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News

North Carolina Board of Pharmacy

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Item 2279 – Reminder: Board Member Elections for Northeastern and Central Districts

Pharmacists are reminded that two positions on the North Carolina Board of Pharmacy will be filled by election this spring: the Northeastern District seat and the Central District seat.

In alphabetical order, the following are candidates for the Northeastern District seat: David Catalano (Wake County), Tom D'Andrea (Wake County), Gene Minton (Halifax County), Christopher Peoples (Franklin County), and Brooke Rawls (Wake County).

In alphabetical order, the following are candidates for the Central District seat: Brett Clevenger (Mecklenburg County), Stan Haywood (Randolph County), Kevin Isaacs (Union County), Max G. Reese (Montgomery County), Scott Romesburg (Union County), and Marianne White (Chatham County).

More information about each of the candidates will be found on the Board's website at *www.ncbop.org*.

All pharmacists licensed and residing in North Carolina as of March 15, 2014, are eligible to vote in the election.

Voting will open in mid-April and run through mid-May, and voting will be electronic and accepted through the Board website. The website will include biographical information for each candidate. All pharmacists in the state will also receive information concerning voting and the candidates by electronic mail.

The election results will be certified at the Board's June 17, 2014 meeting. If run-off elections are required, they will begin shortly thereafter. If not, the winners will be certified and will commence a period of training, leading to commissioning by the governor on May 1, 2015.

Item 2280 – North Carolina Law Prohibits Health Care Providers from Paying Referral Fees

In recent weeks, Board staff has received several inquiries regarding the payment of referral fees to physicians for directing patients to a pharmacy. North Carolina law is clear: "A health care provider shall not financially compensate **in any manner** a person, firm, or corporation for recommending or securing the health care provider's employment by a patient, or as a reward for having made a recommendation resulting in the health care provider's employment by a patient. No health care provider who refers a patient of that health care provider to another health care provider shall receive financial or other compensation from the health care provider receiving the referral as a payment solely or primarily for the referral." NCGS Section 90-401 (emphasis added).

Violation of this statute "shall be grounds for the offending health care provider's licensing board to suspend or revoke the health care provider's license, to refuse to renew the health care provider's license, or to take any other disciplinary action authorized by law." NCGS Section 90-401.

The North Carolina Medical Board emphasizes to its licensees that they "may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company **or pharmacist,** an optical company, or the manufacturer of medical appliances and devices, **for prescribing or referring a patient to said source."** For the Medical Board's full position statement, "Referral fees and fee splitting," visit *www.ncmedboard.org/position_statements/detail/referral_fees_and_fee_splitting*.

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding.* Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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Item 2281 – Caution to North Carolina Pharmacies Concerning 'Secondary' Wholesale Solicitations for Shortage Drugs

Board of Pharmacy staff and staff of the Food and Drug Protection Division of the North Carolina Department of Agriculture & Consumer Services have been made aware that at least one "secondary" wholesaler recently has solicited pharmacies to purchase "shortage" drugs from a primary wholesaler and then resell them to the "secondary" wholesaler. There are several important issues that pharmacies should keep in mind:

1. Any sales of this sort are wholesale prescription drug transactions. Any pharmacy engaged in such transactions that is not also a currently licensed prescription drug wholesaler would be in violation of North Carolina law.
2. The "secondary" wholesaler has suggested that a pharmacy may engage in such transactions without being a wholesaler under a "5% rule" allowing sales to relieve shortages; any such suggestion is false. North Carolina law provides a limited mechanism whereby one pharmacy may, in an emergency situation, transfer a small amount of prescription drugs to another pharmacy. North Carolina law does not provide a mechanism for a pharmacy to sell any amount of a prescription drug to a wholesaler for subsequent distribution to other pharmacies or wholesalers. More information may be found here: *www.ncbop.org/faqs/Pharmacist/faq_Wholesalers.htm.*
3. As most pharmacists are aware, Congress recently passed the Drug Quality and Security Act. Title II of that act, governing drug supply chain security, sets forth many federal law requirements for prescription drug wholesalers. Provisions of this statute are being rolled out gradually, but any pharmacy contemplating becoming a prescription drug wholesaler must be aware of these stringent requirements and prepared to meet them.
4. The issue of "gray market" wholesaling of shortage prescription drugs is one that North Carolina authorities have worked closely with federal officials to monitor and address. A Congressional investigation into these practices, and their often significant threat to the public health and safety, was conducted last year. More information may be found here: *http://democrats.oversight.house.gov/investigation-of-the-gray-market/.*

Item 2282 – Information from the North Carolina Division of Medical Assistance Regarding Waiver of Medicaid Co-Pays

Board staff often receive questions about whether and to what extent state and federal law permit a pharmacy to waive co-payments for Medicaid recipients. Board staff refer such questions (and others concerning North Carolina Medicaid issues) to staff of the North Carolina Division of Medical Assistance (NCDMA), which administers the North Carolina Medicaid program. Pharmacists and pharmacies should note, however, that the NCDMA published an article in the October 2013 edition of the *North Carolina Medicaid Pharmacy Newsletter* on the subject of waiving of Medicaid co-payments to provide additional information in light of a new state law that went into effect on October 1, 2013.

North Carolina Session Law 2013-145, a copy of which may be found at *www.ncleg.net/Sessions/2013/Bills/Senate/HTML/S137v5.htm,* prohibits waiving of Medicaid co-payments as a regular business practice. NCDMA's October newsletter, which contains the article at pages 5-7, may be found here: *www.ncbop.org/PDF/NCDMAnewsletterOct2013.pdf.* Pharmacists or pharmacies with additional questions should contact NCDMA for further information.

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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