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Kentucky Board of Pharmacy News

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Drug Manufacturer and Wholesale Distributor Renewal Deadline Is September 30, 2016

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2016. A drug manufacturer or wholesale distributor may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's website at *www.pharmacy.ky.gov.* If you have any questions concerning the renewal process, please contact the Board office. A drug manufacturer or wholesale distributor application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2016.

Board Meeting and Retreat 2016

The Board office, located in downtown Frankfort, KY, will be the site of the 2016 Board meeting/retreat. The Board meeting will begin at 9 AM on Friday, November 4, 2016. The Board retreat will begin at 8 AM on Saturday, November 5, 2016.

The Board is requesting that any individual or organization submit topics concerning public safety to be considered for discussion at the Board retreat. Please submit any suggestion(s) to Steve Hart, RPh, Board executive director, by September 30, 2016. If you have any questions, please contact the Board office.

Compliance Corner

Continuing Pharmacy Education

Submitted by Katie Busroe, RPh, Inspections and Investigations Supervisor

As required by 201 KAR 2:015, Kentucky-licensed pharmacists must obtain 15 continuing pharmacy education (CPE) hours (1.5 CEUs) annually between January 1 and December 31. A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date is exempt from the CPE requirement for that year. All Kentucky-licensed pharmacists who do not practice in Kentucky must meet the Kentucky CPE requirement of obtaining 15 hours in the calendar year. Board staff audits CPE for all Kentucky-licensed pharmacists by using the National Association of Boards of Pharmacy® (NABP®) CPE Monitor® service or requesting pharmacists to submit proof of CPE to the Board office if the data is not available in CPE Monitor.

Each pharmacist must create an NABP e-Profile and register for the CPE Monitor service to obtain a unique NABP e-Profile ID in order to record Accreditation Council for Pharmacy Education (ACPE)-accredited CPE. All information is maintained in a highly secure environment. When registering for a CPE program, the e-Profile ID and date of birth in MMDD format will be required in order to obtain CPE credit. To ensure the CPE is accurately recorded and matched to each pharmacist's e-Profile, it is important the correct e-Profile ID and date of birth are submitted. If a pharmacist is licensed in multiple states, the pharmacist must include each state of licensure in CPE Monitor in order for each state to access the CPE. If the Board staff cannot access a pharmacist's CPE through CPE Monitor, the pharmacist will be audited and required to submit proof of CPE to the Board office.

Any Board-approved or non-ACPE-accredited CPE programs will not be listed in CPE Monitor at this time; therefore, pharmacists will need to retain those CPE statements of credit in order to submit them to the Board office when requested during the audit period. If a pharmacist is requested to submit proof of CPE, an email will be sent indicating if the CPE meets the requirements or if it will result in disciplinary action. If the email indicates proof of 15 CPE hours was not received, but 15 CPE hours have been obtained, please contact the Board office.

If a pharmacist fails to obtain the required 15 CPE hours in a calendar year, by answering **"No"** to the renewal application question "Have you completed the continuing education requirements of a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between **January 1 and December 31** per 201 KAR 2:015 Section 5(1)(a)?", the resulting disciplinary action is a $250 fine and double the amount of CPE not obtained in addition to the 15 hours required for the current year. If the question is answered **"Yes"** and it is discovered during the audit process that the required CPE was not obtained, the resulting disciplinary action is a $500 fine and double the amount of CPE not obtained in addition to the 15 hours required for the current year. Per 201 KAR 2:270, a CPE violation is expungable if the same violation is not committed in the three-year time period after the completion of the disciplinary sanction and a written request is submitted to the Board.

In 2016, approximately 40 pharmacists self-reported CPE violations on the pharmacist's renewal, and 220 pharmacists were discovered to have CPE violations from the audit.

Changes to Electronic Prescriptions for CS

Submitted by Virginia Whitt, PharmD Candidate

The Board has recently received many questions regarding what changes can be made to an electronically prescribed Schedule II prescription.

Those rules that apply to handwritten Schedule II prescriptions also apply to Schedule II prescriptions that are electronically prescribed. The following is a brief refresher on those items that may or may not be changed.

According to the Drug Enforcement and Professional Practices Branch of the Office of Inspector General, and as last printed in the September 2010 *Kentucky Board of Pharmacy Newsletter,* the following changes are permitted:

- The following may be added or modified **without consulting** the practitioner if the information can be obtained from other reliable sources: patient's address; dosage form; practitioner's address – printed; practitioner's telephone number; and practitioner's Drug Enforcement Administration (DEA) number.

Continued on page 4

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/ucm484765.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 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 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,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] 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.[5] 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)).[4]

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

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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.*

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Continued from page 1

- The following may only be added or modified **after consulting** with the prescribing practitioner, and all consultations must be documented:
  (1) Date of issue – may be added, but **not changed.** DEA does not allow the "Do not fill until" date to be changed even if the physician is consulted.
  (2) Drug strength
  (3) Quantity – may be modified **only** in conjunction with a change of strength, and the total quantity dispensed must not exceed the total dosage authorized. For example, a practitioner prescribes 120 mL of Quillivant XR® 750 mg/150 mL. When reconstituted, the Quillivant is 150 mL. The pharmacist may not contact the prescriber to change the quantity from 120 mL to 150 mL.
  (4) Quantity check-off box marked
  (5) Directions for use
  (6) Refill instructions (Schedules III-V)
  (7) Practitioner's name – printed (not a signature)
- A pharmacist may **never change or add** the patient's name, the name of the controlled substance (CS) (except generic substitution permitted by state law), or the signature of the practitioner.

Both state and federal law still require professional judgment by the pharmacist on every prescription filled. Caution is advised whenever a change or addition is made to any prescription.

Additional information on CS is easily accessible on the Board's website under Frequently Asked Questions.

National Provider Identifiers and You

Submitted by Fred S. Morlan, BS, PharmD Candidate

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the use of a standardized identifier to be used by health care providers, including pharmacists. To fulfill this requirement of HIPAA, the Centers for Medicare & Medicaid Services created regulations that established the National Provider Identifier (NPI). All pharmacists are eligible for an NPI, though it is only required of pharmacists who bill on their own behalf.[1]

Currently, pharmacists are not recognized by Medicare as health care providers and thus cannot bill under Medicare Part B for coverage of services that they provide. Nationally, groups such as the American Pharmacists Association, the National Community Pharmacists Association, and the American Society of Health-System Pharmacists have been pushing for provider status for some time now, and there is reason for optimism that their efforts may finally be leading to success. There are currently two bills in Congress – one in the House and one in the Senate – that would give pharmacists status as health care providers under the law. House of Representatives 592 and Senate 314 have garnered wide support, with over two-thirds of the House and nearly one-half of the Senate cosponsoring the legislation in their respective chambers.[2]

If the bill passes, pharmacists practicing in federally designated underserved areas (which currently include 87 of Kentucky's 120 counties) could potentially bill for services under Medicare Part B.

Recent state efforts to achieve recognition of pharmacists as health care providers have been met with success in California, Oregon, and Washington. In Kentucky, pharmacists recently gained statutory recognition as health care providers for the purpose of initiating the dispensing of naloxone, and efforts are under way to achieve provider status in Kentucky as a result of recent professional initiatives of the Kentucky Pharmacists Association and the Advancing Pharmacy Practice in Kentucky Coalition.

As we move forward with provider status initiatives in Kentucky, pharmacists are encouraged to apply for an NPI so they are ready to implement advanced services when payment opportunities arise. According to a recent search on the NPI registry, only about 40% of pharmacists who practice in Kentucky currently have an NPI.[3] Fortunately, registering for an NPI is a relatively easy and painless process.

How to Get an NPI: Pharmacists may apply for an NPI electronically at *https://nppes.cms.hhs.gov/NPPES/Welcome.do*. There is no cost for applying for one. This process requires the user to create a username and password, log in, and then complete the application. It takes approximately 20 minutes to complete this process.

It is also possible to apply for an NPI with a paper application; there is one available at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS10114.pdf*.

Regardless of the method of applying for an NPI, assistance with the application process can be received by calling the NPI Enumerator team at 1-800/465-3203 or by emailing customerservice@npienumerator.com.

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