April 2000



North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Item 1056 – Disciplinary Actions

Prehearing Conference Recommendations

- Robert E. Adams, Hildebran (DOB May 29, 1940). Heard by Board Member Watts. Competency issues as noted in G.S. 90-85.38(a)(5). Accepted by Adams February 4, 2000. Accepted by Board February 15, 2000.
- **CVS Pharmacy**, 5700 Albemarle Road, Charlotte. Heard by Board Member Watts. Violation of patient counseling rule. Recommendation: Permit suspended one day, stayed one year with conditions. Accepted by **Barry Jasilli** on behalf of CVS November 15, 1999. Accepted by Board February 15, 2000.
- **CVS Pharmacy**, 2104 Statesville Blvd, Salisbury. Heard by Board Member Watts. Violation of patient counseling rule. Recommendation: Permit suspended one day, stayed one year with conditions. Accepted by **Barry Jasilli** on behalf of CVS November 15, 1999. Accepted by Board February 15, 2000.
- **Dana O. Friday**, Durham (DOB November 30, 1970). Heard by Board Member Watts. Dispensing error in the practice of pharmacy. Recommendation: Letter of Warning. Accepted by Friday December 11, 1999. Accepted by Board February 15, 2000.
- James S. Liverman, Hookerton (DOB May 5, 1931); Angelina C.
 Lane, Greenville (DOB February 11, 1962); Edwards Discount Pharmacy, Ayden. Heard by Board Member Moose. Violation of patient counseling rule. Recommendation: License issued to Liverman suspended five days, stayed five years with conditions; license issued to Lane suspended five days, stayed five years with conditions; and permit to operate Edwards Discount Pharmacy suspended three days, stayed five years with conditions. Accepted by Liverman July 23, 1999; Lane August 3, 1999; and Robert Tripp on behalf of the permit July 23, 1999. Accepted by the Board October 19, 1999.
- Jane W. Maney, Mars Hill (DOB January 4, 1971) and Laurel Medical Center, Mars Hill. Heard by Board Member Overman. Dispensing of prescription medication by someone other than a pharmacist or other individual licensed to dispense prescription drugs in North Carolina; one prescription drug erroneously provided to patient in place of what was ordered on prescription. Recommendation: License of Maney suspended seven days, stayed two years with conditions; permit to operate pharmacy suspended 30 days, stayed two years with conditions. Accepted by Maney November 16, 1999; Laurel Medical Center Pharmacy by John H. Estes, executive director November 16, 1999. Accepted by Board February 15, 2000.

PO 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 Web site: www.ncbop.org

- **Rebecca P. Miller**, Cloversville, NY (DOB November 2, 1969) and Eckerd Drugs, 4654 Capital Blvd, Raleigh. Heard by Board Member Moose. Dispensing a prescription drug without the product being properly prepared. Recommendation: Official Board Reprimand. Accepted by Miller July 7, 1999; accepted by **Rick Paderick** on behalf of Eckerd Drugs July 12, 1999. Accepted by Board October 19, 1999.
- Larry W. Nichols, Taylorsville (DOB October 13, 1943). Heard by Board Member Watts. Violation of patient counseling rule. Recommendation: License suspended seven days, stayed two years with active three day suspension and other conditions. Accepted by Nichols November 22, 1999. Accepted by Board February 15, 2000.
- **Eugene S. Simmons**, Siler City (DOB May 14, 1954). Heard by Board Member Watts. Diversion of controlled substances for personal use without authorization of a legal prescriber; while engaged in practice of pharmacy ingested controlled substances to an extent that he was impaired and unable to practice pharmacy without jeopardizing the health and safety of the patients he served. Recommendation: License suspended 30 days, stayed five years with specific conditions. Accepted by Simmons December 27, 1999. Accepted by Board February 15, 2000.
- John Umstead Hospital Pharmacy, Butner. Heard by Board Member Watts. Insufficient number of pharmacists and pharmacy support staff to safely provide pharmaceutical services for patients; allowing non-pharmacists to routinely dispense prescription drugs without the supervision of a pharmacist; using a 28-day dispensing system, which facilitated storage of prescription drugs in the nursing units in excessive quantities, and without regard for a mechanism to recall the products or the security of the products; prescription drugs stored without a system to identify discontinued or outdated drugs; allowing outdated or unusable drugs to stay on the patient care unit instead of being returned to the pharmacy for proper disposal; allowing nurses to perform dispensing functions. Recommendation: Permit suspended five days, stayed three years with specific conditions. Accepted by Daniel Paoloni, pharmacist-manager January 10, 2000; Patricia L. Christian, RN, chief executive officer January 10, 2000; and Don Willis, chief, Adult Mental Health Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services January 11, 2000. Accepted by Board February 15, 2000.

Continued on page 4



National Pharmac

(Applicability of the contents of articles in the National Pharma assumed and can only be ascertained by

IOM Report Addresses Medical Errors

A report released in late 1999 by the Institute of Medicine (IOM) of the National Academy of Science's Committee on Quality of Health Care in America concluded that rigorous changes throughout the health care system, including mandatory reporting requirements, are necessary to reduce medical errors and create a safer health care system.

Citing recent studies that place mortality estimates from medical errors between 44,000 and 98,000 annually, the Committee outlined a plan for government, industry, consumers, and health providers to reduce medical errors; called on Congress to form a national patient safety center to develop new systems that can address persistent problems; and set as a minimum goal a 50% reduction in errors over the next five years.

"Our recommendations are intended to encourage the health care system to take the actions necessary to improve safety," said William Richardson, chief executive officer of the W.K. Kellogg Foundation, Battle Creek, Mich, and chair of the Committee. "We must have a health care system that makes it easy to do things right, and hard to do them wrong."

The report, entitled "To Err Is Human: Building a Safer Health System," is available for a fee by calling 800/624-6242. The IOM is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences.

FDA Issues Final Dietary Supplement Labeling Rules

In the January 6, 2000 *Federal Register*, the US Food and Drug Administration (FDA) published final regulations that define the types of statements that can be made concerning the effects a dietary supplement has on the structure and function of the human body pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA). The regulations are intended to clarify the types of claims that may be made for dietary supplements without prior review by the FDA, as well as the types of claims that require prior authorization through the establishment of criteria for determining when a statement about a dietary supplement is a disease claim.

Under DSHEA, dietary supplements may, without prior FDA review, carry "structure/function" claims (ie, claims that a product may affect the structure or function of the body), but may not, without prior FDA review, carry express or implied claims that they can treat, diagnose, cure, or prevent disease (disease claims). For example, the express disease claim "prevents osteoporosis" and the implied disease claim "prevents bone fragility in postmenopausal women" would be prohibited without prior FDA review. The rule clarifies that express and implied disease claims made through the name of the product (ie, Carpaltum, CircuCure); through a statement about the formulation of a product (ie, contains aspirin); or thorough the use of pictures, vignettes, or symbols (ie, electrocardiogram tracings) can be made. It also permits claims that do not relate to disease, such as health maintenance claims ("maintains a healthy circulatory system"); other non-disease claims ("for muscle enhancement"); and claims made for common, minor symptoms associated with life stages ("for common symptoms of PMS," "for hot flashes").

Under DSHEA and existing regulations, dietary supplement manufacturers are already required to maintain documentation substantiating structure/function claims and must include a disclaimer on their labels that their products are not drugs and receive no FDA pre-market approval. They must also notify the FDA of the claims they are making within 30 days of marketing.

The final rule became effective February 7, 2000. For further information contact Ann Marlin Witt, Office of Policy, Planning, and Legislation (HF-11), FDA, 5600 Fishers Lane, Rockville, MD 20857, 301/827-0084.

Tablet-Splitting Policies Raise Concern

Some state boards of pharmacy are concerned about the cost-saving initiatives of certain health care plans that encourage or mandate the practice of dispensing higher doses of certain medications so that patients must split the tablet to obtain the appropriate dose. Targeted are those high-cost drugs that are available in similarly priced higher- and lower-dose tablets, such as Zoloft[®], which has 50 mg and 100 mg dosages selling for about the same price. Medical insurance plans favoring this method of cost cutting provide pill-cutters to enrollees and instruct physicians to prescribe the higher dosage tablets.

Inaccuracies in tablet splitting, the lack of testing on the effectiveness of split pills, and the potential for overdosing are the primary issues of concern. "As a cost-saving measure, tablet splitting may be considered in certain situations; however, health care insurers should not mandate such practices for financial gain without regard to patient safety," says NABP President Dyke F. Anderson. "The pharmacist is ultimately responsible for providing adequate patient counseling, and for assuring that tablet-splitting is safe and appropriate for the patient."

FDA Targets Illegal Internet Prescription Sales

The US Food and Drug Administration (FDA) is furthering its efforts to combat illegal Internet prescription drug and device sales. The agency recently announced that it has issued, via the Internet, warning letters to a dozen foreign-based Internet

Compliance News

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



Web site operators suspected of illegally offering to sell prescription drugs. This is the first time the FDA has used the Internet as a means for reaching those suspected of violating the Federal Food, Drug, and Cosmetic Act. In each case, the agency sent electronic letters to the domain holders of sites suspected of engaging in illegal prescription dispensing activities. The "cyber" warnings outlined the nature of the alleged violations and requested a formal response. They also explained the statutory provisions that govern interstate commerce of drugs in the US and warned that future shipments of products into this country might automatically be detained and refused entry. To date, the FDA has received one response indicating that the operator will cease its illegal activities. The FDA has indicated that it may use this approach in its efforts to crack down on domestic Web sites conducting illegal activities.

On another front, as part of its attempt to increase public awareness about the health, economic, and legal risks of online sales of prescription drugs and medical products, the agency recently established a Web site to provide consumers with information about buying such products online. The site provides information on FDA enforcement efforts, how to spot health care fraud, and how to protect oneself from dangerous online practices. It also has an electronic complaint form for consumers to report suspect sites. The FDA Web site may be accessed at <u>www.fda.gov</u>.

DEA Issues Guidelines to Avert Drug Abuser Scams

The US Drug Enforcement Administration has posted on its Web site guidelines for health care practitioners to avoid being scammed by drug abusers. The guidelines describe common characteristics of drug abusers (ie, assertiveness, unusual knowledge of controlled substances) and modus operandi often used in their efforts to obtain drugs (ie, seeks services after normal business hours, pressures practitioners by eliciting sympathy or guilt). The guidelines also summarize "do's" and "don'ts" for practitioners.

Entitled "Don't Be Scammed By A Drug Abuser," this publication can be found at <u>www.usdoj.gov/dea/programs/diver-</u> <u>sion/divpub/pub120799.htm</u>.

Pharmacist Impairment

A number of state boards of pharmacy report a growing concern with pharmacists procuring and using prescription medications for their own use. Besides constituting an illegal activity, these activities place the patient and pharmacist in a potentially dangerous situation. In situations where the pharmacist has become impaired and has not sought assistance through a state board-recognized impairment program, disciplinary actions have often resulted. The state boards of pharmacy are encouraging pharmacists to seek assistance if they believe they are suffering from impairment and to avoid disciplinary actions and dangerous situations. Most programs ensure the confidentiality of those who call for assistance.

NABP Announces Internet Licensure and Renewal Program

As early as this spring, if your state board of pharmacy participates in NABP's Internet License and Renewal Program, pharmacists will be able to renew their licenses via the Internet.

The system, which is being developed in conjunction with eGovnet, a provider of Web-based solutions for online transactions, is being pilot tested. NABP plans on having the program fully operational by late spring or early summer. Once activated, pharmacists will be able to renew their license in a matter of minutes using the Internet and a credit or debit card. The system will also allow for the licensing and renewal of pharmacy licenses/registrations and any other entity under the jurisdiction of the state boards of pharmacy.

Computerized NISPC DSM Program Available this Spring

Beginning in May 2000, the National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management (DSM) program will offer pharmacists a new, computerized format of NABP's DSM examinations in anticoagulation, asthma, diabetes, and dyslipidemia.

NABP, owner, developer, and administrator of the DSM exams will utilize LaserGrade, Vancouver, Wash, to administer the examinations. According to NABP Competency Assessment and Support Programs Director Ron Hanchar, LaserGrade has more than 200 testing sites nationwide.

Developed to access the competencies of practicing pharmacists in disease state management, the NISPC DSM program should not be considered "entry-level." NISPC recommends that pharmacists have at least two years of practice experience prior to sitting for the exams.

Pharmacists will have the option of taking one, two, three, or all four of the examinations by appointment. The fee for each examination is \$135, which includes the NISPC credential. Pharmacists registering for two or more exams on the same registration form will pay \$135 for the first exam and \$110 for the others.

For more information about the availability of the NISPC DSM examinations in your state, call NABP at 847/698-6227, or visit NABP's Web site at <u>www.nabp.net</u>.

Stuart R. Young, Durham (DOB June 27, 1953). Heard by Board Member Lockamy. Obtaining, possessing, and consuming controlled substances without lawful authorization. Recommendation: License suspended indefinitely, stayed until March 2004, with specific conditions. Accepted by Young February 4, 2000. Accepted by Board February 15, 2000.

Full Board Hearing

- Joseph Finnan, Rutherfordton (DOB April 10, 1941). Numerous dispensing errors committed in the practice of pharmacy. Finnan to remain under the terms and conditions of Consent Order for a period of five years, beginning November 16, 1999; license revoked, stayed five years with active suspension of 25 days and other specific conditions.
- William R. Francis, West Jefferson (DOB December 30, 1934). Practicing pharmacy more than 60 days after the expiration of his pharmacist license. License suspended one year, stayed five years with active suspension of 90 days from January 18, 2000 and other conditions.

Item 1057 – Spanish Language Labeling

The North Carolina Board of Pharmacy staff has assembled a short article about drug information on prescription labels, which includes a notice for Spanish speaking patients that many pharmacies are making Spanish-language prescription labeling available. Some pharmacies have Spanish in their brochures for over-the-counter (OTC) products that may be of substantial help to the Latino community.

Included in this article will be a coupon for requesting Spanish language labeling on prescriptions. Please be ready to respond if your computer allows you to print common prescription directions in Spanish. Pharmacists who are unfamiliar with medical Spanish may want to obtain the publication *Essential Spanish for Pharmacists*, by Glenn R. Kisch. It is available from the American Pharmaceutical Association, 2215 Constitution Ave, NW, Washington DC 20037-2985, telephone number: 202/628-4410. The verbiage of the coupon appears below for your information.

Recorte este cupón y preséntelo en la farmacia junto con su próxima receta o segunda preparación del medicamento para solicitar indicaciones en español para su receta.

(Cut out this coupon and present it at the pharmacy with your next prescription or refill to request Spanish labeling for your prescription.)

Pharmacist—Please label my prescription in Spanish and give me all available pertinent information in Spanish. Also include this request in my computer records for future prescriptions.

Este es un servicio de la North Carolina Board of Pharmacy y no tiene valor monetario.

Item 1058 – Important CE Facts

The recently completed license renewal season brought a greater than usual number of questions regarding what qualifies as "contact hours" according to the Board's definition. Please understand that the Board's definition may be different from that used by some providers of continuing education (CE).

North Carolina Board of Pharmacy rules at **Section .2201(c)** state that of the 10 required hours of CE, at least five hours 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 the attendee.

Many pharmacists had their license applications renewal returned last year because they failed to complete the required contact hours. Programs approved by American Council on Pharmaceutical Education (ACPE) that contain the letter "L," qualify for contact hour credit. Those programs with the letter "H," meaning home study, and those with the letter "C," meaning combined programs, do not qualify for contact hours in North Carolina.

Please make a note of this for your license renewal this calendar year.

Item 1059 – New FDA Rules Affect Samples

Late last year the Board of Pharmacy received an inquiry from a pharmacist about the possibility of dispensing prescription samples and charging a "dispensing fee." Board staff questioned the US Food and Drug Administration (FDA) as to the legality of a retail pharmacy dispensing prescription drug samples under the conditions listed below.

- The samples are stored separately from other products at the pharmacy under the direction of a physician.
- The physician writes a prescription for a patient on a designated sample prescription pad.
- The sample prescription is filled by the pharmacy in the same manner as any other prescription.
- Only uninsured patients are eligible to be dispensed samples.
- The patient is charged \$4 per prescription by the pharmacy to cover dispensing, record keeping, and counseling, but is not charged for the sample drug itself.

Since FDA has published new rules under the Prescription Drug Marketing Act (PDMA) of 1987, which included samples, we felt it appropriate to ask that agency for guidance.

A reply from FDA Representative **Margaret O'Rourke** included the following two paragraphs:

A review of the legislative history of the PDMA reveals that Congress affirmed the principles that prescription drug samples should only be distributed to licensed practitioners, but also intended to encourage health care institutions to allow qualified pharmacists to physically handle samples. The pharmacy of a hospital or other health care entity may act as custodian for an affiliated practitioner because the storage, handling, and accounting for prescription drug samples in health care institutions is generally more easily and effectively accomplished by the pharmacy than by individual health care practitioners. While the statute permits prescription drug samples to be delivered to the pharmacies of hospitals or other health care entities, the legislative history specifies that a health care entity does not include a retail pharmacy. Retail pharmacies are not permitted to receive, store, or dispense prescription drug samples under the PDMA.

In addition, [because] prescription drug samples may not be sold, traded, or purchased under the PDMA, the charging of a 'dispensing fee,' even though nominal, gives the appearance that the sample is being sold and should therefore be avoided.

We trust the foregoing will provide pharmacists with guidance on this important topic.

Item 1060 – Beyond-Use Date Standards From USP

The US Pharmacopeia (USP) has revised the beyond-use dating requirement for nonsterile, solid, and liquid dosage forms to make them more consistent with requirements for multi-unit containers. The new standard, published in the first supplement of the USP 24 - NF 19 states that the beyond-use date for these products shall be one year or less, unless the stability data or the manufacturer's labeling indicates otherwise. Pharmacists wishing to apply this standard should refer to the original USP document.

Item 1061 – New FDA Web Site

The US Food and Drug Administration (FDA) has established an Internet Web site to provide consumers with useful, easy-tounderstand information about buying prescription drugs and medical products online. This public outreach initiative is part of FDA's action plan to increase public awareness regarding the health, economic, and legal risks of online sales of prescription drugs and medical products.

The FDA has the legal authority to regulate the safety, effectiveness, manufacturing, labeling, and advertising of prescription drugs. By visiting FDA's Web site at <u>www.fda.gov</u> and clicking on the "Buying Medical Products Online," consumers can obtain information about how to protect themselves from dangerous online practices involving the sale of FDA-regulated products.

Consumers who suspect that a Web site is illegally selling human or animal drugs, medical devices, or products may fill out the electronic complaint form provided at this site and e-mail it directly to the FDA.

Item 1062 – Pharmacists Successful on DSM Exams

The North Carolina Board of Pharmacy has administered the Disease State Management (DSM) examinations offered by the National Association of Boards of Pharmacy (NABP) for more than one year. North Carolina pharmacists who have been successful on these exams are:

Asthma: Anita M. Britt, Greenville; Tina P. Brock, Carrboro; Gary A. Camp, Goldsboro; Christine S. Goodman, Pittsboro; Ruth Hall Higgins, Asheville; Lisa G. Kluttz, Burlington; Robert M. Malone II, Zebulon; Vickie D. McLean, Matthews; James B. Millner III, Burlington; Philip D. Minton, Burlington; Nancy T. Moore, Durham; and Alicia Z. Worf, Willow Springs.

Diabetes: Lisa M. Barnett, Asheville; Joe-Jeter Brewton, Asheville; Mark P. Brown, Clinton; Gary A. Camp, Goldsboro; Michelle L. Childs, Durham; Beverly A. Clark, Wilmington; Robert L. Crocker, Farmville; Ruth H. Higgins, Asheville; Teresa T. Jackson, Granite Falls; Robert M. Malone II, Zebulon; Theresa Malone, Zebulon; James B. Millner III, Burlington; April L. Robinson, Taylorsville; Christopher M. Rubino, Graham; Suzanne H. Trautman, Charlotte; Michael G. Williams, Benson; and L. George Williams, Greenville.

Dyslipidemia: Debra G. Aycock, Chapel Hill; Robert F. McClelland, Jr, Rocky Mount; Matthews P. Mielke, Raleigh; Sally P. Morton, Apex; Deana Russell, Roxboro; Catherine J. Shetzline, Chapel Hill; and Greta H. Wolff, Huntersville.

Anticoagulation: John M. Anderson, Gastonia; Debra G. Aycock, Chapel Hill; Christopher M. Jones, Charlotte; David S. McSwain, Gastonia; Rebecca J. Millan, Matthews; Jeffrey Risse, Durham; Deana R. Russell, Roxboro; Catherine J. Shetzline, Chapel Hill; and Greta H. Wolff, Huntersville.

Item 1063 – Computerized DSM Exams

The new, computerized format of the NABP Disease State Management (DSM) examinations will be administered in conjunction with NABP's 96th Annual Meeting at the Opryland Hotel and Convention Center in Nashville, Tenn, from May 6 through May 9.

To be eligible to sit for the exams, pharmacists must hold a license in good standing with their state board of pharmacy. The computerized examination fee for one examination is \$135, including the National Institute for Standards in Pharmacist Credentialing (NISPC) credential. If a pharmacist registers for two or more DSM exams on the same registration form, the cost of the first exam is \$135. The fees for the second, third, and fourth exams are \$110 per examination.

"More than 700 pharmacists in 27 states have already passed one or more DSM examination," says NABP President Dyke F. Anderson. "The computerization of these exams will make the program more accessible to pharmacists throughout the United States."

Item 1064 - Early Refill Myth

Comments have arrived at the North Carolina Board office indicating that some pharmacists have refused to refill prescriptions that they believe have been presented "too early." Occasionally this is accompanied by a statement that says that state law will not allow the early refill of prescriptions. That is not true.

Refilling prescriptions, even if refill authorizations exists, involves judgment. There should be no automatic presumption that because refills remain that the patient is automatically entitled to these drugs.

On the other hand, an early refill should not be automatically rejected if it is brought in prior to the normal refill date. The dosage may have changed, which is the most frequent reason for early refills, or the patient may be planning a trip, or there can be other equally valid reasons for requesting a refill earlier than normal. The pertinent Board rule on the subject is **Section**.**1802(a)**, which uses the term "refilling prescriptions in significant excess of normal therapeutic use." Pharmacists should be aware of that phrase, but after some time, should not automatically deny early refills.

Item 1065 – Altered Controlled Substance Prescriptions

Board staff received several calls on Item 1055 – Percocet Changes, which appeared in the January 2000 issue of this *Newsletter*. Some pharmacists were concerned that the activity described of calling the prescriber and noting a change in the prescription was somehow "altering" the prescription and making it invalid.

That is not the case. As long as the pharmacist is acting in response to the physician's order, such actions are only a clarification of the prescription document and do not adversely affect its validity.

The same activity could occur by verifying strengths of Ritalin or Dilaudid.

Item 1066 – Access to Prescription Records by Local Law Enforcement Agencies

Over the past several months, it has come to the Board's attention that some local law enforcement agencies, such as police and county sheriffs, have attempted to review and obtain pharmacy records without obtaining a search warrant, subpoena, or other court order. G.S. § 90-85.36 governs when pharmacy records may be disclosed and does not specifically permit disclosure to local law enforcement agencies. It does, however, provide that pharmacy records may be disclosed to "any person

Continued from page 5

authorized by subpoena, court order, or statute." G.S. § 90-107 states that prescriptions, order forms, and records for controlled substances shall be open for inspection only to federal and state officers whose duty it is to enforce the laws relating to controlled substances, and to authorized employees of the North Carolina Department of Human Resources. Again, local law enforcement agencies are not included. Consequently, local police and sheriff's departments do not have the right to review and obtain prescription records without first obtaining a search warrant, subpoena, or other court order under normal circumstances.

Pharmacists and permit holders should be aware, however, that G.S. § 90-85.36 does provide that "a pharmacist may disclose any information to any person only when he reasonably determines that the disclosure is necessary to protect the life or health of any person." Legislation may be introduced addressing this issue in the coming year.

Item 1067 – Emergency Oxygen Supply

The Durable Medical Equipment (DME) Subcommittee for the North Carolina Board of Pharmacy met on December 15, 1999. The numerous responses received from providers concerning our request for opinions on the minimum backup oxygen requirements for DME providers across the state was reviewed.

After much discussion, it was the unanimous decision of the committee to adopt an interpretation that in 21 NCAC 46.1608(a)(3)(A), "sufficient backup of oxygen" shall mean a minimum supply of 24 hours. Additionally, the plan of care for specific patients may require more backup oxygen. The organization's disaster plan should address the provision of greater than 24 hours backup oxygen for those clients who live a great distance from the location, and those who are more critical (ie, ventilators, high liter flow, etc).

This is important information considering the approach of hurricane season, which begins in the summer.

Item 1068 – Insurance Coverage for Contraceptive Drugs and Devices

In the 1999 legislative session, Senate Bill 90 was enacted, which provides that a health benefit plan providing coverage for prescription drugs or devices shall provide coverage for prescription contraceptive drugs or devices. The coverage also includes insertion or removal of contraceptive devices and any associated medically necessary examination. Outpatient contraceptive services are covered as well.

The legislation, however, provides an exemption for the health benefits plan of a religious employer if coverage for contraceptive drugs, devices, or outpatient services would be contrary to the employer's religious tenets. Senate Bill 90 applies to health benefit plans that are delivered, issued for delivery, or renewed on and after January 1, 2000.

Item 1069 - Sales Tax on Prescription Drugs

Effective October 1, 1999, the exemption from sales tax for prescription drugs was expanded to include any sale of prescription drugs, including the constituent elements and ingredients used to produce the drugs, the packaging materials, and any instructions or information about the product included in the package with the drugs. The requirement that the sale be pursuant to an actual prescription was removed from the statute as part of Senate Bill 1112.

For example, sales of prescription drugs by a pharmacy to a hospital or medical practice would not be subject to sales tax under the new law.

Page 6 - April 2000

The North Carolina Board of Pharmacy News is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc., to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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

Mark Paulson - Editorial Manager

This Newsletter is printed at a cost of \$.10 per copy.

NORTH CAROLINA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc. 700 Busse Highway Park Ridge, Illinois 60068

Bulk Rate U.S. Postage PAID Permit No. 5744