Pharmacy Issues
Continuing Education Reminders
Edited by Susan Miccio

As another reminder, your license expires on September 30. The renewal notice the Delaware State Board of Pharmacy sends you will explain how to file an online renewal application.

The requirements for renewals and continuing education (CE) are found in 24 Del. C. §2512, Issuance and Renewal of License, and Pharmacy Regulations 1.3 and 1.4. Please remember that at least two hours of CE in each two-year license period must be in the area of medication safety/errors (Regulation 1.4.1.1). Controlled substance CE credit is not required for your 2016 renewal.

The amount of CE required depends on when your Delaware license was issued.

♦ If issued before October 1, 2014, 30 credit hours.
♦ If issued on or after October 1, 2014, 1.25 credit hours per month that you were licensed.

You must complete the required CE credit hours before your license expires.

A program given by a Board-approved Delaware provider or approved by the Accreditation Council for Pharmacy Education (ACPE) automatically qualifies for CE credit. If a program is not already ACPE-approved, you should promptly file a Request for Individual Program Approval form to request the Board’s approval of the program. The form is available at www.dpr.delaware.gov; click on Pharmacy and then on Forms. Do not hinge renewal of your license on approval of a last-minute request! Note that the Board may not approve the program or may approve it for less credit than you request.

Following the renewal, a percentage of pharmacists will be selected for audit of their CE. However, please do not submit CE documentation until you receive the audit notice.

Only pharmacists who are registered as immunizers and who maintain their continuing competency are allowed to administer injectable medications, biologicals, and adult immunizations (Regulation 14.1.3). You will be asked a question about your registration as an immunizing pharmacist on the renewal application. If you are registered as an immunizer, it is your responsibility to take at least two hours of CE, out of the 30 hours required each two-year license period, in the area of immunization. It is the responsibility of each registered pharmacist to maintain his or her current status.

If you fail to renew your Delaware pharmacist license by September 30, your license will lapse. It is illegal to continue practicing without an active license. There is no grace period.

Compounding Update

As most of you are aware, in 2012 a fungal meningitis outbreak tied to contaminated compounded steroid injections made by a Massachusetts firm was associated with infections in over 750 individuals and the deaths of 76 people across more than 20 states. In response, Food and Drug Administration (FDA) conducted inspections of compounding pharmacies across the country, both for cause, in response to serious adverse event reports and reports of quality problems, and proactively to identify pharmacies with deficient sterile compounding practices. During these inspections, FDA observed serious quality problems, including contaminated products and poor sterile practices that created a risk of contamination. Numerous recalls of sterile products were conducted, and numerous pharmacies chose to stop sterile compounding after FDA identified problems with their sterile compounding processes. New problems continue to be identified at compounding pharmacies across the country, which number over 15,000.

In December 2012, FDA convened a 50-state meeting to provide an opportunity for state officials to discuss a variety of issues, including their views on the role of FDA and the states in the oversight of compounding. At about the same time, the United States Congress began considering federal legislation to provide FDA with additional tools to regulate compounding to help prevent another outbreak. These legislative efforts culminated in the enactment of the Drug Quality and Security Act (DQSA). On November 27, 2013, President Barack Obama signed into law the DQSA, legislation that contains important provisions relating to federal and state
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 analgesics 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 up 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 Pharmacopoeial 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 instruction 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 (i.e., 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 Health Care 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.
Must meet certain other conditions, such as reporting
must comply with cGMP requirements; and
oversight. Outsourcing facilities may compound for human and veterinary patient administration. Once facilities are registered, states are assured that FDA will inspect the facilities on a risk-based schedule, hold them to cGMP requirements, monitor the adverse event reports they are required to submit to the agency, and through these activities help improve the quality of drugs compounded at these facilities.

Federal law preempts state law when the latter is inconsistent with the former. Thus, Delaware Pharmacy Regulation 5.1.7, permitting office use compounding without a prescription from licensed pharmacies, had to be amended to be consistent with federal law and to avoid any confusion within the profession. The Board began work on amending this regulation. The Board wanted to be in compliance with federal law but still allow for standards under the parameters of Section 503(B), which permitted compounding for office use by outsourcing facilities. The Board also wanted to leave room for future Congressional/FDA changes by adding the statement “unless authorized by Federal authority.” The Board held two public hearings on this amendment. The regulation was effective March 11, 2016.

The Board has since instituted the outsourcing facility classification under its licensing program. To assist practitioners in obtaining office use compounded products, the Board also compiled a list of licensed outsourcing facilities, which is available on the Division of Professional Regulation’s website at www.dpr.delaware.gov.

Newly Licensed Pharmacists
28 Issued From April 1, 2016, to June 30, 2016


Distributor Permits
26 Issued From April 1, 2016, to June 30, 2016

Dispensary of Hope, LLC – A4-0002292; Pinnacle Distribution, Inc – A4-0002293; National Distribution & Contracting, Inc – A4-0002294; Walgreens Eastern Co, Inc – A4-0002295; Emerson Ecologics, LLC – A4-0002296; Medisca, Inc – A4-0002297; AngioDynamics, Inc – A4-0002298; The Procter & Gamble Distributing, LLC – A4-0002299; The Procter & Gamble Distributing, LLC – A4-0002300; Primary Pharmaceuticals, Inc – A4-0002301; Community Durable Medical Equipment Co, Inc – A4-0002302; Walgreens Specialty Pharmacy #16287 – A4-0002303; Nitrous Oxide Corporation – A4-0002304; West-Ward Pharmaceuticals Corp – A4-0002305; Cangene bioPharma, LLC – A4-0002306; Noramco, Inc – A4-0002307; AWC Specialty RX Consulting, LLC – A4-0002308; Sanofi Pasteur, Inc – A4-0002309; Kenco Logistic Services, LLC – A4-0002310; Sage Products, LLC – A4-0002312; Eli Lilly and Company – A4-0002313; KeySource Acquisition, LLC – A4-0002314; Focus Health Group – A4-0002315; Jacobus Pharmaceutical Company, Inc – A4-0002316; Fagron Sterile Services – A4-0002317; Reliable Pharmaceutical Returns, LLC – A4-0002318

In-State Pharmacy Permits
One Issued From April 1, 2016, to June 30, 2016

SAI SWAMI III, LLC, dba Shayona Pharmacy – A3-0001002

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