



Washington State Pharmacy Quality Assurance Commission

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No. 1215 Washington Immunization Information System

The Washington State Immunization Information System (IIS) is a statewide, web-based system that includes immunization records for more than 8 million people of all ages. About 42 different pharmacy organizations and more than 400 pharmacy sites participate in the IIS. Some pharmacies use the IIS only to look up immunization records for their clients, but others manually enter or have data exchanges between their electronic systems and the IIS.

The IIS offers tools that benefit pharmacists in many different ways. Pharmacists can use the IIS to:

- ◆ Access a more complete immunization record for their clients.
- ◆ Share records with other health care providers.
- ◆ Provide printed immunization records to clients.
- ◆ Identify which immunizations are due or overdue. The IIS immunization forecast is programmed to match the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended immunization schedules.
- ◆ Manage vaccine inventory and identify soon-to-expire vaccines.
- ◆ Run reminder/recall reports to identify clients who are due or overdue for immunizations, and access several tools to help pharmacies contact those patients.

How to Sign Up?

If your organization does not already participate in the IIS, you will need to complete an IIS information sharing agreement and an account application. You can find these forms at https://fortress.wa.gov/doh/cpir/iweb/main_d.jsp#CI. If your pharmacy is under a larger organization that is already using the IIS, contact the help desk at 1-800/325-5599 or waiishelpdesk@doh.wa.gov to add your pharmacy as a new facility and set up user accounts.

Training Materials and Opportunities

If you are interested in scheduling training, please email iis.training@doh.wa.gov. You can also find training materials at https://fortress.wa.gov/doh/cpir/iweb/main_t.jsp. You can subscribe to the monthly Washington IIS newsletter from this [link](#).

No. 1216 Tell Your Story

The Washington State Pharmacy Quality Assurance Commission distributes a quarterly *Newsletter* in collaboration with the National Association of Board of Pharmacy®. The *Newsletter's* intent is to provide information promoting compliance with state laws and rules.

This year, the Commission would like you to tell your story; share your successes in improving your patients' health and safety or in addressing challenges you have faced. Please consider submitting an article or commentary that can help us work together to continue to move pharmacy into the 21st century.

No. 1217 Commission's Rules in Progress

The Commission has reset priorities for its rulemaking agenda. The Commission has taken this action in response to requests from stakeholders, as well as to focus resources on the most urgent rules that need updating.

The Commission has established two committees to make recommendations for modernizing the [pharmacy inspection rules and procedures](#) and on pharmacy technology related to [automated drug dispensing devices](#) and [remote medication order entry](#).

Additionally, the Commission has decided to place on hold rules for sterile compounding and to pull back the second working draft of compounding rules until it receives clarity on the new United States Pharmacopeia (USP) Chapter <797> and which criteria will change. Once that has been established, the Commission will re-engage in the sterile compounding rulemaking. In the meantime,

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been

FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each



vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public

when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at www.fda.gov/Drugs/DrugSafety/ucm458952.htm.

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at www.fda.gov/Safety/Recalls/ucm461939.htm.

the Commission will work with its stakeholders to provide interim guidance to pharmacists. The Pharmacy Inspection Rules Committee will seek stakeholder input in developing a tool for pharmacists and pharmacy investigators to use to assess compliance with USP <797>, in accordance with [RCW 18.64.270\(2\)](#).

The Business Practices Committee is being placed on hold so the Commission may focus its resources on two top priority rules packages. When work is complete on the priority rules, the Commission will reassess its rulemaking priorities.

All stakeholders are invited to actively engage in this work with the Commission; your input is important. If you are not currently involved in a stakeholders group, the Commission encourages your participation. Please send emails to:

- ◆ Pharmacy Inspection Rules Committee: pharmacyinspectionrules@doh.wa.gov
- ◆ Sterile Compounding Tool: sterilecompoundingrules@doh.wa.gov
- ◆ Pharmacy Technology Committee: technologyrules@doh.wa.gov

No. 1218 Important Dates – 2016 Commission Meeting Schedule

The Commission has the following regularly scheduled business meetings for 2016:

- ◆ January 21, 2016 – Seattle, WA
- ◆ March 3, 2016 – Des Moines, WA
- ◆ April 14, 2016 – Tumwater, WA
- ◆ May 26, 2016 – Grays Harbor County – To be determined
- ◆ July 7, 2016 – Tumwater
- ◆ August 18, 2016 – Renton, WA
- ◆ September 29, 2016 – Chelan County – To be determined
- ◆ November 10, 2016 – Des Moines

In an effort to become more transparent, the Commission will make meeting documents available on its meeting web page. Documents prepared and submitted for the Commission's consideration at regular business meetings will be available for public viewing one week before the meeting.

Visit the Commission's [meeting web page](#) for specific location and other meeting information.

No. 1219 Election of Commission Officers

Tim Lynch, MS, PharmD, was elected as chair, and Nancy Hecox, PharmD, CDP, was elected as vice chair when the Commission met on December 11, 2015.

Governor Jay Inslee appointed Tim and Nancy to the Commission on November 11, 2014. Tim is the associate vice president of pharmacy services for CHI Franciscan Health of Tacoma, WA. He has served on the Commission's

workgroup to develop the process used for collaborative drug therapy agreements, and chairs the Pharmacy Inspection Rules Committee. Tim has been a Washington-licensed pharmacist since 1997, and received the Washington State Pharmacist of the Year award in 2010.

Nancy has worked in retail pharmacy at independent and chain drugstores, and has taught pharmacology at Pacific Northwest University of Health Sciences College of Osteopathic Medicine. She holds a chemical dependency counselor credential, and she helped start the Washington Recovery Assistance Program for Pharmacy. In 2015, the Immunization Action Coalition of Washington (IACW) presented her with the IACW Collaborator Award for her impact in promoting, educating, and increasing immunization rates in her community.

No. 1220 Farewell, Albert Linggi

In 2008, then-Governor Christine Gregoire appointed Al Linggi to serve on the Washington State Board of Pharmacy. He returned to public service as an appointee of Governor Inslee in 2014 to the newly formed Washington State Pharmacy Quality Assurance Commission. The Commission has grown under his leadership and his knowledge of all things pharmacy, especially technology. Al, thank you for your dedication and service to the people of this state, and internationally through Doctors Without Borders.

No. 1221 Welcome New Employee Rich Cieslinski

The Commission welcomes Rich Cieslinski as its rules coordinator. Rich worked for the Arizona State Board of Pharmacy for more than 10 years before relocating to Washington State in 2013. Rich's experience as a practicing pharmacist will be an asset to the Commission as it works to update its rules.

No. 1222 Pharmacy Customer Satisfaction Survey

The Commission wants to hear from you. The Commission encourages feedback from license holders regarding the pharmacy license inspection process. The Commission has recently added a link to its website that allows you to complete the [Customer Satisfaction Survey](#) online. The survey is voluntary and anonymous. If you would prefer to speak with the Commission in person, there is an option on the survey to request a phone call.

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