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North Carolina Board of Pharmacy News

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Item 2219 – Board of Pharmacy Election for Northern and Western District Seats

In mid-April, the North Carolina Board of Pharmacy will hold an election for both the Western and Northern District seats.

The Western District consists of Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Haywood, Henderson, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes, and Yancey counties. This seat is presently held by Board President Rebecca Chater, who is serving her second consecutive five-year term and is thus not eligible for reelection.

The Northern District is composed of Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry, and Yadkin counties. Board Vice President Betty Dennis holds this seat and is also serving her second consecutive five-year term, making her ineligible for reelection.

The following pharmacists have submitted the appropriate petitions to place themselves on the ballot:

Western District:

Allan Berg..... Hendersonville
Stephanie Kiser .....Candler
Troy McNeill .....Candler
William Mixon..... Hickory

Northern District:

Carol Day.....Carrboro
Keith Waege..... King
Beth Williams.....Kernersville

Candidate bios and photos are available on the Board's Web site.

Even though only seats from the Western and Northern Districts are up for election this year, **all North Carolina pharmacists residing in the state and licensed by the Board as of March 15, 2011,** are eligible to vote. Voting will begin in mid-April and, just as last year, the Board will provide pharmacists a link to follow where they will log-in using their license number and PIN to vote.

Any pharmacist who wishes to cast a **paper ballot** instead of using the online voting system **must request one in writing. Requests for paper ballots must be received at the Board office by April 20, 2011.** All ballots must be cast electronically, physically delivered to the Board office, or postmarked if the ballot is sent by United States mail, by May 15, 2011. Results of the election and information on whether a run-off election will be required will be announced at the Board's May 17, 2011 meeting. Run-off elections, if necessary, will take place in May-June.

Board members and staff encourage pharmacists to vote in these important elections. North Carolina is the only state that still provides its pharmacists with the opportunity to be directly involved in the selection of Board members.

Item 2220 – DME Subcommittee Election Reminders

In June 2011, the Board of Pharmacy Device and Medical Equipment (DME) Subcommittee will hold an election for the medical oxygen supplier representative seat. This seat is presently held by DME Subcommittee Member Karen L. Womack, who is eligible to run for a second term.

The medical oxygen supplier representative must practice in the particular area for which he or she is nominated, but need not practice exclusively in that area.

If interested in becoming a candidate for the above-mentioned position, a "person-in-charge" of a DME facility (who is the "permit holder" for purposes of North Carolina law) who also meets the practice area qualification stated above may submit a petition to appear on the ballot. Any petitioner must be a registered North Carolina DME permit holder as of March 15, 2011. The petition must be filed in the Board office or postmarked by April 1, 2011. The petition form is available on the Board's Web site, *www.ncbop.org/DME/2011DMENominationForm.pdf.*

Anyone wishing to learn more about the duties of a DME subcommittee member may contact Karen Matthew, director of investigations and inspections, at kmatthew@ncbop.org.

All North Carolina DME permit holders residing in the state as of March 15, 2011, are eligible to vote. Voting will be electronic, whereby a DME person-in-charge in the state will log on to his or her individual Board account to cast an electronic ballot. More details, including instructions for requesting a paper ballot if preferred, will follow in the coming weeks and be posted on the Board's Web site.

Item 2221 – Safe Dispensing of U500 Insulin from the Community Pharmacy

Editor's note: Thanks to Caron Misita, PharmD, BCPS, CDE, CPP, of the UNC Hospitals Highgate Specialty Center Diabetes and Endocrinology practice for this update

Concentrated human insulin (Humulin R U500*)* contains 500 units of insulin in every milliliter and is Food and Drug Administration (FDA)-approved for use in insulin-resistant patients who require daily insulin doses of greater than 200 units. With the continuing obesity and type 2 diabetes epidemics, the use of U500 insulin is becoming increasingly common. However, there is no commercially available

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birthdate (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Visit *www.MyCPEmonitor.net* for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/ucm239821.htm.*

Looking for Risk

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 a 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.*

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a "systematic method of identifying and preventing product and process problems before they occur." FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the "guardians" in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- Explain the important processes and sub-processes of medication use from prescription through administration.
- Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit *www.ismp.org/Tools/pathways.asp.*

To learn more about assessing risk in community pharmacy visit *www.ismp.org/communityRx/aroc/*.

NABP Launches New and Improved NAPLEX/ MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 21 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training 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 Drug Info Rounds video, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

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dosing device intended for use with U500 insulin. As both the FDA and Institute for Safe Medication Practices (ISMP) have identified U500 insulin as a medication with a high degree of potential for adverse medication events, community pharmacists are left in a quandary when presented with patients in need of U500 insulin. How can a pharmacist at the point of dispensing ensure safe use of U500 insulin by patients?

In 2001, ISMP issued a recommendation that health care providers consistently use tuberculin syringes when administering U500 insulin. This avoids confusion as to the number of units that a patient is to administer, since doses are expressed in milliliters rather than units. For example, if a patient were to take 150 units of U500 insulin, the written prescription and the prescription label would describe the dose as 150 units of insulin, measured as 0.3 mL on a tuberculin syringe.

Alternately, Lilly, the manufacturer of Humulin R U500 insulin, suggests using either a tuberculin syringe or a U100 insulin syringe for U500 administration. When using a U100 syringe to dose U500 insulin, the number of unit marks to measure the dose is calculated as the dose in units divided by five. Citing the example above of a dose of 150 units, the appropriate way to describe the dose with a U100 insulin syringe would be 150 units of insulin, measured as 30 unit marks on a U100 syringe (ie, 150 units divided by five).

Despite the ISMP recommendation, given the increased availability and improved insurance coverage with U100 syringes, as well as prescriber familiarity with them, the community pharmacist is likely to encounter many patients whose prescribers have advised use of U100 syringes. The advantages and disadvantages of tuberculin syringes and U100 syringes for U500 insulin administration are summarized in the table below.

While each of these options is suboptimal and has the potential to lead to dosing errors and significant adverse events, both U100 syringes and tuberculin syringes can be used to safely dose U500 insulin. To achieve this level of safety, communication amongst health care providers and intense patient education are paramount. The following are recommendations for appropriate steps to take to avoid adverse events in dispensing U500 insulin:

1. Prescribers should specify on the prescription the dosing device to be used for U500 administration.
   - ♦ If using a tuberculin syringe, express the dose in terms of actual units to be administered and in mL. For example, "Inject 150 units, which is measured as 0.3 mL on a tuberculin syringe, 3 times each day."
   - ♦ If using a U100 syringe, express the dose in terms of actual units to be administered and in unit marks on a U100 syringe. For example, "Inject 150 units, which is measured as 30 unit marks on a U100 syringe, 3 times each day."
2. Pharmacists should not be timid about clarifying dosing instructions with prescribers if there is any question as to the intended dose.
3. Pharmacists should confirm with patients, at the point of dispensing, their understanding of appropriate dosing, ideally using the dosing device of choice that is also being dispensed at that time.

Item 2222 – Update on Unit Dose Medication Supervision Rule

As pharmacists in the state are aware, the Board passed a rule last year that would allow certain technicians employed at in-patient hospital pharmacies, who hold an associate's degree in pharmacy technology, and who are subject to strict pharmacist-manager supervision and quality assurance requirements, to validate work of other technicians in non-dispensing distributive activities such as floor stock replenishment and unit dose packaging. The text of the rule is available at *www.ncbop.org/pdf/21NCAC46.1418SupervisionUnitDoesMedSys.pdf.*

That rule was held for legislative review, and therefore did not go into effect as expected in 2010.

On February 23, 2011, a bill was introduced in the General Assembly to "disapprove" the rule. Accordingly, the rule will not go into effect unless or until there is final action on the bill. If passed, the bill would nullify the rule. The bill may be found at *www.ncleg.net/Sessions/2011/Bills/Senate/PDF/S112v0.pdf.*

Pharmacists, technicians, and others with an interest in the rule and this bill should contact their state senator or representative to discuss. Board staff will provide updates as the legislative process continues.

Tuberculin Syringes vs U100 Syringes for U500 Insulin Administration

Tuberculin Syringe		U100 Insulin Syringe	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**
♦ Avoids dose confusion (expressed in mL)			♦ Dose confusion (expressed in unit marks)
	♦ Not readily available (not stocked in many pharmacies)	♦ Readily available	
	♦ Longer needles (12.7 mm)	♦ Shorter needles (8 mm)	
	♦ Wider needles (27-29 gauge)	♦ Narrower needles (30-31 gauge)	
	♦ Potentially not covered by insurance	♦ Routinely covered by insurance	
	♦ Syringe size (0.5 mL, 1 mL) limits use of small dose increments	♦ Syringe size (0.3 mL) allows use of smaller dose increments (to improve accuracy)	

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