



# North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## ***Item 728 - Disciplinary Actions of the Board***

### ***May:***

**Sherwood Clifton Tate, Shelby.** Prescription misfilling. Official Board Caution.

**William H. Patton, Jerry P. Harper, and Marion Drug-Rite, Marion.** Dispensing prescription drugs without valid prescriptions, refilling prescriptions without authorization, dispensing generic products on prescriptions signed by the physician to dispense as written, misbranding of prescription drugs, failing to record filling dates on prescription documents, and failing to keep and maintain adequate records of the dispensation of prescription drugs; failing to prevent the events from occurring when the permit holder knew or should have known the violations were occurring. Permit suspended for 20 days, stayed for two years with specific conditions, including owners taking jurisprudence examination within one year of date of Order; license of Patton suspended six months, stayed two years with specific conditions; license of Harper suspended six months, stayed two years with specific conditions.

### ***June:***

**Russell V. Cobb, III and Dobson Drug Co., Inc., Dobson.** Selling prescription drugs without valid prescriptions; diversion of prescription drugs; charged with Class I Felonies of prescription drugs. License revoked. Pharmacy permit revoked.

**James L. Patterson, Jr., Statesville.** Obtaining and consuming Schedule IV controlled substance Adipex P and/or its generic equivalent, Phentermine 37.5 mg, without authorization. License suspended indefinitely, stayed five years with conditions.

### ***July:***

**George D. Teal, New Bern.** Obtaining and consuming PV Tussin from the stock of pharmacies where employed without authorization. License suspended 90 days, stayed two years with conditions.

## ***Item 729 - Change of Practice in January***

Most pharmacists are aware that effective January 1, 1993, federal law will require a drug use review program for all Medicaid beneficiaries. Part of this statute also provides for patient counseling for each Medicaid beneficiary who presents a prescription to a pharmacist. The Board is also considering the adoption of rules on patient counseling, which are anticipated to become effective by January 1, 1993.

A number of educational programs are now available on this subject, including one which was inserted into this and the July issue of this *Newsletter*. As of the copy deadline for this *Newsletter*, the University of North Carolina School of Pharmacy and

Campbell University are planning continuing education programs later this year that will provide more specifics on patient counseling and other matters.

## ***Item 730 - Hospital Renewals and JCAHO***

Hospital pharmacists should pay particular attention to this item. During a regular visit of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), one item on their checklist was to determine that professional employees have current licenses to practice. In this state, licenses and permits expire on December 31. However, there is a 60-day grace period following that date during which pharmacists can practice with this year's license and not be in violation of state law.

Normally, JCAHO surveyors will not accept this explanation for visits in January and February. As a result, the Board office gets several panic calls from licensees attempting to get their licenses and/or permits renewed in time for the JCAHO review.

This item reminds all hospital pharmacists, especially directors of pharmacy, that it is in your best interest to have any license or permit promptly renewed prior to January 1.

## ***Item 731 - Additional Guidelines for CE***

At the June and July Board meetings, members discussed the acceptability of certain kinds of continuing education for license renewal. It was their consensus that Cardiopulmonary Resuscitation (CPR), while meritorious, does not meet the intent of the Board rule on this subject.

The members also discussed a situation in which one individual selected in the annual random continuing education audit had obtained all continuing education hours in management improvement, personnel, and other courses designed to improve job performance but not necessarily pharmacy practice skills. It was the members' consensus that the Board would not accept this type of continuing education beginning in the 1993 renewal year. It was also the members' decision to limit preceptors to a total of five hours in any one year for supervising internship.

Please guide yourself accordingly in submitting CE credits for your 1993 license renewal.

## ***Item 732 - The Hugo Rule***

Several years ago, Hurricane Hugo did substantial damage to North Carolina, including some pharmacies. As a result, the Board adopted rule .2502 (i), which requires that each pharmacist manager have a plan to safeguard prescription records and pharmaceuticals in the event of a hurricane or other predicted national disaster.

*Continued on page 4*



# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Compendium and can only be ascertained by examining the original article.)

## Proper Completion of DEA Form 222

Concerned about confusion surrounding the proper completion of DEA Form 222 in regards to the "number of lines completed" and the generic substitution on order forms, the Deputy Assistant Administrator of the Drug Enforcement Administration's Office of Diversion Control, Gene R. Haislip, offered the following clarification in a recent letter to the National Association of Boards of Pharmacy (NABP).

Title 21 of the Code of Federal Regulations (CFR), section 1305.06(b) states that only one item shall be entered on each numbered line. It further states that the total number of items ordered shall be noted on the order form in the space provided. On the current version of DEA Form 222, the aforementioned "space provided" is termed "number of lines completed." When the above requirements are followed to the letter, there is no discrepancy between the number of items ordered and the number of lines completed.

Problems in interpretation have been encountered when the purchaser either uses more than one line to describe an item or voids an item. In the first instance, the correct interpretation would be to list the number of items ordered on the form in the space labeled "number of lines completed." DEA Form 222 will be revised in its next printing to rename the heading "number of items ordered."

The issue of voided lines on the order form is a bit less clear-cut in its interpretation. In strictly interpreting the regulations, the only conclusion that can be reached which is not open for interpretation is that a supplier may not fill an order form which "shows any alteration, erasure, or change of any description" (21 CFR 1305.11(2)). In fact, instructions provided on the reverse side of the DEA Form 222 advise the purchaser not to make erasures or alterations. They state that if an error should be made, all copies of the form should be voided and kept on file.

In addition, the regulations imply that only a supplier, not a purchaser, may void an item on a DEA Form 222. Section 1305.15(a) of the regulations states:

A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

Consequently, only the supplier has the authority to indicate the cancellation on the order form.

A separate but related issue has also been raised regarding generic substitution on order forms. DEA policy does not preclude generic substitution of identical products provided that the name and National Drug Code number of the actual product shipped is reflected on the form. Therefore, it would be acceptable to make a substitution provided that the customer agrees to accept a generic rather than a brand name product, the generic product of a manufacturer other than the one specified, or a brand name product rather than a generic one. Therefore, the purchaser will not be required to submit a new DEA Form 222 to accommodate such a change.

## Drug Offender's Driver's License Suspension

As noted in a Final Rule action published in the August 12, 1992 *Federal Register*, effective September 11, 1992, a new program enacted by the Federal Department of Transportation and Related Agencies Appropriations Act (the Act) "requires the withholding of certain Federal-aid highway funds from states that do not enact legislation requiring the revocation or suspension of an individual's driver's license upon conviction for any violation of the Controlled Substances Act (or for any drug offense as defined by the Act)". As defined in the Act, "Drug Offense" means:

- (1) The possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under the Controlled Substances Act, or
- (2) The operation of a motor vehicle under the influence of such a substance.

As also noted in the definitions section of the Final Rule, "Substance the possession of which is prohibited under the Controlled Substances Act or substance means a controlled or counterfeit chemical, as those terms are defined in subsections 102 (6) and (7) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802 (6) and (7) and listed in 21 CFR §§ 1038.11-15." The Final Rule also specifies "the steps that states must take in order to avoid the withholding of Federal-aid highway funds for noncompliance with 23 U.S.C. 159."

For further information, contact Mr. William Holden, National Highway Traffic Safety Administration (NHTSA), Office of Alcohol and State Programs, Traffic Safety Programs, Room 5130, 400 Seventh Street SW Washington, DC 20590, telephone (202) 366-2722.

# Compliance News

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



## *PMO Drug Labeling and Storage Requirements for Pharmacists Who Dispense Animal Drugs*

The National Conference on Interstate Milk Shipments (NCIMS), in accordance with the Memorandum of Understanding with the Food and Drug Administration, has at its biennial conferences recommended changes and modifications to the Pasteurized Milk Ordinance (PMO). Many of the recommended changes and modifications from the NCIMS in 1989 and 1991 related to the proper labeling, use, and on-farm storage of drugs intended for treating dairy cattle. The intent is to assure proper use of veterinary drugs, to prevent adulteration of the food supply with illegal drug residues through misuse of drugs in food producing animals, and to promote the health of treated animals. The following information is provided for those pharmacists who dispense animal drugs.

Administrative Procedures No. 11 in Section 7, Item 16f of the PMO requires that antibiotics and medicinals stored on Grade A dairy farms shall be properly labeled to include:

1. The name and address of the manufacturer or distributor for over-the-counter drugs, or the name and address of the veterinary practitioner dispensing prescription drugs and drugs intended for extra-label use.

2. Directions for use and prescribed withholding times for milk and meat.
3. Cautionary statements, if needed.
4. Active ingredient(s) in the drug product. (Note: The requirement for listing active drug ingredient(s) on the label is satisfied by the inclusion of the generic, common, established, or chemical name of the drug. Listing drugs by trade or brand names is not satisfactory.)

The Public Health Service/Food and Drug Administration's recommended Pasteurized Milk Ordinance is the basic standard used in the voluntary Cooperative State/Federal Program for Certification of Interstate Milk Shippers, a program participated in by all 50 states, the District of Columbia, and U.S. Trust Territories. The Ordinance is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the public health agencies, the milk industry, and many others as a national standard for milk sanitation.

For additional information, please contact the U.S. Food and Drug Administration, Division of Cooperative Programs, Milk Safety Branch, HFF-346, 200 C Street S.W., Washington, DC 20204-0001.

## *Schedules of Controlled Substances: Exempt Anabolic Steroid Products*

In accordance with Section 1903 of the Anabolic Steroids Control Act of 1990, the Drug Enforcement Administration (DEA) published in the July 22, 1992 *Federal Register*, an interim rule and request for comment regarding the designation of six pharmaceuticals as ex-

empt anabolic steroid products. The products listed below are considered by the DEA's Deputy Assistant Administrator, Office of Diversion Control, to have no significant potential for abuse because of their concentration, preparation, mixture, or delivery system.

Trade Name	Company	NDC Code	Form	Ingredients	Quantity
Estratest	Solvay Pharmaceuticals, Marietta, GA	#0032-1026	tablet	Esterified Estrogens Methyltestosterone	1.25 mg 2.5 mg
Estratest HS	Solvay Pharmaceuticals, Marietta, GA	#0032-1023	tablet	Esterified Estrogens Methyltestosterone	0.625 mg 1.25 mg
Premarin with Methyltestosterone	Ayerst Labs, Inc., New York, NY	#0046-0879	tablet	Conjugated Estrogens Methyltestosterone	1.25 mg 10.0 mg
Premarin with Methyltestosterone	Ayerst Labs, Inc. New York, NY	#0046-0878	tablet	Conjugated Estrogens Methyltestosterone	0.625 mg 5.0 mg
Testosterone Cypionate - Estradiol Cypionate Injection	Steris Labs, Inc., Phoenix, AZ	#0402-0257	Vial	Testosterone Cypionate	50 mg/ml
Testosterone Enanthate - Estradiol Valerate Injection	Steris Labs, Inc., Phoenix, AZ	#0402-0360	Vial	Testosterone Enanthate Estradiol Valerate	90 mg/ml 4 mg/ml

Continued from page 1

This is the hurricane season and, shortly prior to presstime, Hurricane Andrew made its way through Florida and Louisiana. This is an appropriate time to remind pharmacist-managers of their responsibility in this area.

### **Item 733 - Safety Line**

The Governor's Office of Citizen Affairs has published a telephone number to report suspected fire safety, health, or other hazards in your workplace. Reports can be made anonymously.

The Office of Citizen Affairs will receive information and forward it to the appropriate agency, whether it is the Department of Labor, the Insurance Commissioner's Office, or the Occupational Safety and Health Administration. This number is answered during normal business hours. At other times, you may leave pertinent information on an answering machine.

### **Item 734 -irate Customers**

Most community pharmacists will go to virtually any length to avoid confrontations with customers, but there are occasions when nothing will help the situation. If you have a person in your pharmacy, who is disruptive to the health and safety are at risk, you should consider calling the police or sheriff, whichever is appropriate. Many communities have a 911 emergency response number and often just mentioning the use of that service to an unreasonable customer can resolve the issue. It's worthwhile to remember that the authorities exist to protect you as well as everyone else.

### **Item 735 - Refills on PA/FNP Prescriptions**

The Board of Medical Examiners has determined that it is permissible for physician assistants and nurse practitioners to indicate refills on prescriptions. If this is done, it should be accomplished "on the order of" the supervising physician and not as part of the standard protocols for PAs/FNPs.

### **Item 736 - Newsletter Mailing Change**

In the past, the envelope which contained this *Newsletter* would also include an AHEC Continuing Education Calendar. As a cost-saving measure, the Board has decided to mail this publication from Chicago, so you may have noted the absence of information about continuing education programs.

The AHEC calendar will be included with the permit renewal mailing later this month, so please look for it with that material. Future mailings of AHEC program materials will be made within each area. Additional information on ACPE-approved programs can be obtained by calling 1-800/533-3606.

The new procedure, which is on a one-year trial basis, also involves the use of an address list compiled about six weeks prior to mailing. As a result, some of your colleagues may not have

received this issue if they recently changed residence or practice address. Please remind them of the need to promptly notify the Board office of such changes.

### **Item 737 - Sales Tax on Donated Drugs**

The North Carolina Department of Revenue has issued a notice to drug manufacturers, distributors, and retailers relevant to the practice of donating prescription or non-prescription drugs to non-profit organizations. Effective August 1, 1992, G.S. 105-164.13 was amended by adding a new subdivision (13a), which exempts from sales or use tax, legend and non-legend drugs donated to a non-profit organization to be used for charitable purposes. Any drug manufacturer or distributor or retail store that donates such medicines will be required to maintain adequate records to support the claim for exemption.

Other materials relevant to sales tax on prescriptions can be found in Item 655 in the November 1990 issue of this *Newsletter*.

### **Item 738 - Payment for Referrals Prohibited**

At a short session of the General Assembly, a change in statute was adopted, which essentially prohibits the payment to a health care provider for referrals. There is no criminal penalty for violating the statute; however, such activity can be grounds for the health care provider's licensing board to suspend or revoke a license to practice. Although there are few, if any, referrals subject to this statute in pharmacy, you should be aware that the proscription of this activity exists.

### **Item 739 - Interns and Pharmacists**

The members of the Board discussed the possibility that some interns may be using the pharmacist designation prior to passing the licensure exam. The members considered this to be misleading conduct which would be subject to scrutiny in the future.

Students or interns should avoid representing themselves as pharmacists, either on the telephone or by wearing a name tag or other insignia which might be inaccurate and inappropriate. Any printed information should clearly indicate that the student is either an intern or a degree candidate and, therefore, is not yet licensed to practice.

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