April, 1993

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 744 - Disciplinary Actions

November:

Jerome Stevens Pharmaceutical Company, Bohemia, New York. Respondent does not have adequate provisions for the return of the outdated drugs as required. Therefore, Respondent's products are ineligible for use in product selection in North Carolina.

Kent L. Huffman, Greensboro. Failure to establish on a timely basis that at least ten hours of continuing education credit, including at least five contact hours of continuing education, had been obtained and failure to maintain certificates of credit for continuing education for 1991. Cautioned that certificates must be maintained for credit for all future continuing education claimed on license renewal application.

Robert D. Coffey, Kannapolis. Request for reinstatement of pharmacy license denied.

Robert Mike Brown and Caldwell Home Care Services, Gastonia. Order modifying Final Order of December 16, 1991 entered.

January:

Livvie Washington Vann, II, Burlington. Obtaining, consuming, and dispensing controlled substances without authorization. License suspended indefinitely with conditions.

Stephen Lance Morris, Greensboro. Amended Order Reinstating License entered with specific conditions.

Jennifer Hintze Boggs, South Carolina. Same Disciplinary sanctions against North Carolina pharmacist license as the South Carolina Board of Pharmacy imposed against her South Carolina pharmacists license, which is license to practice suspended for a period of five years.

Item 745 – Patient Counseling Update

There have been numerous continuing education programs on patient counseling since the effective date of the Board's rule on this subject, January 4, 1993. In addition, the Board office has received many questions about this subject.

Patients in rest homes seem to pose a special challenge to pharmacists. It is the Board's opinion that the pharmacist needs to be sure the offer to counsel is made either to the patient or the caregiver on all new prescriptions for recipients in rest homes. A different situation exists where a pharmacy department may be open, for example, from 10 a.m. to 6 p.m. while the entire store is open and patients can pick up prescriptions from 9 a.m. to 9 p.m. The Board feels that it is still the dispensing pharmacist's personal responsibility to counsel patients if the offer is accepted. This may be accomplished by telephone under these circumstances.

Staff is concerned that some pharmacists may not be adhering to the spirit of the rule, which requires that the offer to counsel be made in a positive manner to encourage acceptance. We have heard reports that in some pharmacies a very small percentage of patients accept the offer to counsel. If only 5 percent of patients receiving new prescriptions accepted an offer to counsel, this could be very strong evidence of non-compliance with the rule.

It is the position of Board staff that, at the present time, the important factor in the patient counseling rule in hospitals is that patients receive competent counseling when it is appropriate. This being the basic premise and recognizing that in many situations pharmacists are not available when patients are discharged from hospitals, the Board staff will consider the hospital in compliance with the spirit of the rule if counseling occurs by any competent individual such as a physician, registered nurse, or other appropriately trained individual with guidance from the pharmacy. Absent a specific or direct order from the Board itself, staff will operate with this understanding.

It should also be noted that a specific component of patient counseling is prospective drug utilization review. This is a substantial challenge, even for a pharmacist with a computer referenced to multiple drug interactions. There will likely be a time in the future when it will be appropriate for pharmacists to conduct such counseling in hospitals.

Item 746 – Public Service Announcement on Patient Counseling

In late December, the Board distributed a public service announcement (PSA) on patient counseling to most television stations and all radio stations. The text of that announcement follows:

> This year a new law takes effect requiring pharmacists to counsel patients on some prescriptions. The purpose of this new law is to prevent possible complications and improve patient compliance. When you get a new prescription filled give your pharmacist time to inform you about any serious side effects, drug interactions, or

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Cor
and can only be ascertained by examini

Good Compounding Practices Applicable to State Licensed Pharmacies

The question of what distinguishes compounding from manufacturing has been the subject of an on-going debate between the profession of pharmacy and enforcement agencies, such as the Food and Drug Administration (FDA) and the state boards of pharmacy.

During the past year, the FDA issued a series of warning letters to retail establishments it believed were engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner clearly outside the bounds of traditional pharmacy practice. The Agency cited as one of the reasons for such action, the potential for causing harm to the public when drug products are manufactured and distributed in commercial amounts without prior approval from the FDA and without adequate recordkeeping to facilitate the recall of harmful products.

What appeared to be a simple regulatory matter soon escalated into a full-blown crisis when various sectors within the profession denounced the FDA's actions as a further intrusion into the practice of pharmacy by the federal government and a blatant attempt to stop pharmaceutical compounding by pharmacists. In response to the criticism, FDA officials pointed to reports of serious injuries and data which indicated that some establishments were manufacturing over 300,000 dosage units of inhalation therapy per month for 6,000 patients, most of whom lived out of state.

Throughout the debate, the FDA maintained that it did not want to regulate or interfere with the activities of licensed pharmacists engaged in pharmaceutical compounding as part of the traditional practice of pharmacy. At several meetings with NABP and representatives of the profession, the FDA publicly expressed its willingness to defer matters of pharmaceutical compounding to the state boards of pharmacy. FDA emphasized that it was concerned about those large-scale operations that were using retail pharmacy licensure as a means to avoid registering as a manufacturer and adhering to Good Manufacturing Practice Standards (GMPs). During its meetings with NABP, the FDA asked that the Association develop guidelines for pharmacy compounding.

Following is the first of a two-part presentation of the resulting document. NABP intends to incorporate these Good Compounding Practices into its *Model State Pharmacy Act* (*Model Act*), a document used by state boards of pharmacy to develop laws/regulations in their states, to help distinguish pharmaceutical compounding from manufacturing, and to establish uniform standards for regulating pharmaceutical compounding. Part two will appear in the third quarter "National Pharmacy Compliance News" section of this *Newsletter*.

Good Compounding Practices

The following Good Compounding Practices (GCPs) are meant to apply only to the compounding of drugs by State-licensed pharmacies. Applicable portions of the *NABP Model State Pharmacy Act* formed the basis for the development of this document.

Subpart A - General Provisions

The recommendations contained herein are considered to be the minimum current good compounding practices for the preparation of drug products by State-licensed pharmacies for dispensing and/or administration to humans or animals.

Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable State law regulating the practice of pharmacy.

The following definitions from the *NABP Model State Pharmacy Act* apply to these Good Compounding Practices. States may wish to insert their own definitions to comply with State Pharmacy Practice Acts.

"Compounding" - the preparation, mixing, assembling, packaging, or Labeling of a drug (including radiopharmaceuticals) or device (i) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding also includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

"Manufacturing" - the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or Labeling or relabeling of its container, and the promotion and marketing of such Drugs or Devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, Practitioners, or other Persons.

"Component" - any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace.

Pharmacists shall receive, store, or use drug substances for compounding that have been made in an FDA-approved facility. If unobtainable from an FDA-approved facility, pharmacists shall receive, store, or use drug components in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, and pharmacists document such, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.

Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy (as required by State law). The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis is considered manufacturing.

Pharmacists shall not offer compounded drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a prescriber to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.

The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

Subpart B – Organization and Personnel

As in the dispensing of all prescriptions, the pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

All pharmacists who engage in drug compounding, and State-authorized supportive personnel supervised by pharmacists who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Competency and proficiency in the art of compounding for all pharmacists and State-authorized supportive personnel shall be evaluated, documented, and maintained in the files of the pharmacy. Every pharmacist who engages in drug compounding and any supportive personnel who assist in compounding, must be aware of and familiar with all details of these Good Compounding Practices.

It is incumbent upon each State Board of Pharmacy to determine whether non-pharmacist personnel may assist in compounding prescriptions. If non-pharmacist personnel may assist in drug compounding, the State Board of Pharmacy shall determine the responsibilities of supportive personnel and the pharmacist.

Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products(s) being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

Subpart C – Drug Compounding Facilities

Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of non-sterile drug products. The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

Sterile Products

If sterile (aseptic) products are being compounded, the following conditions shall be met: [*Reference the "NABP Model Regulations for Sterile Pharmaceuticals"*].

If radiopharmaceuticals are being compounded, the following conditions shall be met: [*Reference the "NABP Model Regulations for Nuclear Pharmacy"*].

Special Precaution Products

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

Continued from page 1

other potential problems. Your patience will help your pharmacist provide you with better medical care. Sponsored by the North Carolina Board of Pharmacy.

The PSA was produced by Burroughs Wellcome in their corporate video communication center and was set in a pharmacy in Cary. The company prepared the video as a public service and there is no credit given to them in the published material. We feel they should receive appropriate acknowledgement for this service to the public and the profession.

Item 747 – Documenting Results of Patient Counseling

It is **important** that pharmacists document in writing positive outcomes from patient counseling. There are always critics of any new activity such as this, who often cite anecdotes. Therefore, it may be necessary to provide examples of beneficial results from this activity.

When you make a record of such events, please sen
to the Board office so that we can keep track of this a

Item 748 – Tax on Sales to Physicians

The Board has received several comments from pharmacists who have been visited by agents from the North Carolina Department of Revenue. It is a little-known provision of the law that the sales tax exemption for prescription drugs applies only to purchases made by patients. If such purchases are made from a pharmacy by physicians, their office, clinic, or other similar entity, sales tax should be applied to that transaction and remitted to the North Carolina Department of Revenue.

Item 749 – UPIN Numbers

The Board has received many inquiries about obtaining a UPIN number for prescribers. It is our information that prescribers may obtain a UPIN number by contacting CIGNA in Nashville, Tennessee at (615) 244-5600.

Item 750 – Correction in January Newsletter

There were two misprints in the January *Newsletter* which need correction or clarification. While not repeating the erroneous phrase, it is worthwhile to reiterate the rule on continuing education which requires that licensees obtain ten hours each year with not more than 50 percent of those hours attained in correspondence.

In the same context, the item on patient counseling (d)(1) should read: "therapeutic duplication."

Item 751 – Public Hearing on Proposed Rules

At the regular meeting of the Board of Pharmacy in April, the members will consider several changes in current rules as well as some new proposals. One change would prohibit a pharmacist who has violated the laws governing the practice of pharmacy and distribution of drugs from serving as a preceptor for pharmacy students.

Another provision will add a self-inspection form to the annual permit renewal application to be completed by pharmacist-managers. This is planned to be a self-examination and learning tool for pharmacists to determine if they are in compliance with many of the provisions of the law. There will also be a proposal for a verification fee of $15 for reinstating any license to practice.

The Board will also consider a proposal on the dispensing of drugs in excess of the face amount of a prescription, but within the total amount authorized. A different provision will be suggest[illegible] controlled substances or psychotropic drugs.

[illegible] will be made to allow pharmacy students to [illegible]iption information and to counsel patients under the supervision of their preceptor.

A new rule also has been suggested which would allow the emergency refilling of prescriptions for a 72-hour supply of a prescribed medication in a situation where the pharmacist cannot contact the prescriber.

The Board will also consider a proposal to clarify the continuing education requirement and specify that courses must be health care related with the purpose of increasing the pharmacist's professional competence. It also further defines contact hour programs.

The Board will also consider a proposed rule on the disposal of outdated or unwanted drugs. If you wish to receive a copy of any of these proposals, please contact the Board office.

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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