JANUARY, 1981

North Carolina Board of Pharmacy

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

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 339—ARMED ROBBERY OR BURGLARY IN PHARMACIES

The Board has received a number of requests about what procedures to follow with an armed robbery or burglary. We have requested suggestions for such situations from the State Bureau of Investigation and their response in categories before, during, and after the event appears below.

Before—Keep all windows and rear doors locked; provide ample lighting both inside and outside; keep safe locked at all times; keep windows clear of advertising; keep aisles clear; keep display counters low enough to see over them; instruct employees to report (by prearranged signals) suspicious persons; do not return to business after hours in response to a supposedly police call until you verify the call with the police; place height strips on door frame to measure a person leaving the store; conduct training sessions with employees—any plan is better than no plan.

During—Do not resist, be calm and alert; give the robber what he requests but don't volunteer anything; activate alarm only if it does not endanger lives; note anything touched by the robber—it may be evidence; if a written note is given, place it out of sight, he may forget it; carefully observe the robber from head to foot for a complete description including clothing; note exact time and method of escape including car description and license number.

After—Call police first and do not hang up until after they have all needed information; do not call employer first; lock doors and detain witnesses; don't touch anything which may be evidence; have witnesses record individual descriptions of the robber but do not compare notes.

The Drug Enforcement Administration has a publication, *Pharmacy Theft Prevention*, which is available from that agency which contains other suggestions to prevent theft.

ITEM 340—DISCIPLINARY ACTIONS THE BOARD OF PHARMACY

September: A pharmacist appeared to answer charges that he dispensed Dilaudid® on forged prescriptions on 20 different occasions. The pharmacist explained that the patron was a regular customer over a long period of time and had claimed serious injury in a motorcycle accident which required bandages on his face. The Board reprimanded the pharmacist as part of his permanent record with the Board.

Two pharmacists appeared in response to charges that they had dispensed Eskatrol® on 50 occasions in response to forged prescriptions. The recipient of the drug, described as a thin and gaunt individual, was the son of the physician who purportedly wrote the prescriptions. There was conflicting evidence as to the "validity" of the prescriptions. The Board censored and reprimanded one pharmacist and dismissed charges against the other pharmacist.

October: No disciplinary actions.

November: A pharmacist who was employed in a hospital appeared before the Board after pleading no contest in court to the charge of fraudulent diversion of cocaine from the institution. She received a suspended sentence from the court and the Board issued a 120 day active suspension of her license to practice pharmacy.

A pharmacist manager appeared before the Board to answer charges of allowing or permitting an unlicensed person to dispense prescription drugs including, in one case, a controlled substance. No evidence of supervision was present and everyone involved admitted what had occurred. The Board issued an active suspension of the permit for 15 days to begin not later than January 1, 1981.

A person who held a temporary license in pursuit of reciprocity received notice of a hearing to be held at this meeting but declined to appear. The charges involved the personal use of Demerol injectable without a physician's prescription. This is the same person described in the first paragraph of disciplinary actions for July. The Board revoked his temporary license to practice pharmacy.

ITEM 341—PHARMACY CALENDAR

Enclosed with this issue of the Board Newsletter is a calendar of events of interest to North Carolina pharmacists. While it is not possible to note every occasion on such a calendar we hope to have included all significant meetings and events during the year. This is the first attempt to obtain a statewide pharmacy events calendar, which also includes the larger national meetings, and is a joint pro-

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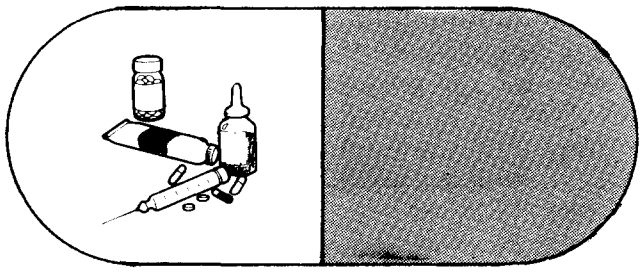
PARTIAL DISPENSING OF CS-II PRESCRIPTIONS ALLOWED FOR LTCF PATIENTS

Partial dispensing of prescriptions for Schedule II controlled substances for patients in long term care facilities (LTCF) is now permissible under a recent amendment to DEA regulations. If such prescriptions are not completely dispensed within 60 days of issuance, a new prescription must then be issued. The amendment is intended to limit the accumulation of controlled substances at LTCF-s, and thereby reduce health care costs resulting from destruction of unadministered doses. The effective date for the new provision was September 15, 1980.

Partial dispensing of CS-II prescriptions for all patients other than those in LTCF-s is not changed by the amendment. That practice is permissible only if a pharmacist is unable to supply the full quantity called for in a CS-II prescription. The remaining portion may be dispensed within 72 hours of the first partial filling. However, if the remaining portion is not or cannot be dispensed within the 72 hour period, the pharmacist shall notify the prescribing practitioner.

The new requirements for partial dispensing of CS-II prescrip-



tions are found in 21 Code of Federal Regulations 1306.13(b) and (c) which reads as follows:

(b) Prescriptions for Schedule II controlled substances written for patients in Long Term Care Facilities (LTCF) may be filled in partial quantities, to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, identification of LTCF, identification of medication authorized (to include dosage form strength and quantity), listing of partial fillings that have been dispensed under each prescription and the information required in Section 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by Section 1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

FDA POLICY RE: EXPIRATION DATING OF UNIT DOSE REPACKAGED DRUGS

An increasing number of pharmacies, both community and institutional, are implementing unit dose packaging systems. Such packaging and systems are useful and convenient in assuring proper administration of medication to patients within hospitals and nursing homes. In instances where drugs are packaged in unit dose containers by pharmacies or shared service repackagers, questions have arisen as to whether the unit dose repackaged drugs need expiration dates based on stability data on the drugs in such containers.

FDA's current good manufacturing practice (CGMP) regulations require drug products to bear expiration dates derived from tests conducted on samples stored in the same immediate container in which the drug is marketed. FDA interprets compliance with the following conditions by unit dose repackagers to meet the stability requirements of the CGMP regulations.

Policy: No action will be initiated against any repackaging firm, including shared services, or drug product in a unit dose container meeting all other conditions of FDA's repackaging requirements solely on the basis of the failure of the repackaging firm to have stability studies supporting the expiration dates used, provided:

1. The unit dose container complies with the Class A or Class standard described in USP XX, General Tests, Single-Unit Containers and Unit-Dose Containers for Capsules and Tablets (page

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955);

2. The expiration date does not exceed six months; and

3. The six month expiration period does not exceed 25 percent of the remaining time between the date of repackaging and expiration date on the original manufacturer's bulk container of the drug repackaged, and the bulk container has not been previously opened.

This policy only applies to solid and liquid oral dosage forms in unit dose containers. FDA will continue to impose all requirements on other dosage forms and other types of packages.

Exceptions: This policy does not apply to antibiotics or to drugs with well-known stability problems, such as nitroglycerin, oral digoxin, or chlorambucil tablets. (Abstracted from FDA CPG 71326.17)

PHARMACIES REQUIRED TO TAKE CONTROLLED SUBSTANCES BIENNIAL INVENTORY

The tenth anniversary of the effective date of the federal Controlled Substances Act will be on May 1, 1981. CSA regulations require all registrants to take a complete inventory of controlled substances on hand every 2 years following the date on which the initial inventory was taken. The initial inventory date was May 1, 1971.

In lieu of a May 1 biennial inventory date, 21 CFR 1304.13 allows a pharmacy or other registrant to take the inventory on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply, or on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If a pharmacy elects either of the latter options, it shall notify DEA of this election and of the date on which the biennial inventory will be taken.

Inventories of Schedule II substances shall be made by an exact tablet or capsule count or measure of liquid contents. If a substance is listed in Schedule III, IV, or V, the registrant shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents is required. The inventory must also be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

FDA ANNOUNCES PPI REQUIREMENT FOR THREE RX DRUGS BEGINNING MAY 1981

Patient package inserts (PPI) for three prescription drugs must be provided to consumers starting in May 1981, FDA has announced. The three drugs are cimetidine, clofibrate and propoxyphene.

FDA has published guidelines for the texts of the first three PPI-s and established a requirement that they be available in pharmacies. Companies that make the drugs may print a PPI just as it appears in the guidelines or may use any version that meets the guidelines.

The manufacturer must provide the PPI-s to the pharmacist, who must give one to the patient with each new prescription dispensed and when a prescription is refilled, if requested by the patient. PPI-s will be available on request in hospitals and nursing homes.

The PPI requirement for these three drugs is the first step in FDA's pilot program to test patient package inserts for ten prescription drugs over the next three years. All ten PPI-s will be evaluated over the three year study along with alternative means for providing patients information about prescription drugs. After the evaluation is completed, FDA will decide whether to proceed with PPI-s for other prescription drugs or adopt an alternative system.

The remaining seven drugs for which patient package insert guidelines are expected to be published this year are ampicillins; benzodiazepines; digoxin; methoxsalen; thiazides; phenytoin and Bendectin. FDA will require these inserts to be dispensed six months after the guidelines are issued.

DOSE OF ISOSORBIDE DINITRATE EXEMPT FROM C-R-Cs INCREASED TO 10mg.

An order issued by the Consumer Product Safety Commission granted an exemption from child resistant container (C-R-C) requirements for isosorbide dinitrate in sublingual and chewable dosage forms containing not more than 10 milligrams of isosorbide dinitrate. An exemption from child-protection packaging for sublingual and chewable dosage forms containing not more than 5 milligrams of isosorbide dinitrate was previously in effect. Based on the absence of past adverse experience resulting from ingestion of the drug, the CPSC believes that child-protection packaging for the larger dosage forms is unnecessary to protect children from serious injury or illness. In addition, the commission believes an exemption is justified because of the seriousness of the consequences should administration of the drug be delayed by accessibility problems due to special packaging.

Accordingly, the CPSC ordered that 16 CFR 1700.14(10)(ii) be amended by deleting 5mg. and inserting **10mg.** in the existing language of the exemptions from child-protection packaging.

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ject of the Association, School, and Board. We all would appreciate your comments.

ITEM 342—OTC TOPICAL HYDROCORTISONE

Recently the FDA has changed topical hydrocortisone in low concentrations from a prescription drug to OTC status. Some pharmacists have taken this opportunity to dispense hydrocortisone from bulk supplies under their own label. This practice is contrary to statute and regulation according to Food and Drug Laws. Hydrocortisone dispensed OTC without a prescription is not exempt from the misbranding portion of Food and Drug Law. Commercial products have been approved for OTC use but only with proper labeling. A pharmacist who desires to dispense hydrocortisone OTC with their label would need to have the label contents approved by FDA to be in compliance.

ITEM 343—COMPUTER DATA SYSTEMS, PHARMACY RECORDS AND REQUIREMENTS OF LAW

Many pharmacists have been approached about installing automatic data systems, or computers, for storing prescription records. This Item is in response to many requests received on this subject. Initial subjects deserving the attention of pharmacists are the preservation of original prescriptions, ready retrievability of prescription records and proper identification of the pharmacist dispensing the drug.

The most troublesome potential problem for pharmacists is that of "down time" or a non-functional period with the system. A secondary or backup manual system is necessary at these times and resolution of a manual with an automatic system into one data base for audit later can be a formidable task. Board Inspectors have found that "down time" is a significant problem and in at least one case lasted for six consecutive weeks. Pharmacists should seriously consider how they might resolve such a problem before making a commitment to an automatic data system.

North Carolina Statute GS 90-106(h) also requires that the pharmacist sign and date a prescription for controlled substances. This effectively precludes the elimination of hard copy. Also, such systems may have difficulty specifying on the label the name of the pharmacist who filled the prescription. The Board has consistently ruled that initials of the pharmacist are insufficient and the name of the pharmacist who fills the prescription must be on the label.

ITEM 344—PRESCRIPTION FORMAT

The Product Selection Law effective for the last year provides for a specific format to be used on prescription blanks. Notice was provided to pharmacists in the August 1979 Newsletter, Item 303. The significant part of this section is that the words "Product Selection Permitted" are specified as on the left and "Dispense as Written" on the right. Prescription formats should conform to this arrangement to be in compliance. It is suggested that pharmacists bring this item to the attention of physicians whose blanks may not agree with current statute.

ITEM 345—SWEET SPIRITS OF NITRE ORDERED OFF MARKET

This Fall the FDA ordered that Sweet Spirits of Nitre be removed from retailers shelves because of its potential for poisoning infants and its lack of proven effectiveness. The final rule of the FDA has resulted in any drug product containing Sweet Spirits of Nitre being misbranded. The ordinary process of recalling the drug has been followed, but this product has wide distribution in various outlets throughout the country for many years. Pharmacists should be alert for this product on their shelves and inform other non-pharmacy retailers who may stock the item of its new status.

ITEM 346—BOARD EXAM DATES

The Board has scheduled two occasions for administering the licensure exam in 1981 and they are January 26, 27 and 28th and June 22, 23 and 24th. Applications for the June examination must be in the Board office by Friday, May 22nd.

ITEM 347—MAILING CONTROLLED SUBSTANCES

The Postal Service has revised its regulations concerning the mailing of poisons, poisonous drugs and medicines and controlled substances. One change is that controlled substances can be sent by regular mail and do not need to be sent certified mail. For individual questions you should contact your local postma

ITEM 348—PUBLICATIONS AVAILABLE

The Board has several publications or other items available which are useful for pharmacists. Inquiries to our office are frequent and we have had several requests for a list with prices where applicable. Currently the items most often ordered are: Pharmacy Law Books, $3.50; Schedule V Record Books, $6.50; Newsletters, single issues free; Binder for Newsletters, $2.00; Annual Reports, $10.00; and Intern/Extern Booklet, $2.75.

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