No. 544: Oregon Board Adopts New Rules

The Oregon State Board of Pharmacy adopted a number of new regulations to become effective in 2015. The following is a brief summary of changes. As always, for questions about the rules and their application, visit the Board’s website or inquire at pharmacy.board@state.or.us.

Biennial Pharmacist Licensure – For the next renewal cycle (beginning mid-2015), Oregon pharmacist licenses will be issued every two years. The license cycle for pharmacists will be from July 1 through June 30 of odd-numbered years. Be aware that the continuing education (CE) requirements are doubled; pharmacists are required to complete 30 hours of CE biennially, which must include a minimum of two hours of law and two hours of patient safety/medication error prevention. The fee for the upcoming 2015 renewal is $120 for a license that will expire June 30, 2017 – what a bargain!

(Note regarding biennial licensure: The biennial CE requirements for pharmacists are effective after July 1, 2015. It is expected that Certified Oregon Pharmacy Technician licenses will be placed into a biennial renewal cycle, to be effective beginning in 2016, pending upcoming rule adoption.)

Technician Licensure Amendments – Effective January 1, 2015, all persons seeking licensure as a technician in Oregon must be at least 18 years of age and hold either a high school diploma or a General Educational Development certificate. Additionally, while all persons seeking initial licensure as an Oregon certified pharmacy technician (CPhT) are required to take and pass a national certification exam, Oregon CPhTs are no longer required to maintain national certification for license renewal. Please note that this rule does not prohibit a person from choosing to keep his or her national certification active, nor does it prohibit an employer from requiring it as a condition of employment. As a result of these changes, be aware that the CE requirements for Oregon CPhTs are now changed. The Board will now require Oregon CPhTs to complete 10 hours of CE annually, which must include at least one hour of law and one hour of patient safety/medication error prevention.

For both pharmacists and technicians, there are new rules that outline the pathways to reinstatement of licenses that have been lapsed, revoked, or surrendered. For example, if a CPhT in Oregon allows the license to lapse for greater than four years, he or she must retake and pass a national certification exam. Additionally, pharmacists and technicians are now required to provide the Board with a current email address. Please take a moment to read the updated rules, which can be found at www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx.

No. 545: Emergency Contraception: Understanding the Law

Frequently changing regulations have led to widespread misunderstanding regarding the provision of emergency contraception (EC) in the United States. Over the years, Food and Drug Administration rules regarding EC have ranged from restricting all EC products as prescription-only, to the most recent federal ruling allowing Plan B One-Step® and generic one-pill levonorgestrel products to be sold over-the-counter with no point-of-sale restrictions or age/identification requirements. The evolution of these rules and the intricacies embedded within them have given both pharmacists and consumers legitimate reasons to be confused.

To help improve pharmacist understanding of when a prescription is required, current dispensing requirements, and to increase customer access to EC, the Oregon Health Authority’s Oregon Reproductive Health Program, the Board, and the Oregon Foundation for Reproductive Health developed a fact sheet titled Emergency Contraception (EC): Understanding the Law. This document includes information about dispensing requirements and updated efficacy guidelines (based on European studies).

Did you know that the Oregon Health Plan (OHP) will cover the cost of certain prescription EC products and over-the-counter EC products? When dispensing over-the-counter EC products without a prescription to female customers with OHP, pharmacists should use the dispensing pharmacy’s National Provider Identifier (NPI). If prescribed, pharmacists should use the prescriber’s NPI. Private health insurance can

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.


System-Based Causes of Vaccine Errors

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.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP’s November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included Haemophilus influenzae type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine’s various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient’s age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient’s vaccine record prior to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient’s medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP’s VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous
PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable “in-service” CE hours from 10 to five. PTCB’s certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by Drug Topics using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports Drug Topics. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled “Top 10 states for pharmacy robberies,” may be found at http://drugtopics.modernmedicine.com/drg-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy’s Pharmacy Security Best Practices document recommends that all Schedule II and III CS be stored in a “safe or substantially constructed steel cabinet that is locked at all times,” with only licensed pharmacists having access.


Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA’s MedWatch Adverse Event Reporting Program.


Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed “quality control procedures that present a risk to sterility assurance,” the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA’s MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.
be used to fill a prescription for EC with no cost-sharing (e.g., co-pay, deductible), depending on the plan. Because policies and procedures for billing and record keeping vary between corporations, it is important that pharmacists and technicians understand their company’s policy regarding these billing and record-keeping processes.

Pharmacists are encouraged to download the new fact sheet, Emergency Contraception (EC): Understanding the Law, from the Oregon Reproductive Health Program’s Reproductive Health Education Materials web page at https://public.health.oregon.gov/HealthyPeopleFamilies/ReproductiveSexualHealth/HealthEducation/Pages/index.aspx. If you have any additional questions, please contact the Oregon Reproductive Health Program at 971/673-0355.

**No. 547: Notes from the Compliance Department: Schedule II Prescription Changes**

The compliance department continues to address the common inquiry: What can be changed on a Schedule II prescription without requiring a follow-up hard copy from the prescriber? As this is not specifically contemplated in the Code of Federal Regulations, the answer may vary depending upon the state in which you practice. In Oregon, any and all changes must be coordinated in a conversation with the prescriber directly, and the pharmacist must document the authorized change(s) granted by the prescriber. This means that another person, such as an on-call practitioner, cannot make changes without furnishing a new hard copy. Changes can be made to the strength, dosage form, date, quantity, and directions. Changes cannot be made to the patient name, prescriber name, or drug entity (or chemical) prescribed. A pharmacist may also add information, such as the date-to-fill, as that is considered part of the directions.

Here is an example. If a prescription is originally written for OxyContin® 20 mg, BID, #60, it can be changed verbally to oxycodone 5 mg, QID, #120 or to oxycodone/APAP 5/325 mg. However, if the prescriber prefers to change it to MS Contin®, then he or she must furnish a new hard copy prescription to the pharmacy, pursuant to federal regulations.