January, 1993

North Carolina Board of Pharmacy

P.O. Box 459, Carrboro, NC 27510-0459
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Published to promote voluntary compliance of pharmacy and drug law.

Item 740 - Disciplinary Actions

August:

Wallace Allen Johnson, Jr., Mount Airy. Violations of Board's Order of June 17 and July 15, 1986; Diversion of controlled substances. License revoked.

September:

Robert K. Atkins and Atkins Home Care Pharmacy, Cary. Filling of prescriptions while license was suspended constituting engaging in practice of pharmacy without a license; violation of Board's March 19, 1991 Order. Pharmacy failed to prevent the events from occurring when the permit holder knew or should have known violations were occurring. License to practice suspended for 120 days with conditions. Pharmacy permit suspended 30 days, stayed for three years with specific conditions.

Joel Paul James, Chapel Hill. Request for reinstatement of pharmacy license denied.

David Ray Bowers, Statesville. Obtaining and consuming controlled substances without authorization. License suspended indefinitely. Conditions for request for reinstatement consideration at a later date set out.

October:

Herman R. Honeycutt and Arnold Drugs, Raleigh. Refilling prescriptions without authorization; creating without authorization new prescriptions once prescriptions for controlled substances had been refilled five times; pled guilty to four felony counts of the unlawful distribution of controlled substances. Pharmacy failed to prevent events described when the permit holder knew or should have known violations were occurring. License to practice pharmacy and the permit to operate pharmacy revoked.

Eugene M. Ussery, Raleigh. Pled guilty to one count of unlawful distribution of a controlled substance; refilling controlled substance prescriptions without authorization. License suspended indefinitely, stayed two years with specific conditions.

James David McKenzie, Matthews. Failure to obtain at least ten hours of continuing education credits, including at least five contact hours of continuing education for 1991, and to obtain certificates of credit for continuing education during 1991. License suspended indefinitely, stayed five years with active 30-day suspension of pharmacy license and other conditions.

Item 741 - Patient Counseling Rule Effective January 4, 1993

Please note that a new section, (c)4, has been added to this adopted patient counseling rule, which alters it from the rule mailed to pharmacies in November.

21 NCAC 46.2504
.2504 Patient Counseling

(a) "Patient Counseling" shall mean the effective communication of information, as defined in this Rule, to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices. This Rule shall apply to pharmacists and to registrants under G.S. 90-85.21. Specific areas of patient counseling include, but are not limited to, those matters listed below that in the exercise of the pharmacist's or registrant's professional judgment are considered significant:
  (1) name, description, and purpose of the medication;
  (2) route, dosage, administration, and continuity of therapy;
  (3) special directions for use by the patient;
  (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
  (5) techniques for self-monitoring drug therapy;
  (6) proper storage;
  (7) prescription refill information; and
  (8) action to be taken in the event of a missed dose.

(b) An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative. Ancillary personnel may make the offer to counsel, but the pharmacist or registrant must personally conduct counseling if the offer is accepted. The offer shall be made orally and in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls. A pharmacist or registrant whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Professional judgment shall be exercised in determining whether or not to offer counseling for prescription refills. An offer to counsel shall be communicated in a positive manner to encourage acceptance.

(c) In order to counsel patients effectively, a reasonable effort shall be made to obtain, record, and maintain, if significant, patient information, including, but not limited to:
  (1) name, address, telephone number;
  (2) date of birth (age), gender;
  (3) medical history:
    (A) disease state(s),
    (B) allergies/drug reactions,

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National Pharmacy

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and can only be ascertained by examining

CPSC Reverses Stance on CRP Waivers

The third quarter, 1992 "National Pharmacy Compliance News" section of this newsletter included an article that discussed the U.S. Consumer Product Safety Commission's (CPSC) decision to interpret Section 4(b) of the Poison Prevention Packaging Act (PPPA) to mean that pharmacists could not rely upon a blanket waiver or previous requests from a patient to supply non-child resistant packaging for prescription drug products.

The National Association of Boards of Pharmacy (NABP), on behalf of its member state boards of pharmacy, contacted CPSC regarding the Commission's reversal of its long-standing policy. Noting that the state boards of pharmacy are committed to protecting the public health and understand the necessary protections provided by child-resistant packaging (CRP), the Association pointed out the significant difficulties placed on the practitioner and the patient by requiring a specific request for non-CRP packaging with each new or refill prescription order.

On November 6, 1992, NABP received a letter from David Schmeltzer, assistant executive director of the CPSC Office of Compliance and Enforcement, that modifies the Commission's reinterpretation of Section 4(b). Mr. Schmeltzer states:

> The staff's letter of February 25, 1992, to the National Association of Boards of Pharmacy stated that the PPPA does not provide for the practice of pharmacies relying on "blanket waivers" from customers to request that all prescriptions be dispensed in non-CRP. After considering responses to its February 25 letter, the staff reconsidered its position with regard to blanket waivers and concluded the statute does not prohibit them.
>
> The staff now agrees that the law does not preclude a pharmacist from relying upon a specific request from a patient, preferably in writing, to have all of his or her medications placed in noncomplying packaging, i.e., a blanket waiver. However, a single request from a patient to dispense a specific prescription in non-CRP is not a basis for the pharmacist to infer the patient wants all subsequent prescriptions to be dispensed in non-CRP. Such a request is not a blanket waiver.
>
> A patient who previously filed a specific blanket waiver request for non-CRP may later change his or her mind about use of such packaging because of changing personal circumstances, but the patient may not remember to inform the pharmacist of the change in CRP preference. It would be a prudent practice for the dispensing pharmacist to periodically check with all patients who have blanket waiver requests on file to ensure that noncomplying packaging continues to be the preferred packaging choice for the patients' prescription drugs.
>
> Section 4(b) of the PPPA (15 USC 1473) provides that drugs which are subject to the special packaging standards and are dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe may be dispensed in noncomplying packages **'only when directed in such order or when requested by the purchaser'** [*emphasis added*].
>
> The purpose of the PPPA and the standard at 16 CFR 1700.14 is to prevent or minimize the risk of serious personal injury or serious illness to children under five years of age by requiring that hazardous household substances, including prescription drugs, be packaged in special child-resistant packaging. The exemption, at Section 4(b) of the PPPA, to the standard for prescription drug packaging is meant to be the exception, not the rule.
>
> The dispensing pharmacist should be aware that it is not up to the pharmacist to decide when to use CRP or non-CRP on prescription drugs. It is the patient's decision to make, although a pharmacist may elect to ask about the patient's preference.
>
> Finally, to help document full compliance with the PPPA, pharmacists may decide to establish some form of recordkeeping procedure, including signed waiver requests, to document each blanket waiver for non-CRP on prescription drugs.
>
> If you have any questions about this or other issues pertaining to the PPPA, please write Compliance Officer Michael Bogumill at the U.S. Consumer Product Safety Commission, Office of Compliance and Enforcement, Washington, DC 20207, or phone him at 301/504-0400.

New Name and Monograph Requirements for Potassium Chloride Injection

Following reports of several deaths caused by the accidental injection of undiluted Potassium Chloride Injection, the USP renamed the product Potassium Chloride *for Injection* Concentrate and put in place new monograph requirements for labeling and packaging. The new packaging and labeling requirements include a black cap with

the words "Must Be Diluted," and a boxed warning on the label that states, "Concentrate Must Be Diluted Before Use." These are intended to decrease the likelihood of mistaking the concentrate for a ready-to-use solution. Also, ampuls must have a black band or series of black bands above the constriction.

The new labeling requirements, including the words "Must Be Diluted" have been in effect since May 15, 1992. The new monograph requirements for all Potassium Chloride for Injection Concentrate products to be packaged with a black cap (or black bands on ampuls) with the words "Must Be Diluted" will take effect on January 15, 1993.

Some products already have conformed to the new packaging requirements. There will be, however, some overlap period of time during which the recently manufactured injection concentrate will have a black top, while older products still in circulation will not have the new label or distinctive packaging.

Handling and Reacting to an FDA Investigator Visit

by Robert C. Fish, Director, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs, FDA

Certainly, the FDA is not involved in the routine inspection and regulation of pharmacies. However, we do have some legitimate reasons for visiting pharmacies in the course of our investigational activities. These visits may be involved with complaint investigations, recalls, inspection of registered pharmacies involved in manufacturing or repackaging, PDMA investigations, or sample collections.

What should the pharmacist do when an investigator appears? I suggest at least some of the following actions. All investigators should identify themselves. Insist on seeing their credentials, which include a photo identification. They should be able to explain the legitimate reason they are there. If not, ask them to tell you the purpose of their visit. We would hope that the pharmacist would cooperate in helping us carry out our legitimate public health duty. This may include answering questions or providing documents associated with the drug products you handle.

If the visit is to inspect a manufacturing or repacking operation, I can understand that this may be more stressful. In such an instance, we are evaluating the operation as it relates to good manufacturing practice requirements. I believe there are several keys to satisfactorily completing such an inspection. First and foremost, make certain that you are communicating. Be sure that the investigator understands what you are doing, how you are doing it, and why. If deviations from GMPs are noted, you likely will receive a written list of observations; the FDA-483. Don't ignore that document. Be sure you understand it and if there are inaccuracies in the document, point them out to the investigator. When the investigator leaves, continue to communicate with your local district office.

Do respond to the FDA-483 and let us know what you are doing about the observations. If things need to be fixed, fix them, and let us know you have done so. Many problems, difficulties, and misunderstandings can be avoided if we have open communication throughout this process.

Pediatric Labeling Requirements

In early October, the Food and Drug Administration (FDA) published a proposed rule to amend its regulations governing the current "Pediatric Use" subsection on professional labeling to provide for the inclusion of more complete information about the use of a medication in children and the hazards associated with such use. The current pediatric labeling requirements were adopted in 1979, and require that specific pediatric indications, if any, be described under the "Indications and Usage" section of the labeling, with appropriate dosage information provided under the "Dosage and Administration" section.

The revision proposed by FDA promotes the safe and effective use of prescription medications in the pediatric population and is one of a number of initiatives to encourage pharmaceutical manufacturers to study the use of prescription medications in children. Besides changing the current "Pediatric Use" subsection of professional labeling, the proposed revision provides that statements regarding pediatric use of a medication for an indication approved for adults must be based on substantial evidence derived from adequate and well-controlled studies. The regulations encourage drug labeling that furnishes adequate information about the use of prescription drugs in children.

Surveys of prescription medication labeling information indicate that relatively few medication labels cover pediatric use. A review of the labeling for all new molecular entities approved from 1984 through 1989 found that 80 percent of the medications provided no information on pediatric use. Surprisingly, even some drugs commonly prescribed and dispensed for children do not include labeling information on pediatric use.

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(C) current list of non-prescription and prescription medications and devices.

(4) pharmacist or registrant comments relevant to the individual's drug therapy.

A "reasonable effort" shall mean a good faith effort to obtain from the patient or representative the foregoing patient information. Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or registrant must review and interpret patient profile information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether and when individual patient history information should be sought from other health care providers.

(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or registrant before each prescription is filled or delivered, typically at the point-of-sale or point-of-distribution to screen for potential drug therapy problems due to:

(1) therapeutic distribution;

(2) drug-disease contraindication;

(3) drug-drug interactions, including serious with prescription or over-the-counter drugs;

(4) incorrect drug dosage or duration of drug treatment;

(5) drug-allergy interactions; and

(6) clinical abuse/misuse.

(e) Unless refused by the patient or representative, patient counseling shall be provided as follows:

(1) counseling shall be "face-to-face" by the pharmacist or registrant when possible or appropriate. If this is not possible, a reasonable effort shall be made to counsel the patient or representative;

(2) alternative forms of patient information may be used to supplement patient counseling;

(3) patient counseling, as described in this Rule, shall be required for outpatient and discharge patients of hospitals, health maintenance organizations, health departments, and other institutions; however, compliance with this Rule in locations in which non-pharmacists are authorized by law or regulation to dispense may be accomplished by such authorized non-pharmacists; and

(4) patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or other institutions where a nurse or other licensed health care professional administers the medication(s).

(f) Pharmacies that distribute prescription medication by mail, and where practitioner-pharmacist-patient relationship does not exist, shall provide counseling services for recipients of such medication in accordance with this Rule.

(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling, shall be maintained for three years in accordance with Section .2300 of this Chapter.

History Note: Statutory Authority G.S. 90-85.6; 90-85.21; 90-85.32; 42 U.S.C. 1396r-8(g); Effective January 4, 1993.

You may be aware of other requirements that are imposed by the federal government on states, counties, or cities without any funding provided. The Rule above was prompted as a result of a requirement contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) that imposed a new standard on Medicaid beneficiaries, but provided no new funding. Until now, most pharmacists felt this was a remote concept that did not affect them. It's a good illustration of how the absence of funding can affect activity at the grass roots level.

Item 742 - Continuing Education Hours

The Board members feel that pharmacists need to have a better ling of what is expected to meet the continuing educa- ement for license renewal. The Board rule specifies that of C.E. must be obtained, with not less than five of those orrespondence or other non-contact courses.

issue in this matter is what qualifies as contact hours. The Board believes that contact hours mean time spent in meetings or other programs which are "live" in nature. Just because a correspondence course claims to issue "contact hour" credit does not mean that it meets the Board's definition of contact hours. Most programs are clearly contact hours or correspondence hours, and there is usually not much difficulty in making that determination. However, one issue that arises is that of televised programs. Board staff interprets programs which consist of merely viewing a video as correspondence, while interactive television programs during which questions are possible and answers are available from the presenter would qualify as contact hour credit.

Item 743 - Penalty for Late Renewal

The Board will not send out reminders to those who have failed to renew their licenses to practice. The grace period expires at the end of February, and all individuals will be expected to have their licenses and permits renewed by that time.

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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