July, 1993

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 752 - Disciplinary Actions

February

Benjamin K. Mobley & Kearns Service Drug Store, Inc., Asheboro. Dispensing controlled substance without authorization; violations of the laws governing the practice of pharmacy or the distribution of drugs. License suspended indefinitely, stayed for five years with active 120 days to begin no later than January 1, 1994 and other conditions. Permit suspended indefinitely, stayed for five years with conditions.

March

Dale C. Bracker, Greensboro. Failed to comply with the rules and regulations of the Board; was negligent in the practice of pharmacy. License suspended 90 days, stayed three years with conditions.

April

James Michael Kinsland. Request for reinstatement of pharmacy license granted with conditions.

Harold Eugene Gillung, South Carolina. Obtaining and consuming controlled substances without authorization; pleading guilty to one felony count of embezzlement of a controlled substance by an employee of a registrant; replacing morphine which had been consumed with saline solution and replacing cocaine which had been consumed with Piperacillin. License revoked.

Item 753 - Patient Counseling Update

The Board members have noted generally good compliance with the new rule that became effective January 4, 1993 requiring pharmacists to obtain patient information, offer to counsel patients on all new prescriptions and other prescription as appropriate, and perform prospective drug utilization review. It should be noted again that an offer to counsel must be made on all new prescriptions, and this offer must be made orally and in person wherever possible. Pharmacists need to use their judgment when counseling patients on prescription refills. It's important to remember that prescription refills are **not exempt** from the rule.

The Board does not expect pharmacists to be perfect in their conduct, but they do expect compliance with the rule. As of the copy deadline for this *Newsletter,* the first disciplinary action for a pharmacist failing to counsel patients has been scheduled for the July meeting. In this regard the members of the Board have directed staff to include the pharmacy permit in any notice of hearing on patient counseling disciplinary actions. Pharmacists who fail or refuse to comply with the rule should understand by this action that they may be placing the pharmacy permit at risk.

While much of the focus on this subject centers on patient counseling, perhaps the most difficult challenge in the rule is prospective drug utilization review. This is a challenging activity which reaches an extreme with multiple drugs and diseases afflicting the same patient. It's noteworthy to remember that prospective drug utilization review needs to occur on each and every dispensing of a prescription.

While hospital pharmacists are exempt from the patient counseling provision of the rule for inpatients, there is no such exemption for prospective drug utilization review. It is the editor's opinion that a thorough prospective drug utilization review cannot be done without a computer connected directly to an information source which contains not only information from FDA-approved labeling, but also common off-label uses.

Item 754 - Pictogram Labels

In a state where at least 20 percent of the adult population is functionally illiterate, the matter of patient counseling takes on real significance. Printed material is specified as an appropriate supplement to such counseling and pharmacists should give consideration to using pictogram labels for their patients who are poor readers or non-readers.

Reports come into the Board office almost every week with examples of mistakes resulting from an inability to read. Perhaps the most striking event occurred in Mount Airy. Barry Gates at The Medicine Shoppe reports that a patient once asked him for a 100-count bottle of the desiccant packet packaged in containers to keep the contents dry. Upon inquiry it appeared that the customer had come across one of these packets and could not understand the word "desiccant" printed on the item. He asked a schoolteacher acquaintance what the word meant, and she replied that it meant "drying out." He misinterpreted this to mean that it would "dry out" a head cold, and consumed one pack for that purpose. He claimed that it was "kind of rough" on him, but it sure did the job, and he wanted to have a supply on hand. This is just one example of the kind of errors, almost all of which go unreported, that result from illiteracy.

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National Pharmacy

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and can only be ascertained by examini

Last quarter's "National Pharmacy Compliance News" featured the first of a two-part presentation of the National Association of Boards of Pharmacy's (NABP) document entitled, "Good Compounding Practices Applicable to State Licensed Pharmacies."

This document was prepared in response to a request from the Food and Drug Administration (FDA) that NABP develop guidelines that would, once and for all, answer the question of what distinguishes compounding from manufacturing. Long a subject of debate among pharmacy practitioners and regulators, the issue entered a new dimension last year when the FDA issued warning letters to those retail establishments it believed were manufacturing, distributing, and promoting unapproved new drugs for human use in a manner it considered to be outside the bounds of traditional pharmacy practice. The situation quickly escalated as various interest groups within the profession of pharmacy accused the FDA of overstepping its authority as a federal agency and attempting to halt pharmaceutical compounding by pharmacists.

The FDA insisted that it was not attempting to interfere with the traditional practice of pharmacy by licensed practitioners, and in meetings with NABP representatives, expressed its willingness to defer matters relating to compounding to the state boards of pharmacy. Its chief concern, FDA stressed, was the large-scale operations that were using retail pharmacy licensure as a cloak to avoid registering as manufacturers and adhering to Good Manufacturing Practice Standards (GMPs).

At NABP's 89th Annual Meeting in May, delegates representing the 51 boards of pharmacy in the United States voted to adopt these Good Compounding Practices and to include them in NABP's *Model State Pharmacy Act and Model Rules.*

Good Compounding Practices Applicable to State Licensed Pharmacies - Part II

Subpart D - Equipment

Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in the "NABP Model Regulations for Sterile Pharmaceuticals" must be followed.

Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

Automatic, mechanical, electronic, or other types of equipment, other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

Subpart E - Control of Components and Drug Product Containers and Closures

Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area, (e.g., floors) and inspection.

Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, stored, and in general maintained in keeping with the "NABP Model Regulations for Sterile Pharmaceuticals." Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. If these processes are performed by the pharmacist, or under the pharmacist's supervision, the *NABP Model Regulations for Sterile Pharmaceuticals* shall be followed.

Subpart F - Drug Compounding Controls

There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight

or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

(a) component name, and
(b) weight or measure.

To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules). Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) capsule weight variation;
(b) adequacy of mixing to assure uniformity and homogeneity;
(c) clarity, completeness, or pH of solutions.

Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

Subpart G - Labeling Control of Excess Products

In the case where a quantity of a compounded drug product in excess of that to be initially dispensed in accordance with Subpart A is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.

At the completion of the drug preparation operation, the product shall be examined by the pharmacist for correct labeling.

Subpart H - Records and Reports

Any procedures or other records required to be maintained in compliance with these Good Compounding Practices shall be retained for the same period of time as each State requires for the retention of prescription files.

All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Chloral Hydrate Overdoses Cause Children's Deaths

The USP Medication Errors Reporting (MER) Program has learned about a number of fatal pediatric overdoses related to Chloral Hydrate. In one instance, a five-year-old boy was prescribed Chloral Hydrate Syrup before undergoing a CAT scan for a skull fracture. The physician ordered a concentration of 500 mg/10 mL, a concentration only available in unit-dose containers most often used in hospitals. The prescription was filled at a neighborhood pharmacy with the correct instructions for use: "Give three teaspoonful prior to CT. If needed, give two more." Instead of dispensing the 500 mg/10 mL syrup, the pharmacist mistakenly filled the prescription with the 500 mg/5 mL syrup, thereby doubling the intended dose. Returning home after the testing was performed, the mother realized that her son had stopped breathing. The boy was taken back to the hospital, where he died.

An old hypnotic drug that is rarely used by adults, Chloral Hydrate has gained popularity for use in children in certain clinical settings because of its wide therapeutic margin. The normal pediatric hypnotic dose of Chloral Hydrate is 50 mg per kilogram of body weight, or 1.5 grams per square meter of body surface, up to a maximum of 1 gram per single bedtime dose. The pediatric dosing for premedication prior to electroencephalographic evaluation is 20 or 25 mg per kilogram of body weight. The *adult* prescribing limit is 2 grams daily. The Institute for Safe Medication Practices, Inc. cautions health professionals to consider the following when using Chloral Hydrate in children:

1. Be aware that Chloral Hydrate Syrup is available in *two* strengths: 500 mg per 5 mL and 250 mg per 5 mL.
2. Children should be dosed by kilogram weight, keeping in mind the maximum therapeutic dose.
3. Prescribers should prescribe in total milligram dose according to metric weight, not the volume of drug.
4. In institutional settings where the concentration dispensed may be unavoidably different from what was prescribed, this should be made clear on the pharmacy label. The volume for administration must also appear on the label and should be communicated verbally to the person responsible for drug administration. A pharmacist should be involved in calculating the correct volume to be administered to each patient and should counsel the responsible person accordingly.
5. Hospital pharmacies should educate all hospital personnel involved in dispensing and administering Chloral Hydrate Syrup in the strengths available in pharmacies and in what constitutes a safe dose.
6. Health professionals must be alerted to the need for careful monitoring of pediatric patients after administration of Chloral Hydrate and implement necessary precautionary measures.
7. Within institutions, only authorized health care professionals should prepare and administer medications. Medical records should be available to research preexisting conditions, including previous episodes of drug sensitivity. Doses administered and follow-up monitoring must be appropriately documented.

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It is precisely this kind of citizen who deserves a thorough counseling on prescription drugs and would benefit from Pictogram labels. Some pharmacists have had difficulty obtaining these items, but David Moody at North Carolina Mutual Wholesale Drug in Durham has indicated that they have a supply on hand.

Item 755 - Rule on Reporting Deaths

Since this rule's March 1, 1992 effective date, there have been 17 deaths reported to the Board. Several of these were due to devices or were not actually attributable to prescription drugs. One important piece of information gained from this effort is that of the ten drug-related deaths in the first year, five were reasonably preventable by pharmacist action or patient counseling.

Another discovery that was made from these reports was that the majority of the deaths reported came from retail stores. This is surprising because community pharmacists are less likely to learn of these deaths, and this may indicate the existence of a situation nobody anticipated.

This item has two purposes. The first is to remind pharmacists to report such events. The other purpose is to note that reporting is not an automatic confession. Only one case out of those reported went to a Board hearing and, although the pharmacist was found negligent, he did not receive an active suspension or revocation of his license.

Representatives of the North Carolina Pharmaceutical Association, the North Carolina Society of Hospital Pharmacists, and the Board of Pharmacy have formed a task force to review the results of this rule. The task force will not have access to the specific reports or information, but will review summaries of these reports for any useful information which may be obtained.

Item 756 - Pharmacy Technicians

One of the indirect effects of patient counseling as a new standard of practice is a greater need for pharmacy technicians. In both the hospital and retail settings, the need for pharmacists to spend their time on prospective drug utilization review and patient counseling creates a void that is naturally filled by technicians.

Perhaps for this or other reasons, attention is being focused on pharmacy technicians. On the national level, the National Association of Boards of Pharmacy (NABP) adopted a resolution at its May, 1993 Annual Meeting in Baltimore supporting the registration of pharmacy technicians by the Board of Pharmacy. The North Carolina Board has not yet moved in that direction, but it will be a topic of discussion in the future.

There are pharmacy technician certification examinations offered by some groups, but neither the North Carolina Board or NABP is involved in such efforts.

Item 757 - Hudson Receives Award

North Carolina Board of Pharmacy Investigator Steve Hudson received the NABP Distinguished Service Award for Inspectors at the Association's 89th Annual Meeting in Baltimore. Steve was honored with the only Distinguished Service Award presented this year for his more than 15 years of excellent investigative work. Upon presenting the award, NABP President David Work stated, "Steve, like DSA recipient Bill Adams from our Board, obtained this award the old fashioned way. . . he earned it."

Item 758 - Safety Line

North Carolina state government has recently published a telephone number for citizens to call if they suspect any fire, safety, health or other hazards in the workplace. The number to call is 1-800/662-7952.

This toll-free number will connect you with the Governor's Office of Citizens Affairs. You do not have to reveal your name in order to report a condition you believe is unsafe.

Item 759 - Employment of a New Pharmacist

The Board would like to stress the importance of verifying the licensure status of a pharmacist before employment begins. Licensure status can be verified by calling the Board office at 919/942-4454, or by examining the wallet cards of prospective employees.

In addition, information related to disciplinary actions acquired by any licensed pharmacist or pharmacy is available upon request. This information will not be volunteered by office staff. It must be specifically requested.

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