



North Carolina Board of Pharmacy

P.O. Box 471, Chapel Hill, NC 27514

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 328—REVISION IN FEE STRUCTURE

In recent years inflation has affected the Board of Pharmacy with at least the same impact that it has had on everyone. Because of the nature of the Board's activity involving travel for inspectors and Board meetings, along with printing and mailing, this office has probably experienced inflation to a greater degree than many other areas. The price of gasoline has doubled in the last two years and higher postal rates are scheduled in the near future. The use of the National Examination, along with our own practical, has raised the cost per candidate and a change in this fee has been justifiable since 1977 when the test was first administered.

In reviewing the budget for 1980-81, the Board adopted a proposal for a new fee structure with the following figures: Pharmacist license renewal—\$40; Pharmacy permit renewals—\$100; Examination \$75; Reciprocity \$200; and Original permits—\$200. The usual procedure in state government is to specify these amounts as maximums and the fees could be lower if expenses can be met and a reserve for unexpected lawsuits maintained.

The last two increases, in similar or identical ratios to the current proposal, occurred in 1973 and 1965. Our costs have increased greatly since 1973. For example, the state rate for mileage reimbursement was 10 cents per mile in 1973 and currently is 19 cents per mile, with a planned increase in the near future. No one enjoys these higher costs, but we trust the pharmacists of North Carolina will understand the need at this time. If you want further information about this proposal, it can be obtained from the Board office.

ITEM 329—NEW PROCEDURE FOR ISSUING PHARMACY PERMITS

By North Carolina General Statute G.S. 90-75, all places where drugs are dispensed must obtain a permit from the Board of Pharmacy. Applications for permits may be obtained from the Board of Pharmacy, P.O. Box 471, Chapel Hill, North Carolina, 27514. Permits are issued to the pharmacist manager whom the Board holds responsible for the operation of the pharmacy in conformance with all laws and regulations after the permit is issued. Issuance of permits or Limited Service Permits occurs in the following manner:

1. Obtain an application for a permit from the Board office.
2. Sub-

mit the completed application to the Board office. The application should be as complete as possible including the anticipated opening date, correct address, hours of pharmacist coverage, hours of operation, equipment to be maintained, specification of ownership and a proposed pharmacist manager. Individuals who sign as pharmacist managers are indicating their intent to remain in the position for the foreseeable future as expressed in Certificate B of the application and the Board will rely on this representation in processing the applications. (See specifically G.S. 90-65 (a)(1) and (b)).

3. Receipt of the application will be acknowledged by the Secretary and an inspector will be designated to perform a pre-opening inspection. It is necessary that such inspections fit, as much as possible, the inspector's travel plans and it is the duty of the applicant to contact the inspector to arrange for this inspection not less than three nor more than four calendar weeks before the actual opening date. This should provide ample time to obtain a DEA registration before opening occurs. In the ordinary course of events, excluding holidays, Board examinations or vacation periods, an inspectors must be contacted during one week for a pre-opening inspection the following week. The fee must be submitted before the pre-opening inspection occurs.
4. The inspection shall include, but not be limited to, the items specified in Board regulation 46.501, proper pharmacist coverage and security. If all items are found in compliance by the inspector, a permit number will be issued in due course. Generally, evidence of items ordered will be acceptable by inspectors for a pre-opening inspection with the exception of a reference library which must be present. In the event that the applicant desires to hasten the process, the permit number may be obtained by telephoning the Board office at the applicant's expense. A change in pharmacist managers between submission and the pre-opening inspection can produce an indefinite delay in issuance of a permit number.

Receipt and issuance of pharmacy permits will be presented to the members of the Board at each regular meeting. Under the provisions of the Administrative Procedures Act and Board regulations, any Board member may call for a hearing on the issuance of any individual permit.

North Carolina Pharmacy Board Phone:
919/942-4454



National Pharmacy

LETTER ON RECALLS FROM FDA COMMISSIONER GOYAN

Dr. Jere E. Goyan, the first pharmacist ever appointed to the position of Commissioner of the Food and Drug Administration, is calling on pharmacists to assist the agency in recalls of drug products. Recalls are designated by the agency in one of three classifications to indicate the relative degree of health hazard presented by the product being recalled.

A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences, is remote. A Class III recall is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Dr. Goyan's letter to all pharmacists concerning their responsibility in acting on recalls is published by the Bureau of Voluntary Compliance in furtherance of the goal of these newsletters "to promote voluntary compliance of pharmacy and drug law."

"Dear Fellow Pharmacist:

As FDA's first pharmacist commissioner, I'd like to ask you to give special attention to recalls by manufacturers or by FDA of dangerous and defective products.

You may hear about a recall through a letter or notice, or from your wholesaler—or you may hear first through the news media. (The more urgent the recall, the more likely the manufacturer or FDA will use a press announcement to reach professionals, as well as the general public, via the quickest method possible—the 6 o'clock news broadcast. These announcements are aimed at *you*.)

However you hear about a recall, please act on it. Your prompt action may mean the difference between life and death, health and injury, or professional trust and doubt.

Professional cooperation, I've often said, can accomplish more than all the regulations in the world—and can reduce the need for additional regulations. I'm for that, but I need your help: *Please be sure that recalled products are promptly removed from sale.*

P.S. May I suggest you look under "United States Government" in your telephone book for the nearest Food and Drug Administration office. Put the telephone number next to your pharmacy telephone, in case you have a question about a recall mentioned in the news.

DEA POLICY STATEMENT EXPLAINS USE OF CONTROLLED SUBSTANCES IN EMERGENCY KITS

General guidelines under which individual state licensing and regulatory boards may adopt specific rules for the use and handling of controlled substances in emergency kits in long term care facilities (LTCF) were published by DEA in the April 9, 1980 Federal Register. Since LTCF's are not controlled premises under federal law, the agency determined that an amendment to current federal DEA regulations was not necessary or desirable. After the comment period, final adoption of the following Statement of Policy is anticipated.

STATEMENT OF POLICY

The placement of emergency kits containing controlled substances in non-federally registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:

A. The source from which a LTCF may obtain controlled substances for emergency kits. The source of supply must be a DEA registered hospital/clinic, pharmacy or practitioner.

B. Security safeguards for each emergency kit stored in the LTCF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. Responsibility for proper control and accountability of such emergency kits within the LTCF to include the requirement that the LTCF and the providing DEA registered hospital/clinic, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.

D. The emergency medical conditions under which the controlled substance may be administered to patients in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21.

E. Prohibited activities which can result in the state revocation, denial, or suspension of the privilege of having or placing emergency kits, containing controlled substances, in a LTCF.

CENTRAL RECORDKEEPING REQUIREMENTS FOR DEA REGISTRANTS—CHANGES PROPOSED

Pharmacies and other registrants under the federal Controlled Substances Act would be allowed to keep records at a central location without a permit under changes proposed by the Drug Enforcement Administration. The system as it presently exists requires a registrant to make application to DEA for a permit to keep central records. The proposed changes would allow a registrant wishing to keep records at a central location to do so without the need of a permit. The registrant would instead notify, in writing, the regional

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director of the DEA region in which it is located of its intention to keep records at a central location, the nature of the records to be kept centrally, and the exact location where the records will be kept. All other requirements currently contained in the affected section [21 CFR 1304.04(a)] will remain the same.

Under the proposal, written notification, in triplicate, must be submitted by registered or certified mail, return receipt requested. Unless informed that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after the date on the return mail receipt. The proposed amendments to 21 CFR Part 1304 follow:

1. Section 1304.04 Maintenance of records and inventories.

a) Every inventory and other records required to be kept under this Part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to paragraph 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Regional Director of the Administration in the region in which the registrant is located.

Unless the registrant is informed by the Regional Director that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Regional Director. All notifications must include:

- 1) The nature of the records to be kept centrally.
 - 2) The exact location where the records will be kept.
 - 3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.
 - 4) Whether central records will be maintained in a manual, or computer readable form.
- b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:
- 1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.
 - 2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.
 - 3) The registrant agrees to deliver all or any part of such records to the registered location within 48 hours of receipt of a written request from the Administration for such records, and if the Ad-

ministration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

4) In the event that a registrant fails to comply with these conditions, the Regional Director may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this sub-paragraph the registrant shall, within the time specified by the Regional Director, comply with the requirements of this section that all records be kept at the registered location.

c) Registrants need not notify the Regional Director or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005.

e) All central recordkeeping permits previously issued by the Administration will expire on September 30, 1980. Registrants who desire to continue maintaining central records will make notification to the local Regional Director as provided in (a) above.

2. Subsections 1304.04(b), (c) and (d) are redesignated as 1304.(f), (g) and (h) respectively.

3. Subsection 1306.22(d) is hereby deleted.

CPSC URGES CRC COUNSELING

The Consumer Product Safety Commission has announced a new program aimed at achieving a reduction in childhood ingestions of prescription drugs. The thrust of the program is compliance with the Poison Prevention Packaging Act. CPSC is encouraging pharmacists to educate their patients how to use the child-resistant closure (CRC). If the customer is unable to use the closure, the pharmacist can advise the patient that conventional packaging is available. CPSC believes this would promote greater consumer acceptance and use of CRC's and eliminate the complaints of the arthritic who, upon encountering difficulty in using a CRC, transfers to another container.

While CPSC is urging the pharmacist to exercise greater discretion, they are planning for increasingly severe action against any pharmacist who persists in ignoring the law. CPSC announced that they will refer evidence of pharmacy non-compliance to the State Boards of Pharmacy. CPSC also is discussing with the Department of Justice and the State Attorneys General ways in which to expedite legal action.

ITEM 330—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

February: A pharmacist appeared to respond to charges that excessive dispensing of Schedule V substances had occurred by him. The person who purchased substantial quantities of Novahistine DH testified against the pharmacist and indicated that he had frequently consumed four ounces at one time and up to sixteen ounces per day. The pharmacist claimed he did not know there was a limitation on dispensing a large amount of this drug. The testimony indicated a shortage of 44.8 gallons of Novahistine DH over the audit period. The Board issued a 90-day active suspension of the pharmacist's license and a 5-year probationary period.

A pharmacist appeared to answer charges that he had refilled prescriptions in excess of that authorized by the physician. Testimony was offered indicating that excessive dispensing apparently occurred on 47 different occasions involving 33 prescriptions. The pharmacist stated that such refilling was not wilfull and that he was currently adhering to the letter of the law. The Board placed the pharmacist on six months probation.

March: A pharmacist responded to a notice of a hearing for a plea of guilty to unlawful possession of Placidyl, a misdemeanor. An affidavit which accompanied the plea was also introduced into evidence and stated, among other things, that the pharmacist had assisted another individual in teaching him how to mix powders which later turned out to be MDA. The pharmacist offered as a defense that he thought he was assisting in a police investigation and that there was no evidence whatsoever of transfers for profit. It was also apparent that the pharmacy in which the event occurred was having economic problems because it later closed. The Board issued an act of suspension of the pharmacist's license for thirty days and a three-year probationary period.

The pharmacy manager at the pharmacy specified in the disciplinary action for February involving Novahistine DH appeared at a hearing because of testimony from the prior meeting. Much of the same testimony was offered in evidence again and the pharmacist manager indicated that he was unaware that the dispensing was oc-

curing to the extent it was. The Board issued a 15-day suspension of the permit for the pharmacy beginning no later than May 15, 1980, and a three-year probationary period for the pharmacist manager.

April: A pharmacist appeared after pleading guilty to Medical fraud which resulted in a suspended sentence and a total fine of \$12,000 plus court costs. The pharmacist responded that there were only two situations where he did not have documentary evidence contrary to that offered by the Attorney General but the excessive cost involved in trying each charge separately and travelling a long distance to Raleigh would have involved excessive costs. Contrary testimony was offered by the Attorney General's office. A total of 24 indictments were involved. The Board issued an active suspension of the pharmacist's license for 60 days and a five-year probationary period. Further actions will appear in the October issue.

ITEM 331—BOARD EXAM DATES

The Board has set the following dates for examinations:

September 22, 23, and 24, 1980

January 26, 27, and 28, 1981

June 22, 23, and 24, 1981

No other dates have been set by the Board at this 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 off views, opinions or policies of the Foundation or the board unless expressly so stated.

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