



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 460—BOARD MEMBER ELECTION

The ballots cast in the election held this Spring for a member of the Board were counted on Monday, May 21, 1984 at the Institute of Pharmacy in Chapel Hill. The results of that election are that **Bill Randall** from Lillington received 1,016 votes, **Van H. King, III** from Wilmington received 378 votes and **C. Louis Shields** from Jacksonville received 318 votes. The next day at the regular Board meeting the Members certified the results as final and declared that Mr. Randall had been elected to a three year term to begin in the Spring of 1985.

ITEM 461—PHARMACY ROBBERIES OR BREAK-INS

In cooperation with the State Bureau of Investigation the Board of Pharmacy is beginning a one year trial program of reporting all robberies or break-ins which involved controlled substances to a toll free number. Pharmacists are encouraged to report these events by calling 1-800-662-7610 and be ready to convey the following information: the name and location of the pharmacy; if a burglary occurred, the means of entry; if a robbery occurred, the number of suspects and their descriptions, weapons used and any statements made by the suspects. In either case you should report the kind and quantity of drugs taken, other merchandise or cash that is missing along with any cost markings or information from price stickers. You should also be prepared to provided the name of any local law enforcement officer involved in the investigation.

Pharmacists should understand that this program does not take the place of calling local law enforcement, police or sheriff, depending on your location and the first report should be to the police or sheriff. We hope you will cooperate in this effort with the State Bureau of Investigation and the Board which will be helpful in attempting to apprehend groups which travel throughout the state performing such crimes. Please have your information ready when calling the toll free number noted above and any other information which you feel is pertinent.

ITEM 462—DISCIPLINARY ACTIONS OF THE BOARD

March: **James Wayne Blanton**, Gastonia, was found guilty of any violation of the Federal Controlled Substances Act and the Board suspended his license for five years with it to be returned only after passing an examination.

Martin Luther Johnson, III, Smyrna, Georgia, pleaded guilty to violations of the State Controlled Substances Act and the Board

suspended his license indefinitely.

Dennis D. Poteat, Old Fort, appeared before the Board in March pursuing the reinstatement of his license to practice pharmacy and it was the Board's decision to replace an Order entered in November of 1983 with an active six months suspension beginning March 20, 1984 and a probationary period including reports submitted to the Board from Narcotics Anonymous.

James Paul Green and **Carolina Pharmacy**, Boone. It was the Board's finding that Mr. Greene dispensed Phenaphen #4 without a prescription on several occasions and other technical violations occurred at Carolina Pharmacy and the Board issued Mr. Greene a reprimand.

April: **Frank C. Kiser** and **Montford Pharmacy**, Asheville. The Board found that Frank C. Kiser dispensed prescription legend drugs and a controlled substance without a prescription and placed Mr. Kiser on a one year probation (30 days suspension, stayed for one year) under certain conditions, one of which is that he must attend 10 hours of continuing education during the next year and certify such attendance to the Board.

Dennis G. Beatty, Lawndale, was found guilty of a felony and Medicaid fraud and it was the Board's decision to issue a five year probation (one year suspended with a stay order for five years) under the normal conditions.

May: **Delbert M. Cranford**, Asheboro, was found to have dispensed prescription drugs and controlled substances pursuant to prescription forgery and it was the Board's decision to place him on a one year probation (60 day suspension, stayed for one year) under certain conditions, including a provision that representatives of Rite Aid, Inc. explain to the Board their policies regarding reporting of pharmacy violations within the next year.

Leon I. Graham, Wallace, was found to have dispensed prescription legend drugs without prescriptions and improperly labeled drugs according to the Product Selection Act and it was the Board's decision to issue a one year probation (30 days suspension with a one year stay order) based on certain conditions, one of which is that Mr. Graham obtain at least 10 hours of continuing education during the next year.

Darrell Estes, Raleigh, had pleaded guilty to certain misdemeanor violations of state law involving Medicaid payments and it was the Board's decision to issue a three year probation (six months suspension with a three year stay order) under certain conditions.

Jerome K. Johnson, Raleigh, had pleaded guilty to certain misdemeanor violations of state law involving Medicaid payments and it

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USP EXPANDS COVERAGE OF LAWS AFFECTING PHARMACY PRACTICE

Joseph G. Valentino, Executive Associate of the USP Convention, recently announced to the state boards of pharmacy throughout the country an initiative being undertaken by the USP to expand its coverages of laws relating to pharmacy practice.

The USP announcement recognized that it is often difficult for pharmacists to keep up to date on the various federal requirements. To aid the pharmacist in staying current on his responsibilities under the various federal acts, the USP/NF has in the past incorporated those portions of the Controlled Substances Act regulations of most concern to practitioners and those portions of the Poison Prevention Packaging Act regulations of most concern to practitioners. The next edition of the USP/NF will contain not only portions of the Controlled Substances Act and Poison Prevention Packaging Act but will also contain those sections of the Federal Food, Drug and Cosmetic Act pertaining to drugs. In addition, selected portions of the current Good Manufacturing Practice regulations for finished pharmaceuticals will be included.

Updates to the various statutes and regulations by any of the federal agencies involved will be carried in the USP/NF supplements as they are issued under the new subscription service.

The incorporation of the various federal acts of direct concern to pharmacists into the USP should provide pharmacists with an effective tool for maintaining currency in the area of federal law.

DEA'S OFFICE OF DIVERSION CONTROL MAKES PHARMACISTS MANUAL AVAILABLE

The Office of Diversion Control as a part of DEA's Diversion Control Program is attempting to assist pharmacists in their understanding of the Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice by making available a 38 page manual entitled "Pharmacists Manual: An Informational Outline of the Controlled Substances Act of 1970".

The manual may be obtained by contacting the Drug Enforcement Administration, U.S. Department of Justice, Washington, DC 20537.

GENERIC SUBSTITUTION OF SCHEDULE II PRESCRIPTIONS

With HMO's, third party payment programs, and state medical assistance programs becoming more and more interested in potential cost savings through generic substitution, a number of questions have arisen regarding the substitution of Schedule II controlled substance prescriptions.

In discussing this topic with Drug Enforcement Administration officials from the Chicago regional office, it has been learned that

DEA will permit generic substitution on Schedule II prescriptions provided that the pharmacist accurately records on the face of the prescription the identification of the product which was actually dispensed.

While allowing pharmacists some leeway in providing a generic product in place of the prescribed brand name product on Schedule II prescriptions, DEA has indicated that it will not permit pharmacists to change the dosage of a prescribed Schedule II product. For instance, if the prescription was written for 100 mg. tablets with the directions "one tablet four times a day", the pharmacist would not be permitted to dispense 50 mg. tablets with the directions of "two tablets four times a day". Such a change would require a new prescription according to DEA.

In summary then, pharmacists are permitted to exercise generic substitution on Schedule II prescriptions as long as they record the identification of the product actually dispensed on the face of the prescription. The strength and dosage schedule of the product dispensed must conform to the strength and dosage schedule of the product prescribed however.

ORDER FORMS REPORTED MISSING

DEA has announced that on or about March 13, 1984, a shipment of blank DEA-222 Schedule II order forms was reported missing between the printer and the Drug Enforcement Administration. The missing shipment consists of 1,400 forms numbered 25,460,000 through 25,461,399. This number is the control number, not the order form number. The control number is printed in red ink on the lower right hand corner of the original or top copy. The control number does not appear on the second and third copy of the form.

This situation may present a serious diversion problem, in that any address could be entered on the form and an order for Schedule II substances could be placed with a registrant.

All pharmacists, not just those working for drug manufacturers or drug wholesalers, should be on the lookout for any of these order forms. The individual or individuals possessing these order forms may attempt to obtain controlled substances by using the forms at a local community or hospital pharmacy.

Pharmacists are urged to contact their closest Drug Enforcement Administration office if they are presented with an order form bearing any of the control numbers listed or if the name and address of the purchaser appears to be manually typed rather than computer printed on the form.

CONTROLLED SUBSTANCE PRESCRIPTION ORDERS/ THE PHARMACIST'S RESPONSIBILITY

The Federal Controlled Substances Act very specifically indicates who may issue prescriptions for controlled substances, how that

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prescription order must be executed, and what the pharmacist's responsibility regarding that prescription order is.

Prescription orders for controlled substances may be issued only by a physician, dentist, podiatrist, veterinarian or other practitioner who is registered with the Drug Enforcement Administration and who is:

1. Authorized to prescribe controlled substances by the jurisdiction (state) in which he or she is licensed to practice;
2. Either registered under the Federal Controlled Substances Act or exempted from registration (military and public health service practitioners). The federal act has special requirements for interns, residents, and foreign physicians.

Every prescription order for controlled substances must be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name address, and registration number of the physician. It is not permissible for a prescriber to forward date several prescriptions and give them all to the patient or to the pharmacist for filling at a future time. In the case of Schedule II prescriptions, where an oral order is not permitted, the prescription order must be written in ink or indelible pencil or must be typewritten and must be personally signed by the practitioner issuing the order. The practitioner need not prepare the entire order personally. The prescription may be prepared by a secretary or nurse for signature by the practitioner but the practitioner is responsible in case the prescription order does not conform in all essential respects to the requirements of the Controlled Substances Act.

Prescription orders for controlled substances in Schedule II may not be refilled. Prescription orders for controlled substances in Schedule III or IV may be refilled up to five times or for six months after the date the prescription was issued if authorized by the practitioner. After the expiration of five refills or the six month time period if the practitioner wishes the patient to continue on the medication, a new prescription order is required.

Under the federal act, a prescriber's nurse or other member of the staff cannot authorize the renewal of a prescription order for a controlled substance in Schedule III or IV that has been renewed five times or is six months old. The authority for prescribing controlled substances is vested only in the license practitioner and cannot be delegated to anyone else. Complicating the matter somewhat for pharmacists, however, is the allowance that nurses or staff members receiving calls from pharmacists regarding renewals of controlled substance prescriptions may act as the physician's agent and may transmit the physician's directives to the pharmacist.

A prescription order for any controlled substance in order to be a valid prescription under the federal act must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional practice. The federal act places the responsibility for the proper prescribing and dispensing of controlled substances upon the prescribing practitioner but a corresponding liability rests with the pharmacist who dispenses the prescription. A request that is

supposedly a prescription order but which is not issued in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription order under the federal act. The pharmacist who knowingly dispenses such a purported prescription order as well as the practitioner who issues it will be subject to the penalties provided for violations of the federal law relating to controlled substances.

The pharmacist then is given the responsibility under the federal Controlled Substances Act to act as a monitor regarding the prescribing and dispensing of controlled substances. The pharmacist becomes the final screen that can prevent the diversion of controlled substances to illegitimate purposes.

MODEL COMPUTER REGULATIONS DEVELOPED

To date, regulations for use of computers in pharmacies have been promulgated in a minority of state jurisdictions. Those that do exist, range from a minimum of direction and control to itemized parameters that cover more than is required to practice pharmacy. Seeing the problems and the need for the development of a standardized approach to assist boards and pharmacists, the National Association of Boards of Pharmacy, during its 80th Annual Meeting in Nashville, adopted model computer regulations.

After careful review of existing state regulations and model regulations developed by industry and pharmaceutical associations, the NABP Committee on Law Enforcement/Legislation completed model regulations geared to "serve as a guideline for all states wishing to utilize such a composite in developing their own regulations." An open hearing on the adopted regulations was held. Based on comments from this hearing, the Committee presented an amended model computer regulation to board representatives from 48 jurisdictions throughout the United States. The regulation was adopted.

According to Joseph J. Rowan, chairman of the NABP Committee on Law Enforcement/Legislation, the committee in developing the model regulations looked at regulations promulgated by state boards of pharmacy and model language developed by the chain industry, other national associations, and the computer industry.

The NABP model computer regulations are meant as guidelines for consideration by NABP member boards of pharmacy. "These regulations are not mandatory," Mr. Rowan said. "We tried to come up with something that each state could adopt to fit its own needs."

The final regulation will be part of a newly revised publication, "The Model State Pharmacy Act and Regulations of the National Association of Boards of Pharmacy." The scheduled publication of the "Model Act" will include updated institutional regulations, nuclear pharmacy regulations, and a model institutional pharmacy inspection form. Due to be released this summer, the publication will be printed in looseleaf style to facilitate updates and additions in the future.

was the Board's decision to issue a three year probation (six months suspension with a three year stay order) under certain conditions.

The Board publishes only those items which are final and have not been appealed. As a result of the February Board meeting two appeals occurred, one from a decision of the Board to revoke a pharmacist's license and another from the decision of the Board to suspend a pharmacist's license for five years. There was one appeal from the April meeting which involved the active suspension of a pharmacist's license for 90 days. Each of these items are on appeal and are not final, therefore are not reported specifically in this *Newsletter*. The results of these proceedings will be printed when matters are finalized.

Readers should understand that in explaining disciplinary actions, the phrase "normal conditions" means that the person cannot violate any laws or regulations pertaining to pharmacy during the period of the stay order. If such violations occur the Board has the authority to activate the suspension or revocation almost automatically. If the person satisfies the conditions of the stay order, then no active suspension or revocation occurs.

ITEM 463—QUARTERLY QUERY

A dentist calls in a prescription to the pharmacy for Sumycin® 500 mg. #12 for a 12 year old patient. When the mother comes for the prescription, she states that the medication is for a "cold". The pharmacist might question the prescription for which, if any of the following:

- I. Dose too high.
 - II. Tetracycline not indicated in children.
 - III. Inappropriate prescribing.
 1. I only.
 2. I and II only.
 3. I and III only.
 4. II and III only.
 5. III only.
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ITEM 464—NEW LAW BOOK AVAILABLE

The Board plans to have available by the time of this *Newsletter* mailing an updated version of the North Carolina Pharmacy Law Book. It contains the revised Pharmacy Practice Act, the only source for up-to-date Board regulations, along with the State Controlled Substances Act, Food and Drug Law and the most commonly referenced section of the Code of Federal Regulations on controlled substances. The last such publication was in 1978 and pharmacists should replace that issue with the current volume. Printing and postage cost have increased substantially and the price for this issue is \$10.00. If you wish to receive a copy, send a check or money order for \$10.00 along with your mailing address and it will be promptly forwarded. The answer to Quarterly Query is 5. III only.

ITEM 465— INSTITUTIONAL PHARMACY REGULATIONS

After hearings in Boone and Chapel Hill during 1983, the Board considered and adopted a set of institutional pharmacy regulations which are included in the Pharmacy Law Book. These regulations contain several new sections and a revision of other sections of regulations pertaining to hospital and institutional pharmacies.

Items which should be of interest to hospital pharmacists include criteria for separate registration of satellite pharmacies or other such activities within an institution, pharmacist control to all keys of the pharmacy, clear definitions of auxiliary drug inventories and emergency drug kits, a revision of procedures for dispensing from emer-

gency rooms, the requirement of automatic stop orders and dispensing of drugs when a patient is discharged from a hospital. These subjects and many other Board regulations are noteworthy for hospital pharmacists. The section of the revised Pharmacy Practice Act allowing pharmacists access to the patient's records in institutions, with the requirement that appropriate entries be made in such records by the pharmacist is also included in the pharmacy law publication. That section, in combination with the regulation regarding automatic stop orders gives substantial authority to pharmacists in institutions along with a corresponding responsibility.

ITEM 466—BOARD HEARING PROCESS

Several comments have been heard in the Board office which indicate an absence of understanding of the hearing process. Disciplinary hearings conducted by the Board occur under the State Administrative Procedures Act, Chapter 150A of the North Carolina General Statutes. This law provides a number of safeguards for individual rights along with instructions necessary to insure due process.

When information is received in the Board office that requires an investigation, this activity is performed by Board Inspectors. The current Inspectors for the Board are Mr. Bobby Belvin who is responsible for the territory in the eastern part of the state, Ms. Terri King who is concerned with the central part of the state and Mr. Steve Hudson for the western part. These individuals would perform any investigation, and report to the Executive Director who has the responsibility of determining if a hearing should be conducted. If an affirmative decision is reached, a citation letter is sent by certified mail to the pharmacist(s) involved. Such letters usually arrive from three to six weeks before the scheduled hearing which ordinarily is in Board offices in Carrboro.

The individual elected and appointed members of the Board are not aware of any of these activities until the hearing occurs. This procedure is followed and only in this way can a pharmacist expect to have a fair and impartial judging of their situation. It is for this reason that Board members who have been contacted about any specific hearing often disqualify themselves and take no part in that particular hearing process. This is why it is often harmful to a pharmacist's case to contact members, directly or indirectly, prior to the hearing. One could expect that the particular member might have a favorable attitude towards the issue in the hearing or he would not have been approached, yet it is this activity which can nullify any "good" which was attempted. Some pharmacists are represented by lawyers at this hearing although it is not required while others respond themselves.

After hearing all testimony and reviewing the evidence in each hearing, the Board members ordinarily render a decision that day which the President reads to the pharmacist at the conclusion of the hearing. The result of the hearing can be appealed within 30 days to the Superior Court of Wake County.

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