



# North Carolina Board of Pharmacy

P.O. Box 459, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## Item 678 - Board Disciplinary Actions

### February:

**William Nemargut, Leland.** Consumption of Schedules II and III controlled substances for his own personal use without a valid prescription; violation of Board's Order dated February 18, 1986. License revoked.

**Perry Diamaduros, Charlotte.** Diverting and consuming controlled substances for personal consumption without authorization. License suspended indefinitely and may not apply for reinstatement of license until final disposition of criminal charges against him or one year from date of Final Order, whichever is shorter and certain other conditions.

**Perry E. Hawkins, Eldon McDaniel & Plaza Hills Pharmacy, Inc., Charlotte.** Filling and refilling prescriptions without authorization and failing to maintain records of the dispensing of prescription drugs. Respondent pharmacy failed to prevent the violations described herein when the permit holder knew or should have known that the violations were occurring. Licenses held by Hawkins and McDaniel suspended for six months, stayed for period of five years with active 30-day suspension for each pharmacist and other specific conditions. Pharmacy Permit suspended for a period of 90 days, stayed for five years with an active seven-day suspension and other specific conditions.

### March:

**Richard Vann Kennerly, Mooresville.** Request for reinstatement of pharmacy license granted with specific conditions.

### April:

**L. Joseph Finnan & Rutherford Rexall Drug Company, Rutherfordton.** Failure to sign controlled substances prescriptions; failure to record patients' addresses on prescriptions; failure to record name of the manufacturer on prescriptions; and refilling prescriptions without authorization. Respondent pharmacy failed to prevent the events described above when the permit holder knew or should have known the violations were occurring and that these actions were in violation of Board's Final Order of November 19, 1985.

Respondent's license to practice pharmacy is revoked, stayed for a period of five years with an active 30-day suspension and other conditions. Permit suspended indefinitely, stayed indefinitely if the pharmacy passes an inspection performed by authorized Board personnel.

## Item 679 - Election Results

On May 21st, the members of the Board of Pharmacy Elections certified the results of the balloting for two, five-year Board terms that will begin in the Spring of 1992. The results are:

### District 1:

Ken W. Burleson	634
Harold Vann Day	814
Linda M. Morgan	299
William VanValkenburgh	392

### District 2:

Laura G. Burnham	331
Frances Gualtieri	327
Joseph L. Johnson, Jr.	193
Jack G. Watts	1,302

A runoff election was requested in District 1, and Mr. Watts was declared the winner in District 2. A ballot for the runoff election is enclosed. Votes must be cast by August 19, 1991, at which time they will be counted in the Board office beginning at 3:00 p.m.

## Item 680 - Foreign Prescriptions

Are prescriptions from physicians in foreign countries valid in this state? This question arises if visiting relatives need a refill, or occasionally when foreign relatives cannot afford or obtain a specific drug. In North Carolina, it is legal to fill foreign prescriptions provided that a legitimate physician/patient relationship exists and a controlled substance is not prescribed. Controlled substance prescriptions must be written by a registrant, and it is unlikely that

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# National Pharmacy

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

## ***Final Rule Affects Partial Filling of Prescriptions for LTCF and Terminally Ill Patients***

The manner of issuance for Schedule II controlled substance prescriptions written either for Long-Term Care Facility (LTCF) patients or for patients diagnosed as terminally ill is due to change on July 3, 1991, when the Drug Enforcement Administration's final rule which amends 21 CFR 1306.05 and 1306.13 takes effect. The following amendments to Section 1306.13, which appeared in the June 3, 1991 *Federal Register*, are of particular interest to state boards of pharmacy.

### **Section 1306.13 Partial filling of prescriptions.**

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a *corresponding responsibility* to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." *A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act.* For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness **may be maintained in a computerized system if this system has the capability to permit:**

Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of

the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Section 1306.13.

## ***Emergency Room Dispensing of Controlled Substances***

*The following memorandum was issued by Gene R. Haislip, Deputy Assistant Administrator of the DEA's Office of Diversion Control, and submitted to the Foundation's office by Paul G. Boisseau, Executive Director of the New Hampshire Board of Pharmacy.*

The Office of Diversion Control has received numerous inquiries from field offices, professional associations, and individuals regarding the Drug Enforcement Administration's (DEA) policy with respect to the dispensing of controlled substances from a hospital emergency room's stock in order to fill a telephone order from an off-site physician for a patient who has not been seen by the emergency room physician. The most common scenario cited is that of a physician who calls the emergency department to order controlled substances for a patient whom he has either seen or consulted with and who is in need of a controlled substance.

The issue at hand is whether the patient must also be evaluated by the emergency room physician (and consequently be charged the attendant fees) or whether the emergency room staff can simply dispense the drugs pursuant to the off-site physician's order. In some cases the situation is further complicated by the fact that the setting is rural and other types of pharmacy services are limited.

DEA regulations prohibit emergency room staff from dispensing controlled substances under these circumstances for several reasons. Sections 1306.11 and 1306.21 set forth the requirements of prescriptions for Schedule II and for Schedules III and IV substances respectively. First, the only person authorized to dispense controlled substances by filling a prescription is a pharmacist. If for Schedule II drugs, those prescriptions must be in writing and must be signed by the prescribing practitioner, unless the situation is an emergency, in which case the quantity prescribed and dispensed must be limited to the amount required to treat the patient for the emergency period. Prescriptions for Schedules III and IV substances may be dispensed by a pharmacist pursuant to either a written or oral prescription made by the prescribing practitioner.

These definitions apply to all prescription orders whether they are filled at a retail pharmacy or at a hospital pharmacy. In any event, the prescription must be issued by a physician in the normal course of his medical practice and it must be

# Compliance News



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

for a valid medical reason. This clearly presupposes a valid doctor/patient relationship in which the patient has been evaluated and examined by the prescribing practitioner. This constitutes the second major issue which precludes emergency room personnel from dispensing controlled substances based on a telephone request from a physician other than the emergency room physician.

A third area of consideration is the distinction between a prescription and an order for medication that is administered to a patient in an institutional setting. Federal regulations clearly distinguish between the two situations, stating that the definition of a prescription does not include an order for medication which is to be administered to the ultimate user. The process whereby an emergency room physician orders controlled substances for a patient being treated in the emergency room is, by definition, not a prescription. (*see 21 CFR 1306.02 (f).*)

One final distinction should be made between controlled substances administered directly to a patient in the emergency room and those dispensed to the patient for use after discharge. In the second instance, the drugs are actually being "dispensed" by the emergency room physician as authorized by 21 CFR 1306.11(b) and 1306.21(b), which state: "An individual practitioner may administer or dispense directly (but not prescribe) a controlled substance . . . in the course of his professional practice without a prescription . . ." This presupposes that the physician has evaluated the patient in question and is not relying on a telephone order from another physician.

Several years ago, DEA published proposed regulations which would have permitted hospital emergency rooms, particularly those in rural areas where no 24-hour pharmacy services were available, to fill orders from community physicians. This proposal was withdrawn due to the overwhelming objections received from professional associations as well as regulatory and enforcement personnel. Clearly, such a practice would weaken regulatory controls at the pharmacy level, and create a new avenue for drug diversion through "telephone forgeries."

## *Human Drugs Distributed to Veterinarians for Animal Use*

FDA is aware of and increasingly concerned about abuse in the promotion, distribution, and use of human drugs for animal use which may result in the adulteration of food due to human drug use in food-producing animals. FDA is also concerned about the potential for subverting the new animal drug approval (NADA) process by creating a disincentive for manufacturers to invest the time and expense required to obtain NADAs for animal use when human drugs are available for veterinary use. This causes an adverse impact on

animal health and the practice of veterinary medicine by denying the veterinarian a source of safe and effective drugs properly labeled for animal use. Drug manufacturers obtaining NADAs often find their veterinary products competing with human drug versions being sold for animal use.

FDA has established the following policy concerning the distribution of human drugs to veterinarians for animal use.

### A. Distribution

The promotion and distribution of human drugs for animal use, as well as the actual use of the products in animals, cause such products to be in violation of the Act as previously described. The products and those responsible for the violations are subject to regulatory action. However, Agency discretion on taking such regulatory actions is based on the following considerations:

Regulatory action recommendations concerning the distribution of human drugs for animal use should contain one, or more, of the following high priority factors:

1. The human drug is intended for use in food-producing animals.
2. Specific intended animal use has been established for the human drug. This is commonly done by labeling, advertising, promotional materials, and direct contact with veterinarians.
3. An approved veterinary version of the human drug is available.

Regulatory action will not ordinarily be considered concerning the distribution of human drugs for use only in non-food-producing animals, provided **all** of the following conditions exist:

1. Intended animal use of the human drug is not established by labeling, advertising, promotional activity, or in any other overt manner.
2. There is no approved veterinary drug version of the human drug available.
3. The human drug does not represent a significant risk to the animal when prescribed, dispensed, or administered by a veterinarian.

### B. Use

The principles of the policy in CPG 7125.06, "Extra-Label Use of New Animal Drugs on Food-Producing Animals," apply to the use of human drugs in food-producing animals by veterinarians. It is the Agency's intention to aggressively seek regulatory action to discourage the use of human drugs in food-producing animals.

The use of human drugs by veterinarians in non-food-producing animals in the normal course of veterinary practice will not ordinarily be of regulatory interest to FDA unless abuse or injury occurs.

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foreign physicians are registered with the Drug Enforcement Administration.

### **Item 681 - Note Manufacturer on Generic Prescriptions**

State law requires the identification of the manufacturer on all prescriptions filled generically. This takes on new importance in light of recent federal legislation that provides for rebates to the federal government from manufacturers whose drugs have been used in federal programs.

It is important that the NDC number of the actual drug dispensed be used on each Medicaid claim. Some pharmacists may use one generic supplier but obtain and dispense other generics occasionally. The blanket use of NDC numbers from one company when a different drug is dispensed could result in charges of filing false Medicaid claims or fraud. New procedures will make detection of this practice easy in the near future.

### **Item 682 - Revised PA/FNP/CNM Formulary**

The North Carolina Board of Medical Examiners has revised the formulary used in determining prescribing rights of Physician Assistants, Nurse Practitioners, and Certified Nurse Midwives as of March 1, 1991. See also the next item.

#### **Approved Formulary**

For persons approved to prescribe, order, or dispense drugs under the provisions of NCGS 90-18.1 and 90-18.2 and Rules 21 NCAC 32L and 21 NCAC 32M

**NO CONTROLLED SUBSTANCES** (Schedules 2, 2N, 3, 3N, 4, 5) defined by the State and Federal Controlled Substances Acts may be prescribed, ordered, or dispensed.

**NO PARENTERAL PREPARATIONS** may be prescribed, ordered, or dispensed except Insulin; immunizations of DPT, MMR, HIB; Tetanus Toxoid; DT; Hyperimmune Serum; Epinephrine; Benadryl; Pneumovax; flu vaccine; and local anesthetics.

**EXCLUDED DRUGS:** Any pure form or combination of the following generic classes of drugs may be prescribed, ordered, or dispensed unless the drug or class of drug is listed as excluded by the formulary. No drugs or classes of drugs that are excluded may be prescribed, ordered, or dispensed except as permitted by Rules 32L and 32M.

**REFILLS:** A prescription may not indicate a refill unless authorized by the supervising physician, with the exception of birth control medications which may be issued for a period not to exceed one year.

**DOSAGE UNITS:** Amount of drug prescribed, ordered, or dispensed can be no more than 100 dosage units or a one month supply.

**PRESCRIPTION NOTATIONS:** Every prescription must be noted on the patient's chart. A second prescription for the same medication may be authorized by telephone and must be entered on the patient's chart and countersigned

by the supervising physician within the approved counter signing time.

**WRITTEN STANDING ORDERS:** According to NCGS 90-18.1 and 90-18.2, written standing orders must be used.

**DISPENSING:** NP/PAs may dispense only those drugs allowed by the Approval Formulary. For dispensing approval, the NP/PA must contact the NC Board of Pharmacy, P.O. Box 459, Carrboro, NC 27510, (919) 942-4454.

#### **Antihistamines**

#### **Anti-infective Agents**

*Drugs excluded are:*

Amebacides

-Carbarsone

-Emetine

-Iodoquinol

-Paromomycin

Chloramphenicol

Oxacillin

Antibiotics

-Minocycline

-Pediatric Tetracycline

-Clindamycin

Antimalarials

-Amodiaquine

-Chloroquine

-Hydroxychloroquine

-Primaquine

-Pyrimethamine

Antivirals

*All excluded except:*

-Amantadine

-Acyclovir

#### **Antineoplastics Agents**

*All agents are excluded.*

#### **Antitussives, Expectorants, and Mucolytic Agents**

#### **Autonomic Drugs**

#### **Blood Formation and Coagulation**

*Drugs excluded are:*

Anticoagulants

#### **Cardiovascular Drugs**

*Drugs excluded are:*

Moricizine

Flecainide

Encainide

Propafenone

Amiodarone

Ethmozine

#### **Central Nervous System Drugs**

*Drugs excluded are:*

Psychotherapeutic Agents

-Antidepressants

-Tranquilizers

-Anxiolytics

Benactyzine

Lithium

Respiratory Stimulants

Cerebral Stimulants

Sedatives & Hypnotics

#### **Diagnostic Agents**

*All agents are excluded.*

#### **Electrolytic, Caloric, and Water Balance**

#### **Enzymes**

#### **Eye, Ear, Nose, and**

#### **Throat Preparations**

*Drugs excluded are:*

Any preparation containing an excluded drug.

#### **Gastrointestinal Drugs**

*Drugs excluded are:*

Any preparation containing an excluded drug.

#### **Gold Compounds**

*All agents are excluded.*

#### **Heavy Metal Antagonists**

*All agents are excluded.*

#### **Hormones and Synthetic Substitutes**

*Drugs excluded are:*

Parathyroid Hormones & Synthetics

Pituitary Hormones & Synthetics

Birth control medications may be issued for a period of one year.

#### **Local Anesthetics**

#### **Oxytocics**

*All agents are excluded.*

#### **Radioactive Agents**

*All agents are excluded.*

#### **Serums, Toxoids, and Vaccines**

*All agents are excluded except:*

Immunizations (DPT, MMR, HIB)

Tetanus Toxoid, DT

Hyperimmune Serum

Epinephrine

Benadryl

Oral Polio Vaccine

Pneumovax

Flu Vaccine

#### **Skin and Mucous**

#### **Membrane Preparations**

*Drugs excluded are:*

Any preparation containing an excluded drug.

#### **Smooth Muscle Relaxants**

#### **Vitamins**

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### **Item 683 - Prescribing by Physician Assistants/Nurse Practitioners / Certified Nurse Midwives**

Questions continue to arise concerning prescribing by these individuals. One way to approach the subject is that, concerning PA/NP/CNMs who have received their six-digit number from the Board of Medical Examiners, there are three classes of drugs. The first group is controlled substances. PA/NP/CNMs cannot issue prescriptions for the dispensing of controlled substances of any kind, including Schedule V drugs. The second category are the drugs excluded on the formulary approved by the Board of Medical Examiners. They cannot prescribe these drugs on their signature alone, but can prescribe these drugs if they are acting on the specific or direct order of the physician prior to the issuance of the prescription. In that case they should sign the prescription "Mary Jones, NP, on the order of Dr. Smith." For example, a physician assistant/nurse practitioner/certified nurse midwife could not prescribe Cloramphenicol or Pediatric Tetracycline on his or her signature alone, but could prescribe these drugs on the order of the supervising physician. The last group includes all other drugs. If a drug is not a controlled substance and not excluded through the formulary, the pharmacist can only assume that it is contained in the protocol or standing order and the PA/NP/CNM can prescribe the drug.

For your information, the formulary is aligned with categories in "Hospital Formulary Service," and differences of opinion regarding the proper therapeutic or generic category of a drug can be resolved by reference to that publication. PA/NP/CNMs cannot authorize refills on a prescription except for oral contraceptives. The amount dispensed at any one time should not exceed 100 dosage units or a one-month supply. When a patient uses all of the first prescription and additional medication is needed, a second separate prescription may be written. In circumstances that require parenteral drugs, the Board of Medical Examiners may approve, in the individual application, written standing orders to cover this specific situation. Pharmacists should understand that PA/NP/CNMs can only prescribe drugs according to the Approved Formulary or specific written standing orders approved in the individual application on file with the Board of Medical Examiners.

### **Item 684 - Fall Board Meetings**

Pharmacy students who attend a Board meeting invariably call it a learning experience, but our normal hearing room is far too small to accommodate many students. At the suggestion of some UNC faculty, the September 17th, October 15th and November 19th meetings have been scheduled at the Institute of Pharmacy to permit student access to hearings and normal business. These are open meetings. The public is welcome, and that includes pharmacists.

### **Item 685 - Psychiatric Association Letter**

The editor recently received a copy of a letter from Dr. Selman, President of the North Carolina Psychiatric Association, to Frank Burton, who at that time was President of the North Carolina Pharmaceutical Association. Dr. Selman noted an ever-increasing vigilance on the part of pharmacists for patient misuse of pharmaceuticals.

The editor believes that it is useful to quote one paragraph from his letter which states,

Upon their recommendations to the Executive Council of the North Carolina Psychiatric Association, the Council joins the Committee's desire to acknowledge and commend pharmacists in North Carolina for their educational role in assisting consumers with pharmaceutical product information and known facts about drug interactions. We also wish to commend them for their vigilance and active role in prevention and intervention of misuse of medications. The North Carolina Pharmaceutical Association has been influential through its educational programs, by encouraging pharmacists to be watchful, and by working in coordination with both physicians and patients.

### **Item 686 - Read the Label on OTCs, Too**

Two complaints of a similar nature have arrived in the Board office concerning pharmacist recommendations for OTC drugs. In each case, a complainant alleged that a pharmacist recommended a common OTC topical spray for a child with chicken pox. Both citizens read labeling on the spray can, which plainly stated that the product should not be used for chicken pox, and reported the incident to our office.

The point is that OTC drugs are not harmless, and pharmacists should guide their conduct accordingly.

### **Item 687 - Wake-Up Call on Recalls**

Considerable effort is expended at the federal and state level to follow through on recalls of pharmaceuticals which may endanger the public. An earlier item on this subject (item # 630) dealt with a pharmacist's reluctance to participate in this process.

Board staff was disturbed to hear of a report from the FDA office in Raleigh that in the checking procedure involved with a recall on Hydroxyzine Pamoate, it was noted that one pharmacy owner in western North Carolina had a stack of unopened letters, including one several months old, which contained the recall in question. This item is intended as a wake-up call for pharmacists on this issue. If you get a letter from the Food and Drug Administration, you should at least open and read it.

### **Item 688 - Intern Activity**

It is generally recognized that the primary purpose of internship is to provide students with a practice-oriented

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learning experience to build toward licensure. While it would ordinarily be expected that a pharmacist would receive telephone prescription orders from prescribers, it is reasonable to expect that students or interns should participate in that process as part of the learning process. Board members have also concurred that interns are included within the intent of the rule on prescription transfers.

### ***Item 689 - Policy on Student Prescription Use***

Pharmacists dispense prescriptions for all segments of society, including school age children. This group uses both short-term therapy, such as antibiotics or decongestants, and maintenance medication for conditions, such as hyperkinesis, which may require controlled substances. There are times when it is necessary or desirable for students to consume a dose of a prescription drug at school in the course of legitimate medical treatment.

It is in the patients' (students') best interest if the school has a specific written policy covering the use of prescription drugs by students during school hours. In the absence of such a policy, the student's use of drugs could be misunderstood as illegitimate. It is also possible that parents would be reluctant to send prescribed medications to school without a clear policy on its usage. Some parents may also erroneously believe that, absent a published policy, prescription drugs are prohibited at school.

It could be worthwhile for pharmacists to check with the school system in their practice area to confirm the existence of a policy on prescription drug use. This is useful information when counseling a parent on prescriptions for their child. If the school does not have a policy, there is one available from the Board of Pharmacy office that was adopted by one school system in this state. The policy is not necessarily intended for every school, but it does address the primary issues and was developed with input from a member of the Board of Pharmacy who is also a member of that school board.

### ***Item 690 - Computer Use in Pharmacies***

Inspectors report a growing number of instances concerning computers which fail to provide information that satisfies the federal rules on controlled substances. Federal rules require that such a system provide via CRT display or hard copy printout, a substantial amount of data which includes **but is not limited to** such information as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of controlled substance prescribed; quantity dispensed; and the total number of refills authorized by the prescriber.

The rules also provide that the computer system be able to produce the current refill history of Schedule III and IV controlled substance prescription orders which shall include but not be limited to the name of the controlled substance; the date of refill; the quantity dispensed; the identification code or name or initials of the dispensing pharmacist for each refill; and the total number of refills dispensed to date for that prescription order. Any daily printout that is generated shall be verified, dated, and signed by the individual pharmacist who refilled such prescription order.

An editorial comment is in order at this point. One frequent question that arises is the situation where a pharmacist does relief work and the daily printout occurs after he leaves that evening. His schedule may not have him returning to that store for a long time. There are also instances in which the pharmacist who works relief would never return to that store again. The question arises, "Whose signature goes on the daily print-out?" The rule specifically states that the printout shall be signed by the pharmacist who filled the prescriptions. If a pharmacist feels that the schedule takes precedence over federal rules, he or she can, of course, argue that point in an appropriate hearing.

Federal rules also require that the computer be capable of producing a printout of refill data such as a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance. Such a printout must include the name of the prescribing practitioner; the name and address of the patient; quantity dispensed on each refill; date of dispensing for each refill; the name or identification code of the pharmacist; and the number of the original prescription order.

### ***Item 691 - Switching Insulin Products***

Situations have been reported to the Board office about promotional efforts to switch patients from one brand of insulin to another without direct medical supervision. Although insulin is an over-the-counter product, it is a very potent pharmaceutical. Its misuse can have serious or fatal consequences. Pharmacists have an important role to play, and often fail to realize the significance that minor changes in the insulin being used can have on the patient. Pharmacists should take the time to consult with the patient's physician, as well as with the patient, before any changes are made in the strength, brand, or type of insulin.

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