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News

North Carolina Board of Pharmacy

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Item 2214 – Reminder Call for Nominations for the Northern and Western District Board Seats

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

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 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 Western District must reside in one of these counties at the time of election.

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.

Details concerning voting procedures will follow in the spring.

Item 2215 – The Facts About, and Processes Involved in, Reporting Suspicious Prescriber Activity to the North Carolina Medical Board

Editor's note: Thanks to Curt Ellis, director of investigations for the North Carolina Medical Board, for authoring this important update.

Without question, pharmacists are the North Carolina Medical Board's (NCMB) best source of information pertaining to the prescribing activities of NCMB licensees (physicians, physician assistants, and nurse practitioners). The most common issue reported to NCMB by pharmacists is the overprescribing of controlled substances. Pharmacists know their customers and are aware of the prescribing habits of health care providers in their area. They are constantly on alert for cash paying drug seekers who only desire brand named controlled substances. Pharmacists report suspected drug seekers to law enforcement and misguided and naive prescribers to NCMB.

Pharmacists recognize patterns of inappropriate or irregular prescribing and report this information to NCMB. Many pharmacists are knowledgeable about the position statements relative to health care providers who may prescribe to themselves, their families, or others

with whom the prescriber has a significant emotional relationship. (To view NCMB's position statements, visit its Web site at www.ncmedboard.org, go to "Professional Resources," and select "Position Statements" from the menu.) Based on information provided by pharmacists, NCMB recently opened investigations concerning licensees who wrote controlled substance prescriptions for a family member and another licensee who provided long-term care for a family member.

When dispensing questions arise, such as wrong dosages, contraindicated medications, or possible prescribing beyond the scope of one's practice, pharmacists should contact the NCMB prescriber directly in order to resolve any misunderstandings. If these concerns cannot be resolved to the pharmacist's satisfaction, they are encouraged to report them to NCMB.

NCMB may take a variety of actions against a licensee who does not prescribe responsibly. Actions range from private letters of concern to license suspension or revocation. NCMB attempts to educate its licensees who strive to provide good care, but who do not prescribe responsibly. A commonly used remediation tool is the interim letter of concern (ILOC). ILOCs generally contain requirements that the licensee obtain prescribing-related continuing medical education, which typically includes an NCMB-approved prescribing course. The licensee may be requested to register with the North Carolina Controlled Substance Reporting System (NCCSRS). After remediation or education, NCMB may conduct additional patient chart reviews to ensure a licensee is prescribing responsibly and keeping appropriate records. When NCMB has more significant concern about a licensee's prescribing, a panel of NCMB members may personally interview the licensee about his or her prescribing, prior to taking action. Cases that reflect reckless or dangerous prescribing can result in loss of Drug Enforcement Administration privileges, and/or medical licensure.

NCMB investigators use a variety of methods to obtain information about licensees who prescribe controlled substances. The NCCSRS is a valuable tool for monitoring outpatient dispensing of controlled substances in North Carolina. It is widely used by pharmacists and NCMB investigators. When an NCMB investigator needs additional prescription records, the investigator may contact pharmacists directly. NCMB investigators may need hard copies of prescriptions or copies of other information to verify prescription data entered in NCCSRS. In these circumstances, pharmacist discretion is needed and investigators meet directly with pharmacists rather than with other pharmacy personnel. NCMB investigators

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DEA Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register*, reminds health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice. Such a practitioner may authorize an agent to “perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient,” and the guidance emphasizes that medical determinations to prescribe CS medications may be made by the practitioner only.

The specific circumstances in which an agent may assist in communicating prescription information to a pharmacy are detailed and include:

- ◆ An authorized agent may prepare the prescription, based on the instructions of the prescribing practitioner, for the signature of that DEA-registered practitioner.
- ◆ For a Schedule III-V drug, an authorized agent may transmit a practitioner-signed prescription to a pharmacy via facsimile, or may communicate the prescription orally to a pharmacy on behalf of the practitioner.
- ◆ An authorized agent may transmit by facsimile a practitioner-signed Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

The guidance also makes clear that generally, Schedule II prescriptions may not be transmitted by facsimile and that hospice and LTCFs are exceptions. Further, Schedule II prescriptions may only be communicated orally by the DEA-registered practitioner and only in emergency situations. DEA stresses that the practitioner should decide who may act as his or her authorized agent and advises that such designation be established in writing. An example written agreement is included in the policy statement, along with additional guidance related to designating an authorized agent. DEA also notes that as electronic prescribing for CS is implemented and its use increases, the role of the agent in communicating CS prescriptions will likely be reduced over time. The DEA policy statement is available on the *Federal Register* Web site at www.federalregister.gov/articles/2010/10/06/2010-25136/role-of-authorized-agents-in-communicating-controlled-substance-prescriptions-to-pharmacies.

FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with the National Association of Boards of Pharmacy® (NABP®), and as part of its Safe Use Initiative, Food and Drug Administration (FDA) encourages pharmacies to stop using the abbreviation APAP and to spell out the drug name, acetaminophen, in effort to help patients avoid acetaminophen toxicity. As explained in an FDA drug safety notice, liver injury

due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are enabling patients to know when their medication contains the drug. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug. The FDA drug safety notice provides more information and is available at www.fda.gov/Drugs/DrugSafety/ucm230396.htm.

In July 2010, NABP recommended that the state boards of pharmacy prohibit the use of the abbreviation APAP on prescription labels, and require that acetaminophen be spelled out. In situations where the board is unable to mandate such a provision, NABP recommended that the boards strongly encourage practitioners to follow this guideline. More information is available on the NABP Web site at www.nabp.net/news/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation/.

The ISMP Ambulatory Care Action Agenda: Learn from Others' Mistakes



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent non-profit 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.

No news is **not** good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems are to the errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

A great way to utilize the ISMP Medication Safety Alert!® Community/Ambulatory Care Edition is by using the Ambulatory Care Action Agenda*. Three times a year, selected items are prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors previously reported to the ISMP Medication Errors Reporting Program (MERP). The agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition during the preceding four



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

months. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts but also important for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion. The staff should reconvene in three months time to determine if the proposed recommendation strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial meeting.

According to the 2011 *Survey of Pharmacy Law*, published by NABP, at least 19 states regulate, require, or recommend a continuous quality improvement (CQI) program to monitor and prevent quality related events. The purpose of the CQI program is to detect, document, and assess prescription errors in order to determine the cause, develop an appropriate response, and prevent future errors. Utilization of the Action Agenda to review externally reported errors combined with review and analysis of internally reported events constitutes a feasible and effective CQI program.

*The Action Agenda is available at no charge on the ISMP Web site, www.ismp.org/Tools/communitySafetyProgram.asp.

Iowa Tracks Group Using Fraudulent CS Prescriptions

The Iowa Department of Public Safety seeks assistance in tracking a group of individuals using fraudulent prescriptions to obtain CS. Specifically, four unidentified individuals have obtained oxycodone using fraudulent prescriptions at a number of pharmacies in Iowa. Similar cases have occurred in Missouri, and it is believed that the same group of people is involved. The subjects are reported to have used multiple aliases, to be in their 20s or 30s, and to have paid in cash. They have also been reported to use crutches when dropping off and picking up prescriptions. The fraudulent prescriptions were on legitimate prescription paper with valid prescriber names, but the addresses on them had been computer generated. Similar cases or relevant information can be reported to Criminal Intelligence Analyst Crystal Munson at the Mid-Iowa Narcotics Enforcement Task Force by calling 515/270-8233, extension 119, or by e-mailing crystal.munson@polkcountyiowa.gov.

Stolen Carbatrol, Adderall XR Surfacing in Supply Chain

Shire, along with FDA, alerts pharmacists and distributors that certain lots of Carbatrol[®] that were stolen on October 17, 2008,

have been found in the supply chain as expired returns. The stolen shipment also contained Adderall XR[®]. The manufacturer warns that more stolen product may still be on the market and that stolen Carbatrol and Adderall XR should not be used or sold because the safety and effectiveness of the product could have been compromised by improper storage and handling or tampering while outside of the legitimate supply chain. The following products and lot numbers are affected:

- ◆ Adderall XR 15 mg, Lot No: A38146A, Expiration Date: 02/29/2012
- ◆ Carbatrol 200 mg, Lot No: A40918A, Expiration Date: 04/30/2010
- ◆ Carbatrol 200 mg, Lot No: A40919A, Expiration Date: 04/30/2010
- ◆ Carbatrol 200 mg, Lot No: A41575A, Expiration Date: 05/31/2010

These lots of Carbatrol and Adderall XR were stolen while in transit from Shire's manufacturing facility in North Carolina to Shire Distribution Center in Kentucky. FDA seeks assistance and asks that any information regarding the stolen Carbatrol or Adderall XR, including suspicious or unsolicited offers for these products, be reported by contacting FDA's Office of Criminal Investigations (OCI) at 800/551-3989, or by visiting the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

Survey of Pharmacy Law's 60th Edition Now Available!

Celebrating its 60th edition as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2011 *Survey of Pharmacy Law* is now available.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 18, Drug Control Regulations, asks whether or not states have CS or drugs of concern scheduled differently than the federal Controlled Substances Act.

Updates for the 2011 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of CS in Sections 26 and 27.

The *Survey* can be purchased online for \$195 by visiting the Publications section of the NABP Web site at www.nabp.net/publications.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

report that North Carolina pharmacists are always gracious when accommodating investigator requests, and have been described as “dropping everything to help us.” An investigator recently stated that, “one thing that cannot be over emphasized is the cooperation and assistance pharmacists provide on a continuing basis.” Pharmacists are aware that NCMB is a qualified health oversight agency and as such is exempt from Health Insurance Portability and Accountability Act privacy regulations.

NCMB accepts anonymous information from any source. Anonymity is provided to all pharmacists who request it and is offered to those who do not. Any pharmacist who is reluctant to report a NCMB licensee for fear of reprisal, should contact the NCMB and provide relevant information anonymously. Anonymous information must be treated cautiously; however, information provided by pharmacists has always proven reliable. Many individuals who anonymously report a concern to the NCMB have a motive for not identifying themselves, and some are more honorable than others. NCMB recognizes that pharmacists have but one motive: to protect the public’s health, safety, and welfare regarding all pharmaceutical matters.

Pharmacists are encouraged to report questions and concerns to the NCMB Investigations Department (800/253-9653). They should ask to speak to Curtis L. Ellis, director of investigations (ext 255) or Donald R. Pittman, director of compliance (ext 214).

Item 2216 – Continuous Professional Development

Editor’s note: Thanks to Toyin Tofade, pharmacotherapy director, Wake Area Health Education Center, for authoring this update.

The Board has adopted a program utilizing continuing professional development (CPD) as a way to learn and renew a pharmacist license. The first opportunity to renew a pharmacist license using CPD was December 2008. To prepare pharmacists interested in this alternative to “traditional” continuing education (CE), several live training sessions were conducted across the state. Many pharmacists have been trained, and over 200 pharmacists in North Carolina have selected CPD as a means of re-licensure.

The Board requires specific training on the CPD process if chosen as a pharmacist license renewal option. If you did not have the opportunity to get trained on CPD and are interested, four Webcasts have been developed and are required training activities:

1. CPD 101
2. Using Reflection to Create a Plan
3. Act/Evaluate/Record Your CPD
4. Continuing Professional Development in North Carolina

These training modules are offered as the North Carolina CPD Toolkit, and may be accessed at this link: www.theceinstitute.org/EducationPartners.aspx. There is a \$40 fee for enrolling.

(Editor’s note: These training modules were developed and are offered by non-Board personnel; the Board does not receive any of the fees charged for participation.)

If you choose to use CPD for re-licensure and are selected to participate in the Board’s annual CE audit, please have the following documents prepared and available for review:

1. A completed CPD learning plan.
2. Learning activity worksheets for each completed activity indicating
 - a. what you learned,
 - b. how much time you spent on it, and
 - c. what resources you used.

3. Accreditation Council for Pharmacy Education number for the CPD Toolkit CE program.

Item 2217 – Board Statement on Pharmacy Technician Students at Practice Sites

As many pharmacists are aware, pharmacy technician education programs in the state (principally at North Carolina community colleges) are increasingly incorporating an experiential component into the curriculum. Some pharmacists have inquired whether hosting pharmacy technician students as part of an experiential education program (1) requires that the students register as pharmacy technicians; or (2) affects the permissible pharmacist to technician ratio.

The Board does not interpret the pharmacy practice act as requiring students enrolled in a pharmacy technician education program to register with the Board when participating in an experiential education course. If, however, the student is employed by the hosting pharmacy as a technician, then the student must register as a pharmacy technician.

Likewise, the Board does not deem a pharmacy technician student participating in an experiential education course to affect the pharmacist to technician ratio. Again, though, if the student is employed by the hosting pharmacy as a technician, then the student must register as a pharmacy technician and his or her presence will affect the pharmacist to technician ratio.

The Board is supportive of quality pharmacy technician education programs, and takes the above positions as a means of encouraging such programs. The Board expects that all pharmacists and pharmacies will abide with both the letter and spirit of this statement.

Item 2218 – Board Statement Concerning Dispensing of Epinephrine Auto Injectors

As pharmacists are aware, there are several epinephrine auto injector products on the market – eg, EpiPen[®], Twinject[™], Adrenaclick[®]. Because epinephrine auto injectors are used in emergency situations, it is crucial that pharmacists dispensing these devices ensure that the patient or the patient’s caregiver is adequately trained on their proper use at the time of dispensing. Pharmacists must not assume that the patient or patient’s caregiver has been trained by others.

Of course, if a prescriber writes for a particular epinephrine auto injector and signs the prescription “dispense as written” (or handwrites “brand medically necessary” where Medicaid patients are concerned), the pharmacist must dispense the indicated product.

If substitution is permitted, the pharmacist may do so as allowed by North Carolina law.

In either case, the pharmacist should be certain that the patient or patient’s caregiver has been trained on proper use of **the particular device dispensed**. Absent such training, a patient’s life could be placed in danger.