July 2016

# North Carolina Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## *Item 2330 – Keith Vance Elected to Northern District Board Seat; Western District Seat Runoff Under Way*

This spring saw two elections for North Carolina Board of Pharmacy member positions in the Northern and Western districts.

Please join the Board in congratulating Keith Vance of Lewisville, NC, for being elected by North Carolina pharmacists to represent the Northern District. Dr Vance is a 2002 graduate of the Campbell University College of Pharmacy & Health Sciences. He owns and operates Lewisville Drug Company. The Board certified the Northern District election results by conference call on May 16, and Dr Vance will take his seat on May 1, 2017.

The Board thanks the other candidates – Cecil Davis and Haywood Rhodes – for their interest in and passion for Board service.

Overall vote totals for the Northern District election were as follows.

| Candidate Number | Candidate Name | Vote Count | Percentage of Total |
|---|---|---|---|
| 1 | Cecil Davis | 536 | 27.6% |
| 2 | Thomas (Haywood) Rhodes | 321 | 16.5% |
| **3** | **Keith Vance** | **950** | **48.9%** |
| 4 | None | 134 | 6.9% |
| | **Total** | **1,941** | **100%** |

As of this writing, the Western District seat is the subject of a runoff election between Bill Mixon and Cathy Huie that will close on June 24. The Western District election saw five candidates. In addition to Mr Mixon and Dr Huie, the Board thanks Chip Etier, Tim Gentilcore, and David Landers for their candidacy.

Overall vote totals in the Western District election were as follows.

| Candidate Number | Candidate Name | Vote Count | Percentage of Total |
|---|---|---|---|
| 5 | Frank (Chip) Etier | 122 | 6.3% |
| 6 | Tim Gentilcore | 265 | 13.7% |
| **7** | **Cathy Huie** | **616** | **31.7%** |
| 8 | David Landers | 100 | 5.2% |
| **9** | **William (Bill) Mixon** | **746** | **38.4%** |
| 10 | None | 92 | 4.7% |
| | **Total** | **1,941** | **100%** |

## *Item 2331 – Clinical Pharmacist Practitioner Rules Amended: Guidance to CPPs and CPP Applicants*

The North Carolina Medical Board and Board of Pharmacy recently collaborated on a series of changes to the rules governing clinical pharmacist practitioners (CPPs) (21 NCAC 46.3101). The chief aims of the amendments are: (1) transfer primary administrative responsibility for CPP application, renewal, and monitoring to the Board of Pharmacy; (2) bring supervising physician consulting and oversight responsibilities in line with those for nurse practitioners and physician assistants (PAs); and (3) allow CPPs to designate "primary" and "back-up" supervising physicians, something that is particularly helpful for CPPs who service patients in a group practice.

Current CPPs and pharmacists planning to apply for the CPP credential have asked a number of questions concerning the changes and the administrative changeover. This document, available on the Board's website, answers questions received and anticipates others, and may be found at *www.ncbop.org/faqs/Pharmacist/AmendedCPPrules3101FAQ.pdf.*

*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.

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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.*

*continued from page 1*

Current CPPs and those planning to apply for CPP status should consult this document. As always, any pharmacist with questions should feel free to contact Board staff.

## *Item 2332 – Board Implements Periodic Criminal Background Checks for Licensees and Registrants*

Consistent with its obligation to protect the public health and safety, the Board has implemented a system to conduct periodic sweeps of the North Carolina court system for public records concerning criminal charges filed, pending, or resolved against Board licensees or registrants.

The Board's procedure for reviewing and, potentially, taking action based upon such public information may be found at *www.ncbop.org/PDF/BackgroundCheckPolicy.pdf.*

Board licensees and registrants are, of course, still obligated to report information concerning criminal charges or dispositions each year as part of the license and registration renewal process.

## *Item 2333 – Information for Pharmacists Dispensing Antibiotics Pursuant to EPT Prescriptions*

The Pharmacy Practice Act and Board rules have always authorized pharmacists to dispense prescription medications prescribed pursuant to expedited partner therapy (EPT). From time to time, Board staff receive questions about the specifics of EPT therapy and dispensing. The Board's colleague, Amanda Fuller Moore at North Carolina Public Health Preparedness and Response, has assembled a frequently asked questions document to guide pharmacists, available at *www.ncbop.org/faqs/Pharmacist/ExpeditedPartnerTherapyFAQsMay2016.pdf.*

## *Item 2334 – Medical Board Monitoring of High-Volume, High-Dose Opioid Prescribers*

The Medical Board has launched an effort to address potentially unsafe opioid prescribing in an attempt to reduce patient harm from misuse and abuse of these medications.

Using data provided in accordance with state law by the North Carolina Department of Health and Human Services, the Board will investigate prescribers who meet one or more of the following criteria:

- The prescriber falls within the top 1% of those prescribing 100 mg of morphine equivalents (MME) per patient per day.
- The prescriber falls within the 1% of those prescribing 100 MMEs per patient per day in combination with any benzodiazepine and is within the top 1% of all controlled substance prescribers by volume.
- The prescriber has had two or more patient deaths in the preceding 12 months due to opioid poisoning.

The Medical Board will determine the appropriateness of prescribing through standard methods, including review of patient records, independent expert medical reviews, and written responses from the prescriber. In an email to physicians and PAs, the Board acknowledged that prescribers identified through the stated criteria may be practicing and prescribing in accordance with accepted standards of care. Given the known risks of opioids and the rising incidence of unintentional overdose deaths, the Board wrote that it has an obligation to verify that care and prescribing are clinically appropriate.

Physicians and others who treat chronic pain are encouraged to review current standards of care by reading the Medical Board's position statement on use of opiates for the treatment of pain. According to the Medical Board, cases that result in public action against the prescriber universally involve one or more significant departures from accepted standards of care.

## *Item 2335 – Comment Period on FDA Draft Guidance Concerning Prescription Drug Compounding to Close Shortly*

As published on the Board's website, on April 15, 2016, Food and Drug Administration (FDA) issued three draft guidance documents concerning human drug compounding. Each of the draft guidance documents may be found at *www.fda.gov/Drugs/DrugSafety/ucm493463.htm*. The comment period on these proposed guidance documents closes July 15, 2016.

The first, titled "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act," does not appear to differ in any way from the plain language of the Drug Quality and Security Act (DQSA) or from the DQSA guidance document prepared by Board staff, which is available at *www.ncbop.org/faqs/FAQsDQSA030615.pdf.*

The second, titled "Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act," contains FDA's first concrete guidance on issues specific to hospitals and health systems. All directors of pharmacy of hospital or health-system pharmacies should closely review this draft guidance.

The third, titled "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act," contains further FDA guidance on how current Good Manufacturing Practice standards apply in "dual-use" facilities, ie, facilities that are registered as Section 503B outsourcing facilities but also compound prescription drugs pursuant to individual patient prescriptions. For a refresher on the state licensing requirements for outsourcing facilities, please visit *www.ncbop.org/faqs/Pharmacist/faq_OutsourcingFacilities.html* to view the guidance document prepared by Board staff.

The cover page of each draft guidance document provides instructions on how and when to provide commentary to FDA. Again, pharmacists wishing to provide comment are advised that the window for doing so will close shortly.



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