October 2006

North Carolina Board of Pharmacy

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Item 2123 – Changes in Investigative Staff and Operations

This summer, long-time Director of Investigations and Inspections Steve Hudson retired. The North Carolina Board of Pharmacy thanks Steve for years of superb service to the citizens of North Carolina. Steve has taken a position as accreditation manager for the National Association of Boards of Pharmacy®, and we look forward to continuing to work with him in his new capacity.

In July 2006, Karen Matthew took over as director of investigations. Karen retired earlier this year from the North Carolina State Bureau of Investigation, and her duties there included numerous investigations of pharmacy-related issues. She brings a wealth of investigative and administrative experience to the Board, and we appreciate her helping us make the transition so smooth.

Finally, the Board has moved investigative operations back to Chapel Hill, NC. The Newton, NC office will remain open for a short period while we complete the transfer, but all complaints and investigative inquiries should be directed to the Chapel Hill office from now on.

Item 2124 – Please Monitor the Board Web Site

As most pharmacists know, the Board's Web site – www.ncbop.org – underwent a substantial update and reorganization over the summer. Board staff constantly updates the site with health news, health advisories, Medicare/Medicaid information, permit and licensure information, and pharmacy law issues. The "Frequently Asked Questions" (FAQ) section is also updated frequently based on inquiries from practitioners. The *Newsletter* only appears four times a year, so Board staff urge practitioners to monitor the Web site as a means of keeping up with important news and developments year round.

Item 2125 – Medicaid Clarifies Its Use of Physician DEA Numbers

Item 2119 in the July 2006 *Newsletter* suggested that North Carolina Medicaid auditors were enforcing requirements of a Drug Enforcement Administration (DEA) number for non-controlled prescriptions for purposes of payment. North Carolina Medicaid states that this is not accurate. North Carolina Medicaid does not recoup monies based on missing or incomplete DEA numbers as part of a prescription. This is not an area that is part of routine Medicaid pharmacy audits. Pharmacists are reminded that they can call Electronic Data Systems for claims submission assistance at 1-800/688-6696 and can call Division of Medical Assistance for general post payment review audit questions at 919/647-8000.

Item 2126 – Medication Guides

Board staff frequently receive questions concerning Food and Drug Administration (FDA)-mandated distribution of Medication Guides. The questions tend to focus on which drugs have Medication Guide requirements and how to obtain Medication Guides for distribution. In response, Board staff has assembled an FAQ review of these issues, which is available at www.ncbop.org/faqs/Pharmacist/faq_MedicationGuidelines.htm. This review includes a link to FDA's Web site listing all drug products with Medication Guide requirements.

FDA's Web site also has Medication Guides available for download. Even so, FDA has stated that it is the manufacturers' responsibility to provide Medication Guides to pharmacies. Based on anecdotal reports to this office, manufacturer compliance (particularly among generic manufacturers) appears spotty at best. If you are not receiving Medication Guides for covered products from the manufacturer, Board staff recommend that you contact the manufacturer and, if necessary, FDA.

Item 2127 – Physician Self-Prescribing, Prescribing for Family Members, and Prescribing by Retired Physicians

Board staff are frequently asked whether or not, and under what circumstances, a physician may self-prescribe, prescribe for family members, or prescribe after retirement. The North Carolina Medical Board has specific policies to deal with each of these circumstances.

Self-treatment and treatment of family members and others with whom significant emotional relationships exist.

Physician

It is the position of the North Carolina Medical Board that, except for minor illnesses and emergencies, physicians should not treat, medically or surgically, or prescribe for themselves, their family members, or others with whom they have significant emotional relationships. The Medical Board strongly believes that such treatment and prescribing practices are inappropriate and may result in less than optimal care being provided. A variety of factors, including personal feelings and attitudes that will inevitably affect judgment, will compromise the objectivity of the physician and make the delivery of sound medical care problematic in such situations, while real patient autonomy and informed consent may be sacrificed.

When a minor illness or emergency requires self-treatment or treatment of a family member or other person with whom the physician has a significant emotional relationship, the physician must prepare and keep a proper written record of that treatment, including, but not limited to, prescriptions written and the medical indications for them. Record keeping is too frequently neglected when physicians manage such cases.

The Medical Board expects physicians to delegate the medical and

Continued on page 4

FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention

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.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm.* October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical®, Micalcin®**) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP®**), sumatriptan (**Imitrex®**), and zolmitriptan (**Zomig®**).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register,* FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors™ accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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surgical care of themselves, their families, and those with whom they have significant emotional relationships to one or more of their colleagues in order to ensure appropriate and objective care is provided and to avoid misunderstandings related to their prescribing practices.

(Adopted May 1991)

(Amended May 1996; May 2000; March 2002; September 2005)

The Retired Physician

The retirement of a physician is defined by the North Carolina Medical Board as the total and complete cessation of the practice of medicine and/or surgery by the physician in any form or setting. According to the Medical Board's definition, the retired physician is not required to maintain a currently registered license and **shall not**:

- provide patient services;
- order tests or therapies;
- prescribe, dispense, or administer drugs;
- perform any other medical and/or surgical acts; or
- receive income from the provision of medical and/or surgical services performed following retirement.

The North Carolina Medical Board is aware that a number of physicians consider themselves "retired," but still hold a currently registered medical license (full, volunteer, or limited) and provide professional, medical, and/or surgical services to patients on a regular or occasional basis. Such physicians customarily serve the needs of previous patients, friends, nursing home residents, free clinics, emergency rooms, community health programs, etc. The Medical Board commends those physicians for their willingness to continue service following "retirement," but it recognizes such service is not the "complete cessation of the practice of medicine" and therefore must be joined with an undiminished awareness of professional responsibility. That responsibility means that such physicians **should**:

- practice within their areas of professional competence;
- prepare and keep medical records in accord with good professional practice; and
- meet the Medical Board's continuing medical education requirement.

The Medical Board also reminds "retired" physicians with currently registered licenses that all federal and state laws and rules relating to the practice of medicine and/or surgery apply to them, that the position statements of the Medical Board are as relevant to them as to physicians in full and regular practice, and that they continue to be subject to the risks of liability for any medical and/or surgical acts they perform.

(Adopted January 1997) (Amended January 2001)

Pharmacists must, of course, apply their professional judgment when choosing whether or not to fill any prescription. The Board of Pharmacy encourages any pharmacist who is concerned about the prescribing habits of a particular physician to first discuss those concerns in a professional manner with the physician. Reference to the above Medical Board policies may facilitate that discussion. If such discussion does not resolve any perceived problem, the pharmacists should contact the Board of Pharmacy, Medical Board, or both.

Item 2128 – Internet-Based "Contact" Continuing Education

At a recent Board meeting, the members considered the issue of obtaining "contact" continuing education (CE) through Internet-based programs. Rule .2201(c) provides:

> (c) All [CE] shall be obtained from a provider approved by the Board. In order to receive credit, [CE] courses shall have the purpose of increasing the participant's professional competence and proficiency as a pharmacist. At least five hours of the [CE] credits must be obtained through contact programs in any calendar year. Contact programs are those programs in which there is an opportunity for live two-way communication between the presenter and attendee.

The consensus of the Board is that so long as an Internet-based program provides an "opportunity for live two-way communication between the presenter and attendee," it may count toward satisfying the contact-hour CE requirement. The Board notes particularly that Accreditation Council for Pharmacy Education-approved CE courses that are considered "live" so indicate in the course number. For example:

The Elements Necessary to Successfully Prove a Malpractice Case Against a Pharmacist

1 hour of CE credit (0.1 CEUs)

ACPE #: 312-000-06-011-L03

The underlined "L" designation for this online program indicates that this is a live program, and the Board will accept such programs as counting toward the contact-hour requirement.

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