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News

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No. 1362 Happy New Year and Thanks From the Commission

The Washington State Pharmacy Quality Assurance Commission wishes everyone a happy new year. The Commission thanks you all for your hard work and contributions in responding to the coronavirus disease 2019 pandemic, and in providing the highest quality of care for patients.

No. 1363 Pharmacist Suicide Prevention Survey

The Commission recently completed a report to the Washington State Legislature on suicide prevention and awareness training for pharmacists.

The 2019 Washington State Legislature directed the Commission through a budget proviso in Engrossed Substitute House Bill 1109(221)(29)(b) to collaborate with the Safer Homes Task Force to develop and conduct a survey of all Washington State-licensed pharmacists on suicide awareness and prevention training. The survey, which included responses from 2,144 licensed pharmacists, assessed if and how pharmacists use suicide prevention training. The report's goal is to identify barriers preventing pharmacists from placing their training into practice.

The survey results showed that a high percentage of pharmacists had taken the training, with nearly one in four pharmacists reporting that they had been able to use the training in their practice. Pharmacists who were able to use the training indicated that they recognized the signs of suicidal behavior in a patient or colleague and were able to help them through the crisis or refer them for professional assistance. For those who were unable to use the training, the most common reasons included time constraints, limited or no contact, and lack of resources.

No. 1364 New Guidance: Access to Drugs Stored Outside of the Pharmacy

At the December 3, 2020 business meeting, the Commission provided guidance on Washington Administrative Code (WAC) 246-945-455 Drugs stored outside of the pharmacy.

The Commission will begin a review of WAC 246-945-455, specifically the requirement in WAC 246-945-455(1)(c) that drugs stored outside the pharmacy may be accessed only by health care professionals licensed under the chapters specified in Revised Code of Washington 18.130.040 acting within their scope, and by nursing students.

The Commission has been informed of potential unintended disruption to the drug supply chain within health care facilities by requiring that only licensed health care professionals may access drugs stored outside the pharmacy. Historical practices have permitted unlicensed employees of health care facilities to access certain drug products for supply chain management needs. To avoid continued disruption, the Commission is providing this guidance document to ensure continuous patient care.

No. 1365 Frequently Asked Questions

Policies and Procedures – Revised October 16, 2020

Q. Are policies and procedures required under the new rules?

A. Yes. Please review Chapter 246-945 WAC to see which policies and procedures apply to your facility.

Q. Which facilities need to have policies and procedures in place and for what?

A. The new chapter (Chapter 246-945 WAC) went into effect on July 1, 2020. The overall goals of this chapter rewrite were to streamline and update the rules that regulate the practice of pharmacy while making them less prescriptive. The new rules rely much more on the professional judgment of the pharmacist or

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National Pharmacy Compliance News

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NABPF
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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 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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facility manager. This leads to a stronger reliance on creating and implementing policies and procedures in all facilities.

For example, WAC 246-945-410(6) states that all facilities must create and implement policies and procedures related to "Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances [(CS)]."

Pharmacy inspectors will emphasize relevant policies and procedures during inspections. Additional guidelines are provided on the self-inspection worksheets, and a breakdown of required policies and procedures can be found here.

Pharmacy Closure Notices

Q. What new changes have been made concerning notifying the Commission when a facility permanently closes?

A. Pharmacies are required to notify the Commission of a permanent closure no later than 30 calendar days before the anticipated permanent closure date (WAC 246-945-480(2)(a)). This is different from the previous rule, which required pharmacies to notify the Commission no later than 15 days before the anticipated date of closing (WAC 246-869-250(1)). Pharmacies should review and follow all reporting requirements contained in WAC 246-945-480 when permanently closing a pharmacy.

Prescription Adaptation and Dosage Form

Q. What does "change dosage form" refer to in WAC 246-945-335?

A. A change in dosage form refers to a change in a conventional finished dosage form, such as a tablet, capsule, solution, suppository, or sublingual. WAC 246-945-335 authorizes pharmacists the option to adapt the prescription to another finished dosage form in the best interest of the patient. Changing the drug products outside of the conventional dosage forms (eg, salts) would fall outside the interpretation and intention of this provision.

Pharmacies Without a Pharmacist On Site and Drugs Outside of a Pharmacy

Q. What rules apply to pharmacies storing, dispensing, and delivering drugs to patients without a pharmacist on site?

A. In addition to the generally applicable pharmacy laws and rules that apply to pharmacies, WAC 246-945-430 contains specific requirements for pharmacists storing, dispensing, and delivering drugs to patients without a pharmacist on site. Further, WAC 246-945-420(4) requires pharmacies that exclusively store, dispense, or deliver drugs to patients without a pharmacist on site to maintain a perpetual inventory.

While the Commission does not evaluate an individual pharmacy's model, examples of such situations that would require compliance with WAC 246-945-430 and WAC 246-945-420(4) include, but are not limited to, pharmacies that dispense and deliver medications via a pharmacy technician without a pharmacist physically on site, or pharmacies that dispense and deliver medications via technological means without pharmacy personnel physically on site.

Q. May a pharmacist supervise ancillary personnel or interns remotely?

A. Yes, but pharmacists should ensure that ancillary personnel or interns are supervised in a manner that meets the Commission's definition of "immediate supervision." Immediate supervision is defined in WAC 246-945-001(44). This includes the ability of pharmacists to employ technological means for supervision of ancillary personnel or interns remotely. Pharmacists are encouraged to review WAC 246-945-001(44) in its entirety when remotely supervising ancillary personnel or interns.

Q. How does a pharmacy register a remote dispensing site for storage and dispensing of medications approved by Food and Drug Administration for treatment of opioid use disorder?

A. Pharmacies interested in registering a remote dispensing site should review the Commission's policy statement (Regulatory Standards Applicable to Remote Dispensing Sites – Opioid Use Disorder) and application form.

Q. Do licensed health care entities with medications stored on site that are supplied by and remain under the control of a pharmacy have to comply with WAC 246-945-455?

A. Yes

Prescription Transfers

Q. What is a prescription transfer?

A. A prescription transfer is a transfer of a prescription between pharmacies. The Commission requirements addressing prescription transfers are found in WAC 246-945-345.

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Q. Do all prescription transfers need to be transferred by electronic means?

A. All **prescription** transfers for non-controlled drugs need to be transferred by electronic means, including facsimile, except in emergencies. Controlled drug prescription transfers must conform to Title 21 Code of Federal Regulations §1306.25.

Q. What qualifies as an emergent situation as it relates to non-controlled prescription transfers in WAC 246-945-345(5)?

A. Whether a situation is "emergent" should depend on the pharmacist's professional judgment and the patient's best interest. The Commission encourages pharmacists to contact their pharmacist inspector with questions about specific situations. While not a requirement, the Commission does consider it a best practice to document the decision to transfer a prescription verbally.

Q. How does the Commission define "verbal prescription" in WAC 246-945-320(1)(a)?

A. At the August 27, 2020 Commission meeting, the Commission stated that the term "verbal prescription" used in WAC 246-945-320(1)(a) is synonymous with the term "oral prescription" used elsewhere in Chapter 246-945 WAC. WAC 246-945-010(7) and WAC 246-945-010(8) state that an "oral prescription . . . must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."

Q. May transferring a prescription by electronic means be delegated to a pharmacy technician?

A. Yes, a pharmacy technician may transfer a non-controlled prescription by electronic means (including facsimile) under the immediate supervision of a pharmacist. The Commission considers the function of transferring a non-controlled prescription by electronic means (including facsimile) to be a non-discretionary function associated with the practice of pharmacy that is delegable to a pharmacy technician pursuant to WAC 246-945-315. The Commission understands that this is a change from the previous rules but acknowledges the direction of the new WAC chapter in adapting to the future advancement in pharmacy practice and patient care services. However, the verbal (or oral) prescriptions transfer to another pharmacy may not be delegated to a pharmacy technician. Further, pharmacy technicians are not permitted at any time to transfer verbal or nonverbal CS prescriptions, according to Drug Enforcement Administration (DEA) and the Commission's rules.

These frequently asked questions and others are posted on the Commission's website. Please direct any questions via email to PharmacyRules@doh.wa.gov.

No. 1366 Fraudulent Schemes Targeting Medical Providers

Warning to Health Care Professionals With Washington Licenses

Beware of scammers falsely claiming to represent the Washington State Department of Health (DOH) – and do not send money to anyone without being certain of the recipient's identity.

This comes in the wake of at least two apparent attempts to defraud Washington providers. One attempt failed, but the other proved costly to a dentist.

In that case, the dentist received a call from someone spoofing the DOH's telephone number, along with two bogus faxes. One fax claimed to be from the DOH. The other claimed to be from the United States Department of Justice. The scammer went to the trouble of copying and using actual logos from both agencies.

The fake DOH fax falsely stated that the dentist's license was suspended. In a misguided attempt to resolve that issue, the dentist wired more than $40,000 to an account in Warsaw, Poland – an account that has nothing to do with the DOH.

In the second case, a licensed pharmacist reported receiving phone calls from a DOH number. The calls, however, did not come from the agency. The pharmacist reported being told that her license is under investigation, which it is not. After being asked questions to which the pharmacist knew the DOH would already have the answers, she hung up. Nevertheless, the same person called back multiple times and left voice mails.

The DOH will never ask providers to wire money to save a license. If any issues arise potentially affecting a health care professional's Washington license, that person will receive written communication via mail and/or via email from an investigator at a verifiable DOH email address. That investigator would also provide a DOH phone number to contact him or her with questions.

No. 1367 Suspicious Orders – Pharmaceutical Wholesalers

The Commission provided new guidance on WAC 246-945-585 Wholesaler—Suspicious orders and due diligence.

Suspicious Order Reports

At the October 1, 2020 meeting, the Commission stated that it will not find licensees deficient or take enforcement

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action against the licensees for failure to comply with WAC 246-945-585(1)(a) **through March 30, 2021.** Wholesalers should submit suspicious order reports to PharmacyRules@doh.wa.gov. Reports are accepted in any readable electronic format (eg, email, Excel attachment), but must include **all** information required in WAC 246-945-585(1)(a)(i)-(ix), as shown below:

(i) Customer name;
(ii) Customer address;
(iii) Customer DEA registration number;
(iv) State license number(s);
(v) Transaction date;
(vi) Drug name;
(vii) NDC number;
(viii) Quantity ordered; and
(ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.

Please send reports with the following subject line nomenclature: Date_CompanyName_SuspiciousOrder Reporting_WAstate.

All wholesaler licensees shall follow WAC 246-945-585(2) through WAC 246-945-585(4) when identifying suspicious orders. Licensees may report using the DEA Automation of Reports and Consolidated Orders System format, but it is not required.

Zero Reports

At the October 1, 2020 meeting, the Commission stated that it would not find licensees deficient or take enforcement action against its licensees for failure to submit zero reports when no suspicious orders have been identified, as required in WAC 246-945-585(1)(b), through **March 30, 2021.**

Exemption From Reporting

The Commission also determined that it would not find licensees deficient or take enforcement action against licensees for failing to comply with WAC 246-945-585(1)(c). This position will remain in effect until the Commission withdraws it at a future business meeting. An exemption application is in development and will be made available for wholesalers that do not distribute CS or drugs of concern upon completion.

Potential Diversion Reports

Finally, the Commission determined that WAC 246-945-585(5), which requires wholesalers to report any customer that is believed to be engaged in potential diversion activity, **is effective as of October 1, 2020.** These reports must be submitted to PharmacyRules@doh.wa.gov **within 30 days** of refusal, cessation, or identification, and must include all information required by WAC 246-945-585(5)(a)-(f):

(a) Customer name;
(b) Customer address;
(c) DEA number;
(d) State license number(s);
(e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk; and
(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.

Please send reports with the following subject line nomenclature: Date_CompanyName_CustomerOrder Reporting_WAstate

Please contact the Commission with any questions at PharmacyRules@doh.wa.gov.

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Lauren Lyles-Stolz, PharmD - State News Editor
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