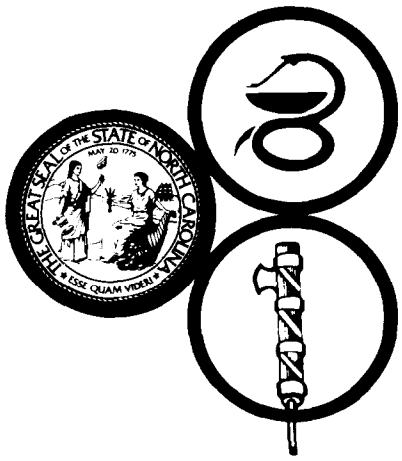
October, 1991



North Carolina Board of Pharmacy

P.O. Box 459, 620H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 692 - Election Result

On August 19th, the ballots for the Run-Off Election for a position on the Board of Pharmacy were counted at the office in Carrboro. The results were: Ken Burleson - 730; Harold Day - 822. These results were certified as final, and Mr. Day will begin serving a five-year term in the Spring of 1992.

Item 693 - Disciplinary Actions

April Pre-Hearing Conferences. Board accepted recommendation of Mr. Moose on Nick Collora, Burlington. Mr. Collora was reprimanded for failing to maintain adequate records and procedures in connection with the handling of controlled substances at K-Mart Pharmacy in Burlington, which resulted in shortages. Mr. Collora received this Reprimand as the pharmacist-manager responsible for the permit although he had not contributed to any such shortage.

Mary Louise Dixon, Raleigh. Board accepted recommendation of Mr. Moose. Ms. Dixon, by her own admission, consumed controlled substances which had not been prescribed by a physician; Ms. Dixon recognized her impaired condition due to the consumption of controlled substances. License suspended six months, stayed five years with specific conditions set forth.

Ronald E. White, Cove City. Board accepted recommendation of Mr. Randall. Mr. White was charged with possession of a controlled substance following an accident in Virginia Beach, Virginia on December 22, 1989; pled not guilty to such charges, was found guilty and, on appeal, entered a plea of nolo contendere to charges which would be dismissed in June of 1991 if no further violations occurred; has not maintained proper records with the North Carolina Board of Pharmacy causing difficulty for the Inspector to conduct an investigation. Case continued until final court decision is rendered in Virginia with conditions.

Robert T. Atkins, Cary. Board accepted recommendation of Mr. Moose. Mr. Atkins did allow or permit Michael Bills to fill and dispense prescriptions including prescriptions for controlled substances while not under the supervision of a pharmacist; this activity occurred on several occasions as established by a Board Inspector. License suspended for 90 days, stayed for three years with conditions.

K-Mart Corporation. Board accepted recommendation of Mr. Moose. K-Mart management reprimanded for having insufficient staff and an inadequate computer system at the K-Mart Pharmacy in Burlington, which was a major cause of shortages of controlled substances at that location.

May: **William B. Cheek, Asheville.** Request for reinstatement of pharmacy license granted with specific conditions.

June: **Joel Allison Ragan, Pfafftown.** Substantial evidence does not exist in the record to establish violations. The Board took no disciplinary action against Mr. Ragan, and the matter was dismissed.

July: **Linda Baker, Chapel Hill,** Pre-Hearing Conference. Board accepted recommendation of Mr. Moose. Ms. Baker was arrested on July 17, 1990 and charged with maintaining a dwelling for purpose of selling drugs, simple possession of marijuana, and possession of drug paraphernalia; knowingly maintained a dwelling house which was resorted to by persons using controlled substances for the purpose of using such substances or which was used for the purpose of keeping or selling controlled substances; pursuant to plea agreement pled no contest to simple possession of marijuana in the District Court of Orange County on June 21, 1991 and was placed on one year of unsupervised probation, provided that she pay a $100 fee and refrain from the practice of pharmacy from July 17, 1990 to July 30, 1991. Upon successful completion of probation, the criminal proceedings against Ms. Baker will be dismissed; voluntarily surrendered license to the Board of Pharmacy on November 7, 1990. License is to be returned to Ms. Baker no earlier than July 31, 1991, following receipt of a request from her for the return of license and that upon return of license that it be suspended 90 days, stayed for two years with conditions.

John H. Lowder; James B. Segars; William Jordan & Service Pharmacy, Marion. Consent Order entered. Dispensing Schedules III and IV controlled substances without a physician's authorization; receiving drug samples and dispensing for a charge if the individual dosage unit was not marked as a sample but only the packaging had been marked. The packaging would be discarded and the samples would be placed in the normal pharmacy stock; dispensing legend drugs without a physician's authorization and in vials with labels stating only the name of the drug and directions for usage; computer system failed to account for all dispensings of prescription drugs to customers, and respondents did not document all prescription drug dispensings in the computer system; drug accountability audit revealed drug shortages. Licenses of Lowder and Segars

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National Pharmacy

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Partial Filling of Prescriptions

Lester Hosto, Executive Director of the Arkansas State Board of Pharmacy, forwarded the following information regarding the amendment of Title 21 Code of Federal Regulations (CFR) 1300.05(a) and 1306.13(b), as reported to him in a letter from DEA Resident Agent in Charge Gary G. Worden.

21 CFR 1300.05(a), *Manner of Issuance of Prescriptions,* was amended by the addition of the term "quantity prescribed."

21 CFR 1306.13(b), *Partial Filling of Prescriptions,* allows for prescriptions for Schedule II controlled substances to be dispensed in partial quantities for patients in Long-Term Care Facilities (LTCF), or patients with a medical diagnosis documenting a terminal illness within a hospice or home care setting. The pharmacist must record on the prescription that the patient is "terminally ill," or an "LTCF patient," recording on the back of the prescription the date and quantity dispensed, amount remaining, and identification of the dispensing pharmacist. Prior to any subsequent filling, the pharmacist must determine that the additional quantities are necessary and do not exceed the total amount authorized. Schedule II prescriptions for "LTCF" and "patients with a medical diagnosis of terminal illness" are valid for up to 60 days from the date of issue. Information pertaining to partial fillings maintained in a computer system will now include all partial dispensing for each prescription.

MPPP Implications for Practicing Pharmacists

The Medicaid Prudent Pharmaceutical Purchasing Provisions (MPPP) component of the OBRA '90 legislation affects state Medicaid programs in two ways. First, it requires that all state Medicaid programs participate under a new reimbursement formula with certain price controls. Second, this legislation mandates patient counseling and Drug Utilization Review (DUR) for Medicaid patients.

In the past, most Drug Utilization Review programs operated on the basis of **retrospective** review as a claims auditing mechanism. Under retrospective review, a claim or medical record is examined for considerations related to cost-containment, control of fraud and abuse, and/or quality of care long after the patient has been treated.

Retrospective review differs significantly from the **prospective** DUR programs mandated by MPPP. Prospective DUR examines drug therapy problems **while the patient is being seen by the physician and/or the pharmacist**. While retrospective reviews will still be conducted, MPPP focusses on prospective DUR as a means of controlling overall health care expenditures by improving the therapeutic outcomes of drug therapy and the overall quality of care.

Under MPPP's requirements, the pharmacist must make reasonable efforts to obtain, record, and maintain records of the following patient information: a) name, address, phone number, date of birth, and gender; b) medical history and disease state; c) allergies; and d) a list of medications and devices currently being used.

Prior to dispensing a prescription to a patient, the pharmacist is required to screen for contraindications, incorrect dosage or duration of therapy; patterns of clinical abuse or misuse; and for drug interactions, including interactions with over-the-counter (OTC) medications. These provisions closely follow the Model Regulations on patient counseling developed by NABP, which were adopted by the membership at the 1990 Annual Meeting in Phoenix, Arizona.

A potential problem area for MPPP is that it provides individual state Medicaid programs with the option of excluding OTC items from coverage. Because this information is not required to be included in the patient's profile record of dispensed medications, pharmacists may, at times, lack necessary information about the OTC medications a patient may be using. In cases where the pharmacist cannot interview the patient or caregiver, it may be difficult to access a patient's medical records to discover whether drug-disease contraindications exist.

The state boards of pharmacy will need to consider the types of pharmacy practice sites that fall under MPPP's purview. Nursing homes already in compliance with current Drug Regimen Review regulations would be exempt from the MPPP DUR provisions. Likewise, hospitals and HMO's **with formularies** would be exempt. However, hospitals **without** formularies and other organizations that have pharmacies (such as planned parenthood clinics) may be included under the MPPP DUR requirements.

Since it appears that the MPPP DUR provisions do not apply exclusively to community pharmacies, state boards will need to consider the comprehensive nature of their regulations in this area for both practice site type and recognition of formularies.

Another consideration is the question of which agency will be responsible for enforcing the DUR provisions. The law says that the DUR program will be designed to **educate** physicians and pharmacists with respect to patterns of fraud and abuse, gross overuse, and inappropriate or medically unnecessary care. This educational function

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ʒ the law of such state or jurisdiction.)

also pertains to potential or actual severe, adverse drug reactions as well as inappropriate therapy.

To facilitate enforcement of these guidelines, the law provides that each individual state establish a Drug Use Review Board. The membership of each review board must include experts from three separate disciplines. Physicians must count for 51 percent of a review board's membership; 35 percent must be pharmacists, and the rest of the board must include non-physician and non-pharmacist members who have expertise in the DUR process. These boards will be charged with supervising both prospective and retrospective review activities and developing active educational outreach programs.

Individual physicians and pharmacists who do not come into compliance with board guidelines for DUR will be referred to the Drug Use Review Board for remedial education and attention. The DUR board may decide to establish sanctions for those practitioners who do not respond to their educational efforts. When these sanctions involve activities that also come under the jurisdiction of state boards of pharmacy, consistency becomes a concern.

Enforcement guidelines for each of these areas are currently in the developmental stages as the state boards of pharmacy (through NABP) and HCFA each strive to clearly delineate their roles in this process. Also of interest is the way in which reports from state DUR Boards to the National Practitioner Databank, which is managed by the Public Health Service, will be handled.

Each state must establish standards for counseling individuals who receive Medicaid benefits. Once in place, the DUR process will assess drug use data against standards pre-determined by state DUR boards based upon current peer-reviewed literature and three basic compendia: *AMA Drug Evaluations*, the *USP/DI* and the *American Hospital Formulary Service*. **MPPP mandates that the DUR provisions be operative no later than January 1, 1993.**

FDA Warns Against Misleading Claims for Oral Contraceptives

In a June 19, 1991 letter to all drug applicant holders (manufacturers), the Federal Food and Drug Administration's (FDA) Divisions of Metabolism and Endocrine Drug Products and Drug Marketing, Advertising, and Communications delineated some informal guidelines regarding acceptable advertising for oral contraceptive products.

Recent promotional materials for these products have exhibited certain themes which the Agency feels may be attempts to establish differences between various oral contraceptives. The Agency deems attempts to differentiate between products within this class to be misleading because they rely on claims that have not been proven to be of actual clinical relevance to the safety and effectiveness of the various products. Examples of these misleading efforts to differentiate between competing products include:

1. Claims of less hormone exposure per cycle or per year.
2. Claims that "phasing" of the product (differences in the amount of hormonal content) minimizes total hormonal dose, and that the slight difference in this phasing is of clinical importance.
3. Claims of a low incidence of breakthrough bleeding.
4. Claims of a low incidence of androgenic effects and/or lipid effects because of a particular progestational agent or dose of that agent.
5. Claims of a lower incidence of common oral contraceptive side effects.
6. Claims that include words such as "natural" or "physiologic" in reference to hormone phasing.

FDA points out that oral contraceptives are all evaluated against the same standards of efficacy and must have a similar level of safety for approval. To date, there have been no data submitted which demonstrate that the differences being cited in the promotion of low dose oral contraceptives exist and, if so, are clinically relevant.

FDA is presently developing a general policy for the advertising of prescription drug products directly to the consumer. Until that policy has been published, manufacturers are requested to submit all proposed direct-to-consumer advertisements for prior review to the Division of Drug Marketing, Advertising, and Communications.

New 'Orange Book' Available

The 11th (1991) edition of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the 'Orange Book') is now available. It can be ordered by subscription for $91 per year from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9371. Orders can also be placed by telephone (202/783-3238) or by fax (202/275-0019). A subscription includes periodic updates of the drug listings.

The publication is also reprinted by the U.S. Pharmacopeial Convention in Volume III of the *USP-DI* series. Further information may be obtained from USP by calling 1-800-277-USPC.

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revoked, stayed for ten years with active 120-day suspension within 12 months of this Order and other conditions. Pharmacist Jordan on probation for a period of five years from the date of this Order. Permit to operate pharmacy revoked, stayed ten years with active seven-day suspension and other conditions.

Pre-Hearing Conference, **George Dillard, Graham.** Board accepted recommendation of Mr. Randall. As pharmacist-manager, Mr. Dillard is responsible for having a system of inventory, recordkeeping, and control of controlled substances at that facility; audit revealed shortages of approximately 20 controlled substances with some shortages approaching 50 percent of the inventory for the period May 5, 1987 through July 18, 1990; incomplete records maintained for Schedule II controlled substances; did not carry-out duties of a pharmacist-manager as required by federal and state statute and the rules of the North Carolina Board of Pharmacy. License suspended 30 days, stayed five years with conditions.

Item 694 - Statutory Changes

The 1991 session of the General Assembly produced few changes in pharmacy law. One change provides that licensure examination contents cannot be disclosed and makes it a criminal offense to tamper with examination questions. The sponsors of this Bill, Sen. J.K. Sherron of Raleigh, and Rep. John C. Hasty, Maxton, deserve a courteous "Thank You" from every licensed professional person for protecting the public in this way.

One of the changes in statute modified the definition of device in the Pharmacy Practice Act. The new wording appears below:

Section 1.G.S. 90-85.3(e) reads as rewritten:

(e) 'Device' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, whose label or labeling bears the statement 'Caution: federal law requires dispensing by or on the order of a physician.' The term does not include: (1) Devices used in the normal course of treating patients by health care facilities and agencies licensed under Chapter 131E or Article 2 of Chapter 122C of the General Statutes; (2) Devices used or provided in the treatment of patients by medical doctors, dentists, physical therapists, occupational therapists, speech pathologists, optometrists, chiropractors, podiatrists, and nurses licensed under Chapter 90 of the General Statutes, provided they do not dispense devices used to administer or dispense drugs.

Therefore, anyone licensed under G.S. 90 (physicians, dentists, etc.) does not need to register with the Pharmacy Board in order to dispense prescription devices. Others, such as sickroom supply outlets, must register with the Board to dispense such devices.

Item 695 - Renewal Reminder

This shall serve as a reminder to pharmacists to renew their licenses as well as any permits for 1992 promptly. In the past, the Board staff has reminded pharmacists of their responsibilities about two weeks prior to the deadline. No such reminder is planned this year, so do not delay the renewal process.

Item 696 - Patient Counseling Rules

A new federal law will essentially require patient counseling by pharmacists or physicians for all Medicaid beneficiaries by January, 1993 (see page 2 of the National News Section). In order to guide pharmacists in this activity, the Board has moved forward with a proposed rule on patient counseling which is an adaptation of the model rules published by the National Association of Boards of Pharmacy. A hearing on this and perhaps other rules is scheduled for January 28, 1992, at 2:00 p.m., in the Trustees Room of the Durham Hilton. The Model Rules are reprinted below, however there may be some technical differences to accommodate statutory references, etc.

Model Regulations for Patient Counseling

Section 1: Definition of Patient Counseling

"Patient Counseling" shall mean the effective communication by the pharmacist of information, as defined in this Act, to the patient or caregiver, in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices. Specific areas of counseling shall include, but are not limited to: a) Name and description of the medication; b) Route, dosage, administration, and continuity of therapy; c) Special directions for use by the patient as deemed necessary by the pharmacist; d) Side effects or interactions that may be encountered, which may interfere with the proper use of the medication or device as was intended by the prescriber, and the action required if they occur.

Section 2: Patient Information

In order to effectively counsel patients, the pharmacist shall make a reasonable effort to obtain, record, and maintain the following patient information, if significant, but not limited to: a) Name, address, telephone number; b) Date of birth (age), gender; c) Medical History: 1. Disease state(s), 2. Allergies/drug reactions, 3. Current list of medications and devices; d) Pharmacist comments.

Section 3: Communication to the Patient

a) A pharmacist shall counsel the patient or caregiver "face-to-face" when possible or appropriate. If this is not possible, a pharmacist shall make a reasonable effort to counsel the patient or caregiver; b) Alternative forms of patient information may be used to supplement patient counseling; c) Patient counseling, as described above and defined in the "Practice of Pharmacy," Section 104 of this Model Act, shall also be required for outpatient and discharge patients of hospitals and institutions; d) Patient counseling, as described above and defined in the "Practice of Pharmacy," Section 104 of this Model Act, shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication(s); and e) The pharmacist shall maintain appropriate patient-oriented reference materials (i.e. *USP-DI, Facts and Comparisons, Patient Drug Facts*, etc.) for use by the patient upon your request.

Item 697 - Thanks to Proctors

The June administration of the licensure exam in Greensboro was greatly assisted by the help of three proctors; Jay Gross, Ed Meade, and Christina Washington. We appreciate their willingness to give up personal free time to assist the profession.

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 laws. 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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