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North Carolina Board of Pharmacy News

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Item 2274– Board Member Elections for Northeastern and Central Districts in Spring 2014

The next North Carolina Board of Pharmacy member election will take place this spring. Two positions on the Board will be filled: The Northeastern District seat presently held by Gene Minton and the Central District seat presently held by Lazelle Marks. They are serving their first five-year terms and thus are eligible to run for reelection.

Candidates must be a resident of the district from which they are elected at the time of the election.

The Northeastern District is composed of Bertie, Camden, Chowan, Currituck, Dare, Durham, Edgecombe, Franklin, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Tyrrell, Vance, Wake, Warren, Washington, and Wilson counties.

The Central District is composed of Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan, Stanly, and Union counties.

Nominations are open through March 15, 2014. Board staff encourages any actively licensed pharmacist living in these two districts to find out more about the election process by attending one of two planned forums (one in each of the two districts; see below) in early 2014. Board staff will be available to answer questions and discuss what it means to serve on the Board.

The first forum will be held on Thursday, January 16, 2014, at 6:30 PM at the McKimmon Center in Raleigh, NC. Address and directions are found here: *https://onece.ncsu.edu/mckimmon/contact.jsp.*

The second forum will be held on Thursday, January 30, 2014, at 7 PM at the Embassy Suites – Charlotte-Concord. Address and directions are found here: *www.embassysuitesconcord.com/get-here/.*

For ease of planning, please e-mail Kristin Moore at the Board office at kmoore@ncbop.org if you plan to attend and indicate which of the two forums you will attend, or call 919/246-1050, ext 209.

Item 2275 – Important Refresher Information Concerning Epinephrine Auto Injectors

In the January 2011 *Newsletter,* in Item 2218, the Board issued the following information concerning the dispensing of epinephrine auto injectors.

> As pharmacists are aware, there are several epinephrine auto injector products on the market – eg, EpiPen®, Twinject™, Adrenaclick®. Because epinephrine auto injectors are used in emergency situations, it is crucial that pharmacists dispensing these devices ensure that the patient or the patient's caregiver is adequately trained on their proper use at the time of dispensing. Pharmacists must not assume that the patient or patient's caregiver has been trained by others.
>
> Of course, if a prescriber writes for a particular epinephrine auto injector and signs the prescription "dispense as written" (or handwrites "brand medically necessary" where Medicaid patients are concerned), the pharmacist must dispense the indicated product.
>
> If substitution is permitted, the pharmacist may do so as allowed by North Carolina law.
>
> In either case, the pharmacist should be certain that the patient or patient's caregiver has been trained on proper use of **the particular device dispensed.** Absent such training, a patient's life could be placed in danger.

Board staff reiterates these crucial public safety points to pharmacists. New epinephrine auto injector products have entered the market since January 2011.

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

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 medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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Currently marketed epinephrine auto injectors include Twinject® (0.15 mg and 0.3 mg per delivery); Adrenaclick (0.15 mg and 0.3 mg per delivery); Auvi-Q™ (0.15 mg and 0.3 mg per delivery); EpiPen (0.3 mg per delivery); and EpiPen Jr® (0.15 mg per delivery). Each product carries an "Orange Book" BX rating with respect to other epinephrine auto injectors.

Lineage Therapeutics markets epinephrine injection, USP auto injector, in 0.15 mg and 0.3 mg strengths. This product is an "Orange Book" AB-rated product to Adrenaclick only.

Critically, different epinephrine auto injectors have different operational instructions. When an auto injector is needed, seconds matter. Accordingly, it is imperative that pharmacists (1) strictly follow relevant law governing substitution and (2) train the patient or caregiver thoroughly on the proper use of the particular device prescribed and dispensed.

Item 2276 – Amended Rules Governing Automated Dispensing Devices Now in Effect

Amendments to Board rules governing automated dispensing devices went into effect on December 1, 2013. The amended rules, which may be found at *www.ncbop.org/LawsRules/rules.3400.pdf,* accomplish two primary changes: (1) all automated dispensing devices are now subject to a single, uniform set of standards; separate standards no longer govern "centralized" and "decentralized" automated dispensing devices and (2) the restocking provisions now allow, in certain circumstances, a registered nurse trained and authorized by the pharmacist manager to conduct restocking tasks provided that a quality assurance validated electronic verification process is in place.

Item 2277 – Federal Drug Quality and Security Act Bringing Changes to Compounding Pharmacy Regulation

On November 27, 2013, the president signed into law the Drug Quality and Security Act (DQSA). DQSA focuses on two broad issues: (1) further refinement of the state and federal roles in regulating compounding pharmacy practices and (2) creation and implementation of a national "track and trace" program intended to ensure integrity of the prescription drug supply chain. Compounding pharmacists undoubtedly have questions about the impact of this statute on their practices. Board staff will continue to provide information as available.

Food and Drug Administration (FDA) has issued guidance on the new statute. Compounding pharmacists are strongly advised to read FDA guidance. Links to FDA guidance documents are found on the front page of the Board's Web site at *www.ncbop.org.*

Item 2278 – Acetaminophen Containing Combination Products – What Does FDA's Approaching January 14, 2014 Deadline Mean for Dispensers?

On January 14, 2011, FDA announced an effort to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. FDA has determined that products containing more than 325 milligrams of acetaminophen present an unreasonable risk of liver injury. Accordingly, FDA announced that manufacturers of prescription drugs containing more than 325 milligrams of acetaminophen would be given until January 14, 2014, to request that FDA withdraw approval of such products. FDA stated that, after January 14, 2014, it could take action to remove prescription drug products containing more than 325 milligrams of acetaminophen from the market. FDA's complete notice on this topic may be found here: *www.federalregister.gov/articles/2011/01/14/2011-709/prescription-drug-products-containing-acetaminophen-actions-to-reduce-liver-injury-from*. Several manufacturers have reformulated combination products (most often oxycodone and hydrocodone combination products) that previously contained 500 milligrams of acetaminophen. Others have not.

Some pharmacists have asked whether they may dispense a prescription for a combination product containing more than 325 milligrams of acetaminophen after January 14. The answer is yes, but some context is necessary. Again, as noted, FDA encouraged manufacturers to voluntarily withdraw and reformulate products containing more than 325 milligrams of acetaminophen. If a manufacturer has not done so by January 14, FDA could take action to remove that manufacturer's product from the market. But unless and until FDA does so, such products remain approved. Still, pharmacists must be aware of the safety risks that prompted FDA's action. Appropriate counseling of patients and prescribers should occur. And pharmacists should also be mindful that reformulated products may have fewer generic alternatives available. In other words, where substitution is authorized for a now 325 milligram acetaminophen-containing product, pharmacists must be careful not to inadvertently substitute a 500 milligram acetaminophen-containing product.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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