

North Carolina Board of Pharmacy

P.O. Box 459, Carrboro, NC 27510-0459
 Carrboro Plaza Shopping Center, Highway 54 Bypass,
 Suite 104-C, Carrboro, NC 27510-1597
 Tel: (919) 942-4454 Fax: (919) 967-5757

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Item 978 – U.S. Congressman Coble Speaks Out for Pharmacists

In a hearing before the Subcommittee on Crime of the U.S. House of Representatives Committee on the Judiciary, North Carolina Board of Pharmacy Executive Director David R. Work was one of four individuals to make statements regarding recent actions involving aggressive pursuit and prosecution of pharmacists' civil infractions by the Drug Enforcement Administration (DEA). Other individual speakers before the Subcommittee included James Phelps of the law firm Hyman, Phelps, and McNamara; Phil Burgess of Walgreens; and Mike Beard, one of the victims of the DEA's efforts in Wichita Falls, Texas.

Earlier in the hearing, DEA personnel had stated that pharmacists often greet DEA agents in stores "with a warm embrace." North Carolina District VI Congressman Howard Coble, after learning of the DEA activities described by the panel, stated "If this is the kind of warm embrace that is being exchanged with DEA, I don't want to be the beneficiary of a hostile embrace. I mean, this is a horror story." Mr. Coble also emphasized his belief that people who are dealing drugs need to be "thrown in jail and let the door slam behind them."

Pharmacists in general, and Mr. Coble's constituents in particular, should thank him for his support of pharmacy in this important matter. His address is 2239 Rayburn House Office Building, Washington, DC 20515; the phone number is 202/225-3065. His North Carolina office phone number is 336/333-5005.

Item 979 – Disciplinary Actions June Pre-Hearing Conferences

Glenn Franklin Bass, Lumberton (DOB: May 6, 1963). Heard by Board member Watts. Removal and ingestion of controlled substances without legal authorization from the pharmacy where he was employed. Consent Order entered: License suspended indefinitely. Accepted by Mr. Bass June 1, 1998; accepted by Board June 16, 1998.

Kelly Morgan Sexton, Tarboro (DOB: December 14, 1967). Heard by Board member Overman. Possessing and consuming controlled substances without legal authorization. Consent Order entered: License suspended five years, stayed five years with specific conditions. Accepted by Mr. Sexton June 8, 1998; accepted by the Board June 16, 1998.

Gene F. Herring, Jacksonville (DOB: February 22, 1943) and Northwoods Drug Company, Inc., Jacksonville. Heard by Board

member Watts. Misbranding prescription drug products by dispensing such products in containers with misleading, expired, or otherwise inaccurate information on the labels. Consent Order entered: License of Mr. Herring and permit to operate Northwoods Pharmacy be placed on probation for one year from the date which the Board accepts the action with conditions. Accepted by Mr. Herring June 5, 1998; accepted by the Board June 16, 1998.

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Joe Jackson Bass, Jr., Wilmington (DOB: April 23, 1959). Consumption of phentermine without authorization. License suspended indefinitely, stayed five years with specific conditions.

Item 980 – Watch Those "Contact" Hours

Beginning with the 1999 renewal year, North Carolina rule will require pharmacists to obtain at least five of their ten required continuing education (CE) hours from "contact programs." Contact programs are those in which there is an opportunity for live two-way communication between the presenter and attendee.

Apparently, some pharmacists have confused the term "contact program" with the term "contact hour," which, according to the American Council on Pharmaceutical Education (ACPE), is a unit of measure of educational credit equivalent to approximately 50 to 60 minutes of participation in an organized learning experience. Do not confuse these terms.

All CE programs will be worth a certain number of "contact hours," but not all will be "contact programs" or live programs. It is easy to tell which programs offered by ACPE-approved providers are live programs. ACPE requires its providers to assign numbers to each program indicating whether the program is live (L) or home study (H). For example, a course numbered 456-777-88-999-L01 would indicate a live program. On the other hand, a course numbered 123-444-55-666-H01 would be a home study course and could not be counted as a live program. Be sure you complete five "contact hours" of "contact programs" (live programs) each year.

As an aside, the Board does accept CE obtained through AHEC programs, university-sponsored programs, local association programs, and other similar activities.

Item 981 – Scrutiny on Patient Counseling

The members of the Board of Pharmacy have continued to express concern about the counseling of patients by pharmacists or

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy, Complete and can only be ascertained by examining

Pharmacy Moves Towards National Credentialing for Disease State Management

In May 1998, a new chapter in pharmacy history began when it was announced that the Health Care Financing Administration (HCFA) had approved a Medicaid waiver that would allow Mississippi pharmacists to receive payment for providing pharmaceutical care to patients in four disease states: anticoagulation, asthma, diabetes, and dyslipidemia. Since then, a coalition of national pharmacy associations and industry representatives have been working to establish pharmacist credentialing for disease state management (DSM), both in Mississippi and across the nation.

The Mississippi State Board of Pharmacy, the University of Mississippi School of Pharmacy, the National Association of Boards of Pharmacy (NABP), and other interested pharmacy groups worked cooperatively to develop a credentialing process for disease state management by HCFA's July 1, 1998 deadline. The result was a process adopted by the Mississippi Board that requires pharmacists to pass a disease state specific examination and participate in a Board-approved, one-day performance skills workshop. The first DSM credentialing examinations for asthma, diabetes, and dyslipidemia were successfully administered to Mississippi-licensed pharmacists on July 8 and 9, 1998.

In a move towards establishing a national credentialing examination, NABP, the National Association of Chain Drug Stores (NACDS), and the National Community Pharmacists Association (NCPA) cooperatively formed the National Institute for Standards in Pharmacist Credentialing (NISPC), whose purpose is to coordinate the development of standards for DSM examination programs. Credentialing development includes setting the standards and guidelines for the DSM examination programs, establishing the skill and knowledge competency expectations for the respective DSM exam programs, and developing the evaluation instruments to assure that each pharmacist who completes the various DSM exam programs possesses the adopted competencies.

"The efforts of our three organizations and other interested members of the pharmacy community have encouraged the development of a quality credentialing program that is objective and defensible," said Carmen A. Catizone, NABP's executive director/secretary. "The program will provide the public with unprecedented access to pharmacists credentialed in disease state management, and will assist pharmacists in pursuing credentialing through a practical, valid, and economical process."

NABP and NISPC have created DSM credentialing examinations for asthma, diabetes, and dyslipidemia. These exami-

nations, along with a fourth exam for anticoagulation therapy, will be offered in cooperation with the state boards of pharmacy, beginning with the first nationwide test administration on October 28 and 29, 1998. Examination programs for other disease states will be developed as required.

The national credentialing model relies on NABP's examinations as the universally recognized "standardizing" credential for disease state management. However, the model also encourages pharmacists to participate in educational programs that they feel best meet their individual needs.

The standards for each of the DSM exams have been made available to organizations that develop educational and experiential programs for pharmacists, such as NCPA's National Institute for Pharmacist Care Outcomes (NIPCO). Release of this information helps ensure that the programs preparing pharmacists for patient care are consistent with the competencies of NABP's examinations.

NABP will also maintain a national database of pharmacists who pass the DSM examinations. The database will be part of NABP's searchable Pharmacist and Pharmacy Achievement and Discipline™ (PPAD™) database, which is available through the Association's Web site at www.nabp.net.

More information about NABP's DSM examinations may be obtained from NABP's Web site or by calling the Association at 847/698-6227. For information about the status of disease state management credentialing in an individual state, contact the state board of pharmacy office.

DEA Clarifies Schedule II Faxing Rule for Hospice Patients

The Drug Enforcement Administration (DEA) recently responded to a request from NABP to clarify the provisions of Title 21, Code of Federal Regulations, Section 1306.11 (g), which permits the facsimile transmission of a Schedule II prescription by a practitioner or his/her agent "...for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state..."

Clarification from the DEA was necessary because of confusion among various state agencies that were incorrectly interpreting the rule to mean that only those patients who reside in a long-term care facility could benefit from necessary prompt adjustments to their pain relief medications. In a letter to NABP, Patricia M. Good, chief of the Liaison and Policy Section of the DEA's Office of Diversion Control, emphasized the rule "was never intended to be 'venue' specific."

"The qualification of Title XVIII certification or state licensure was deemed to be sufficiently broad enough to encompass all circumstances which terminally ill patients would

Compliance News

Compliance news is not intended to be assumed the law of such state or jurisdiction.)



encounter, including those circumstances in which the hospice patient continues to reside in his/her residence," Good explained. "The 'venue specific' interpretation of this regulation, which requires the patient to reside in a location (such as a long-term care facility), clearly is a restriction not placed by, nor intended by, the regulation."

FDA Approves Thalidomide Use, Distribution System

On July 16, 1998, the Food and Drug Administration (FDA) announced that it had approved the drug thalidomide in treating erythema nodosum leprosum (ENL), a serious inflammatory condition in patients with leprosy, along with a restricted system of distribution intended to prevent fetal exposure to the drug. Originally used in the 1950s and 1960s outside the United States as a sedative and as a treatment for morning sickness during pregnancy, thalidomide use by pregnant women resulted in major fetal abnormalities, including amelia (absence of limbs), phocomelia (short limbs), hypoplasticity of the bones, absence of bones, external ear abnormalities, facial palsy, eye abnormalities, and congenital heart defects.

To prevent fetal exposure to thalidomide, the drug's manufacturer, Celgene, has developed a program titled System for Thalidomide Education and Prescribing Safety (STEPS). Only physicians and pharmacists registered in the STEPS program and trained in the risk of teratogenicity may prescribe and dispense thalidomide to patients. Additionally, all patients, both female and male, must comply with mandatory contraceptive measures, patient registration, and patient surveys.

The STEPS program requires that pharmacies dispensing thalidomide agree to several conditions. For example, at the time of first dispensing, the pharmacy must register the patient with the STEPS program, and must obtain and keep on file a signed patient consent form. The pharmacy may only dispense thalidomide based on a prescription that is no more than seven days old and may dispense no more than a one-month supply.

Prescriptions for female patients will not be filled without a physician's written report of a negative pregnancy test conducted within 24 hours of starting therapy. Pregnancy testing will continue to be required weekly during the first month of use, then monthly in women with regular menstrual cycles or every two weeks if cycles are irregular.

Although the number of patients being treated for leprosy in the United States is low (about 2,000 patients), the FDA and Celgene anticipate that thalidomide will be prescribed "off-label" for patients with certain dermatological conditions related to cancer and AIDS.

For further information, contact the FDA at 1-800/532-4440 or log onto the FDA Web site at www.fda.gov. Information may also be obtained from Celgene by calling 1-800/890-4619, ext. 4083.

New "Rx Only" Symbol Causing Confusion

New prescription product labeling requirements established by the Food and Drug Administration Modernization Act of 1997 (FDAMA) for pharmaceutical manufacturers may be causing some confusion among pharmacists and pharmacy staff, according to an article published in the July 1998 issue of *Pharmacy Today*.

Under the FDAMA, manufacturers' prescription packaging must carry, at a minimum, the symbol "Rx only," instead of the statement, "Caution: Federal law prohibits dispensing without prescription." This change was implemented to simplify drug labels and to reduce the incidence of medication errors caused by overcrowded labels.

Some pharmacists and pharmacy personnel, however, appear to be unaware of the new symbol. The article cites a letter to the American Pharmaceutical Association (APhA) from a prescription drug manufacturer that had received reports of pharmacy staff "putting some prescription medications out with the OTC products in error because of the lack of the [federal legend] statement."

Manufacturers must comply with the new labeling requirements by February 19, 2003.

NABP/State Boards Introduce Multistate Pharmacy Jurisprudence Examination

On November 2, 1998, the National Association of Boards of Pharmacy (NABP) begins to administer its new Multistate Pharmacy Jurisprudence Examination™ (MPJE™), a computer-based examination that assists participating state boards of pharmacy in assessing licensure candidates' knowledge of the jurisprudence requirements to practice pharmacy. The MPJE, which replaces the paper-and-pencil Federal Drug Law Examination™ (FDLE®) and many individual state law exams, will assess knowledge of both federal and state pharmacy jurisprudence requirements.

The computerized exam will be administered Monday through Friday, excluding holidays, on a year-round testing schedule through the Cogent Testing Network™. In addition to the test administration for pharmacist licensure candidates, the examination may be used by participating boards of pharmacy as a requirement for licensure transfer between states.

Contact the individual state boards of pharmacy for more information about whether a state requires the MPJE.

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the lack thereof. As of the deadline for this newsletter, the members were considering several proposals for additional emphasis by inspectors both during regular visits and through other means to emphasize the importance of patient counseling. As of this copy deadline, the staff has not yet received specific instructions from the Board members on this important issue. There is no doubt that patient counseling saves lives. The Board's Web site, www.ncbop.org, will contain further information on this subject.

A summary of the rule follows: Patient counseling is required on all new or transferred prescriptions. The offer may be conveyed by a technician; however, please be aware that the words "Do you have any questions?" has been determined by the Board to be a question and is not an offer to counsel. The offer needs to be made in a positive way to encourage acceptance.

Item 982 – Product Selection and Cyclosporine

It has come to the Board's attention that there have been several instances of inappropriate substitution or misreading of prescriptions for cyclosporine. There are two separate and distinct products on the market, Sandimmune® and Neoral®. In a sample of almost 3,000 prescriptions, 24 percent were written as cyclosporine and did not specify the intended formulation.

These two products are not bioequivalent and both products have black box warnings. Safely converting between these formulations often involves dose adjustments and frequent blood level monitoring to ensure proper therapy.

Item 983 – Pharmacy Technicians

As of the deadline for this newsletter, the General Assembly is moving to approve the registration of pharmacy technicians for 1999. More information will be included with permit renewal applications.

Item 984 – "Open Houses" and Drug Diversion

A recent report described a new drug diversion scheme that involved culprits attending real estate "open houses." While on the property, the culprits would look through the owner's medicine cabinet(s) for prescription containers, particularly

those with controlled substances and that indicated there were refills remaining.

After obtaining the information from the label, they would proceed to call in the refill at the pharmacy and obtain drugs illegally in this unique way.

Item 985 – New Rules Effective August 1

Several new rules adopted by the Board of Pharmacy became effective in August. A complete list of these rules can be found on the Board's Web site at "New Developments." These new rules have been incorporated into our Board rules, which can be found under "Literature" at www.ncbop.org.

While eight different sections of our rules were amended, the most significant involved additional requirements for the compounding log, a provision for the electronic transmission of prescription orders, and the creation of an inactive licensure status for retired pharmacists.

- ◆ The compounding log regulation now requires a pharmacy to have a record-keeping system, which includes the date of purchase, supplier, manufacturer, and lot number or other identifier of each ingredient used in each compounded drug product dispensed. Please note that hospitals can comply with this provision by keeping a record of lot numbers only.
- ◆ An important section, .1813, which addresses the electronic transmission of prescription orders, is worth your study.
- ◆ Retired pharmacists can now obtain an "inactive" license without obtaining continuing education, provided they pay the renewal fee. Other provisions apply if such individuals wish to reinstate their license.

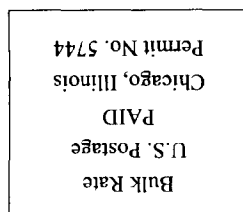
Other sections of our rules were amended, but these are the most significant parts.

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David R. Work, JD, RPh – State News Editor
Carmen A. Catizone, MS, RPh - National News Editor & Executive Editor
Anna Geraci - Editorial Manager

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NORTH CAROLINA BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc.
700 Busse Highway
Park Ridge, Illinois 60068