July, 1994

North Carolina Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Item 789 - Disciplinary Actions

February

Myron S. Sime (DOB, October 22, 1940), and **Blackwelder Hospital Pharmacy**, Lenoir. Obtaining and consuming prescription drugs without authorization and dispensing prescription drugs without child safety closures; failure of pharmacy to prevent the events when the permit holder knew or should have known the violations were occurring. Pharmacist license suspended indefinitely. Pharmacy permit revoked.

Rebecca A. Pyke, Arden (DOB, August 25, 1959). Exam candidate with charges listed on application. Been found guilty or pled guilty or nolo contendere to any felony in connection with the practice of pharmacy and the distribution of drugs; failed to comply with the laws governing the practice of pharmacy and the distribution of drugs. Probation five years, with conditions.

Charles Edward Deaton, Greensboro (DOB, December 24, 1929). Obtaining and dispensing controlled substances and pleading guilty to felonies in connection with the practice of pharmacy or the distribution of drugs. License revoked.

James Dallas Neal, Liberty (DOB, January 19, 1944). Order entered reinstating pharmacy license with specific conditions.

March

Roger L. Simpson, Monroe (DOB, July 21, 1954). Violations of terms of Final Order entered February 7, 1991; obtaining and consuming controlled substances without authorization. Stay of indefinite suspension and respondent's license to practice pharmacy is hereby suspended indefinitely.

James Paul Gabbard (DOB, November 23, 1948), **Stanley J. Gajdik** (DOB, March 30, 1945), and **Fairview Pharmacy Consultants**, Fairview. **Gabbard:** Obtaining and consuming controlled substances without authorization; **Gajdik**: Actions regarding inventory control, record keeping, and security for controlled substances; **Pharmacy:** Failing to prevent the events from occurring when permit holder knew or should have known the violations were occurring. License of Gabbard suspended indefinitely, stayed five years with conditions; License of Gajdik and pharmacy permit: The Board will withhold the entry of any disciplinary action for a period of six months from the date of Final Order, during which time the Board will conduct an audit of pharmacy to insure compliance with the laws and regulations governing the practice of pharmacy and the distribution of drugs.

Item 790 - Patient Counseling

Complaints continue to come to the Board office regarding the absence of patient counseling by pharmacists. A summary of the Board's position on this issue as well as anticipated actions follows.

After receiving a citizen's complaint about a pharmacist's failure to offer to counsel on a new prescription, the Board staff will initiate an investigation. This usually involves a visit by an inspector in an undercover capacity to determine if the complaint can be verified. If there has been a failure to offer to counsel and this can be demonstrated on more than one occasion, Board policy is to bring this matter to a hearing before the Board. If the complaint cannot be verified, a letter is written to the pharmacist explaining what has occurred with a reminder about the patient counseling rule.

Board members have acted on violations of the patient counseling rule in a variety of ways. In relatively minor cases, the members have issued a reprimand or short suspension followed by a probationary period. In other cases, the members have determined that a short to moderate suspension is necessary along with other requirements such as additional continuing education to renew a license and, where justifiable, passing a jurisprudence exam.

It has been the Board's experience that a much higher rate of acceptance of offers to counsel occurs when the pharmacist personally makes the offer. Offers made by technicians or clerical personnel somehow do not convey the importance of the communication. Board rule requires that such offers be made orally, in person, and in a positive manner to encourage acceptance. Offers must be made on **all** new prescriptions and the pharmacist must use **judgment** on refills.

It is the editor's opinion that the phrase, "Do you have any questions?" is not an offer to counsel, but merely a question. In response to several specific inquiries from pharmacists, the following phrase would seem to qualify as a way to make an offer in a positive manner: "There are some important things you need to know about your prescription. Do you have a minute for me to discuss your new drug with you?"

The first year's results regarding the Board's rule on reporting of deaths *(see Item 708)* clearly shows that patient counseling will save lives. It is not just in your patient's best interests, but in your own best interest to make sure that your patient counseling activities meet the professional standard.

National Pharmacy

(Applicability of the contents of articles in the National Pharm. Con
and can only be ascertained by examini

DEA Final Rule – Prescriptions Transmitted by Facsimile

On May 19, 1994, the Drug Enforcement Administration (DEA) modified Title 21 Code of Federal Regulations (CFR) §1306 to allow for the transmission of written prescriptions by a practitioner to a dispensing pharmacy by facsimile. For Schedule II drugs, the original written prescription must still be presented and verified against the facsimile at the time the substances are actually dispensed, and the original document must be properly annotated and retained for filing. For drugs in Schedules III-IV, however, a facsimile copy of a written, signed prescription transmitted directly by the prescribing practitioner to the pharmacy can serve as an original prescription.

The final rule includes two exceptions that will greatly enhance the ability to provide adequate health care to patients in need of home infusion/intravenous (IV) pain therapy and to patients in long-term care facilities (LTCF).

The first exception involving home infusion/IV pain therapy allows for the transmission of a Schedule II prescription by the practitioner or the practitioner's agent to the home infusion pharmacy by facsimile. The home infusion pharmacy may consider the facsimile to be a "written prescription," as required by Title 21 United States Code (U.S.C.) §829(a).

In such cases, it will no longer be necessary for the original prescription to be delivered to the pharmacy prior to or subsequent to the delivery of the medication to the patient's home. The facsimile copy of the prescription shall be retained as an original prescription, and it must contain all the information required by 21 CFR §1306.05(a), including the date issued, the patient's full name and address, and the practitioner's name, address, DEA registration number, and signature. The exception to the regulations for home infusion/IV therapy is intended to facilitate the means by which home infusion pharmacies obtain prescriptions for patients requiring the frequently modified parenteral controlled release administration of narcotic substances, but does not extend to the dispensing of oral dosage units of controlled substances.

The second exception applies to Schedule II prescriptions written for patients in LTCFs, which are filled by and delivered to the facility by a dispensing pharmacy. The same requirements as stated above apply to the transmission of a prescription by facsimile to LTCFs. In both cases, the exceptions will eliminate the need to use the "emergency prescription" provisions for Schedule II controlled substances.

Under current regulations, a pharmacist bears the responsibility for ensuring that prescriptions for controlled substances have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice pursuant to 21 CFR 1306.04(a). Orders purporting to be prescriptions, which are not issued in the usual course of professional treatment, are not considered prescriptions within the meaning and intent of the Controlled Substances Act. A person who issues or fills such an order shall be subject to penalties provided by law. That responsibility applies equally to an order transmitted by facsimile.

Some measures to be considered in authenticating prescriptions sent by facsimile equipment would include maintenance of a practitioner's facsimile number reference file, verification of the telephone number of the originating facsimile equipment, and/or telephone verification with the practitioner's office that the prescription was both written by the practitioner and transmitted by the practitioner or the practitioner's agent.

While not addressing every concern of providers of home infusion/IV pain therapy and medications for patients in LTCFs, this much-needed modification does allow faster response to changing health care needs while continuing to maintain the necessary controls to prevent the diversion and abuse of controlled substances. (Refer to the May 19, 1994 *Federal Register,* Vol. 59, No. 96.)

Diversion and Abuse of Controlled Substance Prescription Drugs

The following information provides some background on current trends observed by federal and state drug enforcement personnel in the United States. Much of this information has been substantiated by DEA, state, and local investigations.

Dilaudid® (hydromorphone) continues to be a drug of choice, with street prices ranging from $25 to $80 per dosage unit. Oxycodone products (e.g. Percodan®, Percocet®) are also seen in illicit traffic. The benzodiazepines most often diverted in the United States include alprazolam (Xanax®), diazepam (Valium®), and clonazepam (Klonopin®). They are reportedly abused alone and in combination with cocaine, "crack" cocaine, codeine combination products, and methadone.

Hydrocodone, a semi-synthetic narcotic listed in Schedule II when used alone and in Schedule III for hydrocodone combination products, is reported as being one of the more popular (and in some areas, the most popular) drugs of abuse. Abused either by itself or in combination with other drugs, hydrocodone is marketed in the United States as the narcotic analgesic found in such products as Anexsia®, Lortab®, Lorcet®, and Vicodin® and as the cough suppressant in Hycodan® and Tussionex®.

Some of the drugs that are reported to be abused in combination with hydrocodone include alprazolam; the non-controlled muscle relaxant, carisoprodol (Soma®); and with phentermine in a practice called "speedballing."

Schedule III products containing combinations of codeine and either aspirin or acetaminophen are frequently abused in combination with benzodiazepines and with carisoprodol. Until glutethimide was moved from Schedule III to Schedule II in March of 1991, the combination of glutethimide and codeine-containing products, known as "sets" or "fours and dors," was a significant problem in the Northeast region of the country and in Southern California. Now, codeine combination products are being abused most frequently with benzodiazepines and with carisoprodol. In one area, meprobamate is also reportedly being abused in combination with codeine-containing products.

Other Schedule III-IV drugs that DEA recognizes as being abused include:

- anabolic steroids - all are Schedule III;
- pentazocine (e.g. Talwin®, Talacen®) - a Schedule IV analgesic used alone and in combination with pyribenzamine;
- phendimetrazine (e.g. Bontril®, Plegine®); and
- propoxyphene napsylate (e.g. Darvocet-N-100®).

The diversion and abuse of carisoprodol mentioned earlier is becoming increasingly widespread in several parts of the United States. It is used by drug abusers to enhance the effects of hydrocodone products and with codeine combination products and alcohol.

(Source: U.S. Drug Enforcement Administration)

Patient Counseling Update: Boards Ready to Take Disciplinary Action

While a majority of the nation's state boards of pharmacy have chosen to implement OBRA 90's patient counseling requirements in a manner that stresses education and deemphasizes disciplinary action, such an approach should not be interpreted to mean that the boards will not enforce the mandates. According to a survey conducted by Walter F. Fitzgerald, an associate professor at the University of Tennessee College of Pharmacy, "many boards are now actively 'shopping' for noncompliance."

The following table lists those states where disciplinary action has not occurred and offers insight into the status of such actions.

Some boards have initiated disciplinary procedures for failure to comply with the mandates. State boards not listed in this table reported actions ranging from informal (e.g., reprimands, warnings) to formal (e.g., license suspension, civil fine) during 1993. They also noted that a variety of complaints were being investigated and actions were pending.

States Reporting No OBRA '90 Disciplinary Actions

Alabama [1,2]	Louisiana [1]	New Mexico [1]
Alaska [1]	Maine [2]	New York [2]
Arkansas [1]	Maryland [9]	Ohio [1,4]
California [4]	Michigan [10]	Oklahoma [1]
Colorado [5]	Minnesota [1]	Pennsylvania [12]
Connecticut [1,2]	Mississippi [1]	Rhode Island [1]
Delaware [6]	Missouri [1,2]	South Carolina [13]
Georgia [2]	Montana [1]	Utah [14]
Hawaii [7]	Nebraska [2]	Vermont [1]
Idaho [8]	Nevada [11]	Washington [2]
Illinois [1,2]	New Hampshire [1]	Wyoming [1,3,4]
Indiana [1,2,3]	New Jersey [1]	

1. Allowing a grace period for pharmacists to implement the necessary activities.
2. Violations found thus far have been very minor and formal disciplinary action was not necessary.
3. Pharmacists reviewed/inspected so far have been found to be in compliance.
4. Allowing transition period - enforcing through education.
5. Mandates have been implemented for Medicaid but are not yet in the pharmacy laws.
6. Implementation of mandates was not effective until November 1993.
7. To date, the board of pharmacy has not received a complaint regarding failure to comply with mandates (which are under the jurisdiction of the Department of Health).
8. Information that would require action has not been given to the board of pharmacy by the DUR board.
9. DUR program has generated statistics demonstrating that the vast majority of pharmacists are making and taking actions to improve care.
10. Mandates not regulated by the board of pharmacy.
11. Mandated counseling was implemented October 1, 1993. Review requirements have not been enforced until counseling established. By October 1, 1994, progressive discipline procedures should be evident.
12. State regulations still in review process.
13. No violations have been reported to the board by the HHS audit team. The board inspectors have not been actively auditing pharmacies for compliance because the board does not have regulations enacted at this time.
14. Board has not been informed of any violations (Medicaid has responsibility).

(Reprinted with the permission of *Drug Topics*, Medical Economics Publishing, Inc., April 11, 1994.)

Item 791 - Election Results

In April of this year, ballots were sent to all North Carolina licensed pharmacists residing in the state. Two positions were up for election, one from the southcentral part of the state and the other from the northeastern part. All five candidates had excellent credentials and would have served the public and pharmacy well.

The ballots were counted on the evening of May 9th in the Board's offices in Carrboro. The results follow. **District #3**: R. Brent Clevenger, 761; Ed Frenier, 706; Wm. Whitaker Moose, 1,321. **District #4:** Albert F. Lockamy, Jr., 1,423; Margaret (Peggy) Yarborough, 1,331.

The Board of Pharmacy Elections certified the results as final at its regular meeting on May 10, 1994. Mr. Moose and Mr. Lockamy will continue their membership on the Board of Pharmacy and begin to serve their five-year terms in the Spring of 1995.

Item 792 - Rules Benefit Pharmacists

Last September a rule went into effect regarding the emergency dispensing of prescription drugs. The rule applies both to hospital and community pharmacists and provides that an emergency supply of up to 72 hours of a prescription drug can be dispensed under some circumstances.

If a pharmacist receives a request for a refill of a prescription and no further dispensings are authorized, it is possible to provide up to a 72-hour supply if the prescription is for a maintenance medication and discontinuance of therapy would have undesirable health consequences. All that is necessary is that the prescriber or prescriber's office be notified of the dispensing within 72 hours of its occurrence *(see Item 763)*.

The Board has also adopted a rule regarding disposal of drugs *(see Item 763)*. The Commission on Mental Health, Developmental Disabilities and Substance Abuse, which makes rules regarding controlled substances, has now adopted a rule effective July 1, 1994, which allows community pharmacists to use the procedure in .3001 for the destruction of controlled substances.

While it's true that most rules adopted by the Board impose new requirements and/or additional work on pharmacists, the two new rules in this item should be welcomed by pharmacy practitioners.

Item 793 - Rule on Mail Order Pharmacy

The Board adopted new rules applicable to out-of-state pharmacies shipping drugs into North Carolina. It applies both to mail order pharmacies and those that use common carriers. It also applies to suppliers of home I.V. therapy. The rule requires representatives of such pharmacies to make a personal appearance at the Board office to obtain a pharmacy permit in the same way that other permits are issued by the Board. Permit fees are identical ($250 for original; $125 for renewal) and other rules apply to their conduct, including provisions to discipline for negligence. There is a specific statement in the Board's patient counseling rule stating that it does apply to mail order pharmacies.

Item 794 - Insulin Backorders

Board staff has received information that wholesalers are reporting some outages of certain types of insulin. Under these circumstances, it certainly would not be in the patient's best interest to expect them to stop using insulin until their normal product has arrived in the pharmacy. Indeed, it could present serious health consequences if such a procedure were followed.

Pharmacists should act in the patient's best interest in this situation and, in conjunction with other members of the health care team as appropriate, arrive at the closest product that satisfies the customer or patient's needs. In this way you will best meet the patient's health care needs.

Item 795 - Request for Records

Pharmacists regularly receive requests for prescription records from individuals, either for themselves or their families. It is perfectly appropriate to release such information, but only to specific individuals as noted in G.S. 90-85.36. Such information is otherwise privileged and should not be disclosed to the public. The following information is offered for your guidance. It is not necessarily a matter of law, but a practice suggestion.

From time to time, a pharmacist may receive a request for prescription information from individuals for their family and not be aware that a divorce or other domestic relations problem exists. If individuals request a list of prescription records for anyone other than themselves, the following three alternatives are offered: 1) Offer to give the total dollar figure for expenses during a certain time period; 2) Obtain telephone authorization from the other adult individual(s) involved, such as the spouse, and record that fact; or 3) Generate the records requested for the individuals and mail them separately to the individual's home address.

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