No. 1238 Rules Update: Where Are We?

The Washington State Pharmacy Quality Assurance Commission continues to make progress on its rulemaking workload. Some of the progress made is reflected in the following updates.

♦ Hospital Pharmacy Associated Clinics: Emergency rules were adopted to set standards for licensing clinics associated with a hospital pharmacy license. The emergency rule went into effect on September 8, 2016. Licensed hospital pharmacies may use the addendum application on the Commission website to add associated clinics to their license or to report changes to associated clinics. The fees assessed when adding associated clinics are based on the category or type of pharmacy services performed at the clinic and on the number of clinics associated with the hospital pharmacy license. The emergency rules will stay in effect without lapse until the Commission adopts permanent rules. The first stakeholder meeting to discuss permanent rules is being planned.

♦ Pharmacy Inspection Process: The Commission had tasked the inspections subcommittee to write draft rules to change the inspection process from a point-based system to a process based on a notice of deficiency/plan of correction model. The subcommittee recently discussed a preliminary draft rule and self-inspection forms. A second meeting is scheduled for November 7.

♦ Pharmacy Technology: The Commission held a rules hearing on August 31 to consider proposed language for standards in the use of automated drug dispensing devices. The Commission suggested substantive changes to definitions and the use of prospective drug use review. The Commission reopened the rule for further stakeholder work. A supplemental rule filing was processed, and the proposed language was reapproved on September 29, 2016. A public hearing is tentatively scheduled for January 5, 2017.

♦ Continuity of Care Refills in Proclaimed Emergencies: The Commission held a public hearing to adopt rules that provide patients’ access to medications during a governor-proclaimed emergency. The Commission made substantive changes at the public hearing held on September 29, 2016, before adopting the rule. Language was added to the permanent rule to allow pharmacists to provide “maintenance medications” to patients who present to pharmacies with no refills or who have expired prescriptions. The emergency rule previously adopted on this subject is under its fourth revision and will remain in force until the permanent rule goes into effect.

♦ Sexual Misconduct Rules: The Commission adopted rules on September 29 updating the definition of sexual misconduct. The definition will include a forcible or nonconsensual act with a person, as well as convictions for sex offenses defined in RCW 9.94A.030. The rule language is consistent with amendments adopted by the secretary of health and other profession boards and commissions. The changes are necessary to aid in investigations and in pursuing allegations of sexual misconduct.

♦ Emergency Outpatient Medication: The Commission has filed proposed rules to amend Washington Administrative Code (WAC) 246-873-060, Emergency outpatient medications, to align the rule with RCW 70.41.480, Authority to prescribe prepackaged emergency medications. Updating the rule will improve public health by removing barriers and will help facilitate patient access to discharge medications when pharmacy services are not available. A public hearing is scheduled for November 10. The Commission is accepting written public comments on the proposed rule until October 31, 2016.

Rules adopted by the Commission are filed with the Office of the Code Reviser and are published in the Washington State Register. Unless otherwise indicated, rules are effective 31 days after filing. Please see the Rules in Progress web page for updates on these and other rule writing projects, and join the interested parties list to receive updates.

No. 1239 Changing Look of Approved Tamper-Resistant Prescription Paper or Pads

Since July 2010, all prescriptions written in Washington State must be on security paper approved by the Commission (formerly known as the Washington State Board of Pharmacy). Approved paper must meet the three security characteristics in law and must be affixed with the Commission’s “seal of approval.” The seal of approval, with its distinctive heat-activated thermochromic ink that changes from green to yellow on prescription paper manufactured with security features, is recognized by pharmacists statewide. However, the look of approved tamper-resistant prescription paper and pads is changing.

Recently, the Commission approved a printing solution that adds industry-recognized security features to plain paper.
Improper and Unsafe Vaccine Storage

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.

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP’s March 26, 2015 newsletter1 contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.2

References

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System’s 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:
(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®, MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. Additional details are available on FDA’s website at www.fda.gov/Safety/Recalls/ucm497812.htm.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with Burkholderia cepacia, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of B. cepacia infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.
vendor demonstrated that its printing solution was capable of producing features to meet each of the three characteristics: preventing unauthorized copying, erasure or modification, and counterfeit forms. However, the plain paper printing solution could not reproduce the current seal in thermochromic ink. In addition, the current seal of approval references the approving authority as the “Board of Pharmacy.” As a result, the seal of approval will undergo a facelift. Over the next several months, the Commission will develop and roll out several communications to stakeholders, including pharmacists and prescribers, to acquaint them with the coming changes. The communication is intended to prepare providers for the new look of prescriptions in Washington State. The approval to use plain paper printing solutions and the new look of the seal of approval will be delayed until March 1, 2017, to ensure providers are well informed and to lessen any uncertainty. The final design will be revealed later. Suppliers and prescribers will be permitted to continue to use forms or paper with the old seal until the inventory is depleted.

Reminder, all vendors must have their tamper-resistant prescription pads, paper, or printing solutions approved by the Commission before marketing or sale in Washington State.

No. 1240 Commission Rule Review Project

RCW 43.70.041 requires the Commission to review all its rules every five years. The goals are to simplify the rules; decrease the time required for obtaining licenses, permits, and inspections; and, wherever possible, reduce the regulatory burden on businesses without compromising public health and safety.

The Commission has 31 chapters of WAC to review by June 30, 2018.

The Commission plans to include time in its business meeting agendas in 2017 for the rule review project. Each meeting notice and agenda will include a set of rules or a rule chapter selected for review at the meeting. The Commission will invite stakeholders to send in their feedback on the selected rules related to specific questions associated with the review project. The Commission will consider stakeholder comments received during its review of the rules.

Later, the Commission will prioritize rules identified for revisions.

No. 1241 Welcome New Commission Staff Member, Angelica Pauley

The Commission is excited to announce that Dr Angelica Pauley joined the Commission as the new pharmacist consultant beginning September 16. Angelica received her bachelor of pharmacy degree from the University of Panama and joined the United States Army shortly thereafter. While stationed in Germany, Angelica enrolled in the University of Washington external doctor of pharmacy program. Returning to the US, she completed her clinical rotations and obtained her doctor of pharmacy degree. She worked in long-term care before returning to Madigan Army Medical Center. Angelica has received numerous awards while in the US Army.

She is an active member of the American Society of Consultant Pharmacists and is preparing to become a certified geriatric pharmacist.

The Commission is confident that she will be an asset to carrying out the Commission’s mission and vision.

The Washington State Pharmacy Quality Assurance Commission News is published by the Washington State Pharmacy Quality Assurance Commission 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.

No. 1242 Save the Dates 2017

Mark your calendar with the following dates for Commission meetings:

- January 5 – King County – Seattle, WA
- February 16 – Des Moines, WA
- March 30 – Thurston County – Location to be determined
- May 11 – Des Moines
- June 22 – Yakima County – Location to be determined
- August 3 – King County – Location to be determined
- September 14 – Spokane County – Location to be determined
- October 26 – Des Moines
- December 14 – King County – Location to be determined

Commission meetings are open to the public. Pharmacists and technicians may earn up to three contact hours of continuing education (CE) (0.3 CEUs) toward CE requirements for license/certification renewal at attending a business meeting. While meetings have a formal structure, there are opportunities at the meeting for the public to address the Commission.

Unless otherwise communicated, Commission meetings start at 9 AM. Please verify the location address on the Commission’s web page before planning to attend. In addition, you may subscribe to the interested parties list to receive notice of upcoming business meetings, agendas, and meeting minutes.

No. 1243 Recognition of 50 Years of Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. Thank you for your dedication to your profession and practice of pharmacy.

The Washington State Pharmacy Association awarded certificates of service on October 8, 2016, at its annual meeting.

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