



North Carolina Board of Pharmacy

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

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 477—ELECTION

Tarheel pharmacists have a special opportunity and obligation to select the pharmacist members of their licensing board. Members are elected from geographic areas and two different positions are up for election this spring for a term to begin in the spring of 1986. **President Randall** appointed two committees to recommend nominees for these positions. For Region 1, consisting of counties west of a line on the eastern edge of Alleghany, Wilkes, Alexander, Catawba, Lincoln and Gaston Counties, the Committee members were **Linda Taylor**, Chairperson; **Ed Frenier**; **Charles Branton**; and **Thomas Briggs**. Region 2 consisted of the north central part of the state from Orange and Person Counties on the east continuing west through Surry and Yadkin Counties. Committee members were **Fred Eckel**, Chairman; **John Badgett**; **David Claytor**; **Linda Butler**; **Carol Singletary**; and **Roger Sloop**.

A brief biography of each candidate is provided for your information. Please complete the ballot and mail it in the enclosed envelope prior to May 10th. Ballots will be counted in an open meeting at the Institute of Pharmacy beginning at about 5 p.m. on Monday, May 20th.

ITEM 478—BOARD DISCIPLINARY ACTIONS

January: **Albert Clay** and **Varina Pharmacy**. Dispensing Schedule V controlled substances other than for a medical purpose. License and permit placed on probation for five years on certain conditions including the submission of a written policy on determining medical need for the dispensing of OTC Schedule V drugs.

Ronald E. Young. Personal use of controlled substances. Five years probation including treatment for drug use.

At the February meeting the Board revoked three licenses to practice pharmacy, however, they are not included in this issue since the time for appeal had not expired prior to the copy deadline.

ITEM 479—MORE ON CONTINUING EDUCATION

At the February meeting of the Board, a new and clarified policy on acceptable continuing education was adopted by the Board. The Board will now accept continuing education offered by providers approved by the American Council on Pharmaceutical Education and programs or meetings approved or sponsored by UNC-Chapel Hill School of Pharmacy including AHECs, the North Carolina Pharmaceutical Association or the North Carolina Society of Hospital Pharmacists or their equivalents for non-resident pharmacists.

Special situations such as preceptor service or graduate school as noted in the January *Newsletter* will still be acceptable.

Pharmacists should take care not to wait until the end of the year to obtain continuing education credit. Illness, accident or other unplanned events can interfere with the best of plans and the most prudent course is to obtain credit well before the end of the year. A list of continuing education scheduled by the UNC School of Pharmacy and the Area Health Education Centers is enclosed for resident pharmacists to assist in selecting desirable programs. Remember that serving your profession, a student, and society as a preceptor for a full summer can qualify for 5 contact hours of continuing education credit. If you are interested, please contact Dr. Jack Wier, UNC School of Pharmacy, Beard Hall, 200H, Chapel Hill, North Carolina 27514 or call him at 919/962-0097.

ITEM 480—MAY INVENTORY, FORMS AVAILABLE

Most pharmacies have a controlled substances inventory date of May 1st in the odd numbered years. This date is approaching and pharmacist-managers need to be cognizant of their responsibilities. Board regulations also require a controlled substance inventory when there is a change of pharmacist manager or a transfer of ownership. Inventory forms are available for a charge of \$3.00 to offset printing and mailing costs. These forms are three hole punched for easy storage and retrieval in the *Newsletter* binder. Both forms and binder can be obtained by mailing a check for \$5.00 to the Board office, P.O. Box H, Carrboro, North Carolina 27510.

ITEM 481—DO YOU REMEMBER WHEN YOU DECIDED TO GO TO PHARMACY SCHOOL?

Studies show that most pharmacy students make their decision in high school. This gives community or hospital pharmacists in practice a good opportunity to influence high school students towards a career in pharmacy. Recruiting material and other information is available free for use in your pharmacy from Dr. George Cocolas at the UNC School of Pharmacy, Beard Hall, 200 H, Chapel Hill, North Carolina 27514, 919/962-0098. The National Association of Chain Drug Stores has a program which has developed brochures and mini-posters promoting pharmacy as a career. These can be obtained from the NACDS contractor in Chicago at a price of \$3.00 per 100 for brochures and \$50.00 per 100 for the four color mini-posters, plus shipping costs with a minimum order for

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

DISPENSING PHYSICIANS— EXEMPT FROM LABELING REQUIREMENTS?

A statement recently made by an official of the Food and Drug Administration seems to imply that while FDA and the Congress are concerned about how legend drugs dispensed to the public are labeled by pharmacists, they are not concerned with how those same drugs dispensed by a dispensing physician are labeled. In a statement made within the last few months, FDA again confirmed a previous statement that declared that the labeling provisions of the Food, Drug and Cosmetic Act [Section 503(b)] that apply to pharmacists do not apply to physicians. In 1979 FDA stated that "although Section 503(b) is applicable to physicians, we have long considered physicians who dispense drugs to patients pursuant to a bonafide doctor/patient relationship to be exempt from strict compliance with the labeling requirements for prescription drugs under 503(b)(2)."

In an October 1984 statement, Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, reaffirmed that position and went on to state that "while physicians are subject to Section 503(b), we do not believe this section was intended on the part of the Congress to interfere with the then well-known dispensing practices of physicians, or that such on-going practices raised safety questions requiring remedial action. Moreover, we are not aware of evidence that our present policy has contributed to problems affecting the public health or safety. Thus, we see no reason for the agency to alter its long-standing position in this matter as expressed . . . above."

It is difficult to believe that Congress actually felt that the public health and safety required that patients receiving prescription drugs from a pharmacist must be protected through mandatory labeling provisions but that when those same patients receive the same drug from a physician, the patient was perfectly safe in receiving the drug with whatever labeling the physician chose to include, perhaps.

It seems only logical that if the protection of the public requires adequate labeling on the part of pharmacists it also requires at least the same labeling from physicians.

PHARMACIES SHOULD NOT DONATE DRUGS

With the well publicized health problems in Ethiopia and Sudan so much in the news, pharmacists are being contacted by religious and other charitable organizations requesting donations of legend drugs for the African relief effort. Pharmacists should not become involved in donating any federal legend drugs to any charitable organizations. Any requests for such donations should be referred to the Food and Drug Administration or your Board of Pharmacy office.

DEA SEEKS INFORMATION REGARDING NALBUPHINE AND BUTORPHANOL

DEA has recently reported receiving inquiries from a number of states requesting data relevant to the control status, abuse and diversion of Nalbuphine (Nubain) and Butorphanol (Stadol). DEA reports that while neither of these agonist-antagonist analgesics are currently controlled under federal law, there have been reports of

diversion and abuse of these substances in some sections of the country. To better ascertain the extent of the diversion, abuse and control of Nalbuphine and Butorphanol, and to more effectively respond to questions and inquiries it is receiving, DEA is soliciting any information which may be available regarding diversion and abuse of these substances. Anyone having such information should forward it to Howard McClain, Jr., Chief Drug Control Section, Drug Enforcement Administration, Washington, DC 20537.

PHARMACIES MAY PROVIDE CS DRUGS TO PHYSICIANS

Pharmacists are often contacted by physicians and dentists and are requested to provide controlled substances to these practitioners for use in their office practices. Under the Federal Controlled Substances Act, pharmacists are allowed to make such distributions of controlled substances but there are some limitations and record-keeping requirements on such distribution.

A common situation is one where the practitioner, be he physician or dentist, will request supplies of controlled substances for office use by presenting the pharmacist with a "prescription" where the patient is indicated as "For Office Use". It is not legal for a pharmacist to distribute controlled substances to the practitioner based on this "prescription". A prescription may not be used to obtain controlled substances for the purpose of redistribution. If one stops to think about the labeling required when controlled substances are dispensed pursuant to a prescription, it becomes immediately clear. When controlled substances are dispensed, the pharmacist is required to place an auxiliary label on the container that indicates that federal law prohibits transfer of that medication to anyone other than for whom it was prescribed. In our scenario the very purpose of the request by the practitioner is redistribution.

There are acceptable mechanisms for accomplishing the requested transfer however. The pharmacist first must make sure that the prescriber requesting the medication is registered under the Federal Controlled Substances Act to dispense controlled substances.

If the product being distributed to the practitioner is a Schedule III, IV or V controlled substance, the distribution must be recorded by the pharmacy and the receipt of the substance must be recorded by the practitioner. The pharmacy distributing the controlled substance must record the name of the substance; the dosage form; the quantity; and the name, address and DEA registration number of the practitioner to whom it was distributed. The date of distribution must also be recorded.

If the substance being transferred is a Schedule II controlled substance, the practitioner must complete a triplicate order form and present it to the pharmacist.

Distribution should be limited to original manufacturer's containers in order to prevent the products from becoming misbranded under the Federal Food, Drug and Cosmetic Act.

The total number of dosage units of controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by that pharmacy during the twelve-month period in which the pharmacy is registered with DEA. If at

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ce N to a particular state or jurisdiction should not be assumed law . such state or jurisdiction.)



any time the distributions to practitioners or other pharmacies does exceed five percent, the distributing pharmacy is required to register as a "distributor" with DEA as well as being registered with DEA as a pharmacy. Pharmacists would be well advised to be sure to stay beneath the five percent limitation, as registration with DEA as a "distributor" brings with it some rather significant security and recordkeeping considerations.

EMERGENCY DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

The "emergency" dispensing of Schedule II controlled substances is an area that is often abused by pharmacists, patients and physicians. Situations where the dispensing of Schedule II controlled substances is requested orally tend to occur far more often than is justifiable, perhaps because physicians and patients are not fully aware of the restrictions DEA places on the dispensing of Schedule II substances. Pharmacists, when confronted with an oral request for dispensing of Schedule II substances, should use that opportunity to review with the patient and the prescriber the limitations placed on such prescribing and dispensing.

The general rule is that no Schedule II controlled substances may be dispensed without the pharmacist first having in his possession a written, signed order from the prescribing practitioner for that drug. In the case of a bonafide emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization from a prescribing practitioner provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period only. Prescribing or dispensing for treatment beyond the emergency period must be pursuant to a separate prescription order. Generally, an "emergency situation" cannot be justified as lasting longer than 72 hours. The rationale here is that the prescriber could cause a written prescription for the substance to be mailed to and be received by the pharmacist within 72 hours, therefore there would be no need for oral requests for dispensing in quantities larger than that required for a 72-hour period.

(2) The prescription order must be immediately reduced to writing by the pharmacist and must contain all information required on a Schedule II prescription except for the personal signature of the prescribing practitioner.

(3) If the prescribing practitioner is not personally known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a duly-licensed practitioner. One method of verification is verifying the practitioner's telephone number with that listed in a telephone directory. In general, the pharmacist must make a good faith effort to ensure proper identity of the prescriber.

(4) Within 72 hours after authorizing an emergency oral prescription order, the prescribing practitioner must cause a written prescription order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. Phar-

macists should note that it is the responsibility of the prescriber to get the prescription order to the pharmacist. It is not the pharmacist's responsibility to send the prescriber a copy of the telephone order requesting that it be signed and returned. The prescription order received by the pharmacist must have written on its face the words "Authorization for emergency dispensing". It is the experience of most pharmacists that those words seldom appear on prescriptions sent to the pharmacist to cover emergency oral prescription dispensing. The written prescription order may be delivered in person or by mail, but if delivered by mail must be postmarked within the 72-hour period.

Upon receipt of the written prescription, the dispensing pharmacist must attach it to the oral emergency order which had earlier been reduced to writing.

If the prescribing practitioner wishes the patient to be treated with the prescribed medication beyond the emergency period, a second prescription for the additional quantity must be written.

According to DEA requirements, if the pharmacist does not receive a written prescription order to cover the emergency dispensing within the 72-hour period, he is to contact the nearest DEA office.

For the purpose of authorizing an oral prescription order for a Schedule II controlled substance, the term "emergency situation" means those situations where:

(1) Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user. This requirement would seemingly eliminate any oral orders for dispensing of amphetamines or barbiturates listed in Schedule II.

(2) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance in Schedule II.

(3) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

All three of these conditions must exist in order to qualify as an "emergency situation". If one or more of these conditions are not met, it is not proper to accept an oral prescription for dispensing of the drug involved.

Many occasions occur where patients on a Schedule II substance return to the pharmacy for a "refill" of their prescription. Pharmacists should take this opportunity to advise the patient that they must plan ahead if they find they are going to need additional medication in that a new written prescription must be in the pharmacist's hands before such dispensing can occur.

It is reasonable to interpret the emergency dispensing provisions as not allowing for oral authorization of "refills" of prescriptions that were dispensed previously to the patient. Refill situations in most instances will not meet the three criteria necessary for an "emergency situation".

100 copies of either publication. Orders should be sent to RADA Recruitment Communications, 2300 Merchandise Mart, Chicago, Illinois 60654, Attn: NACDS Account Coordinator or you may call directly to 312/633-9200.

ITEM 482—DRINKING, DRIVING AND DRUGS

There are frequent reports about driving after drinking alcohol and sometimes vague references to other drugs used. The Insurance Institute for highway safety has published a study based on California information relating to deaths from car accidents with drivers who had consumed alcohol and other drugs. On over 600 deaths surveyed, almost 30 drugs or metabolites were detected. The large leader was alcohol, followed by cocaine and its metabolites, diazepam, phencyclidine, methamphetamine, phenylpropanolamine and ephedrine. Names of other, less prevalent, drugs are available on request from the Board office.

It may also be useful to know that Dr. Arthur McBay, the State's Chief Toxicologist, has reported that cocaine may be the state's leading cause of accidental drug deaths. He reports that cocaine deaths are up 700 percent from 1982. Deaths from antidepressants are even higher in number, and these facts should alert concerned pharmacists to patients they feel may be at risk.

ITEM 483—DISPENSING SCHEDULE V SUBSTANCES

Some pharmacists have indicated uncertainty about the proper procedure in dispensing Schedule V substances and members of the Board have requested that a review of pertinent statute and regulations appear in the *Newsletter*. Essentially, North Carolina follows federal regulations in this area with one minor exception. State statute G.S. 90-106(d) states that the dispensing of a Schedule V controlled substance must be for a medical purpose while there is no such provision at the federal level. Dispensing Schedule V drugs every 48 hours to the same person is almost certainly not for a medical purpose.

The summary below is taken from the Code of Federal Regulations 21 CFR Part 1300 to end which may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. The regulations themselves are not reproduced here but paraphrased for better understanding by readers.

Schedule V drugs may be dispensed pursuant to a prescription but any refills must be authorized by the prescriber. At this time there is no limit on the number of refills or time period as there is with Schedule III and IV drugs. A prescription for a Schedule V drug does not need to have a label stating that it is unlawful to transfer the drug to another person. While this is not directly related to Schedule V drugs, the question has arisen regarding the general use of such "transfer labels" on prescriptions for all drugs either as a phrase on every label or added as an auxiliary label on each prescription dispensed. This is only required on prescriptions for drugs in Schedules II, III and IV and the presence of such wording on other prescription labels could be misleading and result in the product being misbranded. If this phrase is on each prescription label, pharmacists should seriously consider its removal when they order their next supply of labels and apply the "transfer" warning only to those drugs to which it applies.

Schedule V drugs which are not prescription drugs may be dispensed without a prescription only under the following conditions.

(1) The dispensing *must* be by the pharmacist. Other personnel may handle the remainder of the transaction, but federal regulations very specifically state that the dispensing cannot be by non-licensed personnel even if under the supervision of the pharmacist.

(2) Not more than 240 cc of a product containing opium (such as Parepectolin) nor more than 120 cc of a product containing Codeine (such as Terpin Hydrate with Codeine) may be dispensed

to the same individual in any 48-hour period

(3) Unless the purchaser is known to the pharmacist, suitable identification must be furnished, including proof of age since each purchaser must be at least 18 years old.

(4) The pharmacist must maintain a bound record book of such dispensing, which contains:

(a) The name and address of each purchaser.

(b) The name and quantity of controlled substances dispensed.

(c) The date of each purchase.

(d) The name or initials of the pharmacist who dispensed the substance.

ITEM 484—QUARTERLY QUERY

If a pharmacist receives a telephone prescription and the prescriber does not indicate a preference toward substitution, the pharmacist can:

I. Dispense the brand the prescriber ordered.

II. Dispense any generic equivalent drug.

III. Dispense any therapeutically equivalent drug.

1. I only.

2. II only.

3. III only.

4. I and II only.

5. I, II and III.

ITEM 485—MISCELLANEOUS MATTERS

Questions regularly arise about how many dosage units can be dispensed on a prescription for controlled substances in Schedule IV such as Valium, when the recipient receives less than the full amount on refills. For example, if a patient has a prescription for Valium 10 mg., # 100 with 5 refills authorized and receives refills in quantities of 50, how many refills can be dispensed? As far as the staff is concerned, the customer is entitled to the full amount authorized—600 dosage units—providing no dispensing occurs after six months of the day of the prescription's issue and, of course, subject to the pharmacist's professional judgment. Be careful to note the quantity dispensed on refills or an auditor will assume that the full face quantity was dispensed.

Oral orders for dispensing a Schedule II drug in an emergency situation can present a thorny—and sometimes chronic—problem when the prescriber fails or refuses to provide a signed prescription within 72 hours. Federal regulations are clear and specific in this situation and direct the pharmacist to report this situation to the DEA office in Atlanta. Their address and telephone number is: Drug Enforcement Administration, 75 Spring Street, Suite 734, Atlanta, Georgia 30303, 404/222-3328. Failure to report results in the voiding of the original authorization for dispensing, which almost certainly has occurred, and places the pharmacist in the position of dispensing a Schedule II controlled substance without a prescription retroactively. The answer to Quarterly Query is 4. I and II only.

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.

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