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North Carolina Board of Pharmacy

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Item 2223 – Board of Pharmacy Election Results for the Northern and Western District Seats

Please join the North Carolina Board of Pharmacy in congratulating William (Bill) Mixon of Hickory, NC, and Carol Yates Day of Carrboro, NC, who were elected by North Carolina pharmacists as Board members from the Western and Northern Districts, respectively. The Board certified the election results at its May 17, 2011 meeting.

A record total of 3,347 votes were cast between April 11 and May 15. Mr Mixon and Mrs Day each received over 40% of the total votes cast for their district, thereby garnering a substantial plurality of the votes. Once officially appointed by Governor Bev Perdue, Mr Mixon and Mrs Day will take office effective May 1, 2012. In the meantime they will begin training requirements for occupational licensing Board members and learning Board operations and procedures.

Western District

Candidate Number	Candidate Name	Vote Count	% of Total
1	Allan Berg	218	6.5%
2	Stephanie Norris Kiser	1,069	31.9%
3	Troy McNeill	311	9.3%
4	William A. (Bill) Mixon	1,572	47%
5	None	177	5.3%
	Total	3,347	100%

Northern District

Candidate Number	Candidate Name	Vote Count	% of Total
6	Carol Yates Day	1,994	59.6%
7	Keith Waege	265	7.9%

8	Beth Steinbeck Williams	1,008	30.1%
9	None	80	2.4%
	Total	3,347	100%

News

The Board and its staff congratulate Mr Mixon and Mrs Day and wish 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 Western District – Allan Berg, Stephanie Norris Kiser, and Troy McNeill. From the Northern District – Keith Waege and Beth Steinbeck Williams. Their commitment to public service is evident by their candidacy and the showing of support that each garnered during the election.

The next Board election will take place in April/May 2014. 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. Messrs Minton and Marks are serving their first five-year terms and thus will be eligible to run for reelection in 2014.

Item 2224 – Betty Dennis to Serve as Board President for 2011-2012; Gene Minton to Serve as Board Vice President

At the Board's May 2011 meeting, the members selected Betty Dennis to serve as Board president and Gene Minton to serve as Board vice president. Dr Dennis and Mr Minton will serve in these capacities until May 2012.

Item 2225 – ACPE Requires Pharmacists to Obtain a Unique ID as Part of the CPE Monitor Initiative

Many pharmacists are aware that Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy[®] (NABP[®]) have launched CPE Monitor[™] – an electronic system for pharmacists and phar-

continued on page 4

NC Vol. 33, No. 1 Page 1



National Pharmacy

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Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE MonitorTM service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy[®] (NABP[®]) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at www.nabp.net/programs/cpe-monitor/cpe-monitor/service in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at www.nabp.net/programs or at www.MyCPEmonitor.net. CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal

laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- ♦ Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

Compliance News

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cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts. Further, ISMP calls on FDA to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at www. ismp.org.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies



This column was prepared by 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 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.

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

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 is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning: Benzocaine Use and Rare, But Serious Condition

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at www.fda.gov.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 30 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at www.fda.gov.

macy technicians to track completed continuing pharmacy education (CPE) credits.

Participation in CPE Monitor requires pharmacists to obtain an NABP e-Profile ID. Beginning later this year, the e-Profile ID will be required by ACPE to receive continuing education (CE) credits from ACPE-accredited providers. Pharmacists and pharmacy technicians will receive a unique ID after setting up their e-Profile with NABP. Beginning in the latter part of 2011, pharmacists and pharmacy technicians will provide their NABP e-Profile ID and date of birth (month and day only) to an ACPE-accredited provider when registering for CPE or submitting a request for credit. The system will then direct electronic data from ACPE-accredited providers to ACPE and then to NABP, ensuring that CPE credit is officially verified by the providers.

Once information is received by NABP, pharmacists and pharmacy technicians will be able to log in to access information about their completed CPE activities. After a transition period, ACPE-accredited CPE providers will no longer be required to distribute statements of credit. Pharmacists who have not already done so are encouraged to set up their e-Profile now. More information and instructions to set up your NABP e-Profile to obtain your ID are available at www.MyCPEmonitor.net.

Please note: North Carolina pharmacists will still be required to self-report all CE into their Board of Pharmacy account through their personal login at the Board's Web site. ACPE (or ACPE providers) will not download CE information into your Board of Pharmacy account. Although Board staff continues to explore means by which CE providers (whether ACPE or otherwise) may access the Board's system directly to input CE information for attendees, that capability does not yet exist. In 2012, use of the e-Profile ID system will, however, allow Board staff to readily retrieve verification of ACPE-accredited CE credits electronically, simplifying pharmacists' record keeping obligations for that type of CE.

Item 2226 – Inquiries Regarding the Addition of DEA Numbers to Controlled Substance Prescriptions By Pharmacists

Board staff has received a number of inquiries from pharmacists asking whether it is "legal" for a pharmacist to add a Drug Enforcement Administration (DEA) number to a controlled substance prescription when the prescriber omits that information. These inquiries have been provoked, it appears, by a number of third-party plan auditors who have demanded recoupment based on supposedly "illegal" controlled substance prescriptions on which the pharmacist has added the prescriber's DEA number.

Assertions that the addition of a DEA number to a controlled substance by a pharmacist is "illegal" are, in a word, false. DEA's own Web site states that "pharmacists are instructed to adhere to state regulations or policy" concerning changes or additions to controlled substance prescriptions (www.deadiversion.usdoj.gov/faq/general.htm#rx-7).

Furthermore, Board Rule .2301 (21 NCAC 46.2301) specifically provides that pharmacists may retain and add a DEA number to a controlled substance prescription when the provider inadvertently leaves it off.

Pharmacists are advised that a bill pending at the North Carolina General Assembly would, among other things, prohibit insurance or pharmacy benefit manager auditors from demanding recoupment based on assertions of "legality" that differ from Board of Pharmacy requirements. More information on that bill may be found at www.ncleg.net/gascripts/BillLookUp/BillLookUp.pl?Session=2011&BillID=H644.

Page 4 - July 2011

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