drugs will be dispensed to eligible patients. Additional information can be found on the RoundtableRx website at *www.roundtablerx.org* and on the Board's website.

Independent Pharmacist Prescribing by Protocol

Pharmacists are now able to independently prescribe self-administered hormonal contraceptives, nicotine replacement medications, and opiate antagonists, provided they:

- ♦ follow a protocol developed by the Board in consultation with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses;
- ♦ complete appropriate training programs and continuing education; and
- ♦ provide appropriate counseling to patients.

The protocols are available on the Board's website and contain all of the information that pharmacists will need to prescribe these medications. When issuing prescriptions using the Board's protocols, the pharmacist is considered to be the prescriber of record.

Note that pharmacists can also continue to issue legally valid prescriptions issued under existing protocols that they have in place with licensed practitioners – provided the protocol allows the pharmacist to prepare a legally valid prescription. However, for prescriptions issued under those protocols, the practitioner is considered to be the prescriber of record.

Generic Substitution

In Minnesota, pharmacists are not limited in their substitution decisions by the ratings of drugs in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the"Orange Book"). Under Minnesota Statutes §151.21, pharmacists may substitute – and in most cases are required to substitute – any generically equivalent product, which, in the professional judgment of the pharmacist, is therapeutically equivalent to the brand-name product prescribed. No reference is made to "Orange Book" classifications in Minnesota law.

Minnesota law does not require products to be of the same dosage form in order to be substitutable so long as the products are generically equivalent and, in the professional judgment of the pharmacist, the products are also therapeutically equivalent. For example, it is permissible to substitute a capsule for a tablet as long as both dosage forms contain the same active ingredient – and, in the pharmacist's professional judgment, both dosage forms will produce the same therapeutic effect for the patient. A pharmacist does not need to contact the prescriber to make such changes. If a pharmacist needs more information before making a substitution decision, the pharmacist might want to consult the "Orange Book," even though there is no legal requirement to do so.

Pharmacists should not make generic substitutions for high-risk drugs, such as warfarin, without discussing the change with the prescriber. For high-risk drugs, it is critical that the pharmacist, prescriber, and patient all understand any changes that are made.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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