October 2010

# North Carolina Board of Pharmacy News

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## *Item 2209 – Elections for Northern and Western District Board Seats in Spring 2011*

April and May 2011 will bring elections for the Northern and Western District seats on the North Carolina Board of Pharmacy.

The Northern District seat is presently held by Board Vice President Betty Dennis. Dr Dennis will complete her second consecutive five-year term on the Board of Pharmacy in May 2012, and therefore is not eligible for reelection.

The Northern District is composed of Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry, and Yadkin counties. A candidate for the Northern District must reside in one of these counties at the time of election.

The Western District seat is presently held by Board President Rebecca Chater. Mrs Chater will complete her second consecutive five-year term on the Board of Pharmacy in May 2012, and therefore is not eligible for reelection.

The Western District is composed 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. A candidate for the Northern District must reside in one of these counties at the time of election.

All pharmacists licensed in North Carolina and residing in the state as of March 15, 2011, are eligible to vote in this election. Details concerning voting procedures will follow in the spring.

Candidates who wish to stand for election may submit a petition signed by 10 pharmacists residing in the relevant district to the Board of Pharmacy by March 10, 2011.

Serving on the Board of Pharmacy is a high calling. Membership requires a singular, and unwavering, commitment to the protection of the public health and safety. Any pharmacist interested in learning more about the duties, time commitments, and Ethics in Government Act requirements that come with service on the Board is encouraged to contact any Board member or Jay Campbell, the Board's executive director.

## *Item 2210 – Renewal Season Begins November 1, 2010*

The annual license, permit, and registration renewal period begins November 1, 2010. The Board renews licenses electronically. No paper renewals are accepted, nor will any paper renewals be sent to licensees. Pharmacists should visit the Board's Web site, *www.ncbop.org*, and follow the prompts for renewing online. To renew a pharmacist license for 2011, the licensee must acquire 15 hours of continuing education (CE), and eight of those hours must be contact hours. Up to five surplus CE hours may be carried over for up to one year. In other words, a pharmacist who acquires 20 hours of CE in 2010 may carry over the excess five hours into 2011.

Pharmacists are reminded that all licensees shall give the Board notice of a change of mailing address or a place of employment within 30 days after the change (NCGS §90-87.17). Pharmacists who have not notified Board staff of current employment information will not be allowed to renew. At any time during the year you may update your employment information by completing the Pharmacist Change of Employment Notification Form on the Board Web site. Please note: **if you are unemployed or retired,** you still must notify Board staff of your status. In addition, your street address is a required field. The system will not allow renewal of your 2011 license unless you provide a street address. You will still be allowed to use your PO Box as your mailing address. You may update your residential address online during the renewal process or via the Board's Web site at any time.

## *Item 2211 – Continuing Confusion and Frustration on Electronic Prescriptions for Controlled Substances*

Board staff continues to receive many inquiries concerning electronic prescriptions for controlled substances (CSERx). By way of recap:

Drug Enforcement Administration (DEA) issued a CSERx rule that was "effective" earlier this year. As noted in prior updates, however, the rule is effective only in the academic sense. That rule requires any system that either transmits or receives CSERx to be "certified" as meeting DEA's security and control standards in the CSERx rule. At press time DEA had not certified any transmitting or receiving system as meeting these security standards. Accordingly, CSERx still does not meet federal law requirements. Much more information about the rule and its operation may be found at *www.ncbop.org/faqs/Pharmacist/ControlledSubstanceE-RXFAQsApr2010.pdf*. DEA has published frequently asked questions on CSERx, which may

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## FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.*

## FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.*

## FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.*

## Safeguards to Implement with 'High Alert' Medications

*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.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag

check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

**Comparison to prescriber's order:**

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

**Additional cognitive checks:**

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

## *ASCO/FDA Program Provides Information on Expanded Access for IND Applications*

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- A thorough explanation of all expanded access programs available
- Links to key references and resources that are relevant to the slide content
- Selected virtual meeting presentations from ASCO Annual Meetings
- Helpful resources to use with patients

The program is available at *http://university.asco.org/Expanded Access* and participants may earn a certificate of participation or completion.

## *Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data*

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admissions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at *www.samhsa.gov/newsroom/advisories/1007140544.aspx*.

## *USP Recommends Patient-Centered Standards for Prescription Labels*

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at *http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d*.

## *Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document*

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- Recommendations: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm*.
- Response Letter: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149*.
- Scope of Contemporary Pharmacy Practice, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150*.

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be found at *www.deadiversion.usdoj.gov/ecomm/e_rx/index.html#faq*.

So where does that leave everyone? Basically, at the same place we have been all along. Any electronically signed prescription for a controlled substance does not satisfy federal law at this time. DEA has also stated clearly (see the DEA link above) that prescribers may not print or print and fax a prescription for a controlled substance that is electronically signed. Rather, the practitioner may print or print and fax a controlled substance prescription that they have actually signed (with the exception of Schedule II prescriptions, which may be faxed only for residents of long-term care facilities or for terminally ill patients). A pharmacist who receives an electronic prescription for a Schedule III, IV, or V medication may call the prescriber, confirm the prescription, and treat it as a verbal order.

Board staff is aware that a number of physicians and physician office managers have insisted that electronic prescriptions for controlled substances are allowable. This insistence, however well intentioned, is simply not correct. Both the North Carolina Medical Board and the North Carolina Medical Society have distributed this update to their licensees and members.

Unquestionably, the state of being for CSERx is one that is frustrating and confusing. Let's all hope that DEA will – and will quickly – certify CSERx prescribing systems. In the meantime, Board staff encourages pharmacists and prescribers to communicate with their electronic prescribing system vendors about those vendors' efforts to become certified. Those wishing to register complaints about the implementation – or lack thereof – of the CSERx rule should contact DEA. Board staff will continue to provide updates on this issue.

## *Item 2212 – Caution About Disposal of Copiers and Printers That May Contain Private Health Information in Memory*

Pharmacists should be aware that many copiers and printers store digital images of documents copied or printed in memory. When such copiers or printers are discarded or returned to a vendor, both the privacy provisions of the Pharmacy Practice Act and Health Insurance Portability and Accountability Act require that reasonable measures be taken to ensure that a patient's protected health information is not disclosed. Board staff encourages pharmacists to discuss this issue with their copier or printer vendors and implement appropriate policies and procedures.

## *Item 2213 – Reminder to Pharmacists Concerning Responsibilities/Opportunities in the Event of a Natural Disaster*

This update was occasioned by Hurricane Earl's approach to the northeastern North Carolina coast at the time of writing. Hopefully, in the weeks between this writing and publication, Earl spun harmlessly back out to the Atlantic and North Carolina was spared other serious storms. Still, each August to November is hurricane season along the eastern seaboard and pharmacists should keep the following in mind during this time.

**First,** remember your authority under Rule .1815 (21 NCAC 46.1815), which states that if a pharmacist is unable to obtain refill authorization due the prescriber's "inability to provide medical services" (often the case in the wake of a natural disaster), then the pharmacist may provide a one-time 90-day refill to the patient so long as:

(1) The prescription is not for a Schedule II controlled substance;
(2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
(3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
(4) The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by Section .2300 of these Rules and signs that order;
(5) The dispensing pharmacist or permit holder notifies, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

**Second,** under North Carolina insurance law (NCGS §58-3-228), health benefit plans must have in place a procedure to "waive time restrictions on filling or refilling prescriptions for medication" including "waiver or override of electronic 'refill too soon' edits to pharmacies and shall include provision for payment to the pharmacy in accordance with the prescription benefit plan and applicable pharmacy provider agreement" so that a patient may obtain a refill and/or replacement prescription when, among other things, a patient lives in an area that is "declared to be under a state of emergency in a proclamation issued by the Governor." Questions about this law should be directed to the North Carolina Department of Insurance (NCDOI). Information about contacting the NCDOI may be found at *www.ncbop.org/faqs/Pharmacist/faq_Insurance.htm*.

**Third,** pharmacist managers are required to "prepare a plan to safeguard prescription records and pharmaceuticals and minimize the interruption of pharmacy services in the event of a natural disaster such as hurricane or flood."



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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