No. 1233 Legislation – 2016 Rollup

The 2016 legislative session was another busy one for pharmacy-related bills. While this was a short 60-day session, a 30-day special session followed. The sessions resulted in the following changes that affect pharmacy. As the following are short descriptions, visit the Find Bills section of the Washington State Legislature website at www.leg.wa.gov for more information. If you insert the bill number you can see the entire language that passed. For the laws that require rulemaking, visit the Washington State Pharmacy Quality Assurance Commission’s website for information on how to participate. The Commission encourages participation by the regulated community and public.

♦ House Bill (HB) 6421 – Epinephrine Autoinjectors.
  Allows an authorized health care provider to prescribe epinephrine autoinjectors to an authorized entity. An authorized entity may include restaurants, youth sports leagues, or others. The Washington State Department of Health must develop a form for tracking incidents using epinephrine autoinjectors and annually publish a report from these findings. This bill became effective June 9, 2016.

♦ Senate Bill (SB) 6238 – Prescribing Non-Narcotic Schedule II Controlled Substances (CS).
  This bill amends RCW 69.50.402 and allows prescribing of a non-narcotic Schedule II CS for any disease state or condition approved by Food and Drug Administration, not only those listed in the current law. This bill became effective June 9, 2016.

♦ Engrossed Substitute HB 2458 – Concerning Prescription Donation Program.
  This bill allows a patient or representative to donate certain prescriptions and supplies to a pharmacy for redistribution free to other uninsured patients. Donations are limited to those with a time temperature indicator. This bill becomes effective on January 1, 2017. The Commission will be developing rules to support this law.

♦ HB 2681 – Authorizing Pharmacists to Prescribe and Dispense Contraceptives.
  Pharmacists have already been able to prescribe or dispense contraceptives if they have a collaborative drug therapy agreement with a prescriber. This law requires the Commission to create a sticker or sign to be displayed at a pharmacy with the ability to modify or initiate self-administered contraception. This will increase the awareness of the availability of this service. This law becomes effective January 1, 2017.

♦ HB 2793 – Suicide Awareness and Prevention Education.
  This law directs the University of Washington (UW) School of Social Work to establish a safe homes task force. This task force will have a suicide prevention and firearms subcommittee and a suicide prevention and pharmacy subcommittee when funds are available. The pharmacy subcommittee includes representatives from pharmacy associations, schools, and the Commission. The bill adds pharmacist to the list of providers who must receive one-time training on suicide assessment, treatment, and management. The Commission will develop rules to support this requirement. The UW and Washington State University schools of pharmacy are also directed to develop curriculum on suicide assessment, treatment, and management for students. Also, the Department of Health and the Commission are required to develop written material on suicide awareness and prevention for pharmacies to post or distribute by January 1, 2017. This law became effective June 9, 2016.

♦ Substitute Senate Bill (SSB) 6569 – Creating a Task Force on High Out-of-Pocket Pharmacy Costs.
  The Department of Health must convene a task force by July 1, 2016, to examine high out-of-pocket medication costs. The recommendations or a summary of discussions must be submitted to the legislature by December 1, 2016.

♦ SSB 6203 – Updating Statutes for Pharmacy Practice in Long-Term Care Settings.
  This law establishes standards for the practice of pharmacy in long-term care settings.
FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency’s approach to opioid medications. The objective of the plan is to “focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief,” indicates the FDA news release. FDA’s plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analogues labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA’s website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484763.htm.

More Selected Medication Safety Risks to Manage in 2016

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.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers’ IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients “per liter.”

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an institutional sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization, and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%. The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that
most of these errors happened within the first 14 days after discharge. The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

USP Publishes Chapter on Handling Hazardous Drugs in Healthcare Settings

A new general chapter, 800> Hazardous Drugs—Handling in Healthcare Settings, has been published as part of a suite of health care quality standards included in the United States Pharmacopeia—National Formulary (USP–NF) by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter 800 is available in both the First Supplement to USP 39–NF 34 and the USP Compounding Compendium.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,” pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ ucm211957.htm.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739 .htm?source=govdelivery&utm_medium=email&utm _source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/ SafetyInformation/SafetyAlertsForHumanMedicalProducts/ ucm493871.htm.
care settings, including defining long-term care facility, closed-door long-term care pharmacy, shared pharmacy services, and chart orders, and stocking emergency and supplemental dose kits. The bill also establishes that an authorized agent for a prescriber may be a registered nurse in addition to a pharmacist or physician. The bill also amends laws regarding electronic transmission and storage of prescription information. The Commission will develop rules to support this law. This law became effective June 9, 2016.

♦ SB 6558 – Hospital Pharmacy Licensing to Include Clinics. This bill further clarifies SB 5460 from the 2015 legislative session. It allows a hospital pharmacy license to include individual practitioner offices and multipractitioner clinics owned, operated, or under common control. The regulation will be based on the level of service provided. The Commission is writing emergency rules to have in place by September 8, 2016. The Commission has also authorized developing permanent rules.

♦ SB 5549 – Registration and Discipline of Pharmacy Assistants. Pharmacy assistants were already registered through the Commission and were subject to discipline under the Uniform Disciplinary Act, RCW 18.130, as are other professions. This law allows the secretary of the Department of Health to establish a fee for registering as a pharmacy assistant. The Department of Health has begun the fee rule process. The Commission will also revise some rules to be consistent with this new fee. The fees should be in place by February 1, 2017.

♦ Substitute HB 2448 – Practice of East Asian Medicine Therapies. This law requires the Department of Health to work with the East Asian Medicine Advisory Committee (acupuncturist) to define point injection therapy. Point injection therapy can include injection of substances such as saline, sterile water, herbs, minerals, vitamins in liquid form, and others. It does not include CS. This law became effective June 9, 2016.

♦ SSb 5857 – Regulation of Pharmacy Benefit Managers. This bill moves the regulation of pharmacy benefit managers from the Department of Revenue to the Office of the Insurance Commissioner. This law allows the insurance commissioner to set fees and to develop an appeal process. This law became effective June 9, 2016.

No. 1234 Rules Update: Where Are We?

It is all hands on deck at the Commission as rule writing activities are under way. The following is a list of some of the current rule topics the Commission is examining for amendments or adopting new Washington Administrative Code (WAC) entries.

♦ Hospital Pharmacy Associated Clinics: Two stakeholder meetings were held to develop emergency rules to implement 2016 legislation. The Commission will consider the draft for adoption in late July, with writing work on permanent rules to start soon thereafter.

♦ Pharmacy Inspection Process: Following three stakeholder meetings, the Commission authorized moving forward with the notice of deficiency process for inspections.

♦ Pharmacy Technology: The Commission approved rule language at its May meeting for the use of automated drug distribution devices (ADDDs). Following internal review, the proposed language (CR-102) is being published in the state registry to open the official public comment period and to schedule a public rules hearing.

♦ Continuity of Care Refills in Proclaimed Emergencies: The Commission approved the proposed “permanent” rule language at its April meeting to allow licensed pharmacists to provide temporary prescription refills to patients during governor-proclaimed emergencies and approved moving forward in the rulemaking process. The CR-102 for this rule is under internal review.

♦ Sexual Misconduct Rules: A public rules hearing was held at the May meeting. Following a review of the proposed rule language and public testimony, the Commission continued its decision on the rule requesting clarification on the amended language. The rule will be considered at the July 7, 2016 business meeting.

♦ Emergency Outpatient Medication: The Commission authorized moving forward with rulemaking at its October 2015 meeting. Public comments gathered in June will be shared with the Commission at its July business meeting, where it will consider the rule language for approval.

In addition to all of the RCW and WAC changes, the Commission and its staff are conducting a formal review of all rules under the Commission’s jurisdiction. The goals of the review, which was mandated by the legislature in 2013 (SSB 5679), are to decrease the number of rules, simplify the process, and decrease the time required for obtaining licenses, permits, and inspections, as applicable, in order to reduce the regulatory burden on businesses without compromising public health and safety. The Commission is working on a plan to involve stakeholders in the formal review process. Visit the Commission’s Rules in Progress web page for updates.

No. 1235 Electronic Prescriptions for Controlled Substances and Their Signature Requirements

All 50 states, including Washington State, have rules in place allowing electronic prescriptions for controlled substances (EPCS), including Schedule II medications. Pharmacies and practitioners wishing to use EPCS must first select software that meets the requirements of Title 21 Code of Federal Regulations (CFR) §1311. The software application provider must be approved by the federal Drug Enforcement Administration (DEA), and in Washington State it must also be approved by the Commission.
Practitioners may not transmit, and pharmacies may not receive, EPCS until their software provider obtains a third-party audit or certification review that determines that their software application complies with DEA’s requirements and provides the audit/certification report to the practitioner/pharmacy.

Some practitioners and pharmacists are unaware or confused about the meaning of the term “electronic prescription” pertaining to EPCS. Under Title 21 CFR §1300.03, electronic prescription is defined as a prescription that is generated on an electronic application and transmitted as an electronic data file. Therefore, an electronic prescription does not include prescriptions transmitted by facsimile, even if generated electronically and transmitted via fax, or printed on a computer printer.

An electronic signature is defined as a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message. According to DEA, electronic signatures are required on all electronically communicated prescriptions and are not allowed on CS prescriptions delivered by fax or hard copy to the pharmacy. CS prescriptions sent from fax to fax, computer to fax, printed on a computer printer, or manually written must all contain a manual signature. A manual, or wet, signature means the practitioner directly signs the prescription by hand using ink or indelible pencil. Signing a signature pad on a computer so the prescription is printed or faxed with the signature image, or stamping the prescription with a signature stamp, does not meet DEA requirements for manual signatures. This also applies to EPCS where the electronic transmission fails and the prescription is returned to the practitioner by the intermediary. These prescriptions must be manually signed by the prescriber before being faxed to the pharmacy, even if they include an electronic signature.

Pharmacists should recognize they are responsible for ensuring CS prescriptions meet DEA signature requirements and contacting the prescriber whenever necessary.

No. 1236 Residential Treatment Facilities Use of ADDDs

At the May 26, 2016 business meeting, the Commission adopted a policy and procedure regarding the use of ADDDs in residential treatment facilities (RTFs). The policy and procedure interprets Chapter 246-872 WAC, Automated Drug Distribution Devices, to allow RTFs duly licensed by the Department of Health to utilize ADDDs. Further, the policy and procedure states an RTF must either qualify as a medical facility under RCW 70.40.020(7) or obtain a health care entity license. To qualify as a medical facility under RCW 70.40.020(7), the RTF must be operated in connection with a hospital or be under the supervision of a licensed physician. By qualifying as a medical facility, these types of residential facilities are not required to obtain a health care entity license.

If an RTF is neither operated in connection with a hospital nor has a responsible physician on staff, it does not qualify as a medical facility and is required to obtain a health care entity license in order to use an ADDD. The full policy and procedure, and explanatory flowchart mapping out the various pathways for an ADDD, can be found on the Commission’s website.

No. 1237 Rx Fraud Alert Project Reactivated

The Department of Health and the Commission reactivated the Rx Fraud Alert Project last month. This system allows a health care provider who becomes aware of a fraudulent prescription to fill out a web-based form with specific information regarding the prescription and submit it to the Department of Health. The Commission then makes that information available to the pharmacies registered with the Rx Fraud Alert distribution list and posts the report on the Rx Fraud Alert web page and in the prescription monitoring system. The Commission hopes this report will serve as a tool to help prevent additional fraudulent prescriptions from being dispensed. The report form is available online. The Commission hopes that you, as a valued partner, make your colleagues aware of this tool and this communication. The Department of Health and the Commission appreciate your continued efforts to work with staff to address prescription drug misuse. Please let the Commission know what you think of this tool by completing an anonymous survey on the Rx Fraud Alert web page.

Pharmacies can sign up to receive alert notices via email by providing a pharmacy site-specific email address to DOH-RX-FRAUD-ALERT.