October, 1994

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

P.O. Box 459, Carrboro, NC 27510-0459
Carrboro Plaza Shopping Center, Highway 54 Bypass,
Suite 104-C, Carrboro, NC 27510-1597

Item 796 - Disciplinary Actions

April:

Willard E. Gares, Charlotte (DOB: May 18, 1937). Indulgence in use of drugs (alcohol). License suspended indefinitely, stayed five years with conditions.

Richard Phillip Jump, Greensboro (DOB: November 23, 1947). Dispensing controlled substances without valid prescriptions. Consent Order entered. License revoked.

Phar-Mor, Greensboro. Violations of patient counseling rule. Cautioned concerning the violations, and directed to ensure that all personnel employed by the pharmacy are aware of and comply with requirements of rule .2504.

May:

Livvie Washington Vann, III (DOB: November 8, 1946) and Drug Emporium, Greensboro. Violations of patient counseling rule (.2504) and Vann violation of the Board's Order Modifying Final Order and Reinstating License, dated July 20, 1993. Pharmacist and pharmacy are cautioned and directed to insure that all personnel employed in the pharmacy are aware of all requirements of 21 NCAC 46.2504, especially the requirement for Drug Utilization Review found in (c) and (d) of that rule.

June:

Hoover Henry Hilliard, Jr., Greensboro (DOB: November 5, 1944). Obtaining and consuming controlled substances without authorization. License suspended indefinitely, stayed ten years with conditions.

Stephanie Susan Balga Priester, Hendersonville (DOB: April 4, 1967). Obtaining and consuming prescription drugs without authorization. License suspended indefinitely.

Robert K. Atkins, Cary (DOB: May 2, 1945). Dispensing prescription drugs without authorization. License revoked.

James Michael Kinsland, Franklin (DOB: November 19, 1959). Obtaining and consuming controlled substances from pharmacy stock without authorization. License revoked.

July:

John Kenneth Carter, Tabor City (DOB: February 25, 1946). Obtaining and consuming controlled substances from pharmacy stock without authorization and dispensing prescription drugs without authorization. License suspended indefinitely.

Mary Louise Markow-Sears, New Bern (DOB: April 30, 1960). Pled guilty to one count of misdemeanor attempt to possess a controlled substance in district court; alcohol abuse. License suspended indefinitely, stayed five years with completion of six months active suspension currently serving and other specific conditions.

George Wesley Harris, Chapel Hill (DOB: August 23, 1931). Failure to offer or provide patient counseling. License suspended 30 days, stayed three years with an active seven-day suspension and other conditions.

Item 797 - Prescribing Rules Changed for PAs, FNPs

Prescribing rights have changed for physician assistants, nurse practitioners, and certified nurse midwives, and the approved formulary has been abolished for prescribing purposes. These practitioners may now prescribe drugs pursuant to written protocols, which outline the relationship between the supervising physician and mid-level practitioner.

In most situations, the pharmacist previously had no specific knowledge of what was contained in individual protocols. Therefore, the pharmacist could not be responsible for any activity beyond those protocols, unless they knew or should have known their contents.

Nurse practitioners and physician assistants who have DEA registrations (beginning with the letter "M") can also prescribe controlled substances with some limitations. Prescriptions for all drugs in Schedules II and III cannot exceed a one-week supply, and may not be refilled without the specific written or verbal order from the supervising physician. For other drugs, the prescriber may authorize refills for up to one year with the condition that all rules pertaining to controlled substances must apply.

Under these circumstances, physician assistants, nurse practitioners, and certified nurse midwives should be questioned about their prescriptions on the same basis that questions would arise with other prescribers, such as physicians, dentists, and optometrists.

The Board of Pharmacy has not yet revised its rules on the dispensing of drugs by mid-level practitioners. Any proposed changes will have adequate written notice in this *Newsletter.*

Pharmacists may also be interested to know that physician assistants have a provision in their rules which allows them to obtain 100 hours of continuing medical education for every two-year period, at least 40 of which must be AMA Category I or equivalent.

Item 798 - Note for Hospital Pharmacists

An article appeared in a recent journal of the American Society of Hospital Pharmacists from Mike Cohen, who has

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Co
and can only be ascertained by examin

Federal and State Actions Against Ephedrine Abuse

The June 30, 1994 decision to remove a player from the World Cup soccer competition because he tested positive for ephedrine and several ephedrine-like drugs in his system has highlighted the growing controversy surrounding ephedrine abuse.

Ephedrine's stimulant properties have made the drug a desired "upper" that can be easily obtained over-the-counter in many states in a 25-mg dosage unit. At truck stops, grocery stores, and convenience stores, ephedrine may be sold under the brand names "Mini Thins," "Dynafed," and "Efedrin."

According to the *1994 American Hospital Formulary Service (AHFS) Drug Information,* "the central nervous stimulating effects of ephedrine may result in nervousness, anxiety, apprehension, fear, tension, agitation, excitation, restlessness, weakness, irritability, talkativeness, or insomnia . . . Large parenteral doses of ephedrine may cause confusion, delirium, hallucinations, or euphoria."

The drug's increasing abuse and illicit use have prompted federal and state legislation to control its sale and distribution.

Federal Actions

In the March 17, 1994 *Federal Register,* the Drug Enforcement Administration (DEA) noted that all of the methcathinone laboratories seized by the DEA since 1991 and 75 percent of the methamphetamine labs seized since 1993 have used ephedrine as a precursor. To control this use, the DEA published a proposed rule that would eliminate the previous upper limit for ephedrine transactions that do not require reporting or record-keeping under the provisions of the Chemical Diversion and Trafficking Act of 1988 (CDTA).

Noting that the CDTA imposes reporting and recordkeeping requirements for regulated transactions which meet or exceed the threshold amounts of a listed category, the proposed rule also states that ephedrine has been a listed chemical under the provisions of the CDTA since the Act's passage in late 1988.

The threshold for ephedrine transactions originally established to require reporting and recordkeeping was 1.0 kg or greater for domestic and import/export transactions. This amount is equivalent to at least 40,000 ephedrine 25-mg tablets or capsules. DEA has determined that in order to effectively curtail the diversion of ephedrine, there should be no threshold for ephedrine transactions. This change would subject all transactions involving bulk ephedrine and single-entity ephedrine drug products to the applicable provisions of the Controlled Substances Act (CSA).

The Domestic Chemical Diversion Control Act (DCDCA) of 1993 amends the CSA to eliminate the establishment of thresholds for listed chemicals. By eliminating thresholds, all regulated transactions, regardless of size, are subject to CDTA reporting and recordkeeping requirements. [For more information, refer to the March 17, 1994 *Federal Register,* Vol. 59, No. 52.]

State Actions

Many states have also implemented regulations in reaction to clandestine laboratory operations in the state and a growing number of ephedrine-related deaths and emergency room incidents.

To provide a summary of state actions concerning ephedrine and ephedrine-combination products, the National Association of Boards of Pharmacy (NABP) conducted a survey of the state boards of pharmacy in July, 1994. The tables on these two pages summarize the restrictions placed on ephedrine in various states.

States with Restrictions on the Sale of "Ephedrine-Only" Products

Arizona [1]	Nevada [5]	Oklahoma [1]
Florida [2]	New Jersey [6]	Oregon [2]
Idaho [2]	New Mexico [2]	Washington [2]
Michigan [3]	North Dakota [7]	Wisconsin [4]
Missouri [4]	Ohio [1]	

1. Listed in Schedule V.
2. Legend Drug.
3. Possession of more than 4 grams requires a prescription.
4. Listed in Schedule IV.
5. Listed in Schedule III.
6. 50 mg is prescription only; less than 50mg is OTC.
7. 50 mg capsules and injectables are legend; 25 mg capsules are OTC.

The following states are considering proposals to list "ephedrine-only" products as controlled substances: Alabama, Minnesota, and South Dakota.

As the "States with Restrictions on the Sale of 'Ephedrine-Only' Products" table indicates, 14 of the states responding to NABP's survey have placed some type of restriction on the sale of products containing ephedrine only, and three additional states are considering proposals to schedule ephedrine-only products as controlled substances. Six of the surveyed states reporting restrictions have listed single-entity ephedrine products in a controlled substance schedule, and five of the states designate it as a legend drug.

The "States with Restrictions on the Sale of 'Ephedrine-Combination' Products" table shows that 11 states have designated restrictions for ephedrine-combination products, with three of those states listing these combination products in a controlled substance schedule, and two states listing the products as non-controlled legend drugs. Two states are considering proposals to list ephedrine-combination products as controlled substances.

When compiling the tables, NABP did not have information from the following states and jurisdictions: Colorado, Connecticut, the District of Columbia, Hawaii, Indiana, Maine, Massachusetts, Pennsylvania, Utah, Vermont, and West Virginia. The

Compliance News

ıpliance. ws to a particular state or jurisdiction should not be assumed
ng the law of such state or jurisdiction.)

remaining 40 states did respond to the survey.

If you would like more information about ephedrine restrictions in your state, contact your state board of pharmacy office.

States with Restrictions on the Sale of "Ephedrine-Combination" Products

Florida [1]	Nevada [5]	Virginia [8]
Idaho [2]	New Mexico [1]	Washington [9]
Michigan	Ohio [6]	Wisconsin [3]
Missouri [3,4]	Oregon [7]	

1. Legend Drug.
2. Legend, Formulary List.
3. Listed in Schedule IV.
4. Products containing "ephedrine-combination" are still considered Schedule IV if the other ingredient is "therapeutically insignificant."
5. The combination must be an active ingredient or ingredients of specific use.
6. Listed in Schedule V.
7. OTC formulations are exempted on a case-by-case basis.
8. May not be sold in combination with caffeine.
9. 25 mg/dosage unit in combination with other ingredients in therapeutic amounts.

The following states are considering proposals to list "ephedrine-combination" products as controlled substances: Oklahoma and South Dakota.

NABP Releases Patient Counseling Survey Results

Now that state regulations implementing the prospective drug utilization review and patient counseling requirements of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) have been in place for over a year, the National Association of Boards of Pharmacy (NABP) has commissioned Elrick & Lavidge, a national, independent market research firm, to survey patients and caregivers about whether they are being counseled by their pharmacists at the time they are receiving their prescription medications from the pharmacy.

In July 1994, researchers at Elrick & Lavidge surveyed representative households from across the nation in which respondents had personally received a prescription from a pharmacy within the past six months, and personally used or administered the medication to another person. Elrick & Lavidge certifies the accuracy of this survey at 95 percent.

The survey results were surprising. While 40 states have extended OBRA 90's mandate to all citizens, not just Medicaid patients, only four consumers in ten, or 38 percent of those surveyed, stated that someone in the pharmacy offered to have a pharmacist discuss the prescription medication with them. In those instances where counseling was offered, the pharmacist made the offer to counsel about 65 percent of the time, while pharmacy clerks and technicians did so about 30 percent of the time. A resounding 71 percent of those respondent patients or caregivers who were offered counseling accepted.

The survey also found that at a time when many state boards of pharmacy are warning of liability issues and urging their licensees to have their patients sign a form stating that they have refused the offer to counsel, only about one-third, or 34 percent, of the respondent patients or caregivers who refused counseling on their medication were asked to do so.

NABP also asked Elrick & Lavidge to discover what information was being covered during the counseling session. Using the 12 items listed in OBRA '90 as a guide, the survey found that at least 93 percent of the time pharmacists told their patients how and how often to take their medication. Eighty-five percent of the time, patients were reminded of the dosage amount and the name and a description of the medication. Seventy to 75 percent of the time the pharmacist told the patient how long the medication should be taken, discussed any special directions or precautions that should be exercised, as well as the reason for taking the medication and any side effects that might occur while using the medication. And in just over half of the counseling sessions, the pharmacist provided information about refilling the prescription and the results that could be expected after taking the medication. Less than half of the time, pharmacists told their patients how to monitor the effects of their medications and what they should do in the event of a missed dose. Ninety-nine percent of the survey respondents felt that their pharmacist had clearly presented the information.

Elrick & Lavidge's surveyors also asked respondents what factors they considered when selecting a pharmacy. Using a five-point scale in which the number five equated to "very important" and the number one indicated "not important at all," the location of the pharmacy, with a mean score of 4.27, was the most important factor; the price of the prescription came in second with a mean score of 3.83; and counseling followed closely with a mean score of 3.77.

Using the same five-point scale, 71 percent of those surveyed assigned the number five when asked if it was important to have pharmacists counsel patients on their prescription medications.

NABP President Paul G. Boisseau discussed the results of the patient counseling survey with the delegates to NABP's Executive Officers Conference in Washington, DC. "The survey results clearly indicate that too few patients and caregivers are being counseled on their prescription medications," he told the audience. "However, in those pharmacies where counseling is taking place, the pharmacist is doing a pretty good job of communicating the necessary information."

Continued from page 1

gained some fame as a collector of prescription errors. In the article, Cohen discussed the severe difficulty that he had obtaining an emergency dose of a prescription drug for his wife.

A contact person for Cohen confirmed that the incident did not take place in North Carolina, nor should it have occurred in this state. The Board adopted a rule, which became effective on September 1, 1993, that allows a pharmacist to provide a 72-hour supply of a prescription drug under emergency circumstances. An emergency supply can be legally dispensed if the pharmacist determines that the medication is essential for the patient to maintain health, and that denial of the drug would cause substantial problems for the patient. It is necessary that the pharmacist then notify the prescriber or the prescriber's office within 72 hours.

The Board's enforcement policy was also clarified in the April, 1992 issue of this *Newsletter.* Item 711 clearly states that pharmacists should have no fear of Board action if they are reasonably responding to a patient's pain or other needs on a one-time basis. While some practitioners "hide behind the law," under these circumstances that excuse is not valid in this state.

Item 799 - Pharmacist Workload

The Board continues to receive expressions of concern from pharmacists about their extra workload and their ability to comply with the rule on patient counseling. Because of these concerns, the North Carolina Board presented a resolution addressing this issue at the National Association of Boards of Pharmacy's Annual Meeting in May.

The resolution, which was adopted, provides for a research project that would determine the effect of pharmacist workload on the public health and safety. The project would also assess such matters as prescriptions per time period, technician assistance, computer capabilities, patient counseling, drug utilization review, hours worked by pharmacy department employees, working conditions, and scheduled meal breaks

Project results are scheduled to be available no later than May of 1996. When the results are released, they will be published in this *Newsletter* and other places.

Item 800 - All Units Are Not Equal

A recent USP publication noted a possible problem with units of different drugs. One incident was discussed that involved a nurse who used a one mL insulin syringe, based on the concentration of 100 units of insulin per mL, to administer a 25-unit dose of calcitonin injection. Although the nursing home staff normally used one mL tuberculin syringes to measure the calcitonin, the syringes were unavailable. The concentration of the calcitonin was 200 units per mL. Instead of calculating the dose of mL, the nurse measured the dose in units on the insulin syringe thinking that a unit of one drug is equal to a unit of another. Consequently, the patient was given double the dose of 50 units of calcitonin.

Some practitioners may not understand that the term "unit" is not analogous to any metric measure, and that there is no universal equivalency between different units. Pharmacists who are in a position to educate other health professionals about this matter should guide their conduct accordingly.

Item 801 - "As Directed" for Labeling

From time to time, pharmacists may receive prescriptions with instructions from the prescriber that state, "As Directed." It is the editor's opinion that pharmacists have an affirmative duty to be sure that patients understand the intended directions of the prescriber. Any vagueness on this issue should be resolved prior to the patient leaving the pharmacy with the prescription drug.

Item 802 - Counseling of Patients in Rest Homes

Board members have requested that the Executive Director remind pharmacists who serve rest homes that they have an affirmative duty to offer to counsel patients in those facilities. Such pharmacists should not rely on rest home employees to convey prescription information to their residents.

Item 803 - Board Action and Service as a Preceptor

Pharmacists should understand that their service as a preceptor is a privilege that can be withdrawn by the Board. A rule does exist which states that a pharmacist who has been found in violation by the Board, pleads guilty or no contest, or is found guilty of violating laws, rules, or regulations governing the practice of pharmacy or the distribution of drugs cannot serve as a preceptor without approval by the Board.

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
Janice Teplitz - Editorial Manager

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

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

NORTH CAROLINA BOARD OF PHARMACY

Nonprofit Organization
U.S. Postage
PAID
Park Ridge, Illinois
Permit No. 75