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Item 2283 – Board Member Election Results for Northeastern and Central Districts

Please join the North Carolina Board of Pharmacy in congratulating Gene Minton of Littleton, NC, and Stan Haywood of Asheboro, NC, who were elected by North Carolina pharmacists as Board members from the Northeastern and Central Districts, respectively. Mr Minton was elected to a second five-year term, and many pharmacists will recall that Mr Haywood previously served as a Board member from 2000 to 2010.

A total of 2,931 votes were cast during the election period. Mr Minton received over 40% of the total votes cast for the Northeastern District position, thereby garnering a substantial plurality of the votes. Mr Haywood received the largest number of votes of the Central District candidates. Kevin Isaacs received the second highest vote total among Central District candidates. Though Mr Isaacs could have requested a run-off election, he graciously conceded the election.

Messrs Minton and Haywood will begin their terms (or, in Mr Minton's case, continue his term) on May 1, 2015, once commissioned by Governor Pat McCrory.

Board staff congratulates Messrs Minton and Haywood and wishes them every success in their mission to protect the public health and safety of North Carolina's citizens.

The Board expresses its heartfelt appreciation to the other candidates for Board membership. From the Northeastern District: David Catalano, Tom D'Andrea, Christopher Peoples, and Brooke Rawls. From the Central District: Brent Clevenger, Kevin Isaacs, Max Gardner Reece, Scott Romesburg, and Marianne White.

Northeastern District

Candidate Number	Candidate Name	Vote Count	Percentage of Total
1	David Catalano	315	10.7%
2	Tom D'Andrea	286	9.8%
3	Gene Minton	1,367	46.6%
4	Christopher Peoples	248	8.5%
5	Brooke Rawls	545	18.6%
6	**None**	170	5.8%
	Total* =	**2,931**	**100%**

Central District

Candidate Number	Candidate Name	Vote Count	Percentage of Total
7	Brent Clevenger	318	10.8%
8	Stan Haywood	1,011	34.5%
9	Kevin Isaacs	486	16.6%
10	Max Gardner Reece	474	16.2%
11	Scott Romesburg	264	9%
12	Marianne White	297	10.1%
13	**None**	81	2.8%
	Total* =	**2,931**	**100%**

Item 2284 – NCPRN Annual Fall Conference

The North Carolina Pharmacist Recovery Network (NCPRN) invites the pharmacy community to take part in its Annual Fall Conference. This year's conference will take place October 9 and 10 at The Hawthorne Inn & Conference Center in Winston-Salem, NC. Pharmacy continuing education will be provided by Campbell University. Please visit *www.ncprn.org* for more information.

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

Item 2285 – Immunization Update: What Every North Carolina Pharmacist Needs to Know

By Courtney Humphries, PharmD, PGY1 Community Pharmacy Practice Resident, Kroger Pharmacy

With the passage of House Bill 832, Expanded Role of Immunizing Pharmacists, North Carolina pharmacists are now able to impact patients' lives by providing additional vaccines via protocol. These vaccines, which can be administered to patients 18 years of age or older, are pneumococcal, herpes zoster, hepatitis B, meningococcal, Td/Tdap vaccine (not to a patient with an open wound), and influenza (to patients 14 years of age or older). Any additional Centers for Disease Control and Prevention-recommended vaccine can be administered via a prescription.

There are some key pieces of the new legislation that are important for every immunizing pharmacist to be aware of. These are:

- Pharmacists must be trained on the North Carolina Immunization Registry (NCIR). Any independent pharmacy not affiliated with Mutual can contact Hope Watson (hope.watson@dhhs.nc.gov) for more information about the NCIR.
- Prior to administering a vaccine (except for influenza), the pharmacist should access the registry to determine if the vaccine is appropriate.
- Within 72 hours of vaccine administration, pharmacists should notify the primary care provider (PCP) identified by the patient **and** document the vaccine in the NCIR.
  - Documenting in the NCIR will not automatically notify the PCP; this should be completed by each pharmacy.
  - Influenza vaccines are not required to be documented in the NCIR.
  - If the NCIR is not operable, document as soon as possible.
- If a patient does not have a PCP, then the pharmacist should provide him or her with a copy of a document outlining the benefits of having one. This document is available via the Board website at *www.ncbop.org/PDF/WhatIsAPrimaryCarePhysician.pdf.*
- A minimum standard screening questionnaire and safety procedures have been developed and should be used to prepare appropriate changes to protocols. This document is available via the Board website at *www.ncbop.org/PDF/ImmunizingPharmacistsMinScreeningQuestionnaire091313.pdf.*
  - The screening questions should appear as written on consent forms used by the pharmacy. Consent forms may contain additional questions to the 14 already established.

Need more information? Visit one of these reliable resources:

- North Carolina Board of Pharmacy: *www.ncbop.org*
- North Carolina Immunization Branch: *www.immunize.nc.gov/providers*
- North Carolina Association of Pharmacists (Coming soon: sample protocols, consent forms, etc): *www.ncpharmacists.org*

Item 2286 – Public Hearing on Proposed Amendments to Rule 21 NCAC 46 .2507, Administration of Vaccines by Pharmacists, to Be Held July 14, 2014

Related to Item 2285, left, Board of Pharmacy and North Carolina Medical Board staff have proposed revisions to the rule governing pharmacist administration of vaccines to harmonize it with the new statute.

A public hearing will be held on July 14, 2014, at 5 PM at the North Carolina Board of Pharmacy office, located at 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Any person may object to the proposed amendment by attending the public hearing on July 14, 2014, and/or by submitting a written objection by July 14, 2014, to Jay Campbell, executive director, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, via fax at 919/246-1056, or via e-mail at jcampbell@ncbop.org.

The North Carolina Board of Pharmacy is interested in all comments pertaining to the proposed rule. All persons interested and potentially affected by the proposal are strongly encouraged to read this entire notice and make comments on the proposed rule.

More information on this and other rulemaking proceedings by the Board may be found here: *www.ncbop.org/rulemakings.htm.*

Item 2287 – Executive Director Jay Campbell Elected to the NABP Executive Committee

At the National Association of Boards of Pharmacy® (NABP®) Annual Meeting, Jay Campbell was elected to serve a three-year member term, representing District 3, on the NABP Executive Committee. An active member of NABP, Mr Campbell has served on many of the Association's task forces and committees, including the Task Force on Prescription Drug Diversion from Common Carriers and the Task Force to Review and Recommend Revisions to the Controlled Substances Act, for which he served as chairperson. In 2013, Mr Campbell received the Lester E. Hosto Distinguished Service Award from NABP.

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