April 2007

# North Carolina Board of Pharmacy

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### *Item 2133 – Update on the North Carolina Practical Examination*

As many practitioners are aware, the North Carolina Board of Pharmacy has proposed amendments to Rules .1505 and .1507 that would eliminate the North Carolina practical examination as a condition of licensure. The amendments would replace the practical examination with a review of licensure candidates' qualifications by Board staff. Moreover, the amendment would reduce the review fee from $200 to $75.

Board staff has received a number of calls inquiring whether the Board will administer a practical examination in June. Preceptors may well – and understandably – be getting the same question from pharmacy students. Board staff advises all licensure candidates to **assume that there *will* be a practical examination in June and prepare accordingly**.

The rule amendments have cleared the notice-and-comment stage and have been adopted by the Board. Even so, these amendments must still clear review by the Rules Review Commission (RRC) prior to implementation. Board staff does not expect any resistance to these amendments from the RRC. But, as observers of the rule-making process are aware, predicting RRC response to proposed amendments is an inexact science at best.

Licensure candidates are advised to read their application materials **carefully**. Because of the pending amendments, the application materials contain some specific directions about fees, fee deadlines, and notices that differ from years past.

### *Item 2134 – Board Staff Receiving Complaints from Physicians about Refill Authorization Faxes*

Several physicians in North Carolina have complained to the Board about the volume and nature of refill authorization faxes transmitted to their practices. These faxes, examples of which appear to be automatically generated, are causing at least two problems in physicians' offices. First, the sheer volume is overwhelming some practices. Second, the refill requests are often for medications that the physician has discontinued.

Board staff advises pharmacies that automatic refill requests of this nature can interfere with the physician-pharmacist relationship, with potentially negative consequences to patients. Moreover, generating refill requests for discontinued medications could result in a refill being inadvertently authorized by the physician and risking harm to the patient.

As a matter of basic professional courtesy and respect, Board staff strongly advises pharmacists to coordinate their refill authorization request methods with physicians' offices and to select a method that fits the particular practice and patients. One size does not fit all in this area.

### *Item 2135 – Update on the Work Hours Rule*

A number of pharmacists have inquired about the implementation status of the work-hour/break rule that the Board promulgated in 1998 and that the North Carolina Supreme Court affirmed in 2006.

Despite the Supreme Court's ruling late last year, several procedural hurdles remain before implementation. The rule is proceeding through the publication process and may have become effective by the time this *Newsletter* is published. Board staff will keep pharmacists updated through the Web site – *www.ncbop.org*.

### *Item 2136 – Illegal Internet Operations Continue to Solicit Independent Pharmacies in North Carolina*

Previous *Newsletter* items have alerted independent pharmacists that illegal Internet operations are soliciting them to act as "fulfillment" centers. This continues to occur. The typical "pitch" is that an Internet-based operation will forward some number of prescriptions to the pharmacy on a daily or weekly basis, for which the pharmacy may charge an extraordinarily large cash price. The prescriptions, unsurprisingly, will consist primarily of controlled substances (CS). These offers are indeed too good to be true and pharmacists should not accept them.

Board staff encourages pharmacists who receive these offers, however, to gather as much information as possible about the operator and forward that information to the Board office. Alert, diligent pharmacists in recent months have provided Board staff with information that allowed immediate action, including issuing cease and desist notices and alerting federal law enforcement authorities.

Please monitor the Board Web site, where you will find information about illegal Internet operations as Board staff members receive more information.

### *Item 2137 – Roll Out of the Controlled Substances Reporting Act*

Most pharmacists are aware that the General Assembly enacted a CS reporting system last year. The statute requires all dispensers to report information about CS prescriptions to the state (more detail about the statute may be found at the Board's Web site).

*Continued on page 4*

## FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

## Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

## Changes in Medication Appearance Should Prompt Investigation


*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

## *FDA Launches CDERLearn Educational Tutorial on MedWatch*

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

## *ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000*

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

## *Deadline Approaches for Pharmacists to Use NPI Numbers*

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at *https://nppes.cms.hhs.gov*.

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Though effective in April 2006, the statute has not yet been implemented. The North Carolina Department of Health and Human Services reports that the system is scheduled to be rolled out on July 1, 2007. Health Information Design, Inc has contracted with the state to implement the program. By the time this *Newsletter* is published, pharmacists should have received materials from Health Information Design describing the program, the electronic format for transmitting the required data, and a user manual. If you have not received this information, please contact Johnny Womble via e-mail at johnny.womble@ncmail.net.

## *Item 2138 – Board Policy Concerning Bad Checks that Accompany Technician Registrations/Renewals*

By law, the pharmacist-manager is responsible for ensuring that all pharmacy personnel employed at the pharmacy are properly licensed or registered. This includes, obviously, ensuring that all pharmacy technicians are currently registered with the Board.

Each year, the Board of Pharmacy receives a number of pharmacy technician applications or renewals accompanied by bad checks. Efforts to collect payment on such checks have proved difficult at best.

When a technician registration/renewal check is returned to the Board for insufficient funds, Board staff issues a first notice demanding payment from the technician. If the first notice is not successful, Board staff issues a second notice, this time to the pharmacist-manager at the employing pharmacy.

Going forward, if the second notice does not result in appropriate payment being rendered to the Board, Board staff will issue the pharmacy permit, pharmacist-manager, and technician a notice for disciplinary action. A technician who has not paid the registration or renewal fee is **not a properly registered technician.** Employing such technicians, therefore, violates North Carolina law.

**Board staff will also begin posting the *names and registration numbers of any technicians who have submitted bad checks on the Board's Web site.*** Pharmacist-managers are **strongly** encouraged to monitor this list periodically to ensure that any technicians they employ do not appear.

## *Item 2139 – Registration of Pharmacy Students Who are Employed as Pharmacy Technicians*

In the April 2006 *Newsletter* (Item 2107), the Board stated its policy about when and under what circumstances a student enrolled in a school of pharmacy approved by the Board must register as a technician. Under that policy, a pharmacy student "employed at a pharmacy as a technician . . . must register with the Board . . . ." A pharmacy student "working at a pharmacy as part of a school-sponsored experiential program – ie, the student is not employed, but is receiving instruction pursuant to a preceptor-student relationship . . . does not have to register with the Board as a technician."

Upon further reflection, the Board has decided to alter its policy concerning pharmacy students and technician registration. Effective immediately, a pharmacy student "enrolled in a school of pharmacy approved by the Board under G.S. 90-85.13" is not required to register as a technician. The Board believes that this policy is more consistent with the language of the pharmacy technician statute and will minimize confusion among pharmacy students, pharmacist-managers, and preceptors.

Even with this change in policy, however, the Board emphasizes the following:

- The student must be enrolled in a school of pharmacy to avoid the registration requirement. "Pre-pharmacy" students who are not actually enrolled in a school of pharmacy must register if employed by the pharmacy to perform technician duties. Students who are enrolled in a school of pharmacy and plan to work in a pharmacy during holiday or semester breaks do not have to register as technicians if they plan to return to school for the next session.
- The pharmacist-manager retains responsibility for ensuring that all activity in the pharmacy is compliant with the laws and rules governing the practice of pharmacy, including registration of all personnel who perform technician duties (excluding students as clarified in this statement).
- If a Board investigation determines that a pharmacy student working as a technician has violated the laws or rules governing the practice of pharmacy, then the Board will share that information with the student's school of pharmacy. Moreover, such a determination could ultimately impact the student's ability to obtain a license to practice pharmacy, as well as result in other legal consequences.



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