16

Dispensing of Controlled Substances

The Federal Harrison Narcotic Act was originally passed in 1914 and was designed to protect the health of the American people and to serve as a source of tax revenue to the Government. Regulation No. 5 of the Harrison Narcotic Act and subsequent treasury department decisions concerned themselves with the practical application of this law.

In 1965, the Federal Food, Drug and Cosmetic Act was amended by the passage of the Drug Abuse Control Amendments of 1965. Thus, the combination of the Federal Harrison Narcotic Act and the Drug Abuse Control Amendments of 1965 formed the basis for the control of the majority of special drugs within the hospital environment. In 1970, the Congress enacted the Comprehensive Drug Abuse Prevention and Control Act, which in effect, combined the Federal Harrison Narcotic Act and Drug Abuse Control Amendments of 1965 and imposed stricter controls over a large number of stimulant and depresant drugs. Thus, the new law required the profession of pharmacy to devise new ways to control a large segment of the medications dispensed.

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

The above act, also known as Public Law 91-513, and as the Controlled Substances Act, has as its purpose to "amend the Public Health Service Act and other laws to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse."[1]

The Act is divided into four "titles" dealing with the following subjects:

Title I — Rehabilitation Programs Relating to Drug Abuse
Title II — Control and Enforcement
Title III — Importation and Exportation; Amendments and Repeal of Revenue Laws
Title IV — Report on Advisory Councils

Title I, Rehabilitation Programs Relating to Drug Abuse amends Part D of the Community Mental Health Centers Act to include under its provisions persons with drug abuse and drug dependence problems. In addition, it provides for increased budgetary allocations for drug abuse education programs; funding for special projects for narcotic addicts and drug dependent persons; broader treatment authority in public health service hospitals; and research under the Public Health Service Act in drug use, abuse and addiction.

Title II, dealing with control and enforcement is also known as the Controlled Substances Act. In passing this Act, the Congress made the following findings and declarations:

1. Drugs included under this title have a legitimate and useful medical purpose and are necessary to maintain the health and general welfare of the American people.
2. Illegal importation, manufacture, distribution, possession and improper use of controlled substances have a detrimental effect on the health and welfare of the American people.
3. The manufacture, local distribution, and possession of controlled substances have a direct effect upon interstate commerce.
4. Local distribution and possession of controlled substances contribute to the interstate traffic in such substances.
5. It is not a practical matter to attempt to differentiate between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.
6. Federal control of both types of traffic is essential.
7. The United States must establish effective control over domestic and international traffic in controlled substances to be in compliance with the Single Convention of Narcotic Drugs of 1961 to which it was a party.

In order to understand the contents of Title II completely, it is necessary first to be familiar with the definitions contained within the text:

Addict: any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power or self-control with reference to his addiction.

Administer: the direct application of a controlled substance to the body of a patient or research subject by a practitioner or his agent or by the patient or research subject at the direction and in the presence of the practitioner.

Agent: an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser; exceptions being common contract carriers and warehouse men.

Control: the addition of a drug or other substance, or immediate precursor, to a schedule under Part B of this title, whether by transfer from another schedule or otherwise.

Controlled Substances: a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV or V of Part B of this title. The term does not

include distilled spirits, wine, malt beverages or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

Counterfeit Substance: a controlled substance whose container or label has, without authorization, the identification of a producer other than the actual producer.

Deliver or Delivery: the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

Depressant or Stimulant Substance:

(A) a drug which contain any quantity of (1) barbituric acid or any of the salts of barbituric acid; or (2) any derivative of barbituric acid which has been designated by the Secretary as habit-forming under section 502 (d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(d)]; or

(B) a drug which contains any quantity of (1) amphetamine or any of its optical isomers; (2) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (3) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit-forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

Dispense: to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the legal order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

Dispenser: a practitioner who so delivers a controlled substance to an ultimate user or research project.

Distribute: to deliver (other than by administering or dispensing) a controlled substance.

Distributor: a person who so delivers a controlled substance.

Drug: the same as that provided by section 201 (g) (1) of the Federal Food, Drug, and Cosmetic Act.

Immediate Precursor: a substance which

(A) the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substances; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substances.

Manufacture: the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable state or local law by a practitioner as an incident to his administration or dspensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

Manufacturer: a person who manufacturers a drug or other substance.

"Marihuana": all parts of the plant *Cannabis sativa L.*, whether growing or

not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

Narcotic Drug: means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(A) opium, coca leaves and opiates.

(B) a compound, manufacture, salt, derivative, or preparation of opium, coca leaves or opiates.

(C) a substance (any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any substance referred to in (A) or (B) above. Excluded are decocainized coca leaves or extracts of coca leaves which do not contain cocaine or ecgonine.

Opiate: any drug or other substance possessing an addiction-forming or addiction-sustaining liability similar to morphine or being converted into a drug having such capabilities.

Opium Poppy: the plant (excluding the seeds) of the species *Papaver somniferum L.*

Practitioner: a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Production: includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

Ultimate User: a person who has lawfully obtained and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

AUTHORITY TO CONTROL

Part B of Title II authorizes the Attorney General to apply the provisions of this title to the controlled substances listed within Section 202 of this title and (a) add to such a schedule or transfer between such schedules any drug or other substance if he finds that such material has a potential for abuse, and (b) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule. In making these decisions, the Attorney General is required to give consideration to the following factors:

1. The drug's or other substances' actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effect, if known.
3. The state of current scientific knowledge regarding the drug or other substance.
4. Its history and current pattern of abuse.

5. What, if any, risk there is to the public.
6. Its psychic or physiologic dependence liability.
7. Whether the substance is an immediate precursor of a substance already under this title.

The Attorney General may disregard the requirements of this title and control any drug or substance if control of such is required by United States obligations under international treaties, conventions or protocols. He may also, without regard to the findings required by this title, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. Excepted is the drug dextromethorphan although the exclusionary wording allows for its control at some future time if such becomes necessary.

SCHEDULES FOR CONTROLLED SUBSTANCES

The key section of Public Law 91-513 is Section 202(a) for within it is created the five schedules of controlled substances, known as Schedules I, II, III, IV and V. The listings within each schedule must be updated and republished one year after the date of enactment and annually thereafter.

Except where control is required by a United States obligation, a drug or other substance may not be placed in any schedule unless the findings required for each schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I
   (A) The drug or other substance has a high potential for abuse.
   (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
   (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II
   (A) The drug or other substance has a high potential for abuse.
   (B) The drug or other substance has recurrently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
   (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III
   (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
   (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
   (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV
  (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
  (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
  (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V
  (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
  (B) The drug or other substance has a currently accepted medical use in the United States.
  (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated.

REGISTRATION REQUIREMENTS

Part C of this title describes the registration of manufacturers, distributors and dispensers of controlled substances. Generally, it authorizes the Attorney General to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensation of controlled substances.

Every person falling into one or more of the above cited areas must obtain annually a registration issued by the Attorney General. Exempted from registering are the following:

1. An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting within the usual scope of the business or employment.
2. A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance is in the usual scope of his business or employment.
3. An ultimate user who possesses such substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

Since the new law went into effect, the Internal Revenue Service and the Food and Drug Administration are no longer issuing a registration authorizing a person or firm to handle controlled substances. Registration with the Bureau of Narcotics and Dangerous Drugs (BNDD), now DEA, became effective with the new law. (*See* footnote, p. 330)

The registration fees are as follows:

Manufacturer (includes repackers and relabelers)	$50
Distributor (wholesalers)	25
Importer or Import Broker/Forwarder	25
Exporter or Export Broker/Forwarder	25
Foreign Firm (manufacturing for importation into the U.S.A.)	25
Retail Pharmacy	5
Hospital and Clinic	5
Practitioner	5
Researcher	5
Analytical Laboratory	5
Teaching Institution	5

The Attorney General may, in accord with the rules and regulations promulgated by him, inspect the establishment of a registrant or applicant for registration.

Registration may be granted to the applicant if the Attorney General determines that such registration is in the public interest. The following are some of the factors that are considered in determining the public interest:

1. Maintenance of effective control against diversion of the controlled substances into other than legal channels;
2. Compliance with applicable state and municipal law;
3. Prior conviction record of the applicant;
4. Past experience in the distribution of controlled substances;
5. Such other factors as may be relevant to and consistent with the public health and safety.

REGISTRATION EXEMPTION FOR HOSPITAL HOUSE STAFF

When the Federal Controlled Substances Act became effective on May 1, 1971 every physician was required to register with the Bureau of Narcotics and Dangerous Drugs, now DEA, in order to prescribe, dispense and administer controlled substances. This policy applied to interns, residents, and foreign-trained physicians working in hospitals. The only exception allowed was where a person administered or dispensed controlled drugs as the employee of the registrant, such as a nurse or intern working with in-patients in a registered hospital.

The problem this policy caused soon became apparent in that interns, residents and foreign-trained physicians had to obtain BNDD, now DEA, registrations even though their occasion to use the registration was limited to the times they prescribed controlled substances in the emergency or ambulatory clinics. To alleviate this situation, an alternative procedure was developed which allowed the temporary or provisionally licensed doctor to prescribe controlled substances without an individual registration with DEA.

Under the new policy, the intern, resident or foreign-trained physician does not have to register individually but may use the hospital's registration number for writing prescriptions, provided that the hospital complies with the following:

First, the hospital has the responsibility for verifying that the intern, resident or foreign-trained physician may lawfully write prescription while working in the hospital.
Second, the hospital must assign a code system which designates individual physicians using the hospital's registration number. This code serves as the intern's, resident's or foreign-trained physician's individual number in lieu of the DEA[a] registration number.
Third, the hospital must assure that the individual physician uses the full number assigned to him and not merely the code number which the hospital added to its registration number to identify him. In addition, the physician should have his name stamped, or typed, or hand-printed on the hospital's prescription form.
Fourth, upon the request of an outside pharmacy, law enforcement agency, or other registered person seeking to verify the authority of the prescribing individual practitioner, the hospital will determine whether or not the prescription is written by one of its staff by checking the name and code number of the physician as requested against a current list of internal code numbers and the corresponding individual practitioners.

SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES

The following eight groups of activities are deemed to be independent of each other:

1. Manufacturing (including repackaging and relabeling) controlled substances.
2. Distributing controlled substances.
3. Dispensing (including prescribing and administering) narcotic and non-narcotic, and conducting research with non-narcotic, and conducting instructional activities with narcotic and non-narcotic controlled substances listed in schedules II through V.
4. Conducting research with narcotic controlled substances listed in schedules II through V.
5. Conducting research and instructional activities with controlled substances listed in schedule I.
6. Conducting chemical analysis with controlled substances in any schedule.
7. Importing controlled substances.
8. Exporting controlled substances listed in schedules I through IV.

[a]A new agency, the Drug Enforcement Administration, was created under Reorganization Plan No. 2 of 1973 which assumed the functions of various enforcement arms of the Department of Justice, including the Bureau of Narcotics and Dangerous Drugs (BNDD), and the investigative functions of the Bureau of Customs. Effective date was July 1, 1973.

Every person who engages in more than one group of independent activities must obtain a separate registration for each group of activities, with the following exceptions. Any person, when registered to engage in the group of activities described hereinafter shall be authorized to engage in the coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities: For example—

1. A person registered to manufacture or import any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class which he is not registered to manufacture or import.
2. A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture.
3. A person registered to conduct research with a basic class of controlled substances listed in schedule I shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the application for registration.
4. A person registered to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered to conduct chemical analysis or instructional activities and to persons exempted from registration pursuant to Section 301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances.
5. A person registered to conduct research with narcotic controlled substances listed in schedules II through V shall be authorized to conduct research with non-narcotic controlled substances listed in schedules II through V.

One or more controlled substances listed in schedules II through V may be included in a single registration to engage in any independent activity. Only one basic class of controlled substance listed in schedule I, and no controlled substances listed in other schedules, may be included in a single registration, except that a registration to conduct chemical analysis with basic classes of controlled substances listed in schedule I may include more than one basic class and also controlled substances listed in any other schedule.

SEPARATE REGISTRATIONS FOR SEPARATE LOCATIONS

A separate registration is required for each principal place of business or professional practice at one physical location where controlled sub-

stances are manufacturered, distributed, or dispensed by a person. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office and where no supplies of controlled substances are maintained shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed by a person.

EXEMPTION OF AGENTS AND EMPLOYEES

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment. An individual practitioner who is an agent or an employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employer or principal practitioner in lieu of being registered himself. For example, a pharmacist employed by a hospital need not be registered individually to fill a prescription for controlled substances if the hospital pharmacy is so registered.

TIME FOR APPLICATION FOR REGISTRATION

Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered may engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued to him.

EXPIRATION OF REGISTRATION

Any person who is registered may apply to be re-registered not more than 60 days before the expiration date of his registration.

At the time any person is first registered, he will be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all persons within any group will be the last day of the month designated for that group. In assigning any person to a group, the DEA may select a group the expiration date of which is less than 1 year from the date such person was registered. If the person is assigned to a group which has an expiration date less

than 3 months from the date on which the person is registered, the registration will not expire until 1 year from that expiration date; in all other cases, the registration will expire on the expiration date first following the date on which the person is registered.

APPLICATION FORMS

Individuals seeking registration under the Act are required to file special forms. A person applying for registration:

1. To manufacture or distribute controlled substances shall apply on DEA Form 225.
2. To dispense narcotic or non-narcotic, or to deduct research with non-narcotic, or to conduct instructional activities with narcotic or non-narcotic controlled substances listed in schedule II through V, shall apply on DEA Form 224.
3. To conduct research with narcotic controlled substances listed in schedules II through V, shall apply on DEA Form 225.
4. To conduct research with a controlled substance listed in schedule I, shall apply on DEA Form 225, with two copies of a research protocol describing the research project attached to the Form.
5. To conduct instructional activities with a controlled substance listed in schedule I, shall apply as a researcher on DEA Form 225 with two copies of a statement describing the nature, extent and duration of such instructional activities attached to the Form.
6. To conduct chemical analysis with controlled substances listed in any schedule, shall apply on DEA Form 225.
7. To import or export controlled substances listed in any schedule, shall apply on DEA Form 225.

Applications for registration must include all of the information called for in the form, unless the item is not applicable, in which case this fact must be indicated. In addition, each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. Another person may be authorized to sign for the applicant, if proof of authority (e.g. general power of attorney) accompanies the application.

MODIFICATION IN REGISTRATION

Any registrant may request a modification of his registration by submitting a letter of request to the Registration Branch, Drug Enforcement Agency, Central Station, Washington, D.C. 20005. Each letter of request for modification must be signed and dated by the same person who signed the most recent application for registration or reregistration.

INVENTORY REQUIREMENTS

Every registrant, other than an individual practitioner, must on the day he is first registered and every two years thereafterr, make a complete and accurate record of all stocks of controlled substances under his control. The record must indicate the date on which the inventory was taken and whether taken at the close or opening of business; be signed by the person responsible for the taking of the inventory; and be maintained at the location appearing on the registration for a period of two years.

The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Under the law, a registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in schedules II through V which he prescribes or administers in the lawful course of his professional practice. However, he must keep records with respect to such substances that he dispenses other than by prescribing or administering. A registered individual practitioner is not required to keep records with respect to non-narcotic controlled substances listed in schedules II through V which he dispenses in any manner unless he regularly charges his patients, either separately or together with charges for other professional services, for such substances so dispensed (e.g. when he substitutes his services for those of a pharmacist).

In addition to the above, Section 307 (a) through (3) requires that, after inventory, every registrant shall maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered or otherwise disposed of by him. A perpetual inventory is not required.

Furthermore, records to be kept must be in conformity with the regulations of the Attorney General; they must be maintained separately from all other records of the registrant; the records of the non-narcotic controlled substances must be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant; and all records pertaining to this law must be maintained for a period of two years.

PRESCRIPTIONS

In studying the contents of Section 309 which follows, the reader is urged to make constant reference to the Federal Food, Drug, and Cosmetic Act Section 503(b).

Section 309 provides the following requirements:

1. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without prescription of a practitioner.
2. Drugs may be dispensed on an oral prescription in an emergency situation.
3. Prescriptions shall be retained in conformity with the requirements of this law.
4. No prescription for a controlled substance in Schedule II may be refilled.
5. Controlled substances in Schedule III or IV may not be dispensed without a written or oral prescription in conformity with Section 503 (b) of the Federal Food, Drug, and Cosmetic Act.
6. Such prescriptions may not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times after the date of the prescription unless renewed by the practitioner.
7. No controlled substance in Schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

Prescriptions filled with controlled substances in Schedule II must be written in ink or indelible pencil and must be signed by the practitioner issuing them.

No prescription for a controlled substance in Schedule II may be refilled and such prescriptions, as well as prescriptions for narcotic substances in Schedules III, IV and V, must be kept in a separate file.

Prescriptions for controlled substances in Schedule II or IV may be issued either orally or in writing and may be refilled if so authorized. These prescriptions may not be filled or refilled more than 6 months after the date issued, or be refilled more than 5 times after the date issued. After 5 refills or after 6 months the practitioner may renew any such prescription. A renewal should be recorded on a new prescription blank and a new prescription number should be assigned to that prescription.

OFFENSES AND PENALTIES

Part D concerns itself with a listing of prohibited acts, most of which are familiar to the pharmacist. Examples include:

1. Dispensing controlled drugs without first becoming registered.
2. Removing, altering or obliterating a symbol or label required by this title.
3. Refusing or failing to make, keep or furnish any record, report, notification, declaration, order or order forms, statement, invoice or information required under this title.
4. Refusing an entry into any premises or inspection authorized by this title.

Finally, the section provides for various penalties to be assessed for the various violations and range from fines, imprisonment or both depending upon the seriousness of the violation.

LABELING AND PACKAGING REQUIREMENTS

Labeling and packaging requirements under this law are cited in Section 305 (a), (b), (c) and (d). Generally, they require that containers of controlled substances must meet the labeling requirements of the Federal Food, Drug, and Cosmetic Act or the regulations to be promulgated by the Attorney General.

Each controlled substance manufactured after December 1, 1971 must have on its label a symbol designating to which schedule it belongs. The symbol will be a letter C with the Roman numeral I, II, III, IV or V. This symbol will appear in the upper right hand portion of the label. Manufacturers and other registrants will be given adequate time, to be specified by regulations, in order to comply with the symbol requirements.

MODEL SET OF HOSPITAL CONTROLLED SUBSTANCES REGULATIONS

The Controlled Substance regulations here set forth comply with Title II of the 'Comprehensive Drug Abuse Prevention and Control Act of 1970' and subsequent amendments or proclamations concerned with the implementation of the Federal Law. The law is administered by the Drug Enforcement Agency. This regulation deals specifically with Schedule II substances which include drugs formerly known as Class A narcotics, amphetamines, methamphetamines, and any subsequent additions.

Definitions:

1. "Order": The direction for the drug, strength and frequency of administration as written on the Doctor's Order Sheet of the patient's Medical Record.
2. "Prescription": The direction for the drug, strength, quantity, and frequency of administration as written on a prescription blank by a doctor for dispensing by the Pharmacy.
3. "Administer": The word "administer" is employed when a nurse or other properly qualified individual gives medication to a patient, pursuant to the order of a qualified practitioner.
4. "Dispense": The word "dispense" is employed when a pharmacist gives medication to a nurse or other properly qualified individual in accord with the directions of a properly written prescription.
5. "Doctor": This term is herein employed to indicate an individual who has qualified for and has received a number from the Drug Enforcement Agency.

6. *Controlled Drugs Requisition* (Fig. 63) is used by the head nurse to order drugs from the Pharmacy.
7. *Daily Controlled Drugs Administration Form* (Fig. 64) serves three purposes: a 24-hour administration record for all Schedule II substances administered, allows space for inventory count for each nursing shift, and a section which serves as a record of losses and as a basis for review of errors.
8. *Monthly Controlled Drugs Inventory* (Fig. 65) serves as a monthly dispensing record for each nursing unit and receipt for Schedule II substances dispensed directly from Pharmacy.

Registration

A. *HOSPITAL*
The hospital is registered with the Drug Enforcement Agency.

B. *DOCTORS*
Doctors (Practitioners), in order to prescribe narcotics for or order administered (dispensed) to their patients in the hospital, must be licensed to practice under the laws of the state and must be duly registered with the DEA.

C. *INTERNS and RESIDENTS*
Interns and Residents who are attending patients in the hospital or hospital clinics must obtain a license to practice medicine in this State. According to the *Federal Register*, Vol. 36, No. 140, p. 13390, registration requirements were waived to allow interns and residents to dispense and prescribe controlled substances under the registration of the hospital by which they are employed, provided that:
   a. Such dispensing or prescribing is done in the usual course of professional practice.
   b. Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he is practicing.
   c. The hospital which employs him has determined that the individual practitioner is so permitted to dispense or prescribe drugs by the jurisdiction.
   d. Such individual practitioner is acting only within the scope of his duties within the hospital.
   e. The hospital authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident, or foreign physician so authorized. The code number shall consist of numbers or letters, or a combination thereof and shall be a suffix to the hospital's DEA registration number. Example: AM1901176-WH2.

A Hospital House Staff Identification card may be obtsined from the Medical Staff Registrar and the DEA number will be issued by the Pharmacy upon request.

Hospital Control Procedures

A. *RESPONSIBILITY for CONTROLLED SUBSTANCES in the HOSPITAL*
The administrative head of the hospital is responsible for the proper safeguarding and the handling of controlled substances within the hospital. Responsibility for the purchase, storage, accountability and proper dispensing of bulk controlled substances within the hospital is delegated to the Pharmacist-in-Chief. Likewise, the Head Nurse of a nursing unit

is responsible for the proper storage and use of the nursing unit's controlled substances.

B. PREPARATION of ORDERS

All controlled substances orders and records must be typed or written in ink or indelible pencil and signed in ink or indelible pencil.

C. ORDERING WARD STOCK CONTROLLED SUBSTANCES from the PHARMACY

1. A requisition for ward stock controlled substances is completed by placing a check mark opposite the name, strength, form of the controlled substance desired. The completed form is then sent to the pharmacy along with the empty containers and the nurse's inventory sheet. Figure 63 is an example of this type of form.
2. Before any new controlled substances are issued to a ward, the previous supply must be fully accounted for. Therefore, each request for a new supply must be accompanied by the Daily Controlled Drugs Administration Form shown in Figure 64. Whenever a new supply of drug is issued, it is accompanied by one of these forms. This form serves three purposes: a 24-hour administration record for all Sched-

Ward _____ Code _____ Date _____

Each floor is entitled to 2 containers of each of the following tablets and 2 units of the injectables. Empty bottles except tubex, along with narcotic or barbiturate accounting sheets must be returned to the pharmacy. All other narcotics and barbiturates must be ordered for and charged to the patient. These special narcotic and barbiturate orders must be accompanied by a prescription.

No. of Tabs-Caps mls.	(✓)	Check item needed	Price
25		Codeine Sulfate Tablets 15 mg	
25		Codeine Sulfate Tablets 30 mg	
10		Codeine Sulfate 30 mg Tubex	
10		Codeine Sulfate 60 mg Tubex	
10		Hydromorphone (Dilaudid) 2 mg Tubex	
10		Hydromorphone (Dilaudid) 4 mg Tubex	
10		Meperidine HCl 50 mg Tubex	
10		Meperidine HCl 75 mg Tubex	
10		Meperidine HCl 100 mg Tubex	
25		Meperidine HCl Tablets 50 mg	
10		Morphine Sulfate 8 mg Tubex	
10		Morphine Sulfate 10 mg Tubex	
10		Morphine Sulfate 15 mg Tubex	
10		Methadon HCl Ampul 10 mg /1 ml	
15		Methadon HCl Tablets 5 mg	
15		Percodan Tablets	
25		Chloral Hydrate Capsules 500 mg	
1		Pentobarbital Injection 50 mg /ml 20 ml	
25		Pentobarbital Capsules 50 mg	
25		Phenobarbital Tablets 15 mg	
25		Secobarbital Capsules 50 mg	

FORM 193 REV.

Fig. 63. Requisition form for ward stock controlled substances.

PETER BENT BRIGHAM HOSPITAL
DAILY CONTROLLED DRUGS ADMINISTRATION FORM

DATE _____ FLOOR _____

PATIENT'S NAME	Specific Description of Drug Ordered and Strength	Number of Tabs or ml	Strength Used	Ordered By—Doctor	Administered By—Nurse	Time Given

SIGNATURE OF NURSE _____

SUMMARY OF DAILY REPORT

	On Hand at Beginning of This Period	Received	Total	3 p.m. Count	11 p.m. Count	7 a.m. Count	Used
Codeine TBX 30 mg							
60 mg							
Codeine Tabs 15 mg							
30 mg							
Hydromorphone TBX (Dilaudid) 2 mg							
4 mg							
Meperidine TBX 50 mg							
75 mg							
100 mg							
Meperidine Tabs 50 mg							
Morphine TBX 8 mg							
10 mg							
15 mg							
Methadone Tabs 5 mg							
Methadone 10 mg/ml							
Percocet Tabs							
Dead. Tr. Opium							

3 p.m. Signature _____ /
11 p.m. Signature _____ /
7 a.m. Signature _____ /

Fig. 64. Daily Controlled Drugs Administration Form.

ule II substances administered, allows space for inventory count for each nursing shift, and a section which serves as a record of losses and as a basis for review of errors.

3. Whenever a dose of a drug is lost or wasted on the ward, the nurse in charge must prepare a report to cover the incident. This is accomplished by using a special report form shown in Figure 66. This report is prepared in duplicate and sent to the pharmacy along with the nurse's account sheet and a request for a new supply of drug. The original is filed in the pharmacy and the duplicate is forwarded to the Nursing Office.

D. DOCTOR'S ORDERS for ADMINISTRATION of CONTROLLED DRUGS

The doctor's orders for the administration of ward stock controlled drugs must be written on the doctor's order sheet of the patient's chart. However, if the desired controlled drug is not on ward stock a complete controlled drug prescription must be written on a hospital prescription blank. The signed prescription must be sent to the pharmacy. A notation must then be made on the patient's chart by the doctor or nurse indicating that the doctor's signature for the order is in the pharmacy.

A *controlled drug order* must be *written* by a *licensed physician or a registered intern or resident.*

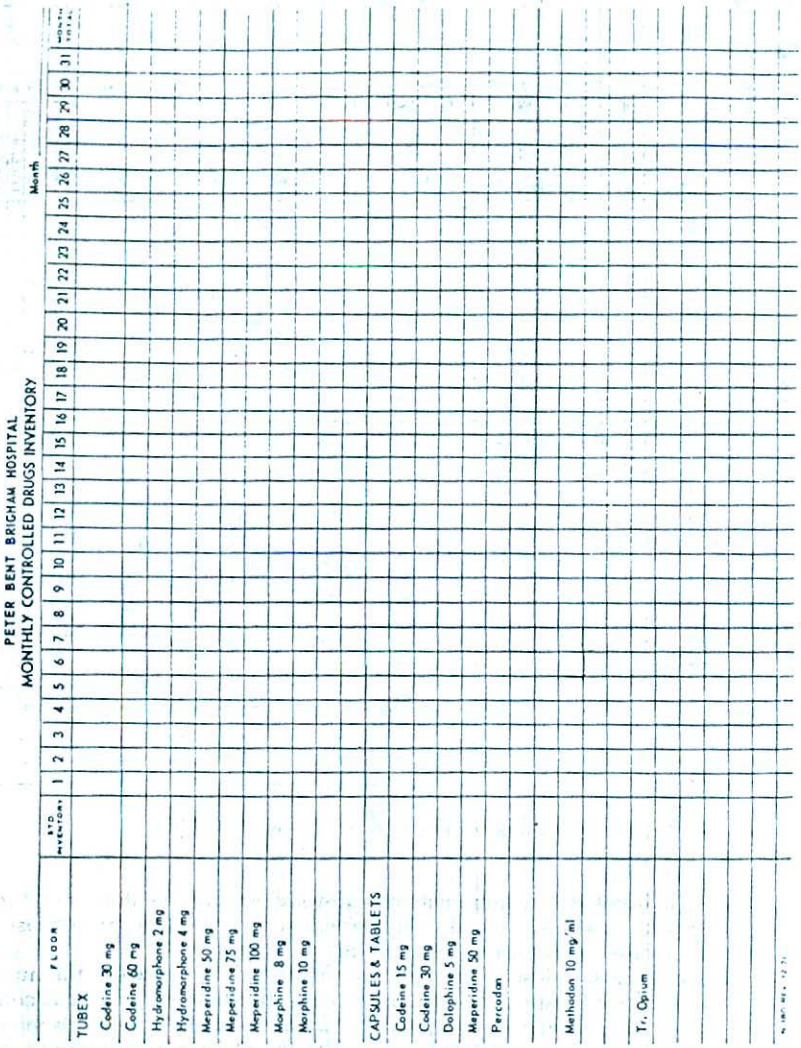


Fig. 65. Monthly Controlled Drugs Inventory Form.

E. *INFORMATION WHICH MUST APPEAR on the DAILY CONTROLLED DRUGS ADMINISTRATION SHEET*

The full information required on the Daily Controlled Drugs Administration Sheet (Fig. 64) is as follows:

1. Date
2. Amount given
3. Patient's full name
4. Patient's hospital number

REQUEST FOR REPLACEMENT
OF CONTROLLED SUBSTANCE LOSS OR WASTE ON WARDS

Date _____

Send Original and One Copy
TO PHARMACY

Name of Drug _____ Quantity _____ ml. Tab.

Bottle No. _____ Narcotic Sheet No. _____

Explicit statement of what happened:

_____
Signature of Nurse Making Report

Attested by Head Nurse or
Nursing Supervisor _____

Reviewed by Pharmacist _____

This report must be prepared in duplicate and sent to the Pharmacy. The signed report is brought to the Pharmacy along with a requisition for a new supply of the lost narcotic. The report will be signed by the Pharmacist on duty. The reports will be retained in the pharmacy.
Form 248

Fig. 66. Controlled Substance Loss or Waste Form.

5. Name of doctor ordering
6. Signature of nurse administering

The following information is requested for auditing purposes and is not required by Federal law:

1. Number of tablets or ml administered
3. Filing out inventory column (to be retained for Pharmacy).

F. *DOCTOR'S SIGNATURE*

The doctor's full name or initials are required on the doctor's order sheet. The doctor's full name is required on a controlled drug prescription. In each of the above, the signature must be by the doctor's own hand.

G. *PRO RE NATA (p.r.n.) or SI OPUS SIT (s.o.s.) ORDERS*

A p.r.n. or s.o.s. order for controlled drugs must be discouraged except under special circumstances.

H. *TELEPHONE ORDERS*

A doctor may order a controlled drug by telephone in case of necessity. The nurse will write the order on the doctor's order sheet, stating that it is a telephone order and will sign the doctor's name and her own initials. The controlled drug may then be administered at once. The order must then be *signed by the doctor* with either his signature or his initials within 24 hours.

I. VERBAL ORDERS

A verbal order may be given by a doctor in an *extreme emergency* where time does not permit writing the order. The nurse must write the order on the doctor's order sheet. The doctor must sign the order with either his signature or his initials within 24 hours.

J. *ORDERING NON-WARD STOCK CONTROLLED DRUGS from PHARMACY*

Drugs which are not stocked on the nursing stations may be ordered from the Pharmacy on written prescription only.

The amount of drugs sent to the nursing unit is the amount covered on the prescription by the doctor's signature. If more is needed a new signed prescription must be obtained. The prescription must have the following information:

1. Patient's full name
2. Patient's address or hospital number
3. Date
4. Name and strength of drug prescribed
5. Total amount of drug to be dispensed
6. Registration number of the licensed physician

The prescription must be written in ink or indelible pencil. It shall not bear erasures, or alterations of any kind.

A doctor may not write a prescription for controlled drugs for his own use.

K. *PRESCRIBING CONTROLLED DRUGS in the OUT-PATIENT DEPARTMENT*

Prescriptions for Schedule II and other controlled substances drugs may be dispensed from Pharmacy and must include the following information.

a. Patient's full name
b. Patient's address or hospital number
c. Date
d. Name and strength of drug prescribed.
e. Quantity of drug to be dispensed
f. DEA number and signature of physician
g. Frequency and route of administration

The prescription must be written in ink or indelible pencil and shall not bear cross outs or erasures. Discharge prescriptions for Schedule II drugs must be picked up by a registered nurse.

L. *DISPENSING CONTROLLED DRUGS for HOME USE when PHARMACY IS CLOSED*

Occasionally patients who require drugs for use at home are discharged from the hospital or released from the Emergency Ward during hours when the Pharmacy is closed. Whenever possible, a prescription signed by a member of the staff who has a License to practice medicine and a DEA number should be obtained.

A staff physician whose DEA number is issued to an outside office should use his own prescription blank. If this is not available, then he must insert his office address on the hospital prescription blank. This will permit the patient or his relative to purchase the drugs at an outside pharmacy. If no physician is available, or during hours when the local pharmacies are closed, the following procedure is allowed, but only as an EMERGENCY MEASURE:

The attending doctor will calculate the smallest amount of the drug necessary to treat the patient until the Pharmacy opens. He will write a prescription for this amount and the nurse may dispense the medication from her stock supply. The prescription will be presented to the pharmacy the following morning for replacement of stock.

M. *PROCEDURE in CASE of WASTE, DESTRUCTION, CONTAMINATION ETC.*

1. *Aliquot Part of Narcotic Solutions Used for Dose:*
   The nurse shall use the proper number of tablets or ampuls from nursing stock. She shall record the number of tablets or ampuls used and the dose given in the proper columns on Daily Controlled Drugs Administration Form (Fig. 64). She shall, in arriving at the proper aliquot part, expel into the sink that portion of the solution that is not used.
2. *Prepared Dose Refused by Patient or Cancelled by Doctor:*
   When a dose has been prepared for a patient but not used, due to a refusal by the patient or because of cancellation by the doctor, the nurse shall expel the solution into the sink and record why the drug was not administered. Examples: "Discarded," "Refused by patient" or "order cancelled by Dr. _____." The head nurse of the unit shall countersign the statement.
3. *Accidental Destruction and Contamination of Drugs:*
   When a solution, ampul, tablet etc., is accidentally destroyed or contaminated on a Nursing Unit, the person responsible shall indicate the loss on Figure 66.

MISCELLANEOUS REGULATIONS

1. Ward supplies of narcotics are to be used only for patients on the ward. They may not be given to patients to take home (except as an emergency measure as noted above) and are not for the treatment of employees.
2. Narcotic prescriptions may not be refilled.
3. A nurse, though the agent of a hospital or doctor, as such, may be partially or wholly responsible for the violation of any of the

regulations described above or any others under the Federal Narcotic Act as amended, but not included here.

4. Federal regulations do not allow a shortage from a vial of injectable narcotic.
5. A physician may not prescribe narcotics for his own personal use.

CONTROL OF NARCOTICS BY NURSES

Once the narcotics for the pavilion have been dispensed from the pharmacy, the nursing service assumes the responsibility for the administration, control and auditing of the inventory.

The auditing of the narcotic inventory takes place with each change of nursing shift. At this time, both the nurse coming on duty and the nurse going off duty take a physical count of the narcotics then on the nursing station. If the tally is correct both sign the audit record (Fig. 67). If the tally is incorrect, then a check of the medications ordered for the day by the physicians is in order so that the omission of recording is immediately corrected. On the other hand, if the error cannot be explained, then a narcotic loss report must be executed and forwarded to the department of pharmacy.

NARCOTICS DELIVERY TO NURSING STATION

The delivery of narcotics from the pharmacy to the nursing station may be assigned to any reliable person in the hospital's employ. It is usually entrusted to a member of the messenger staff since it is presumed that sufficient control records are maintained so that any narcotics that are delivered for illegal use would be immediately detected and appropriate measures taken for their recovery.

EIGHT HOUR NURSE AUDIT RECORD

DATE	7 A. M.		3 P. M.		11 P. M.	
	SIGNATURE ON-COMING NURSE	INITIALS OFF-GOING NURSE	SIGNATURE ON-COMING NURSE	INITIALS OFF-GOING NURSE	SIGNATURE ON-COMING NURSE	INITIALS OFF-GOING NURSE

RETURNED TO THE PHARMACY BY _____

DATE _____

Fig. 67

Charges to Patients for Narcotics

Charging for narcotics depends upon the policy of the individual hospital. Many hospitals make a charge for each dose received while others make a flat charge to cover all narcotics and hypnotics. In general, hospitals include narcotics along with other floor stock drugs for which no specific charge is made to the patient. Where there is a split policy in operation, the general plan is not to charge the patient for routinely used narcotics but to make a charge for those that must be obtained on special order.

Narcotics which commonly fall into the routinely used category are Codeine Phosphate Injection, Codeine Sulfate Tablets and Morphine Sulphate Injection.

One factor affecting the decision as to which narcotic drug should be included in the per diem charge is its cost. Accordingly, large teaching hospitals with a sterile products manufacturing section produce, at reasonably low cost, a large variety of injectable narcotic preparations and therefore make these available to the patient at no charge.

Smaller hospitals, which purchase their narcotics in ampul form, find it necessary to charge for each dose administered.

PROTOCOL FOR REPORTING DRUG ABUSE OR DIVERSION

Because of the possibility of drug abuse or diversion of controlled substances in the hospital, the Director of Pharmacy Services in collaboration with the Director of Personnel and the Director of Security should develop a protocol for use when drug abuse or diversion is detected. By so doing, confusion is avoided when an incident occurs. The following is a sample protocol that could be modified to meet the needs of a specific institution.

I. *Drugs included in this Protocol*
   All drugs in Schedules 2, 3, 4, and 5 of the Controlled Substances Act of 1970. These drugs are listed in the Current Practice Manual, 1-16-1.

II. *Persons affected by this Protocol*
   Employees, patients, and visitors, of The Peter Bent Brigham Hospital.

III. *Explanation of Outside Agencies*
   A. D.E.A.—Federal Drug Enforcement Administration.
   B. D.I.U.—Diversion Investigation Unit of the State Police
   C. Board of Pharmacy—Massachusetts State Board of Pharmacy
   D. Local Police—Self explanatory

IV. *Events covered by this Protocol which should be reported to Outside Agencies*
   A. Diversion—Any unexplained loss or theft of controlled substances.
   B. Abuse—Any problems such as unusual behavior which are suspected to be caused by the use of controlled substances.

V. *Procedure for reporting suspected diversion or abuse within the hospital*
   A. An employee who has knowledge of drug diversion or abuse by a fellow employee, patient, or visitor has an obligation to report such information.
   B. Any incident involving drug diversion or abuse shall be reported by the person involved or the person observing the incident.

C. Reporting should be done in the following manner:

DIVERSION

Report in writing on Controlled Substances Incident Report Form to the Pharmacy:

1. Known loss or theft.
2. Discrepancy found in inventory or audit.
3. Observation of container seals and caps which have been tampered.
4. Any other incident in which diversion is suspected.

ABUSE

1. The first occurrence of an unusual behavior by an employee should be observed and reported to the supervisor for evaluation.
2. If in the judgment of the supervisor the employee is incapable of performing normal work functions, it should be suggested that the employee go to the Employee Health Clinic.
3. If the employee refuses, the employee should be sent off duty by the supervisor, and the event should be reported to the Personnel Department.
4. If the employee is seen in the Employee Health Clinic and it is determined that the problem is due to the employee's use of controlled substances without prescription of a physician or in a manner differing from that indicated by the prescription, this should be reported in writing by the Employee Health Clinic to both the Pharmacy and the Personnel Department. If the employee refuses to provide a blood sample, the employee should be sent off duty by the supervisor and the event should be reported to the Personnel Department.
5. If abuse is suspected of a patient or visitor, this should be reported to the Hospital Security Department who will send a copy of the report to the Pharmacy.

VI. *Investigation of incidents within the hospital*

A. The number of hospital personnel involved in investigating a possible abuse or diversion should be limited.

B. Reports received by the Pharmacy will be investigated to determine if diversion is involved. This investigation will include:
   1. Verification of records which should reflect the drug, dose, by whom prescribed, by whom administered, time of administration, and to whom administered.
   2. A check of the 8-hour Nursing Service Audits.
   3. If necessary an assessment will be made with nursing and medical assistance of the patient response to the medication.

C. Investigation of potential employee abuse will be conducted by the department involved with the consultation of the Employee Health Clinic and the Personnel Department. The Hospital Security Department will assist in any investigation as requested.

D. Investigation of potential abuse by patients and visitors will be conducted by the Hospital Security Department.

E. Factual information gained during the investigation should be cosigned by the individuals gathering the information.

F. The rights of individuals will be respected and police methods will be avoided by hospital personnel.

G. If it is determined in the internal investigation that diversion or abuse

is not involved, the incident report will be filed in the Pharmacy, or in some cases of abuse it will be filed in the Personnel Department, and observed for the possible development of a pattern.

H. If diversion is suspected by the Pharmacy or abuse reported by the Employee Health Clinic or the Personnel Department, then the outside agencies will be contacted.

VII. Procedure for making reports to outside agencies

A. The Pharmacy is responsible for making reports.

B. Pharmacy to notify Hospital Security Department before making report.

C. **For reporting diversion:**

1. Pharmacy will call D.E.A. and describe event.
2. Call will be followed with a certified letter describing event.
3. D.E.A. will send copies of Report Form #106.
4. Pharmacy will call local police, describe the event, and advise police that D.E.A. has also been contacted.
5. Call will be followed with a certified letter describing the event.
6. Upon receipt of Form #106 Pharmacy will complete copies and send to—
   a. D.E.A. (Pharmacy will send two (2) copies and D.E.A. will forward one (1) to D.I.U.)
   b. Board of Pharmacy
   c. Local police

D. **For reporting abuse:**

1. Pharmacy will call D.E.A., D.I.U., and local police describing event.
2. Pharmacy will follow calls with certified letters to each agency describing the event.

VIII. Ground for dismissal of hospital employees

A. Felony conviction on a drug charge.

B. An established drug dependency.

1. This will first result in a suspension.
2. If the condition is cured, the employee will be reinstated to a low risk area.
3. If the condition is not cured, dismissal will take place.

IX. Educational Program

The Personnel Department will conduct periodic educational programs to assist personnel in carrying out their responsibilities which are described in this Protocol. Assistance in conducting these programs will be obtained from the Pharmacy, Nursing Service, the Hospital Security Department, and the D.E.A.

Mailing of Controlled Substances

The Drug Enforcement Administration has published the mailing requirements for controlled substances as set forth in the U.S. Postal Services (Domestic) regulations TL-34, 3-7-75, Issue 97. The DEA-Postal Service regulations are reprinted for your information:

124.5 Controlled Substances, Narcotics (18 U.S.C. 1716)

.51 Definitions

.511 Controlled Substances

A controlled substance is any narcotic, hallucinogenic, stimulant or depressant

drug in Schedules I through V of the Controlled Substances Act (Public Law 91-513), 21 U.S.C. 801, et. seq., and the regulations thereunder, 21 C.F.R. 1300, et. seq.

.512 Narcotic Drugs

Narcotic drugs, as defined in the Controlled Substances Act, include opium, cocaine and opiates (synthetic narcotics) and the derivatives thereof.

.52 Declarations as to Injurious Nature

Controlled substances are, by reason of their addictive nature or capacity for abuse, hereby declared to be Articles, Compositions, or materials which may kill or injure another within the intent and meaning of 18 U.S.C. 1716.

.53 Nonmailable Generally

Except under the conditions specified in 124.5 controlled substances are nonmailable matter and shall not be conveyed in the mails or delivered from any post office or station thereof nor by any letter carrier.

.54 Mailing Requirements

.541 Authorized Mailings

Controlled substances may be transmitted in the mails between persons registered with the Drug Enforcement Administration or between persons who are exempted from registration such as military, law enforcement, and civil defense personnel in the performance of their official duties. Prescription medicines containing non-narcotic controlled substances may be mailed from a registered practitioner or dispenser to an ultimate user. Prescription medicines containing narcotic drugs may be mailed only by Veterans Administration medical facilities to certain veterans. Parcels containing controlled substances must be prepared and packed for mailing in accordance with the requirements of 124.542.

.542 Preparation and Packing

a. The inner container of any parcel containing controlled substances must be marked and sealed in accordance with the applicable provisions of the Controlled Substances Act, 21 U.S.C. 801, and the regulations promulgated thereunder, 21 C.F.R. 1300 et seq.

b. The inner container of prescription medicines containing controlled substances must, in addition to the marking and sealing requirements set forth in *a*, be labeled to show the name and address of the practitioner, or the name and address of the pharmacy or other person dispensing the prescription if other than the practitioner, and the prescription number.

c. Every parcel containing controlled substances shall be placed in a plain outer container or securely overwrapped in plain paper.

d. No markings of any kind which would indicate the nature of the contents shall be placed on the outside of any parcel containing controlled substances.

.543 Use of Registered Mail Required

Parcels containing controlled substances, including those sent to DEA Regional Offices for disposal (see 21 CFR 1307.2) generally must be sent by registered mail, return requested. The Drug Enforcement Administration number or ex-

emption status of the sender shall be set forth in the sender's address Section of Form 3877, as applicable. This information shall appear in the following format:

DEA REGISTRATION No. 654321

or

DEA Exempt—Police

.544 Regular Mail Permitted

The following may be sent by regular mail without regard to the provision of 124.543:

a. Prescription medicines containing non-narcotic controlled substances listed in Schedule II in amounts not exceeding 100 dosage units.
b. Prescription medicine containing non-narcotic controlled substances listed in Schedules III, IV, and V in amounts not exceeding a 100-day supply or 300 dosage units whichever is less.
c. Physician's sample of medicines containing non-narcotic controlled substances in amounts not exceeding the limitations; set forth in 124.544 *a* or *b*.

.55 Exempt Shipments

Small quantities of unknown matter suspected of containing controlled substances may be sent by regular mail without regard to the other provisions of 124.5 only when addressed to a Federal, state or local law enforcement agency for law enforcement purposes. Such mailings must comply with 124.542 (c) and (d).

.56 Violations

Violations of this section shall be referred to the Inspection Service.

OTHER SYSTEMS

Although the system herein described for the distribution of floor stock narcotics has been used by many hospital pharmacists and has been found to be dependable and satisfactory, some hospital pharmacists have developed modifications for which they claim the advantage of saving personnel time and the reduction of the possibility of error.[1,2]

In addition, the pharmaceutical industry has developed new concepts in the packaging of narcotics for distribution in the hospital. One of these systems provides narcotic injectables in a single-dose ampul which is packaged in a space-saving, see-through dispenser of ten, which in turn is packaged in a carton of two floor-stock dispenser trays. Narcotic tablets are being packaged in strip packs thereby permitting the pharmacist and the nurse to easily identify each individual tablet up to the time of its consumption as well as to "measure count" for inventory purposes.[3-6]

SPECIAL USES

The ASHP Technical Assistance Bulletin on Institutional Use of Controlled Substances[7] provides two sections (VIII and IX) that are of importance to the Hospital pharmacist. They are as follows:

VIII. RESEARCH, LABORATORY PROCEDURES AND INSTRUCTIONAL USES

(A) *Registration.*

(1) *General.* Persons engaged in research, laboratory procedures or instructional uses with controlled substances are required to register under the Controlled Substances Act. A person already registered to dispense controlled substances in Schedules II through V is authorized by virtue of such registration to use controlled substances in research and related activities including preclinical and clinical investigations of drugs, laboratory procedures and for instructional use without separate registration, provided they are otherwise permitted to do so under applicable federal and state laws. Methadone research or dispensing is not authorized for persons registered to dispense controlled substances unless the general requirements discussed in Section IX of these Guidelines are complied with.

(2) *Use of Schedule I Drugs.* The conduct of research with controlled substances listed in Schedule I requires separate registration. Registration for Schedule I research requires submission of a research protocol with the application describing each research project. Research will be authorized only with those substances listed in an approved research protocol.

(3) *Separate Locations.* If research or related activities are conducted with controlled substances in more than one general physical location, a separate registration is required for each location.

(B) *Records and Reports.*

(1) *General Requirement.* Each person registered or authorized to conduct research or related activities with controlled substances is required to keep records. A registered person using a controlled substance in research conducted at a registered establishment need not maintain separate records if the establishment maintains records in compliance with an IND. The registered person must notify DEA of the name, address and registration number of the establishment maintaining the investigational use records. Notice to DEA is given in the form of an attachment to the application for registration or re-registration.

(2) *Inventory.* The inventory requirements of a person registered to dispense or authorized to conduct research or related activities with controlled substances include an accounting for each controlled substance in finished form and controlled substances awaiting disposal,

held for quality control purposes or maintained for extemporaneous compoundings or similar purposes.

(3) *Receipt and Dispensing.* Receipt and dispensing records must be kept by the registrant. If the registrant is a hospital, the required records should be kept by the pharmacist in the same manner as records for other controlled substances.

(C) *Security.* In a registered institution the pharmacist should be the custodian of all controlled substances. Controlled substances may be dispensed only to or for authorized investigators, laboratory personnel or instructors. The pharmacist should be responsible for the security of controlled substances used in research and related activities.

IX. METHADONE

(A) *Registration and Approval.*

(1) *General.* The use of methadone in an institution is controlled jointly under FDA and DEA regulations. The FDA methadone regulations (21 CFR 310.305) provide for approved uses of methadone in a hospital and in a methadone treatment program. A hospital may be approved to dispense methadone for detoxification and temporary maintenance of inpatients or for analgesia in severe pain for both inpatients and outpatients. If a hospital desires to establish a methadone treatment program for detoxification and maintenance of drug-dependent persons, separate approval is required. In either case, the hospital must be registered with DEA to dispense Schedule II controlled substances in addition to receiving approval under the FDA methadone regulations.

(2) *Hospital Use of Methadone.* In order for a hospital pharmacy to lawfully receive or dispense methadone for its approved hospital uses, the hospital must submit form FD 2636, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Temporary Maintenance Treatment." The application must be approved by the responsible state authority and the FDA. The form requires detailed information about the hospital, including the name of the pharmacist responsible for receiving and securing supplies of methadone.

(3) *Methadone Treatment Programs.* To obtain approval to establish a methadone treatment program, the sponsor must submit Form FD 2632, "Application for Approval of Use of Methadone in a Treatment Program." The application must receive the approval of the responsible state authority and the FDA with the concurrence of DEA. In order to assure that each participating physician in a methadone treatment program is aware of his professional and administrative responsibilities, the FDA requires that form FD 2633, "Medical Responsibility Statement for use of Methadone in a Treatment Program," be completed by each physician licensed to dispense or administer methadone in an approved

program. These statements must accompany the program application. All patients in the program are required to give their consent for treatment by signing Form FD 2635, "Consent for Methadone Treatment."

(B) *Records and Reports.*

(1) *Hospital Use of Methadone.* All records must be kept in compliance with the DEA requirements for Schedule I and II controlled substances. Hospitals must also maintain accurate records traceable to specific patients and they must include dates, quantity and batch or code marks of the drug dispensed. Methadone records must be retained for a three-year period instead of the two-year period required for other controlled substances. The hospital does not have to submit a detailed annual report. The hospital is required to report to FDA annually the name and address of all physicians who prescribed methadone for outpatient use during the previous year.

(2) *Methadone Treatment Program.* All records must be kept in compliance with the DEA requirements for Schedule I and II controlled substances. The FDA methadone regulations require also that there be accurate records traceable to specific patients and they must include dates, quantity and batch or code marks of the drug dispensed. The record retention period for methadone records is three years. The methadone treatment program is required to file an annual report with the responsible state authority and the FDA. The content of the annual report is detailed in FD Form 2634, "Annual Report for Treatment Program Using Methadone."

(C) *Security.* The FDA regulations require that the security for methadone treatment programs must be in compliance with DEA guidelines prior to final FDA approval.

SELECTED READINGS

Regulations No. 5, I.R.S. Publication No. 428 (6-29), Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

Hibbard, F.J., Bair, J.N., and Sylvester, K.L.: Pharmacy-Based Controlled Substances Distribution for a University Campus. Am. J. Hosp. Pharm., *40*:74–77, 1983.

ASHP Technical Assistance Bulletin and Hospital Drug Distribution and Control. Am. J. Hosp. Pharm., *37*:1097–1103, (Aug.) 1980.

REFERENCES

1. Davis, Neil M.: A Case Study in Narcotic Control, Hospitals. J.A.H.A., *36*:56, 1962.
2. Eckel, Fred M. and Latiolais, Clifton J.: An Effective Narcotic Control System Using Electronic Data Processing. Am. J. Hosp. Pharm., *22*:9:519, 1965.
3. Mabol, Philip D.: Evaluation of a New Ready-to-Dispense System for Oral Narcotics. Am. J. Hosp. Pharm., *24*:10:543, 1967.
4. Zellers, Darryl D. and Derewiczs, Henry J.: Twenty-Four Hour Narcotic Disposition Recording System. Am. J. Hosp. Pharm., *24*:10:550, 1967.

5. Wirth, Bradford P.: A Computerized System for Restricted Drug Control and Inventory. Am. J. Hosp. Pharm., *24*:10:556, 1967.
6. Austin, Leonard H.: A Simplified Narcotic Distribution System. Am. J. Hosp. Pharm., *24*:10:561, 1967.
7. ASHP Technical Assistance Bulletin on Institutional Use of Controlled Substances. Am. J. Hosp. Pharm., *31*:582–588, (June) 1978.

17

Tax-Free Alcohol—Its Procurement and Control

Because the hospital is a prime user of tax-free alcohol which is commonly purchased, stored, dispensed and accounted for by the hospital pharmacist, it seems proper to devote a separate chapter to the technical procedures involved in the above processes.

The hospital pharmacist should obtain from the U.S. Government Printing Office the latest document[1] governing the distribution and use of tax-free alcohol. In addition, the local assistant regional commissioner will make available the appropriate "Industry Circular," a publication of the Office of the Commissioner of Internal Revenue, Alcohol and Tobacco Tax Division.

Although this chapter will deal with the various aspects of Section D, Part 22, Code of Federal Regulations, the reader is cautioned to make reference to the Federal publication and where questions arise to consult freely with the assistant regional commissioner.

In the following discussion, the various sections of Part 22 will be listed along with their subtitles. Where the section should be of particular interest to the hospital pharmacist, its content will be quoted and, where necessary, elaborated upon. Samples of all the forms discussed in the various sections may be obtained from the Assistant Regional Commissioner (Alcohol and Tobacco Tax) for study along with the appropriate section. These regulations are effective June, 1985.

FEDERAL REGULATIONS

Subpart—Definitions

§ 22.11 Meaning of terms.

When used in this part and in forms prescribed under this part, the following terms have the meanings given in this section. Words in the plural form include the singular, and vice versa, and words importing the masculine gender include the feminine. The terms "includes" and "including" do not exclude things not enumerated which are in the same general class.

Alcohol. Spirits having a proof of 190° or more when withdrawn from bond, including all subsequent dilutions and mixtures thereof, from whatever source or by whatever process produced.

Area supervisor. The supervisory officer of the Bureau of Alcohol, Tobacco and Firearms area office.

ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any function relating to the administration or enforcement of this part.

CFR. The Code of Federal Regulations.

Clinic. When used in this part the term includes veterinary clinics.

Delegate. Any officer, employee, or agency of the Department of the Treasury authorized by the Secretary of the Treasury directly, or indirectly by one of more redelegations of authority, to perform the function mentioned or described in the context.

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of the Treasury, Washington, D.C.

Executed under penalties of perjury. Signed with the prescribed declaration under the penalties of perjury as provided on or with respect to the claim, form, or other document or, where no form of declaration is prescribed, with the declaration "I declare under the penalities of perjury that this _____(insert type of document, such as statement, report, certificate, application, claim, or other document), including the documents submitted in support thereof, has been examined by me and, to the best of my knowledge and belief, is true, correct, and complete."

Fiduciary. A guardian, trustee, executor, administrator, receiver, conservator, or any person acting in any fiduciary capacity for any person.

Gallon or wine gallon. The liquid measure equivalent to the volume of 231 cubic inches.

Hospital. When used in this part the term includes veterinary hospitals.

Initial order. The first order of tax-free alcohol placed by a permittee or Governmental agency with a distilled spirits plant or vendor, and, the first order placed following the issuance of an amended or corrected permit.

Liter or litre. A metric unit of capacity equal to 1,000 cubic centimeters of alcohol, and equivalent to 33.814 fluid ounces. A liter is divided into 1,000 milliliters (ml). The symbol for milliliter or milliliters is "ml".

Permit. The document issued under 26 U.S.C. 5271(a), authorizing a person to withdraw tax-free alcohol from the premises of a distilled spirits plant and use such alcohol under specified conditions.

Permittee. Any person holding a permit, on Form 5150.9, issued under this part to withdraw and use tax-free alcohol.

Person. An individual, trust, estate, partnership, association, company, or corporation.

Proof. The ethyl alcohol content of a liquid at 60° Fahrenheit, stated as twice the percent of ethyl alcohol by volume.

Proof gallon. A gallon at 60° Fahrenheit which contains 50 percent of volume of ethyl alcohol having a specific gravity of 0.7939 at 60° Fahrenheit referred to water at 60° Fahrenheit as unity, or the alcoholic equivalent thereof.

Region. A Bureau of Alcohol, Tobacco and Firearms Region.

Regional director (compliance). The principal ATF regional official responsible for administering regulations in this part.

Restoration. Restoring to the original state of recovered tax-free alcohol, including redistillation of the recovered alcohol to 190° or more of proof and the removal of foreign materials by redistillation, filtration, or other suitable means.

Secretary. The Secretary of the Treasury or his delegate.

Spirits or distilled spirits. The substance known as ethyl alcohol, ethanol, or spirits of wine, having a proof of 190° or more when withdrawn from bond, including all subsequent dilution and mixtures thereof, from whatever source or by whatever process produced.

This chapter. Title 27, Code of Federal Regulations, Chapter I (27 CFR Chapter I).

U.S.C. The United States Code.

Subpart C—Administrative Provisions

Authorities

§ 22.21 Forms prescribed.

(a) The Director is authorized to prescribe all forms required by this part, including bonds, applications, notices, claims, reports, and records. All of the information called for in each form shall be furnished as indicated by the headings on the form and the instructions on or pertaining to the form. In addition, information called for in each form shall be furnished as required by this part.

(b) ATF Publication 1322.1, Public Use Forms, is a numerical listing of forms issued by the Bureau of Alcohol, Tobacco and Firearms. This publication is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(c) Requests for forms should be mailed to the ATF Distribution Center, 3800 South Four Mile Run Drive, Arlington, Virginia 22206.

§ 22.22 Alternative methods of procedures; and emergency variations from requirements.

(a) *Alternate methods of procedures.*—(1) *Application.* A permittee, after receiving approval from the Director, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. A permittee wishing to use an alternate method of procedure may apply to the regional director (compliance). The permittee shall describe the proposed alternate method or procedure and shall set forth the reasons for its use.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1375, as amended (26 U.S.C. 5311))

Liability for Tax

§ 22.31 Persons liable for tax.

All tax-free alcohol removed, sold, transported, or used in violation of law or regulations in this part, is subject to all provisions of law relating to taxable alcohol, including the requirement for payment of tax on the alcohol. The person removing, selling, transporting, or using tax-free alcohol in violation of law or regulations pertaining to tax-free alcohol shall be required to pay the lest distilled spirits tax on the alcohol.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1314, as amended (26 U.S.C. 5001))

Destruction of Marks and Brands

§ 22.33 Time of destruction of marks and brands.

(a) Any person who empties a package containing tax-free alcohol shall immediately destroy or obliterate the marks, brand, and labels required by this chapter to be placed on packages of tax-free alcohol.

(b) A person may not destroy or obliterate the marks, brands or labels until the package or drum has been emptied.
(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended (26 U.S.C. 5206))

Document Requirements

§ 22.35 Execution under penalties of perjury.

(a) When any form of document prescribed by this part is required to be executed under penalties of perjury, the permittee or other authorized person shall:

(1) Insert the declaration "I declare under the penalties of perjury that I have examined this _____(insert the type of document such as claim, application, statement, report, certificate), including all sup-

porting documents, and to the best of my knowledge and belief, it is true, correct, and complete"; and

(2) Sign the document.

(b) When the required document already bears a perjury declaration, the permittee or other authorized person shall sign the document. (Act of August 16, 1954, 68A Stat. 745 (26 U.S.C. 6056))

§ 22.36 Filing of qualifying documents.

All documents returned to a permittee or other person as evidence of compliance with requirements of this part, or as authorization, shall except as otherwise provided, be kept readily available for inspection by an ATF officer during business hours.

Subpart D—Qualification

Application for Permit, Form 5150.22

§ 22.41 Application for industrial alcohol user permit.

(a) *Users.* Each person desiring to withdraw and use tax-free alcohol shall, before commencing business, file an application on Form 5150.22 for, and obtain a permit, Form 5150.9, except permittees who were previously qualified to withdraw and use tax-free alcohol on the effective date of this regulation.

(b) *Filing.* All applications and necessary supporting documents, as required by this subpart, shall be filed with the regional director (compliance). All data, written statements, affidavits, and other documents submitted in support of the application are considered a part of the application.

(1) Applications filed as provided in this section, shall be accompanied by evidence establishing the authority of the officer or other person to execute the application.

(2) A State, political subdivision thereof, or the District of Columbia, may specify in the application that it desires a single permit authorizing the withdrawal and use of tax-free alcohol in a number of institutions under its control. In this instance, the applicable, Form 5150.22, or an attachment, shall clearly show the method of distributing and accounting for the tax-free alcohol to be withdrawn.

§ 22.42 Data for application, Form 5150.22.

(a) Unless waived under § 22.43, each application on Form 5150.22 shall include as applicable, the following information:

(1) Serial number and purpose for which filed.

(2) Name and principal business address.

(3) Based on the bona fide requirements of the applicant, the esti-

mated quantity of tax-free alcohol in proof gallons, which will be procured during a 12-month period (one calendar year).

(4) Location, or locations where tax-free alcohol is to be used, if different from the business address.

(5) Statement showing the specific manner in which, or purpose for which, tax-free alcohol will be withdrawn and used.

(6) Statement that tax-free alcohol will be stored in accordance with the requirements of this part.

§ 22.44 Disapproval of application.

The regional director (compliance) may, in accordance with Part 200 of this chapter, disapprove an application for the permit to withdraw and use tax-free alcohol, if on examination of the application (or inquiry), the regional director (compliance) has reason to believe that:

(a) The applicant is not authorized by law and regulations to withdraw and use alcohol free of tax;

(b) The applicant (including, in the case of a corporation, any officer, director, or principal stockholder, and, in the case of a partnership, a partner) is, by reason of their business experience, financial standing, or trade connections, not likely to maintain operations in compliance with 26 U.S.C. Chapter 51, or regulations issued under this part;

(c) The applicant has failed to disclose any material information required, or has made any false statement as to any material fact, in connection with their application; or

(d) The premises at which the applicant proposes to conduct the business are not adequate to protect the revenue.

§ 22.45 Organizational documents.

The supporting information required by § 22.42(a)(7) includes, as applicable:

(a) *Corporate documents.* (1) Certified true copy of the certificate of incorporation, or certified true copy of certificate authorizing the corporation to operate in the State where the premises are located (if other than that in which incorporated).

(2) Certified list of names and addresses of officers and directors, along with a statement designating which corporate officers, if applicable, are directly responsible for the tax-free alcohol activities of the business.

(3) Statement showing the number of shares of each class of stock or other evidence of ownership, authorized and outstanding, the par value thereof, and the voting rights of the respective owners or holders.

(b) *Articles of partnership.* True copy of the articles of partnership or association, if any, or certificate of partnership or association where required to be filed by any State, county, or municipality.

(c) *Statement of interest.* (1) Names and addresses of persons owning

10% or more of each of the classes of stock in the corporation, or legal entity, and the nature and amount of the stockholding or other interest of each, whether such interest appears in the name of the interested party or in the name of another for him or her. If a corporation is wholly owned or controlled by another corporation, persons owning 10% or more of each of the classes of stock of the parent corporation are considered to be the persons interested in the business of the subsidiary, and the names and addresses of such persons shall be submitted to the regional director (compliance) if specifically requested.

(2) In the case of an individual owner or partnership, name and address of every person interested in the business, whether such interest appears in the name of the interested party or in the name of another for the interested person.

Industrial Alcohol User Permit, ATF F 5150.9

§ 22.48 Conditions of permits.

Permits to withdraw and use tax-free alcohol will designate the acts which are permitted, and include any limitations imposed on the performance of these acts. All of the provisions of this part relating to the use or recovery of tax-free alcohol are considered to be included in the provisions and conditions of the permit, the same as if set out in the permit.

§ 22.49 Duration of permits.

Permits to withdraw and use tax-free alcohol are continuing unless automatically terminated by the terms thereof, suspended or revoked as provided in § 22.51, or voluntarily surrendered. The provisions of § 22.58 are considered part of the terms and conditions of all permits.

§ 22.50 Correction of permits.

If an error on a permit is discovered, the permittee shall immediately return the permit to the regional director (compliance) for correction.

§ 22.51 Suspension of revocation of permits.

The regional director (compliance) may institute proceedings under Part 200 of this chapter to suspend or revoke a permit whenever there is reason to believe that the permittee—

(a) Has not in good faith complied with the provisions of 26 U.S.C. Chapter 51, or regulations issued under that chapter;

(b) Has violated the conditions of that permit;

(c) Has made any false statements as to any material fact in the application for the permit;

(d) Has failed to disclose any material information required to be furnished;

(e) Has violated or conspired to violate any law of the United States relating to intoxicating liquor or has been convicted of an offense under Title 26, U.S.C., punishable as a felony or of any conspiracy to commit such offense;

(f) Is, by reason of its operations, no longer warranted in procuring and using tax-free alcohol authorized by the permit; or

(g) Has not engaged in any of the operations authorized by the permit for a period exceeding two years.

§ 22.52 Rules of practice in permit proceedings.

The regulations of Part 200 of this chapter apply to the procedure and practice in connection with the disapproval of any application for a permit and in connection with suspension or revocation of a permit.

§ 22.53 Power of attorney.

An applicant or permittee shall execute and file with the regional director (compliance) a Form 1534, in accordance with the instructions on the form, for each person authorized to sign or to act in its behalf. Form 1534 is not required for persons whose authority is furnished in accordance with § 22.42(a)(10).

§ 22.54 Photocopying of permits.

A permittee may make photocopies of its permit exclusively for the purpose of furnishing proof of authorization to withdraw tax-free alcohol from a distilled spirits plant.

§ 22.55 Posting of permits.

Permits issued under this part will be kept posted and available for inspection on the permit premises.

Changes After Original Qualification

§ 22.57 Changes affecting applications and permits.

(a) *General.*—(1) *Changes affecting application.* When there is a change relating to any of the information contained in, or considered a part of the application on Form 5150.22 for a permit, the permittee shall, within 30 days (except as otherwise provided in this subpart) file a written notice with the regional director (compliance) to amend the application.

(2) *Changes affecting waivers.* When any waiver under § 22.43 is terminated by a change to the application, the permittee shall include the current information as to the item previously waived with the written notice required in paragraph (a)(1) of this section.

(3) *Changes affecting permit.* When the terms of a permit are affected by a change, the written notice required by paragraph (a)(1) of this

section (except as otherwise provided in this subpart) will serve as an application to amend the permit.

(4) *Form of notice.* All written notices to amend an application on Form 5150.22 with—

(i) Identify the permittee;

(ii) Contain the permit identification number;

(iii) Explain the nature of the change and contain any required supporting documents;

(iv) Identify the serial number of the applicable application, Form 5150.22; and

(v) Be consecutively numbered and signed by the permittee or any person authorized to sign on behalf of the permittee.

(b) *Amended application.* The regional director (compliance) may require a permittee to file an amended application on Form 5150.22 when the number of changes to the previous application are determined to be excessive, or when a permittee has not timely filed the written notice prescribed in paragraph (a)(1) of this section. If items on the amended application remain unchanged, they will be marked "No change since Form 5120.22. Serial No. _____."

(c) *Changes in officers, directors and stockholders*—(1) *Officers.* In the case of a change in the officers listed under the provisions of § 22.45(a)(2), the notice required by paragraph (a)(1) of this section shall only apply (unless otherwise required, in writing, by the regional director (compliance)) to those offices the incumbents of which are responsible for the operations covered by the permit.

(2) *Directors.* In the case of a change in the directors listed under the provisions of § 22.45(a)(2), the notice required by paragraph (a)(1) of this section shall reflect the changes.

(3) *Stockholders.* In lieu of reporting all changes, within 30 days, to the list of stockholders furnished under the provisions of § 22.45(c)(1), a permittee may, upon filing written notice to the regional director (compliance) and establishing a reporting date, file an annual notice of changes. The notice of changes in stockholders does not apply if the sale or transfer of capital stock results in a change in ownership or control which is required to be reported under § 22.58.

(Approved by the Office of Management and Budget under control number 1512-0335)

§ 22.58 Automatic termination of permits.

(a) *Permit not transferable.* Permits issued under this part are not transferable. In the event of the lease, sale, or other transfer of such a permit, or of the operations authorized by the permit, the permit shall, except as provided for in this section, automatically terminate.

(b) *Corporations.* (1) If actual or legal control of any corporation holding a permit issued under this part changes, directly or indirectly,

whether by reason of a change in stock ownership or control (in the permittee corporation or any other corporation), by operation of law, or in any other manner, the permittee shall within 10 days of the change, give written notice to the regional director (compliance). The written notice shall be accompanied by (or within 30 days of the change) an application and supporting documents on Form 5150.22 for a new permit. If an application on Form 5150.22 for a new permit is not filed within 30 days of the change, the outstanding permit will automatically terminate.

(2) If an application on Form 5150.22 for a new permit is filed within the 30-day period prescribed in paragraph (b)(1) of this section, the outstanding permit will remain in effect until final action is taken on the application. When final action is taken, the outstanding permit will automatically terminate and the permittee shall forward it to the regional director (compliance) for cancellation.

§ 22.61 Change in name of permittee.

(a) *Permit.* When the only change is a change in the individual, firm, or corporation name, a permittee may not conduct operations under the new name until a written notice, accompanied by necessary supporting documents, to amend the application and permit has been filed and an amended permit has been issued by the regional director (compliance).

(b) *Bond.* If required to file a bond, the permittee shall furnish a consent of surety on Form 1533 or a new bond to cover the change in name.

(Approved by the Office of Management and Budget under control number 1512-0335)

§ 22.62 Change in trade name.

Where there is to be a change in, or addition of, a trade name, the permittee may not conduct operations under the new trade name until a written notice has been filed and an amended permit has been issued by the regional director (compliance). A new bond or consent of surety is not required for changes in trade names.

(Approved by the Office of Management and Budget under control number 1512-0335)

§ 22.63 Change in location.

(a) *Permit.* When there is to be a change in location within the same region, a permittee may not conduct operations at the new location until a written notice, accompanied by necessary supporting information, to amend the application and permit has been filed and an amended permit has been issued by the regional director (compliance).

(b) *Bond.* If required to file a bond, the permittee shall furnish a consent of surety on Form 1533 or a new bond to cover the new location. (Approved by the Office of Management and Budget under control number 1512-0335)

§ 22.64 Return of permits.

Following the termination, surrender or revocation of a permit, or the issuance of a new or amended permit, caused by a change, the permittee shall (a) obtain and destroy all photocopies of the previous permit from its suppliers and (b) return the original of the permit or obsolete permit to the regional director (compliance) for cancellation.

Registry of Stills

§ 22.66 Registry of stills.

Part 196 of this chapter applies to stills located on the premises of a permittee. The listing of a still on Form 5150.22 and the issuance of a permit constitute registration of that still in lieu of filing Form 26.

Permanent Discontinuance of Use of Tax-Free Alcohol

§ 22.68 Notice of permanent discontinuance.

(a) *Notice.* A permittee who permanently discontinues the use of tax-free alcohol shall file a written notice with the regional director (compliance) to cover the discontinuance. The notice will be accompanied by the permit, and contain—

(1) A request to cancel the permit.

(2) A statement of the disposition made, as provided in § 22.154, of all tax-free and recovered alcohol, and

(3) The date of discontinuance.

(b) *Bonds.* The bond of a permittee may not be canceled until all tax-free and recovered alcohol has been properly disposed of in accordance with the provisions of this part.

(Approved by the Office of Management and Budget under control number 1512-0335)

Subpart E—Bonds and Consents of Surety

§ 22.71 Bond.

(a) Any bond previously approved, under this chapter, on Form 1448 (5150.25) which fulfills the penal sum requirements of paragraph (b) of this section shall remain valid and will be regulated by the same provisions of this subpart as it refers to bonds on Form 5150.25.

(b) Each person who intends to withdraw more than 1,500 proof

gallons of tax-free alcohol per annum shall file a bond, Form 5150.25, before issuance of the permit. The penal sum of the bond will be as follows:

Minimum annual withdrawals	Bond penal sum
0 to 1,500 proof gallons	No bond required.
Over 1,500 but not over 3,000 proof gallons.	$2,000 plus $100 for each additional 100 proof gallons up to a maximum of $3,000 (2,500 proof gallons).
Over 3,000 but not over 6,000 proof gallons.	$3,000 plus $200 for each additional 100 proof gallons up to a maximum of $7,500 (5,250 proof gallons).
Over 6,000 proof gallons	$7,500 plus $250 for each additional 100 proof gallons up to a maximum penal sum of $15,000 (9,000 proof gallons).

(c) The following are some examples:

If your annual withdrawals are	Your penal sum is
1,250 proof gallons	No bond required.
2,800 proof gallons	$3,000 ($2,000 plus $1,000 ($100 × 10 units), last 300 proof gallons does not require additional bond coverage).
8,250 proof gallons	$13,000 ($7,500 plus $5,500 ($250 × 22 units), the remaining 50 proof gallons does not increase the bond since it is not an "additional" 100 proof gallon unit).

§ 22.72 Evaluation of bond penal sum.

(a) *Permittee's evaluation.* Each permittee shall, for the period from January 1 through the following December 31, make an annual evaluation of its previous and future needs for tax-free alcohol. Based on the results of this evaluation:

(1) The permittee shall file a new bond in increased penal sum, if the existing bond no longer meets the penal sum requirements of § 22.71, or

(2) The permittee may file a new bond in decreased penal sum, if the existing bond exceeds the penal sum requirements of § 22.71.

(b) *Authority of regional director (compliance).* The regional director (compliance) may, at any time, require a permittee to file a new bond in a larger penal sum, or require a satisfactory explanation why a new bond should not be filed.

(Chapter 390, Pub. L. 80-280, 61 Stat. 648 (6 U.S.C. 6, 7))

Subpart F—Premises and Equipment

§ 22.91 Premises.

All persons qualified to withdraw and use tax-free alcohol shall have premises suitable for the business being conducted and adequate for the protection of the revenue. Storage facilities shall be provided on the premises for tax-free alcohol received or recovered. The storage facilities may consist of a combination of storerooms, compartments, or stationary storage tanks.

§ 22.92 Storage facilities.

(a) Storerooms or compartments shall be so constructed and secured as to prevent unauthorized access and will be equipped for locking. These storage facilities shall be of sufficient capacity to hold the maximum quantity of tax-free alcohol which will be on hand at one time.

(b) Each stationary storage tank used to hold tax-free alcohol shall be equipped for locking in such a manner as to control access to the spirits. All stationary storage tanks shall be equipped with an accurate means of measuring the spirits.

§ 22.102 Prohibited uses.

(a) *Usage.* Under no circumstances may tax-free alcohol withdrawn under this part be used for beverage purposes, food products, or in any preparation used in preparing beverage or food products.

(b) *Selling.* Persons qualified under this part are prohibited from selling tax-free alcohol, using tax-free alcohol in the manufacture of any product for sale, or selling any products resulting from the use of tax-free alcohol. A separate charge may be made by a hospital, sanitarium or clinic for medicines compounded with tax-free alcohol and dispensed to patients for use on the premises, as provided in § § 22.105 and 22.106. Hospitals may not furnish tax-free alcohol for use of physicians in their private practice.

(c) *Removal from premises.* Persons qualified under this part may not remove tax-free alcohol or products resulting from the use of tax-free alcohol from the permit premises unless specifically authorized by the terms of their permit, or permission is obtained from the regional director (compliance), except that:

(1) Products made through the use of tax-free alcohol which contain no alcohol may be removed to other premises for the sole purpose of further research; or

(2) Under the provisions of § § 22.105 and 22.106, clinics operated for charity and not for profit may compound bona fide medicines with tax-free alcohol, and dispense the medicine from the premises for use by its patients outside of the clinic, if the furnishing of the medicine is not conditioned upon payment.

(d) *Liability for tax.* Permittees who use tax-free alcohol in any manner prohibited by this section become liable for the tax on the alcohol. Any permittee who sells tax-free alcohol also becomes liable for special (occupational) tax as a liquor dealer.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1314, as amended, 1343, as amended, 1362, as amended (26 U.S.C. 5001, 5121, 5214))

§ 22.103 States and the District of Columbia.

Except as otherwise provided in this section, tax-free alcohol withdrawn by a State or political subdivision of a State, or the District of Columbia shall be used solely for mechanical and scientific purposes, and except on approval of the regional director (compliance), the use of tax-free alcohol or the use of any resulting product will be confined to the premises under the control of the State or political subdivision of a State, or the District of Columbia. Tax-free alcohol withdrawn for use in hospitals, clinics, and other establishments specified in §§ 22.104 through 22.108, operated by a State, political subdivision of a State, or the District of Columbia, shall be used in the manner prescribed for those establishments.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 22.104 Educational organizations, colleges of learning, and scientific universities.

(a) *Educational organizations.* Educational organizations authorized to withdraw and use tax-free alcohol under § 22.101 are those organizations which normally maintain a regular faculty and curriculum and which normally have a regularly enrolled body of students in attendance at the place where their educational activities are regularly carried on and which are exempt from Federal income tax under 26 U.S.C. 501(a).

(b) *Colleges of learning.* Colleges of learning, for the purposes of this subpart, have a recognized curriculum and confer degrees after specified periods of attendance at classes or research work.

(c) *Scientific universities.* Scientific universities include any university incorporated or organized under any Federal or State law which provides training in the sciences.

(d) *Uses.* Tax-free alcohol withdrawn by educational organizations, scientific universities, and colleges of learning shall be used only for scientific, medicinal, and mechanical purposes. Use of tax-free alcohol and resulting products are limited by the provisions of § 22.102.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 22.105 Hospitals, blood banks, and sanitariums.

(a) Tax-free alcohol withdrawn for use by hospitals, blood banks, and sanitariums shall be used exclusively for medicinal, mechanical (anal-

ysis or test) and scientific purposes and in the treatment of patients. The use of tax-free alcohol and of products resulting from the use of tax-free alcohol shall be confined to the permit premises, except as provided in this section and § 22.102. Medicines compounded with tax-free alcohol on the premises of a hospital or sanitarium, for use of patients on the premises, may not be sold, but a separate charge may be made for the medicine.

(b) A hospital, operating a clinic on premises, may withdraw tax-free alcohol for use in the clinic, if the clinic is operated for charity and not for profit. Medicines compounded with tax-free alcohol may be dispensed to patients at a clinic for use outside of the clinic, if the furnishing of the medicine is not conditioned upon payment.

(c) A hospital or sanitarium, operating a pathological or other laboratory on premises, may withdraw tax-free alcohol for authorized use in the laboratory.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 22.106 Clinics.

Tax-free alcohol withdrawn by clinics operated for charity and not for profit shall be used only for medicinal, scientific, and mechanical purposes and in the treatment of patients. Medicine compounded with tax-free alcohol may be dispensed to patients for use off the premises, if the furnishing of the medicine is not conditioned upon payment. A separate charge may be made for medicine compounded on the clinical premises with tax-free alcohol for use of patients on the premises. Except as provided in this section and in § 22.102, the use of tax-free alcohol shall be confined strictly to the premises of the clinic.

(Sec. 201. Pub. L. 85-859, 72 Stat. 1362, as amended (26 U.S.C. 5214))

§ 22.107 Pathological laboratories.

(a) Pathological laboratories, not operated by a hospital or sanitarium, may withdraw and use tax-free alcohol if exclusively engaged in making analyses or tests for hospitals or sanitariums. If a pathological laboratory does not exclusively conduct analyses or tests for hospitals or sanitariums, it does not qualify for the permit issued under this part.

(b) A pathological laboratory which uses tax-free alcohol for any other purpose, except as provided in this section, shall become liable for the tax on the alcohol.

(c) Except as provided in § 22.102, the use of tax-free alcohol and of products resulting from the use of tax-free alcohol shall be confined strictly to the permit premises.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1314, as amended. 1362, as amended (26 U.S.C. 5001, 5214))

§ 22.108 Other laboratories.

Laboratories, other than pathological laboratories specified in § 22.107, may withdraw and use tax-free alcohol exclusively in scientific research. The use of tax-free alcohol or of products resulting from the use of tax-free alcohol shall be confined strictly to the laboratory premises, except as provided in § 22.102.
(Sec. 201, Pub. L. 85-859, 72 Stast. 1362, as amended (26 U.S.C. 5214))

Subpart H—Withdrawal and Receipt of Tax-Free Alcohol

§ 22.111 Withdrawals under permit.

(a) *General.* The permit, Form 5150.9, issued under Subpart D of this part, authorizes a person to withdraw tax-free alcohol from the bonded premises of a distilled spirits plant or, under the provisions of 26 U.S.C. 5688(a)(2)(B), receive alcohol from the General Services Administration.

(b) *Photocopying of permit, Form 5150.9.* (1) As provided in § 22.54, a permittee may make photocopies of its permit, or amended permit, for the exclusive purpose of furnishing proof of authorization to withdraw tax-free alcohol.

(2) A permittee need only furnish the photocopy of its permit, or amended permit, to a distilled spirits plant for the "initial order" from that distilled spirits plant.

(3) When a permittee makes photocopies of its permit, Form 5150.9, each copy shall be signed, dated, and contain the word "COPY" across the face.

(4) A permittee is responsible for obtaining and, as applicable, destroying all photocopies of its permit from distilled spirits plants when (i) an amended or corrected permit is issued which supersedes the copy on file, (ii) the permit is canceled by reason of requalification as a new permittee, (iii) the permit is revoked or suspended, or (iv) upon permanent discontinuance of use of tax-free alcohol.

(c) *Withdrawals under permit.* (1) When a permittee places an initial order for tax-free alcohol it shall forward a signed copy of the permit, for retention by the distilled spirits plant, along with the purchase request.

(2) When the permittee places a subsequent order for tax-free alcohol, the purchase request, in addition to any other information, shall contain the permit identification number and date of issue along with a statement that the permittee possesses a valid permit to withdraw tax-free alcohol, a copy of which is on file.

(3) Shipments shall not be made by a proprietor of a distilled spirits

plant until it is in possession of a signed copy of a valid permit, Form 5150.9.
(Sec. 201, Pub. L. 85-859, 72 Stat. 1395, as amended (26 U.S.C. 5555))

§ 22.112 Regulation of withdrawals.

(a) Each permittee shall regulate its withdrawals of tax-free alcohol to ensure that (1) the quantity on hand and unaccounted for does not exceed the capacity of the storage facilities, and (2) the cumulative quantity withdrawn or received in any calendar year does not exceed the quantity authorized by the permit, Form 5150.9. Recovered alcohol and alcohol received from the General Services Administration shall be taken into account in determining the total quantity of alcohol on hand.

(b) For the purpose of this section, tax-free alcohol and recovered alcohol shall be considered as unaccounted for if lost under circumstances where a claim for allowance is required by this part and the claim has not been allowed, or if used or disposed of in any manner not provided for in this part.

§ 22.113 Receipt of tax-free alcohol.

(a) When tax-free alcohol is received, it shall be placed in the storage facilities prescribed by § 22.91 and kept there under lock until withdrawn for use. Unless required by city or State fire code regulations or authorized by the regional director (compliance) or the terms of the permit, the permittee may not remove tax-free alcohol from the original packages or containers in which received until the alcohol is withdrawn for use. If the tax-free alcohol is transferred to "safety" containers in accordance with fire code regulations, the containers to which they are transferred shall be appropriately marked to identify the package from which transferred, the quantity transferred, the date of transfer, and the name and address of the vendor.

(b) When tax-free alcohol is received, the permittee shall ascertain and account for any losses in transit in accordance with Subpart I of this part. The permittee shall note any loss or deficiency in the shipment on the record of receipt.

(c) Records of receipt shall consist of the consignors invoice or bill. Records of receipt may be filed in accordance with the permittee's own filing system as long as it does not cause inconvenience to ATF officers desiring to examine the records. The filing system shall systematically and accurately account for the receipt of all tax-free alcohol.

§ 22.114 Alcohol received from the General Services Administration.

Any nonprofit charitable institution holding a permit on Form 5150.9, and receiving alcohol from the General Services Administration under the provisions of 26 U.S.C. 5688(a)(2)(B), shall include any quantity of

alcohol received in computing the quantity of tax-free alcohol that may be procured under its permit during the calendar year. The alcohol, on receipt, shall be placed in the storage facilities prescribed in § 22.91 and kept there under lock until withdrawn for use.

Subpart I—Losses

§ 22.121 Liability and responsibility of carriers.

(a) A person or carrier transporting tax-free alcohol to a consignee or returning the alcohol to the consignor is responsible for the safe delivery and is accountable for any tax-free alcohol not delivered.

(b) A person or carrier transporting tax-free alcohol in violation of any law or regulation pertaining thereto, is subject to all provisions of law relating to alcohol subject to and the payment of tax thereon, and shall be required to pay the tax.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1314, as amended [26 U.S.C. 5001)]

§ 22.122 Losses in transit.

(a) *Reporting losses.* Upon discovering any loss of tax-free alcohol while in transit, the carrier shall immediately inform the consignee, in writing, of the facts and circumstances relating to the loss. In the case of theft, the carrier shall also immediately notify the consignee's regional director (compliance) of the facts and circumstances relating to the loss.

(b) *Recording losses.* At the time the shipment or report of loss is received, the consignee shall determine the quantity of tax-free alcohol lost. The consignee shall note the quantity lost on the receiving document and attach all relevant information to the record of receipt, prescribed in § 22.113. For the purpose of maintaining the records prescribed in Subpart M of this part, receipts on tax-free alcohol shall only include the quantity actually received.

(c) *Claims.* A claim for allowances of losses of tax-free alcohol shall, as prescribed in § 22.125, be filed:

(1) If the quantity lost in transit exceeds 1 percent of the total quantity shipped and is more than 5 proof gallons, the consignee shall file a claim for allowance of the entire quantity lost; or

(2) If the loss was due to theft or other unlawful removal, the consignee shall file a claim for allowances of the entire quantity lost, regardless of the quantity or percentage involved.

(Reporting approved by the Office of Management and Budget under control number 1512-0335; recordkeeping approved by the Office of Management and Budget under control number 1512-0334.)

§ 22.123 Losses on premises.

(a) *Recording of losses.* A permittee shall determine and record, in the records prescribed by Subpart M of this part, the quantity of tax-free or recovered alcohol lost on premises—

(1) At the end of each semi-annual period when the inventory required by § 22.162 is taken, or

(2) Immediately upon the discovery of any loss due to casualty, theft or other unusual causes.

(b) *Claims.* A claim for allowances of losses of tax-free alcohol shall be filed as prescribed in § 22.125, in the following circumstances—

(1) if the quantity lost during any semi-annual inventory period exceeds 1 percent of the quantity to be accounted for during that period, and is more than 10 proof gallons, or

(2) if the loss was due to theft or unlawful use or removal, the permittee shall file a claim for allowances of losses regardless of the quantity involved.

(Approved by the Office of Management and Budget under control number 1512-0334)

§ 22.124 Incomplete shipments.

(a) Subject to the provisions of this part and Part 19 of this chapter, when containers of tax-free alcohol have sustained losses in transit other than by theft, and the shipment will not be delivered to the consignee, the carrier may return the shipment to the distilled spirits plant.

(b) When tax-free alcohol is returned to the distilled spirits plant, in accordance with this section, the carrier shall inform the proprietor, in writing, of the facts and circumstances relating to the loss. In the case of theft, the carrier shall also immediately notify the shipper's regional director (compliance) of the facts and circumstances relating to the loss.

(c) Subject to the limitations for loss prescribed in § 22.122, the proprietor of the distilled spirits plant shall file a claim for allowance of the entire quantity lost, in the same manner provided in that section. The claim shall include the applicable date required by § 22.125.

§ 22.125 Claims.

(a) Claims for allowances of losses of tax-free or recovered alcohol shall be filed, on Form 2635 (5620.8), with the regional director (compliance) within 30 days from the date the loss is ascertained, and shall contain the following information:

(1) Name, address, and permit number of claimant;

(2) Identification and location of the container(s) from which the tax-free or recovered alcohol was lost, and the quantity lost from each container;

(3) Total quantity of tax-free or recovered alcohol covered by the claim and the aggregate quantity involved:

(4) Date of loss or discovery, the cause or nature of loss, and all relevant facts, including facts establishing whether the loss occurred as a result of negligence, connivance, collusion, or fraud on the part of any person, employee or agent participating in or responsible for the loss; and

(5) Name of carrier where a loss in transit in involved.

(b) The carriers statement regarding a loss in transit, prescribed by § 22.122 or 22.124, shall accompany the claim.

(c) The regional director (compliance) may require additional evidence to be submitted in support of the claim.

See Figure 69 for ATF Form 1451 which is used to report the annual use of tax-free alcohol.

CONTINUING WITHDRAWAL PERMITS

On November 23, 1982, the Department of the Treasury Bureau of Alcohol, Tobacco and Firearms issued Industry Circular No. 82-13 entitled Continuing Withdrawal Permits for Tax-Free Alcohol Users. The Circular, addressed to Tax-Free Alcohol Users and Distilled Spirits Plant Proprietors (DSP) states:

Purpose. The purpose of this circular is to advise industry members of the new regulations regarding the elimination of the requirement for tax-free alcohol users to annually make application for and receive a new withdrawal permit.

The final rule, T.D. ATF-103, amended regulations in 27 CFR Parts 211 and 213. The specific changes which affect tax-free alcohol users and DSP proprietors are as follows:

(a) Tax-Free Alcohol Users—Withdrawal permits issued on Form 1450 (5150.13) to tax-free alcohol users which are annotated to expire on April 30, 1983, will continue in effect indefinitely. It is not necessary to submit an application for renewal of the May 1, 1983–April 30, 1984 withdrawal permit, or for any succeeding withdrawal permit. (Section 213.111 of 27 CFR is removed).

(b) Shipments by DSP Proprietors—DSP proprietors are authorized to make shipments after April 30, 1983, of tax-free alcohol to users whose permits expire on April 30, 1983. This authorization is based on the fact that all the above mentioned withdrawal permits will be "valid" after the expiration date, indefinitely, in the same manner as "limited" withdrawal permits.

ATF believes this amendment will significantly reduce administrative burdens on both industry and the Government.

Inquiries. Inquiries concerning this circular should refer to it by number and be addressed to: Assistant Director, (Regulatory Enforcement),

FORM 2600 (REV. 7-80)

U. S. TREASURY DEPARTMENT - INTERNAL REVENUE SERVICE

APPLICATION FOR PERMIT TO USE ALCOHOL FREE OF TAX

1. INDUSTRIAL USE PERMIT *(If amendment of industrial use permit)*

TF –

This form shall be executed in duplicate and filed with the assistant regional commissioner of the region in which the premises are situated.

Applications on this form which are not executed in accordance with instructions and regulations or which do not contain all the information required by the regulations will be returned to the applicant or permittee for correction.

TO ASSISTANT REGIONAL COMMISSIONER (ALCOHOL AND TOBACCO TAX) *(City and State)*

2. DATE OF APPLICATION

Application is hereby made for an industrial use permit to use alcohol free of tax, as described herein.

3. APPLICATION MADE BY *(If individual owner, give full name and address; if partnership, give full name and address of each person interested in enterprise; if corporation, give name of corporation, State under laws of which incorporated and address of principal office)*

4. TRADE NAME AND OFFICE WHERE REGISTERED

5. MAXIMUM NO. PROOF GALLONS WHICH WILL BE ON HAND, IN TRANSIT, AND UNACCOUNTED FOR AT ANY ONE TIME

6. SERIAL NUMBER

7. PURPOSE FOR WHICH FILED *("For original industrial use permit," "For amendment of industrial use permit to authorize (state privilege desired)," etc.)*

8. PERMIT IS FOR
- ☐ USE OF ALCOHOL FREE OF TAX
- ☐ RECOVERY OF TAX-FREE ALCOHOL

9. *(If application is made by central authority, as a State, municipality, university, etc., for use of alcohol by an agency, institution, department, etc., thereof, the name of such agency, etc., shall be stated)*

10. PREMISES ON WHICH ALCOHOL WILL BE USED *(Number, street, city or town, zone, State)*

11. ALCOHOL TO BE USED IN THE FOLLOWING MANNER *(The specific use which will be made of the alcohol and resulting products (if any), that is, the purpose or purposes for which the alcohol will be used, shall be stated explicitly, and not in general terms. For example, when the alcohol is to be used at a hospital, the specific purposes for which the alcohol will be used shall be stated, such as clinical use, treatment of patients, compounding medicines for use of patients in the hospital, preserving specimens of anatomy, etc. If alcohol so used is recovered, state that fact)*

12. SIZE AND COMPLETE DESCRIPTION OF THE ALCOHOL STORAGE FACILITIES

CONDITIONS

The applicant fully understands that any permit that may be issued pursuant to this application will be subject to the following conditions:

1. That this application contains no misrepresentation of fact; that he and all persons employed by him in any connection with such permit privileges, and all persons employed by him while on the permit premises, will in good faith observe and conform to all the terms and conditions of said permit, the laws of the United States relating to the manufacture, taxation, and control of and traffic in, intoxicating liquors, and all regulations issued pursuant to such laws which are now, or may hereafter be, in force; and he will pay the tax, together with penalties and interest, on all alcohol diverted while being transported to him, and on all alcohol withdrawn, transported, used, or disposed of by him in violation of laws and regulations now or hereafter in force; and that he and all persons interested in the business to be conducted under said permit are duly qualified, under the law and regulations pertaining thereto, to receive the permit privileges herein applied for.

2. That all data, written statements, evidence, affidavits, and other documents, submitted in support of this application, or upon hearing thereon, shall be deemed to be included in the provisions and conditions of this application and any permit issued pursuant thereto the same as if set out at length therein.

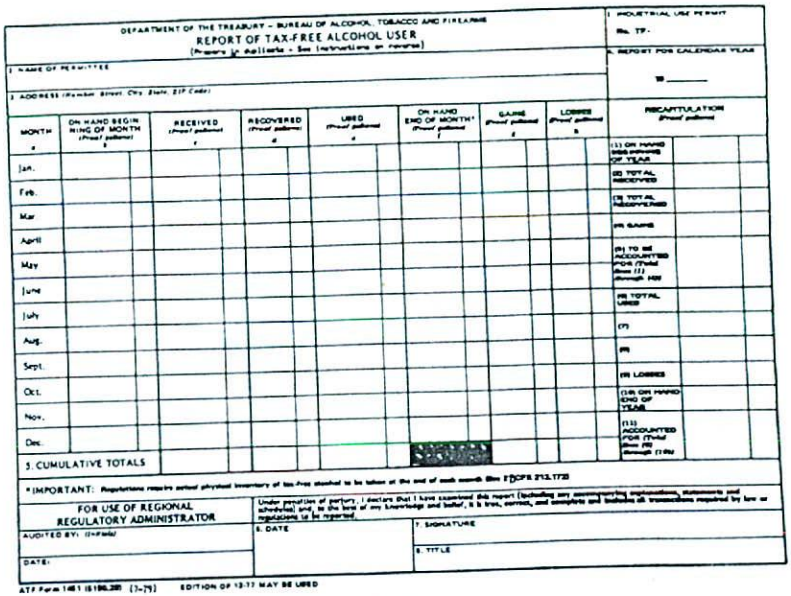
I declare under the penalties of perjury that this application has been examined by me and to the best of my knowledge and belief is a true, correct, and complete application.

13. SIGNATURE OF APPLICANT

14. BY *(Name and capacity)*

FORM 2600 (REV. 7-80)

Fig. 68



DEPARTMENT OF THE TREASURY – BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

REPORT OF TAX-FREE ALCOHOL USER

(Prepare in duplicate - See instructions on reverse)

1. NAME OF PERMITTEE

2. ADDRESS (Number, Street, City, State, ZIP Code)

MONTH	ON HAND BEGINNING OF MONTH (Proof gallons)	RECEIVED (Proof gallons)	RECOVERED (Proof gallons)	USED (Proof gallons)	ON HAND END OF MONTH* (Proof gallons)	GAINS (Proof gallons)	LOSSES (Proof gallons)
	a	b	c	d	e	f	g
Jan.							
Feb.							
Mar.							
April							
May							
June							
July							
Aug.							
Sept.							
Oct.							
Nov.							
Dec.							
5. CUMULATIVE TOTALS							

RECAPITULATION (Proof gallons)

(1) ON HAND BEGINNING OF YEAR

(2) TOTAL RECEIVED

(3) TOTAL RECOVERED

(4) GAINS

(5) TO BE ACCOUNTED FOR (Total lines (1) through (4))

(6) TOTAL LOSSES

(7)

(8)

(9) LOSSES

(10) ON HAND END OF YEAR

(11) ACCOUNTED FOR (Total lines (9) through (10))

*IMPORTANT: Regulations require actual physical inventory of tax-free alcohol to be taken at the end of each month. (See 27 CFR 213.172)

FOR USE OF REGIONAL REGULATORY ADMINISTRATOR

AUDITED BY: (Initials)

DATE:

Under penalties of perjury, I declare that I have examined this report (including any accompanying statements and schedules) and, to the best of my knowledge and belief, it is true, correct, and complete and includes all transactions required by law or regulations to be reported.

6. DATE

7. SIGNATURE

8. TITLE

ATF Form 1481 (5150.28) (3-79) EDITION OF 12-77 MAY BE USED

Fig. 69

Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW, Washington, DC 20226.

DISPENSING ALCOHOLIC LIQUORS TO PATIENTS

In the summer of 1965, the Internal Revenue Service division of Alcohol and Tobacco Tax issued **Industry Memorandum No. NA 65-7** to hospitals and similar institutions. The purpose of the memorandum was to advise hospitals and institutions regarding liability for special tax which may be incurred by dispensing alcoholic liquors to patients.

Memorandum No. NA 65-7 provides that:

Internal Revenue laws impose special taxes on persons engaging or carrying on the business or occupation of selling, or offering for sale, any alcoholic liquors for use as a beverage whether or not such liquors are fit for such use. Regulations issued pursuant to Internal Revenue law provide that hospitals and similar institutions furnishing liquor to patients are not required to pay special tax, provided that no specific or additional charge is made for the liquor so furnished. This regulation is found at section 194.187 of the Federal Liquor Dealer regulations. The words "no specific or additional charge" are interpreted as applying, for example, to those cases where a hospital or institution makes a fixed charge for treatment, subsistence, medicine, etc., and the over-all fee or charge remains the same regardless of whether alcoholic liquors are furnished to the patient.

A hospital or similar institution incurs liability for special tax as a retail liquor

dealer whenever it furnishes an alcoholic liquor to a patient, whether pursuant to a prescription or otherwise, under conditions constituting a sale. These conditions would include any manner of accounting for a specific or additional charge made to a patient for alcoholic liquor furnished him. Totaling of charges for various items under a general headline, such as "Drugs and Dressings," would not give relief from special tax liability, if a charge for alcoholic liquors is one of the items included in the total.

Any hospital or similar institution which dispenses alcoholic liquors under conditions constituting a sale will be required to pay special tax as a retail liquor dealer. Special tax is paid by filing a tax return on Form 11 with the District Director of Revenue in the District in which the hospital is located. The special tax rate for a retail liquor dealer is $54.00 for each fiscal year beginning July 1.

ALCOHOL RECORDS AND AUTOMATIC DATA PROCESSING

Industry Circular No. 65-5 was issued to advise users of tax-free alcohol, among others, of the provisions of **Revenue Procedure 64-35, I.R.B. 1964-37, 21.**

The revenue procedure requires that the methodology built into a computer's accounting program "must include a method of producing from the punched cards or tapes visible and legible records which will provide the necessary details required by the regulation covering the respective operations, or such details must be available in supplemental records."

In addition, the revenue procedure suggests that the Assistant Regional Commissioner, Alcohol and Tobacco Tax, be notified in advance of the actual installation of an automatic data processing system in order to assure the adequacy of the system as it relates to the required records.

SELECTED READINGS

All of the following publications can be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402.

Distribution and Use of Denatured Alcohol and Rum, Part 211 of Title 26, Code of Federal Regulations, I.R.S. Publication No. 443.

Formulas for Denatured Alcohol and Rum, Part 212, Title 26, Code of Federal Regulations, I.R.S. Publication No. 368.

Distribution and Use of Tax-Free Alcohol, Part 213, Title 27, Code of Federal Regulations, ATF 5100.9 (12-77).

Drawback on Distilled Spirits Used in Manufacturing Nonbeverage Products, Part 197, Title 26, Code of Federal Regulations, I.R.S. Publication No. 206.

Rules of Practice in Permit Proceedings, Part 200, Title 26, Code of Federal Regulations, I.R.S. Publication No. 289.

REFERENCES

1. Distribution and Use of Denatured Alcohol and Rum, and Tax-Free Alcohol; Final Rule Part II Department of the Treasury Bureau of Alcohol, Tobacco and Firearms. Federal Register, March 6, 1985.
2. Kaul, A.F., Vogenberg, R., and Harsfield, J.C.: Simplified Method of Calculating and Recording the Use of Tax-Free Alcohol. Am. J. Hosp. Pharm., *39*:1525–1528, 1982.

18

Dispensing During Off-Hours

At one time, the major criticism of the small hospital was the lack of clinical ancillary services on a 168 hour per week basis. Over the years, the clinical laboratories, radiology, blood bank and the emergency service have successfully coped with the demand. The one area which has not kept pace has been the pharmaceutical service. Many reasons have been offered for this dilemma, the major ones being the shortage of trained personnel and the prohibitive cost. The percentage of hospital pharmacies providing around-the-clock service has increased from 6% in 1975 to 12% in 1978.[1] and to 19.3% in 1982.[2] The 1982 figures showed 24-hour service in 2.8% of the hospitals with less than 200 beds, 25.4% in hospitals with between 200 to 399 beds, and 70.3% in hospitals with 400 or more beds.[2]

Much has been published relative to the various means whereby a hospital may provide 24-hour a day pharmacy coverage[3,4] and the following represents a brief review of them.

USE OF NURSING SUPERVISORS

The first and probably the commonest method employed today is to permit the evening and night nursing supervisor to enter the pharmacy and provide a limited type of service. Although this method is the most widely used, it is dangerous and in some areas an illegal practice. Those who advocate such a practice are prone to cite the argument that there exists a correlation between the nurse selecting a medicine from the drug cabinet on the pavilion and selecting the same item from the pharmacy. The fallacy of this view is the fact that medications which have been forwarded to the nursing station have already had the benefit of special packaging, handling and labeling by professionally competent and legally qualified individuals.

Therefore, if this is the only means available to the small hospital, it should be practiced with caution. Nursing personnel serving in this category should be specifically prohibited from compounding a mixture and restricted to dispensing from the selection of pre-labeled and prepackaged items.

EMERGENCY BOXES AND NIGHT DRUG CABINETS

The literature is replete with data concerning emergency boxes and night drug cabinets. Since these two items serve a different purpose, we shall discuss them separately.

The *emergency box*, although an integral part of the twenty-four-hour a day pharmacy coverage, is necessary to expedite treatment in situations where time is of the essence. Therefore, the emergency, or as it is often called the "STAT" box, must be large enough to contain the necessary supplies and yet sufficiently compact to facilitate handling them. The box should be kept in a readily accessible place, known to all ward personnel, and should be ready for use at all times. In order to accomplish this goal, the pharmacy should have reserve boxes prepared so that the units may be handled on an exchange basis and thereby reduce the period of time a ward may be without a ready-to-use emergency box.

If it is the hospital's policy to make a charge for the supplies used from the emergency box, then the nurse should prepare a charge ticket and submit it to the pharmacy along with the "used" box.

Some of the larger teaching hospitals have expanded on the emergency box concept and have developed the "emergency cart" or "resuscitation cart." These mobile units have on them the same basic supplies contained in the emergency box plus facilities for the administration of oxygen, the application of suction, and a cardiac pacemaker.

For the convenience of those desiring to establish an emergency box, a list of the pharmaceuticals and ancillary supplies which should be in it is given in Chapter 4, p. 114. However, where the services of a Pharmacy and Therapeutics Committee are available, the pharmacist should consult with the Committee prior to the adoption of a specific list of supplies.

Once an emergency box system is put into effect, the hospital pharmacist is reminded that it should not be forgotten. Many of the drugs which may be placed in the unit may deteriorate if not used within a reasonable period of time, and therefore are useless in an emergency. Therefore, a system of checking all emergency boxes must be initiated and pursued on a regular basis.

One such system requires the hospital pharmacist to check each emergency box on a monthly basis in order to remove outdated and deteriorated medications. This system requires placing an inventory and product control card in the box (Fig. 70). First, it serves as an inventory of the emergency box; second, it shows when the unit was last checked; and third, it provides the nursing personnel with adequate directions for replenishing any item which may have been used.

The *night drug supply cabinet* is basically an adjunct to the charge floor stock medications already on the pavilion. These units also range

EMERGENCY BOX INVENTORY & CONTROL CARD

Inventory	Product	Monthly Control Check J	F	M	A	M	J	J	A	S	O	N	D
6 ampuls	Aminophyllin 250 mg I.V.	V	V	V	V								
4 ampuls	Calcium Gluconate 10 ml I.V.	V	V	V	V								
6 ampuls	Digitoxin 0.2 mg I.M.	V	V	V	V								

Fig. 70.

from a simple cabinet with drawers to large elaborate installations which include narcotic vaults and refrigerated compartments.[5]

The large cabinets are usually constructed in a wall of the pharmacy so that the unit may be serviced from within the pharmacy yet is accessible from the corridor side to authorized nursing personnel.

The night drug supply cabinet should be stocked with pre-packaged and labeled containers of the drug listed in the hospital formulary which the Pharmacy and Therapeutics Committee deems advisable. In addition, many hospitals also store certain medical and surgical supplies such as Foley catheters, oxidized cellulose and elastic hosiery.

The nursing supervisor opening the unit is required to leave a properly identified charge ticket listing the item removed and to whom it was administered. The next morning, pharmacy personnel restock the unit and forward the charge tickets to the accounting office.

Although the cost of purchase and installation of a night service cabinet may seem high to those who have inquired about such a unit, it would seem to be reasonably safe to state that the control of inventory which such a unit provides will more than offset its initial purchase and installation. Any plans for the construction of a new pharmacy or the renovation of existing quarters should include such a unit.

USE OF PHYSICIANS

Next to the use of registered pharmacists, a safe administrative and legal practice would be to prohibit nursing personnel from entering the pharmacy after hours and require that the physician enter the pharmacy and obtain any special medication not provided through the floor stocks, night cabinets or emergency box.

The major drawbacks to this method are first that the physician might waste a great deal of time searching for a product in unfamiliar surroundings and second, in these days of physician shortages, it is an unfair burden to place upon their already heavily taxed work hours.

This system does, however, possess one major advantage in that

rather than enter the pharmacy, the physician may be influenced to use a drug which will accomplish the same purpose, yet is more readily available.

PHARMACIST-ON-CALL

Like all professional personnel, the hospital pharmacist understands the necessity of providing twenty-four-hour coverage and, therefore, will not hesitate to accept his share of an on-call assignment. In order to encourage this type of coverage, many administrators have developed bonus or extra pay plans to compensate the pharmacist.

Where the hospital employs a number of pharmacists, the institution of a rotational plan of on-calls will not burden any single individual.

In communities where more than one hospital is in operation, it is recommended that the pharmacists join forces in providing twenty-four hour on-call service. Under such a system, one pharmacist will be assigned to on-call duty for any one period of time and he, therefore, will answer the needs of both institutions. This type of cooperation will spread out the frequency of on-call duty and, at the same time, acquaint a second person with the routine of each hospital in case of an emergency or sick leave and vacation coverage.

PURCHASED SERVICE

Hospitals employing only one staff pharmacist have found a practical solution to the dilemma by contracting with the local community pharmacy for night, holiday and vacation relief for the staff pharmacist.

This method is a safe and legal one which, while protecting the drug needs of the hospital and patient, establishes good will in the community and perhaps a better understanding of the efforts of the hospital to safe-guard the health needs of the area on a round-the-clock basis.

Where there is more than one pharmacy in the community, care should be taken to avoid any claims of favoritism or politics. One method by which this may be accomplished is to develop a set of specifications and requirements concerning the desired service and request the local establishments to submit their bids. Obviously, the specifications should be so prepared that only the retail pharmacies with adequate staff, inventory, and delivery service can qualify to bid.

In recent years, much has been done to make drugs available on the pavilions in order to cope with every emergency. Some of these methods include the use of mechanical dispensing units, self-medication programs and centralized unit dose dispensing system available around the clock.

EXTENDING PHARMACY SERVICE HOURS

Emergency after-hour pharmacy services in hospitals have been replaced by around the clock coverage by staff pharmacists. In those smaller hospitals that are currently struggling to provide safe medications during off-hours, efforts should be made to convince hospital administration to financially support the broader pharmaceutical coverage. One survey[2] reveals that hospital pharmacists utilized the following reasons to convince management to support the extension of services:

1. Provided continuity for the IV admixture program.
2. Provided continuity for the unit dose program.
3. Provided medication to the night shift that is least experienced and newest to the hospital; reluctance or refusal by, and the time constraints on the night nursing supervisor allowed more involvement with nursing rather than pharmacy problems.
4. Provided continuity with the drug information service.
5. Provided continuity for the drug monitoring system.
6. Helped to prevent serious medication error(s) at night.

The ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control provides the following statements with regard to emergency medical supplies and the provision of pharmaceutical service after hours:[6]

Emergency Medication Supplies. A policy to supply emergency drugs when the pharmacist is off the premises or when there is insufficient time to get to the pharmacy should exist. Emergency drugs should be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies. The emergency drug supply should not be a source for normal "stat" or "p.r.n." drug orders. The medications included should be primarily for the treatment of cardiac arrest, circulatory collapse, allergic reactions, convulsions, and bronchospasm. The pharmacy and therapeutics committee should specify the drugs and supplies to be included in emergency stocks.

Emergency drug supplies should be inspected by pharmacy personnel on a routine basis to determine if contents have become outdated and are maintained at adequate levels. Emergency kits should have a seal which visually indicates when they have been opened. The expiration date of the kit should be clearly indicated.

Pharmacy Service When the Pharmacy is Closed. Hospitals provide services to patients 24 hours a day. Pharmaceutical services are an integral part of the total care provided by the hospital, and the services of a pharmacist should be available at all times. Where around-the-clock operation of the pharmacy is not feasible, a pharmacist should

be available on an "on-call" basis. The use of "night cabinets" and drug dispensing by nonpharmacists should be minimized, and eliminated wherever possible. (See Chapter 14, Fig. 46.)

Drugs must not be dispensed to outpatients or hospital staff by anyone other than a pharmacist while the pharmacy is open. If it is necessary for nurses to obtain drugs when the pharmacy is closed and the pharmacist is unavailable, written procedures covering this practice should be developed. They generally should provide for a limited supply of the drugs most commonly needed in these situations; the drugs should be in proper single-dose packages and a log should be kept of all doses removed. This log must contain the date and time the drugs were removed, a complete description of the drug product(s), name of the (authorized) nurse involved, and the patient's name.

Drugs should not be dispensed to emergency room patients by nonpharmacist personnel if the pharmacy is open. When no pharmacist is available, emergency room patients should receive drugs packaged, to the extent possible, in single unit packages; no more than a day's supply of doses should be dispensed. The use of an emergency room "formulary" is recommended.

SELECTED READINGS

Ross, A.J.: Extended Hours of Service. Pharm. J., *221*:526–527, (Dec.) 1978.
Upton, J.H.: Justifying 24-Hour Pharmaceutical Services. Am. J. Hosp. Pharm., *39*:2072–2078, (Dec.) 1982.

REFERENCES

1. Stolar, M.H.: National Survey of Hospital Pharmacy Services—1978. Am. J. Hosp. Pharm., *36*:316:316–325, (Mar.) 1979.
2. Kessler, H. and Davis, N.M.: Survey of 24-Hour, 7-Day/Week Hospital Pharmacy Service. Hosp. Pharm., *19*:5:327, (May) 1984.
3. Hassan, William E. Jr.: Six Ways to Provide Pharmacy Coverage After Normal Hours, Hospitals. J.A.H.A., *32*:54, May 16, 1958.
4. Jeffrey, Louis P.: Around the Clock Pharmacy Service. Am. J. Hosp. Pharm., *15*:12:1064, 1958.
5. Thompson, Richard F. and Feely, William J.: A Pharmacy Night Cabinet. Hospital Pharmacy, *6*:10:21, (Oct.) 1971.
6. ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control. Am. J. Hosp. Pharm., *37*:1097–1103, (Aug.) 1980.

19

Hospital Reimbursement

Because of the remarkable change in the manner in which the health care industry is reimbursed, it is important for the institutional practitioner to be aware of these reimbursement systems and their evolution. Irrespective of the reimbursement methodology of the third party payors or the jurisdiction in which the hospital is located, there is an impact on the daily operation of the department of pharmacy services.

BLUE CROSS PLAN

Established in the 1930s, the concept of the Blue Cross plan today boasts a membership of upwards of 60 million people. The importance of this plan is further emphasized when one learns that in some hospitals nearly 75% of all admissions are covered by a Blue Cross plan.

Under this type of coverage the hospital is paid, in addition to a portion of the room and board charge, an amount for ancillary services which is determined by a "reimbursement formula" or published charges, whichever is the lower.[a] In arriving at the actual dollar rate of reimbursement, the Blue Cross auditors exclude the cost of teaching, research and capital expenditures.

Since the reimbursement rate for ancillaries includes the cost of drugs, the pharmacist should be aware of the fact that the drug portion of this reimbursement is arrived at by determining the average drug cost per patient day.

The average drug cost per patient day is calculated by dividing the actual cost of drugs issued by the hospital for the fiscal year by the total number of patient days for the same period. The average cost per patient day is also ascertained for all other ancillary services rendered by the hospital.

A state-approved reimbursement formula is then applied to the average cost per patient day figures which then results in a dollar rate which will be paid to the hospital for every Blue Cross patient day of service rendered to the plan's subscribers.

With the advent of the DRG prospective payment system, Blue Cross,

[a]Varies with plan.

as Medicare intermediary, reimburses hospitals for all Medicare patients on that basis.

Many Blue Cross plans have developed and operate a wholly owned HMO subsidiary as a defensive measure to prevent an erosion of Plan membership to competing alternative health care delivery systems.

COMMERCIAL INSURANCE PLANS

Present-day insurance plans are of the deductible and co-insurance type. The deductible portion of the policy is primarily intended to eliminate small nuisance claims. However, many individuals who have a Blue Cross plan paid for by their employer purchase a commercial policy with the deductible portion being the maximum allowed by the Blue Cross plan. One of the reasons advanced for this is the lower cost to the subscriber and yet it provides him with extremely broad hospitalization insurance.

Because the deductible and co-insurance type of policy often provides for a specific maximum aggregate benefit, insurance carriers imposed the co-insurance factor as a control on the quantity and type of medical care to be received by the policyholder. Under such plans, the insurance carrier will pay a stated percentage of the medical expense and the policyholder undertakes to pay the balance.

Under the commercial insurance plans, the insured, if he has no other type of coverage, pays the deductible amount of his policy and the co-insurance amount, the balance being covered by the insurance company.

From the above brief comparison of the Blue Cross plan with that of a commercial type health insurance plan, it should be clear that the Blue Cross subscriber utilizing the hospital pays for his drugs and other ancillary services on the basis of actual cost to the hospital, whereas the patient without any form of coverage or with commercial health insurance may pay the hospital's published charges.

MEDICARE COST-PER-CASE MANAGEMENT CONCEPT

The 1982 Medicare Amendments made drastic changes in hospital payment policies. These changes (1) replaced routine per diem cost limits with total operating cost-per-case limits; (2) authorized "incentive payments" to hospitals that hold costs below a Medicare cost-per-case target; and (3) mandated the development of a prospective payment proposal for consideration by the Congress in 1983.

Historically, the Medicare program was created in 1965 to improve access to needed health services by the elderly. It provided for a comprehensive benefit package for patients with modest cost-sharing; physician payment based on usual, customary and reasonable fees; and

hospital payment based on "reasonable costs." It was these incentives that caused increased utilization and intensity of services that has nearly bankrupted the system.

The new revisions limit average Medicare reimbursable total operating cost-per-case. For each hospital, two limits are set: a target cost-per-case and a Section 223 maximum allowable cost-per-case. The lower of these two limits is applied, although costs in excess of the target cost-per-case are partially reimbursable while 100% of the costs in excess of the Section 223 limit must be absorbed by the hospital.[18]

The cost-per-case target is calculated by applying an allowable rate of increase to the hospital's actual historical cost-per-case. The limit applies to total operating costs, including both routine and ancillary services but excluding capital and teaching costs. The allowable rate of increase is determined by the HCFA market basket index plus one percent. Hospitals able to contain their average cost-per-case to a level below their target ae permitted to retain 50% of the savings.[18]

MEDICARE PROSPECTIVE PRICING CONCEPT

On March 24, 1983, Congress approved a Medicare prospective pricing plan as part of the Social Security Amendments of 1983. Unlike the system of the Tax Equity and Fiscal Responsibility Act cost-per-case limits, the approach to Medicare prospective pricing (1) sets pricing for each Diagnosis Related Group (DRG) rather than establish a case mix adjusted cost-per-case limit for the hospital; (2) severs the traditional relationship between Medicare revenues and costs; and (3) places the hospital "at risk" for differences between average costs within DRGs and the DRG prices.[19]

Because of the "at-risk" factor, hospitals must be managed within the limits of available revenues and therefore must control the length of stay, use of ancillary services and the mix of patients admitted within each DRG.

Basis of Payment

The discharge will be the unit of payment in the Medicare prospective pricing system. Over a 4-year period, a system of prospective pricing will be phased in that establishes separate urban and rural national DRG price schedules, adjusted for variations in wage levels. During the phase-in period, the payment for each Medicare discharge will be computed by blending a hospital-specific cost-per-case amount, the regional urban or rural price for the DRG to which the patient is assigned (adjusted for variations in wage levels), and the national urban or rural price for the DRG to which the patient is assigned (adjusted for variations in wage levels).

- In the first year, the payment for each Medicare patient will be equal to:
— 75% of the hospital-specific cost-per-case amount; PLUS
— 25% of the regional average price for the patient's DRG.
- In the second year, the payment for each Medicare patient will be equal to:
— 50% of the hospital-specific cost-per-case amount; PLUS
— 37.5% of the regional average price for the patient's DRG; PLUS
— 12.5% of the national average price for the patient's DRG.
- In the third year, the payment for each Medicare patient will be equal to:
— 25% of the hospital-specific cost-per-case amount; PLUS
— 37.5% of the regional average price for the patient's DRG; PLUS
— 37.5% of the national average price for the patient's DRG.

In the fourth year, payments will be based on the urban or rural national average price for each DRG, adjusted for differences in area wages.[19]

The American Hospital Association has succinctly summarized this legislation as follows:[19]

Hospitals and Services Covered. All hospitals except long-term, children's, psychiatric and rehabilitation hospitals. Distinct part psychiatric and rehabilitation units of general hospitals are also exempt, and hospitals designated as sole community providers are given special treatment. Outpatient services and services provided in exempt distinct part units of general hospitals will be paid for on the basis of retrospectively determined costs.

Effective Dates. Prospective payment replaces the TEFRA cost-per-case limits in hospital fiscal years beginning on or after October 1, 1983.

Unit of Payment. When the prospective pricing system is fully phased in separate prices will be established for each of the Medicare Diagnosis Related Groups (DRGs). During the phase-in period payments will be calculated on a per-discharge basis.

Method of Computing Payments. During a three year phase-in period, the payment for each hospital discharge will be a blend of a hospital cost-per-case amount, a regional average price for the DRG to which a patient is assigned, and the national average price for the patient's DRG. Separate DRG prices will be computed for urban and rural hospitals. The regional and national prices will be adjusted for the wage level in the hospital's area. Beginning in the fourth year, prices will be set on the basis of the national average price for urban or rural hospitals.

Price Adjustment Factor. During the first two years of prospective pricing a base year cost-per-case will be rolled forward by the rate of increase in the hospital market basket, plus one percent for technology. Adjustments will be made to ensure that total Medicare expenditures are no greater under prospective payment than under the TEFRA cost-per-case limits. In subsequent years, the price adjustment factor will

be determined by the Secretary in consultation with an independent commission.

Payments for "Outliers" and "Atypical Cases". "Atypical" or "outlier" cases include patients whose length of stay exceeds the average for the DRG by either a fixed number of days or a fixed number of standard deviations and, if approved by HCFA, patients whose costs are a "fixed multiple" of the average cost in the DRG to which the patient is assigned. Payments for "outlier" cases will be based on the "marginal costs" of the days beyond the cut-off level.

Payment of Exempt Providers. Hospitals exempt from the prospective payment system, including distinct part rehabilitation and psychiatric units of general hospitals will be reimbursed on the basis of retrospectively determined costs, subject to the cost-per-case limit on the allowable rate of increase established by TEFRA. The "section 223" limit will not apply to these hospitals.

Treatment of Capital Costs. During the first three years of the program, capital expenses will be reimbursed on the basis of retrospectively determined costs. Separate identification of capital costs incurred after the date of enactment may be required. Capital costs will be incorporated into the prospective prices beginning in year four.

Treatment of Education Costs. The direct expenses of approved education programs will be reimbursed on the basis of retrospectively determined costs.

Treatment of Indirect Medical Education Costs. The indirect costs of medical education will be reimbursed on the basis of an "indirect medical education allowance" equal to 12.12% of direct operating costs for each increment of 0.1 in the ratio of full time equivalent interns and residents to beds.

Appeals. Hospitals may appeal the incorrect application of the prospective pricing methodology and errors in calculation. The adequacy of the prices established by the correct application of the methodology may not be appealed.

DRUG UTILIZATION REVIEW (DUR)

Hoffman[20] has described a strategy aimed to reduce drug expenditures with a drug utilization review (DUR) program. The importance of this type of program is underscored by the spiraling rise in health care expenditures and the influence of costly new drug technology. The program described consists of a utilization review of high cost drugs for which a lower cost alternative exists. The following is a condensation of the essential elements of the Hoffman strategy:

1. Establish drug usage criteria through literature review and consultations.
2. Obtain medical staff approval and endorsement.

3. Inservice the pharmacy staff on the approved drug usage criteria.
4. Employ a DUR pharmacist who will, on a daily basis, compare the prescribed drug use to the approved criteria and contact the prescriber when the usage appears to be inappropriate.

Hoffman[20] also presents a job description for a DUR pharmacist. Some of the representative duties include but are not limited to:

1. Implements DUR programs as needed in conjunction with the pharmacy and medical staff.
2. Conducts regular educational programs for medical, nursing and pharmacy staffs regarding drug utilization.
3. Monitor drug expenses and utilization on a regular basis.
4. Maintains and updates DUR literature file.
5. Assists in the maintenance of the hospital drug formulary.

PRICING OF DRUGS

Much has been published concerning the pricing of prescriptions in the retail pharmacy.[1–3] In addition, various pricing schedules have been developed and made available to the community pharmacist.[4]

On the other hand, the problem of pricing policy has remained local in nature. That is, some state hospital pharmacy groups have undertaken pricing surveys and have published the data obtained.[5] This type of information, although of local comparative value, does nothing in the way of establishing a workable nation-wide hospital pharmacy prescription pricing formula from which each hospital may develop its own schedule of prescription prices.

At the present time, too many hospital pharmacists establish prescription prices blindly. That is to say, their prices are simply based on a percentage mark-up over cost. The percentage selected is usually that of a neighboring hospital or what is thought to be prevalent in the local community pharmacies.

In hospitals with low direct and indirect costs, the arbitrarily selected percentage mark-up figure may be high enough to permit a profitable operation. If, on the other hand, the direct and indirect costs are high, an operating loss seems a reasonable certainty.

Therefore, it behooves the hospital pharmacist to work closely with the comptroller in order to establish the departmental direct and indirect cost. Once ascertained, this figure when divided by the number of prescriptions filled will result in a unit prescription portion of the operational expense. From this, it should not be too difficult for the pharmacist to visualize the end of the spectrum in which he is operating. In this calculation, "the number of prescriptions filled" has been used as the denominator. For general purposes, "prescription" here is intended to mean out-patient prescription, take-home drug prescription

and in-patient drug order since irrespective of how the medication is administered or where it is consumed, the *dispensing* aspect remains the same.

To this point, discussion has been aimed at developing an equitable price for drugs to be charged to all categories of patients and yet to be in a position to fully protect the hospital's financial interests in any transaction involving the sale of drugs to patients who do not have any form of insurance, as well as those who are covered by a commercial carrier whose policy provides for the payment of posted charges. Therefore, nothing has been mentioned of those patients whose hospital and medical needs are paid for by third party payors, other than Blue Cross, Medicare and commercial insurance companies. These third party payors may be welfare agencies, industrial accident groups, or various governmental bureaus providing aid to the blind, to families of dependent children, to crippled children or for vocational rehabilitation.

Patients admitted to the hospital under the sponsorship of these agencies are accepted for a specified all-inclusive per diem rate, generally the Medicaid rate. Therefore, any difference between the hospital's posted charges and the per diem rate is considered to be an allowance by the hospital.

However, when the patients of some of these agencies are seen in the hospital clinics and receive a prescription, an entirely different pricing policy may be put into effect. This special pricing schedule is usually prepared by the agency and becomes a part of the agency's contract with the hospital.

PER DIEM DRUG CHARGE

The itemized pharmacy charges for 250 patients were studied to determine the average daily charges for drugs and pharmaceutical services. A comparison of the actual charges and the projected per diem rate indicated that the per diem rate would produce the same revenue as the itemized charging method. The per diem system enabled the hospital to reduce administrative and accounting costs while continuing to provide quality pharmaceutical service.[17]

Other hospitals have explored various methods of combining the per diem drug charge with fees for special clinical services. Yet others have advocated flat fees based on the medication record; a mark-up plus a dose fee and a combined product and service per diem fee. These concepts may be explored further by reading the articles cited under **Selected Readings** at the end of this chapter.

PROFESSIONAL FEE CONCEPT

The fee concept has been defined[6] as follows.

"... the exclusive use of a professional fee to meet all operating expenses, including overhead and compensation, but not the actual cost of drug and container."

Many hospital pharmacists have developed a professional fee system to be used in their hospitals.[7-10] These individuals report that the concept has found acceptance with both the public and medical staff.

One hospital pharmacist[11] states:

"This system incorporates two basic elements in the charge; the cost of the medication and an added fee that will recover the expense of operating the pharmacy and the share of the total hospital expense assumed by the pharmacy. These two elements are combined into one charge to the patient."

The professional fee concept should not be confused with the traditional retail theory of "mark-up" or "margin." These two terms generally imply that a per cent of the wholesale cost or selling price is used as the basis for recovering all direct and indirect expenses.

Many pharmacists are of the opinion that, as a professional member of the health team, the pharmacist should make a charge for his services which is separate and distinct from the cost of the medication and its container. It is further argued that the fee concept is more equitable to and better understood by the patient since he is accustomed to paying professional fees to doctors, dentists or lawyers.

The House of Delegates of the American Society of Hospital Pharmacists adopted the following resolution.[12]

Whereas the professional fee concept is recognized as a project consistent with the objectives, basic truths and goals of the ASHP statement on Goals for Hospital Pharmacy, now therefore be it
RESOLVED that the Society urge the adoption of the professional fee concept by hospital pharmacists, and be it further
RESOLVED that the Society assist hospital pharmacists in adopting the professional fee concept by providing information in the American Journal of Hospital Pharmacy, at continung education programs, and through related sources.

In order to make use of the fee concept in the pricing of prescriptions, the hospital pharmacist should become acquainted with all aspects of his direct and indirect operating costs so that he may arrive at a "fee" which in fact will meet all operating expenses. The thought has been advanced, in some circles, that a professional fee should be the same for all pharmacists in any one locality. Although this concept of standardizing the professional fee rates highly when one considers the public relations aspect, it is not advisable according to sound business and legal principles.

Reimbursement for pharmaceutical services under Title XIX (Medicaid) programs is now based upon "actual acquisition costs of the drug

plus a fixed fee." The "fixed fee" is the terminology used by the Federal government for "professional fee."

At the present time, there rages within the profession a controversy relative to the definition of the term "acquisition cost." The issue seems to center around the role to be given to free goods, special discounts and direct purchasing credits in ascertaining the actual acquisition cost.

BREAK-EVEN POINT PRICING

A useful tool in the overall analysis of cost-volume-profit relationships is the break-even point which is defined as that level at which there is neither profit or loss.

Foulke[13] states that the existence of a break-even point is not a matter of theory but is a practical analytical factor which is useful in the comparison of net sales, expenses and operating profits within a budget; to ascertain the necessary increase in net sales to justify expansion of plant or personnel and to determine the effect upon net profits by any changes in personnel or material costs.

The application of the break-even principle has been applied to the pricing of drugs both in the in-patient and out-patient pharmacies.[14]

To adapt the break-even point to the pricing of drugs requires that the pharmacist be in a position to ascertain the fixed and indirect expenses of his department, and then be in a position to charge to the dispensing unit its fair share of these expenses.

In general, the costs of a department of pharmacy should include its proportionate cost of the hospital's administration, maintenance and housekeeping, depreciation of plant and equipment, and labor. These figures may be obtained from the hospital's comptroller since they are usually required of him in the preparation of the hospital's annual report to the Department of Public Health's Division of Hospitals. If these figures are not available, then the pharmacist may, with the co-operation of the comptroller, determine them.

For example, the pharmacy's share of the maintenance and housekeeping costs may be determined by calculating the total cost of these services to the hospital and dividing this figure by the total number of square feet of floor space utilizing these services. The resulting figure is the maintenance and housekeeping costs per square foot. By taking the total number of square feet in the pharmacy dispensing unit and multiplying by the maintenance-housekeeping cost per square foot, the pharmacy dispensing unit thereby is charged with its fair share. The actual cost of these services divided by the number of prescriptions filled on an average day results in the cost of these services per prescription.

1. Total cost of maintenance and housekeeping to the hospital	$100,000
2. Total of number square feet in the hospital	100,000
3. Maintenance-Housekeeping costs per square foot	$1.00
4. Pharmacy dispensing unit in square feet	25
5. Maintenance-Housekeeping costs per sq. ft. of dispensing unit (#3 multiplied by #4)	$25.00
6. Number of prescriptions filled daily	100
7. Maintenance-Housekeeping cost per prescription	$.25

Other indirect overhead costs such as the unit's share of administration, heat, light, water (these are not usually metered to each department) may be similarly obtained by arriving at a common denominator such as square feet or space; total number of personnel employed or number of quota hours assigned to the department.

Depreciation of equipment and direct costs, such as the pharmacist's time, cost of container and label, laundry, etc., are readily calculable.

Once the direct and indirect operational costs are determined, to them is added the cost of the container and the cost of the drug. The total of these factors represents the break-even point.

COMPUTERIZED PRICING AND INVENTORY CONTROL

A computerized on-line pharmacy pricing and inventory control system has been developed and is in use in a 940-bed hospital. The program requires input of only four pieces of information: (1) patient number; (2) drug identification number; (3) dose factor; and (4) total number of doses dispensed.

In the pricing formula, the charge to the patient is calculated by adding the product of the total cost of medication and the mark-up factor to the product of the dose fee and the total number of doses received.

The system is stated to have the following advantages: (1) the patient or third party payor can be given an itemized bill for all pharmaceutical charges; (2) the system accounts for all medication costs whether or not they are charged to the patient; (3) the revenue for the department can be projected and adjusted accurately; (4) the charges are fair and equitable; (5) the patient is charged for medication administered only; and (6) the system produces accurate statistical reports for both the pharmacy and financial departments. A major disadvantage is stated to be the number of man-hours needed for the pricing function.[16]

PUBLIC LAW 89-97 (MEDICARE)

This legislation provides three programs for health insurance and medical care under the Social Security Act.

The basic responsibility for administration of the insurance program is vested in the Secretary of Health and Human Services. Within this authority, the administrative and operational responsibility will be in the Social Security Administration, with responsibility for certain professional aspects in the Public Health Service.

The Social Security Administration will make use of state agencies and organizations to assist in the administration of the program.

In view of the fact that drugs will be an integral part of the care rendered under these programs, it is essential that the hospital pharmacist familiarize himself with the basic requirements of each in order that he may develop proper charge procedures for the drugs dispensed to the enrollees.

I. TITLE XVIII (A)—COMPULSORY HOSPITAL PROGRAM

The first of these programs, the "compulsory hospital program," became effective July 1, 1966, and provides the following basic benefits to about 19 million persons aged 65 or older:

1. *In-patient hospital services*—For up to 90 days in semi-private accommodations during an illness. The patient pays the first $400 of the costs. If he stays in the hospital for more than a 60-day period, he also pays $100 for each day between 61st and 90th days. Psychiatric hospital in-patient services are limited to 190 days during a lifetime.
2. *Posthospital extended care services*—For up to 100 days, beginning January 1, 1967. The patient pays $18 for each day over 20 days.
3. *Posthospital home health services*—Nurses' or technicians' services for up to 100 home visits after discharge from a hospital or extended care facility.
4. *Out-patient hospital diagnostic services*—Patient pays $75 deductible and 20% of any charges in excess of $75 during a 20-day period.

Life-time reserve—Limited to 60 days during which the patient is required to pay for services rendered up to $200 per day.

The "in-patient hospital services" benefits includes drugs and biologicals ordinarily furnished by the hospital for the care and treatment of in-patients. "Posthospital extended care services" include drugs and biologicals ordinarily furnished by the nursing home. Drugs and biologicals are presently excluded from coverage in the "posthospital home health services."

The terms "drugs and biologicals" are specifically limited by the law to drugs included (or approved for inclusion) in *The United States Pharmacopeia, The National Formulary, The United States Homeopathic Pharmacopeia, New Drugs*, or *Accepted Dental Remedies*, and

drugs approved by the Pharmacy and Therapeutics Committees of the furnishing hospitals.

This program will be financed by increased social security payments. Payments for benefits will be made directly by the Federal Government to the providers of services who have entered into an agreement with the Secretary of Health and Human Services or by selected private insurance carriers who will act as intermediaries.

II. TITLE XVIII (B)—VOLUNTARY INSURANCE PROGRAM

The second of the programs, the "voluntary insurance program," became effective on July 1, 1966, and provides medical insurance for persons 65 or over who elected to enroll under it at a cost of $3 each. It was financed from premiums paid by the enrollees and by funds appropriated by the Federal Government. The services provided under this program are:

1. Home health services for up to one hundred visits during a calendar year.
2. Medical and other health services including:
   a. Physicians' and surgeons' services, whether furnished in the hospital, office, or home.
   b. Diagnostic x rays and laboratory tests, electrocardiograms, and other diagnostic tests.
   c. Surgical dressings and splints; casts and other devices for reduction of fractures and dislocations; braces and artificial limbs; prosthetic devices; rental of durable medical equipment such as iron lungs, oxygen tents, hospital beds, and wheelchairs used in patients' homes.
   d. Ambulance services.

Payment for these services will be made by the Federal Government directly to the provider of such services or by private insurance carriers based upon a co-payment factor. Drugs and biologicals are specifically excluded from "home health services." They are only covered in the "medical and other health services" if they cannot be self-administered and if they are furnished either as an incident to a physician's professional service or as a hospital service incident to a physician's service rendered to outpatients.

III. TITLE XIX—MEDICAID

Basically, Title XIX is an extended Kerr-Mills type of program. As written, it will have the following effects:

1. Serve to foster the present "vendor payment" type of system by increasing the amount of Federal matching funds under a formula based on state per capita income (ranges from 55 to 83%).

2. Consolidate all state programs under one state administrator.
3. Broaden the scope of state programs to include more people and more services for many of these people by providing at least the following services to those eligible:
   a. In-patient hospital services
   b. Out-patient hospital services
   c. Other laboratory and x-ray services
   d. Skilled nursing home service
   e. Physician's services

Under this program the supply of drugs is optional, but it is felt that most states will elect to supply them.

Title XIX is potentially larger than the other two Medicare programs since it authorizes and encourages government-assisted medical care to *all* persons receiving public assistance and to many other persons in need of medical aid regardless of age. It has been estimated that this program could encompass as many as 35 million people.

CONDITIONS OF PARTICIPATION

The rules governing the aspects of the Medicare program are known as the *Conditions of Participation for Hospitals.* These were issued by the Social Security Administration after extensive consultation with the Health Insurance Benefits Advisory Council—commonly referred to as HIBAC.

Accordingly, it is from this document[15] that the following information governing the participation of hospitals and allied health agencies is obtained.

General Hospitals

Since the Joint Commission on Accreditation of Hospitals has adopted a requirement for utilization review, any hospital accredited by this group would generally be conclusively presumed to meet all the conditions for participation in the program.

The regulations also provide that accreditation by the American Osteopathic Association, or any other national accrediting body, may also be accepted if it is reasonable to do so, as evidence that a hospital meets some or all of the conditions of participation.

Further stipulations require the hospital to be licensed, certified or approved by the state (local law equivalents to licensing meet this requirement) and it must substantially comply with regulations pertaining to medical records, medical staff by-laws, pharmacy and therapeutics committees to mention a few.

Further requirements necessary to the health and safety of patients may be imposed by the Government; however, these health and safety

requirements cannot be more strict than the comparable conditions enforced by the Joint Commission on Accreditation of Hospitals.

The regulations also permit the state to establish stricter requirements if such are specified under its Federal-State medical assistance programs. These stricter requirement may be enforced by the sovereign state even if they are not used in its own programs.

Psychiatric and Tuberculosis Hospitals

In order to avoid paying for care that is merely custodial in nature, the conditions of participation require that the institution:

(1) be accredited by the Joint Commission on Accreditation of Hospitals:
(2) maintain clinical records which are adequate to ascertain the degree ad intensity of treatment furnished to the insured; and
(3) meet staffing requirements commensurate with those needed for carrying out an active treatment program.

The regulations also dictate that a distinct part of the institution may participate as a psychiatric or tuberculosis hospital, if it meets the above conditions, even though the institution of which it is a part does not. Also, if the distinct part of the institution meets requirements equivalent to accreditation requirements, it may qualify under the program even though the institution is not accredited.

Conditions of Participation for an Extended Care Facility

An extended care facility is liberally defined as a skilled nursing home or a distinct part of an institution, such as a ward or wing of a hospital.

An institution which is primarily for the care and treatment of mental diseases or tuberculosis is excluded from the definition of an extended care facility.

In general, extended care facilities will be required to have an agreement with a hospital for the transfer of patients and interchange of medical records. This requirement may be waived where an extended care facility has attempted, in good faith, to arrange a transfer agreement but failed and the State agency finds that the facility's participation in the hospital insurance program is in the public's interest and essential to assuring necessary care to the insured inhabitants of the community.

It should be emphasized that the requirement for a transfer agreement does not mean that a patient would have to be transferred between a hospital and extended care facility which have such an arrangement between them. A transfer agreement with any hospital would qualify the facility so that the patient's extended care would be paid for if he was admitted upon transfer from some other hospital.

Since the extended care facility is expected to render high-quality convalescent and rehabilitative care, it must meet the following requirements. They include:

(1) around-the-clock nursing services with at least one registered nurse employed full time;
(2) the availability of a physician to cope with emergencies;
(3) utilization review;
(4) proper methods for handling drugs; and
(5) the maintenance of adequate medical policies, governing the nursing care and related services.

Conditions of Participation for a Home Health Agency

Visiting nurse organizations, hospital-operated home-care services as well as agencies specifically established to provide a broad spectrum of home health services are examples of home health agencies which may qualify under the program. A private organization providing home care on a profit basis may qualify if it is licensed, where State law requires it, and if it meets specified standards.

In general, a home health agency in order to partipate will have to be:

(1) publicly owned; or
(2) a nonprofit organization exempt from Federal taxation; or
(3) licensed and meet staffing requirements and other conditions and standards prescribed by regulation.

It should be recognized that not all institutions desiring to participate will be certified for this purpose. Therefore, it will be possible for an insured person to encounter a medical emergency and find that he is admitted to a hospital not participating in the hospital insurance program. In these situations, the law permits the payment of benefits for emergency hospital diagnostic services or in-patient care until it is no longer necessary from a medical point of view to care for the patient in a non-participating institution provided that the hospital agrees not to charge the patient amounts (except the deductibles and co-insurance) in addition to the program's payments for covered services.

Conditions of Participation for Hospitals: VIII Pharmacy or Drug Room

Drugs and biologicals furnished to hospital patients for their use while in-patients will be paid for under the health insurance program provided that the conditions of participation applicable to the pharmacy or drug room are complied with.

The following are conditions of participation as they apply to the hospital pharmacy.

STANDARD A—PHARMACY SUPERVISION

There is a pharmacy directed by a registered pharmacist or a drug room under competent supervision.

Factor 1. The pharmacist is trained in the administration of hospital pharmacy.

Factor 2. The pharmacist is responsible to the administration of the hospital for developing, supervising, and coordinating all the activities of the pharmacy department.

Factor 3. If there is a drug room with no pharmacist, prescriptions are compounded by a qualified pharmacist elsewhere, and only storing and distributing are done in the drug room. A consulting pharmacist assists in drawing up the correct procedures, rules, and regulations for the distribution of drugs, and visits the hospital on a regularly scheduled basis in the course of his duties. Whenever possible, the pharmacist, in dispensing drugs, works from the prescriber's original order or a direct copy.

STANDARD B—PHYSICAL FACILITIES

Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs.

Factor 1. Drugs are issued to floor units in accordance with approved policies and procedures.

Factor 2. Drug cabinets on the nursing units are routinely checked by the pharmacist. All floor stocks are properly controlled.

Factor 3. There is adequate space for all pharmacy operations and the storage of drugs at a satisfactory location provided with proper lighting, ventilation, and temperature controls.

Factor 4. If there is a pharmacy, equipment is provided for the compounding and dispensing of drugs.

Factor 5. Special locked storage space is provided to meet the legal requirements for storage of narcotics, alcohol, and other prescribed drugs.

STANDARD C—PERSONNEL

Personnel competent in their respective duties are provided in keeping with the size and activity of the department.

Factor 1. The pharmacist is assisted by an adequate number of additional registered pharmacists and such other personnel as the activities of the pharmacy may require to insure quality pharmaceutical services.

Factor 2. The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:
(i) Chief pharmacist; (ii) One or more assistant chief pharmacists; (iii) Staff pharmacists; (iv) Pharmacy residents (where a program has been activated); (v) Non-professionally trained pharmacy helpers; (vi) Clerical help.

Factor 3. Provision is made for emergency pharmaceutical services.

Factor 4. If the hospital does not have a staff pharmacist, a consulting pharmacist has overall responsibility for control and distribution of drugs and a designated individual(s) has responsibility for day-to-day operation of the pharmacy.

STANDARD D—RECORDS

Records are kept of the transactions of the pharmacy (or drug room) and correlated with other hospital records where indicated. Such special records are kept as are required by law.

Factor 1. The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for: (i) Maintaining adequate control over the requsitioning and dispensing of all drugs and pharmaceutical supplies; (ii) Charging patients for drugs and pharmaceutical supplies.

Factor 2. A record of the stock on hand and of the dispensing of all narcotic drugs is maintained in such a manner that the disposition of any particular item may be readily traced.

Factor 3. Records for prescription drugs dispensed to each patient (in-patients and out-patients) are maintained in the pharmacy or drug room containing the full name of the patient and the prescribing physician, the prescription number, the name and strength of the drug, the date of issue, the expiration date for all time-dated medications, the lot and control number of the drug, the name of the manufacturer (or trademark) and (unless the physician directs otherwise) the name of the medicaiton dispensed.

Factor 4. The label of each out-patient's individual prescription medication container bears the lot and control number of the drug, the name and the manufacturer (or trademark) and (unless the physician directs otherwise) the name of the medication dispensed.

STANDARD E—CONTROL OF TOXIC OR DANGEROUS DRUGS

Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage.

Factor 1. The medical staff has established a written policy that all toxic or dangerous medications, not specifically prescribed as to time or number of doses, will be automatically stopped after a reasonable time limit set by the staff.

Factor 2. The classificaiton ordinarily thought of as toxic or dangerous drugs are narcotics, sedatives, anticoagulants, antibiotics, oxytocics and cortisone.

STANDARD F—COMMITTEE

There is a committee of the medical staff to confer with the pharmacist in the formulation of policies.

Factor 1. A Pharmacy and Therapeutics Committee (or equivalent committee), composed of physicians and pharmacists, is established in the hospital and serves as the liaison between the medical staff and the pharmacist.

Factor 2. The committee assists in the formulation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures, and all other matters relating to drugs.

Factor 3. The committee performs the following specific functions: (i) Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice of drugs; (ii) Develops and reviews periodically a formulary or drug list accepted for use in the hospital; (iii) Establishes standards concerning the use and control of experimental drugs and research in the use of recognized drugs; (iv) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital; (v) Makes recommendations concerning drugs to be stocked on the nursing unit floors and by other services; (vi) Prevents unnecessary duplication in stocking the same basic drug and its preparation.

Factor 4. The committee meets at least quarterly and reports to the executive committee and the medical staff.

STANDARD G—DRUGS TO BE DISPENSED

Drugs dispensed are included (or approved for inclusion) in the *United States Pharmacopoeia, National Formulary, United States Homeopathic Pharmacopeia, New Drugs,* or *Accepted Dental Remedies* (except for any drugs unfavorably evaluated therein), or are approved for use by the Pharmacy and Therapeutics Committee (or equivalent committee) of the hospital staff.

Factor 1. The pharmacist, with the advice and guidance of the Pharmacy and Therapeutics Committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs.

Factor 2. There is available a formulary or list of drugs accepted for use in the hospital which is developed and amended at regular intervals by the Pharmacy and Therapeutics Committee (or equivalent committee) with the cooperation of the pharmacist (consulting or otherwise) and the administration.

Factor 3. The pharmacy or drug room is adequately supplied with preparations so approved.

ASHP GUIDELINES FOR IMPLEMENTING AND OBTAINING REIMBURSEMENT FOR CLINICAL PHARMACEUTICAL SERVICES[21]*

During the past 10 years, pharmacies in institutions and other organized settings have been evolving from a product-centered structure to a more service-oriented practice. This trend will continue as drug therapy becomes more complex and sophisticated. Many innovative pharmaceutical services have been described in recent literature. Examples of these services are formalized patient education sessions and pharmacokinetic consultations. Many pharmacists are planning on initiating these and other new programs in their institutions. However, until these activities become the "norm," they may have to meet certain

*Approved by the ASHP Board of Directors, November 13–14, 1980. Originally developed by the ASHP Task Force on Payment for Pharmacy Services; reviewed and approved by the ASHP Council on Clinical Pharmacy and Therapeutics.

administrative requirements. These are: (1) obtaining approval from the institution's administration for the provision of the service on a routine basis (along with the resources required); (2) delineating the costs of the service and an appropriate patient charging mechanism; and (3) obtaining reimbursement and payment for the provider.[a]

The ASHP Task Force on Payment for Pharmacy Services has concluded that, generally, there are no policies of Blue Cross plans, private insurance companies, or other third-party carriers that prohibit their reimbursing and paying providers for clinical pharmacy services. However, their support is predicated upon acceptance and endorsement of the service by the involved administrative and medical staffs (and, in the case of those covered by private insurance plans, by their desire to have the service as a covered benefit of their plan).

This document presents a set of general guidelines for use in obtaining administrative support and subsequent reimbursement and payment for a new pharmaceutical service. Often, many steps of the process may be omitted. For example, it should not be necessary to conduct a preliminary trial of a widely accepted, though not universally adopted, service (such as use of patient medication profiles). Likewise, it may not be necessary to generate cost or other data if they are available in the literature or elsewhere. The context in which these guidelines are written is that of a pharmacy director working in a hospital—they are adaptable to other situations as well (such as a pharmacist providing services as part of a medical group practice).

Guidelines

1. Prepare, for the provider's administration, a written proposal for a short-term (e.g., three-month) implementation project for the proposed service. This document should include the following elements:
   a. A clear, concise description of the service.
   b. The rationale for the service. Include published references if available.
   c. Written support for the service by the pharmacy and therapeutics committee and other appropriate parties (e.g., infections committee, department of nursing).
   d. The expected benefits of the service to patients and the institution in terms of costs and quality of care as measured by indices such as: (i) decrease in length of stay; (ii) decrease in the incidence of therapeutic failures; (iii) decrease in drug expenditures.
   e. Estimated start-up and operating expenses and revenue[b] of the service, plus its personnel, equipment, and material requirements.
2. Obtain formal approval of the implementation project from administration.

[a]The term "provider" refers to an individual practitioner (e.g., pharmacist) or organization (e.g., hospital or group practice).

[b]Depending upon the acceptance of the service within the health-care system and in cooperation with the provider's fiscal offices, a determination should be made if payment for the service can or should be received.

3. Initiate the project, keeping complete records of all expenses, outputs (i.e., the number of patient consults or whatever quantitative measure is appropriate), and man-hours devoted to it. This information will be needed in developing charges for the service and for obtaining reimbursement and payment.
4. Upon its completion, prepare a report of the implementation project for administration. This report should contain fiscal and workload data, including total pharmacy cost per patient or service unit and a suggested charge based on these data. Information on acceptance of the program by patients and staff should be included, as should whatever measures of its effectiveness (see 1.d.) are possible. This report should also project the manpower and financial resources needed to perform the service as a regular pharmacy function.
5. Obtain formal approval from administration to implement the service provider-wide.
6. Assist the institution's administration and financial manager in developing the information needed to include the costs of the service in its reimbursement agreements with third-party carriers. In obtaining this reimbursement, certain administrative requirements (such as formal approval of the service by the pharmacy and therapeutics committee) may have to be met.
7. It may be useful to prepare annual updates on the impact of the service (reporting, for example, annual cost savings or decreased readmissions over a baseline period). Annual assessments of the financial and manpower requirements of the service also will be useful in preparing pharmacy budgets.

These guidelines pertain to reimbursement and payment to institutions or other organized providers for the costs of pharmaceutical services. There may be circumstances under which pharmacists wish to obtain direct reimbursement or payment, as independent practitioners, for their services. The procedures outlined in this document, generally, are applicable to these situations as well. It should be noted, however, that such direct remuneration may be extremely difficult to obtain and may, in fact, possess certain disadvantages (such as substantial paperwork requirements).

USE OF CHARGE CARDS

Most hospitals are reimbursed for prescription drugs—both in-patient and out-patient—by third-party payors or a direct billing basis. Lately, some institutions have begun to accept charge-card systems such as **Master Card** and **Visa** to cover not only out-patient prescription drug charges, but for all other services rendered by the hospital.

A number of companies have been formed to act as prescription program administrators for insurance companies, private firms, government agencies, HMO's and other organizations who offer their employees a prescription reimbursement program. These programs represent a fringe benefit to the employees. Also, it is to the advantage of

the sponsoring firm to avoid the cost of establishing and monitoring a reimbursement program and to have someone else perform this function. The procedure followed is that the outside contractor enters into an agreement with a firm to supply identification cards and reimbursement services for all that firm's employees. The employee then has the prescription filled at a pharmacy and uses the identification card to pay for the prescription (generally a co-payment is involved).

The pharmacist, in order to obtain reimbursement, collects all such evidence of prescription activity and submits it to the contractor for reimbursement in the aggregate via a prescription claim form. The contractor then processes each prescription claim on a computer, verifying product identification, costs, eligibility, and completeness of data and reimburses the pharmacy for all valid claims. The contractor then bills the contracting firm, or its insurance carrier, for its services plus the cost of the prescription.

SELECTED READINGS

Smith, W.E. and Weiblen, J.W.: Charging for Hospital Pharmaceutical Services: Product Cost, Per Diem Fees and Fees for Clinical Services. Am. J. Hosp. Pharm., *36*:355–359, (Mar.) 1979.

Fish, K.H., Jr.: Charging for Hospital Pharmaceutical Services: Computerized System Using a Markup and a Dose Fee. Am. J. Hosp. Pharm., *36*:360–363, (Mar.) 1979.

Dirks, I. and Pang, F.J.: Charging for Hospital Pharmaceutical Services: Combined Product-Service Per Diem Fees. Am. J. Hosp. Pharm., *36*:363–365, (Mar.) 1979.

Wyatt, B.K.: Charging for Hospital Pharmaceutical Services: Flat Fee Based on the Medication Record. Am. J. Hosp. Pharm., *36*:365–367, (Mar.) 1979.

Iglehart, J.K.: Health Policy Report. Medicare Begins Prospective Payment of Hospitals. N. Engl. J. Med., *308*:23:1428, (June 9) 1983.

Huffman, Jr. D.C. and Kilgore, S.M.: Changing Concepts in Hospital Reimbursement. Current Concepts in Hosp. Pharm. Mgt., *6*:3:13, (Fall) 1984.

Curtis, F.R.: Looking Beyond DRGs: Opportunity for Hospital Pharmacy. Am. J. Hosp. Pharm., *41*:721–723, 1984.

REFERENCES

1. *Systematic Prescription Pricing Digest.* Syracuse, Bristol Laboratories, Inc.
2. *The Lilly Digest.* Indianapolis, Eli Lilly & Co.
3. *The American College of Apothecaries Operational Survey.* Philadelphia, American College of Apothecaries.
4. *The Universal Prescription Costing and Pricing Calculator.* Rutherford, N.J., Becton, Dickinson & Co.
5. Narinian, George: Pharmaceutical Pricing in Hospitals. Hosp. Mgt., *90*:2:83, 1960.
6. Hartlieb, Charles J., Flack, Herbert L., and Abrams, Robert E.: A Rational Method of Prescription Pricing—The Professional Fee Concept. J.A.Ph.A. Pract. Ed., *21*:11:696, 1960.
7. Latiolais, Clifton J.: Experiences with the Professional Fee System in Hospital Pharmacy Practice at Ohio State University Hospital. Am. J. Hosp. Pharm., *23*:9:511, 1966.
8. Butler, John L. and Parker, Paul F.: Experience with the Professional Fee System in Hospital Pharmacy Practice at the University of Kentucky Medical Center. Am. J. Hosp. Pharm., *23*:9:516, 1966.
9. Rourke, Sr. Mary Vera: Experiences with the Professional Fee System in Hospital Pharmacy Practice at Mercy Hospital (Buffalo). Am. J. Hosp. Pharm., *23*:9:520, 1966.

10. Ulan, Martin S.: Experiences with the Professional Fee System in Hospital Pharmacy Practice at the Hackensack Hospital. Am. J. Hosp. Pharm., *23*:9:522, 1966.
11. Kashino, Minoru: Experiences with the Professional Fee System in Hospital Pharmacy Practice at the Palo Alto-Stanford Hospital Center. Am. J. Hosp. Pharm., *23*:9:518, 1966.
12. Provost, George P.: An Opportunity for Hospital Pharmacy. Am. J. Hosp. Pharm., *23*:9:487, 1966.
13. Foulke, R.A.: *Practical Financial Statement Analysis*. 5th ed. New York, McGraw-Hill Book Co., 1961.
14. Provost, George P. and Hiller, William M.: How Break-Even Pricing of Drugs Works. The Modern Hospital, *94*:122, 1960.
15. Health Insurance for the Aged. Conditions of Participation for Hospitals. Publication HIM-1 (2–66), Social Security Administration, U.S. Department of Health, Education and Welfare, Washington, D.C.
16. Fish, K.H.: Charging for Hospital Pharmaceutical Services: Computerized System Using a Markup and a Dose Fee. Am. J. Hosp. Pharm., *36*:360–363, (Mar.) 1979.
17. Dirks, I. and Pang, F.J.: Charging for Hospital Pharmaceutical Services: Combined Product-Service Per Diem Fees. Am. J. Hosp. Pharm., *36*:363–365, (Mar.) 1979.
18. Anon. Medicare Payment: Cost-Per-Case Management Special Report No. 1, August 1982. American Hospital Association, Office of Public Policy Analysis, Chicago, Ill. 60611.
19. Anon. Medicare Payment: Cost-Per-Case Management Special Report No. 3, April, 1983. American Hospital Association, Office of Public Policy Analysis, Chicago, Ill. 60611.
20. Hoffmann, R.P.: A Strategy to Reduce Drug Expenditures with a Drug Utilization Review Program. Hosp. Pharm., *19*:1:7–12, 1984.
21. ASHP Guidelines for Implementing and Obtaining Reimbursement for Clinical Pharmaceutical Services. Am. J. Hosp. Pharm., *38*:386, (Mar.) 1981.

20

Prepackaging in the Hospital

Prepackaging of drugs is not a new concept to the profession of pharmacy. It has been in practice since the apothecary of old grew his own herbs and drugs and harvested and packaged them for sale. Many retail pharmacies purchase various over-the-counter tablets and syrups in bulk quantities and prepackage the material in smaller-sized containers.

In the hospital pharmacy, the concept of prepackaging is utilized in both the large and the small hospital for it is, oftentimes, the means of coping with the periods of peak demand for pharmaceutical service. In the small hospital, the pharmacist may prepackage only those items which he considers require too much time if filled only when called for. In some hospital pharmacies, items which fall into this category are narcotics, barbiturates oily products, heavy syrups or magmas.

Most large hospitals have found it economical to prepackage all ward stock items as well as the often prescribed tablets, capsules, syrups, ointments and creams used both by the in-patients as well as the out-patient clinics. Because of the scope of ths phase of a large hospital pharmacy operation, it often requires a separate work force, special equipment, and detailed control procedures to ensure against the possibility of errors.

PREPACKAGING POLICY—ITS DETERMINATION

The decision as to what product and how much of it should be prepackaged is one which can be made only after a comprehensive study of the local situation. No rule of thumb can be reasonably stated which would be applicable in a majority of the instances.

Some of the factors which must be considered are:

a. Demand for the product.
Is it a year 'round demand or is it a seasonal demand?
Is the demand one which originates from the clinics or the pavilions?
Can this product be purchased in quantities to meet the demand, yet have it packaged in small units by the manufacturer at a price lower thân the hospital cost to prepackage the same item in a similar container?

b. What size units should be packaged? How many of each size?
c. What type of containers and closures must be used in order to maintain therapeutic integrity?
d. What special labeling will be required?
e. Can the item be machine packaged or must hand counting be resorted to?
f. What is the stability of the product?
Is it dated?
g. What will the unit cost of prepackaging amount to? Who should pay it?

Those experienced with the problem are convinced that almost every item in the pharmacy can be prepackaged. This includes preparations considered to be free ward stock as well as the items prescribed as charge drugs.

The size of each container of drug can best be ascertained by consulting the nursing service as well as the Pharmacy and Therapeutics Committee. The nursing service can be most helpful in providing data concerning the quantities and rate of use of such items as ward stock hypnotics, sedatives, antitussives, antiseptics, mouth washes, back rub lotions, etc. On the other hand, the Pharmacy and Therapeutics Committee can establish a quota regarding the number of capsules and tablets or volume of liquid preparations which may be sent to the pavilions. The figure is usually included in the published formulary as the quantity to prescribe and is arrived at by a decision not to permit more than a specific number of days of therapy on any one drug order. In a majority of hospitals, 20 to 25 capsules or tablets are considered as adequate for hospitalized patients and are therefore the commonly prepackaged sizes.

Insofar as prepackaging for the out-patient clinic is concerned, the most important factor to be considered is the cycle for obtaining subsequent appointments. If it is accepted hospital policy to schedule patients for appointments every 30 or 45 or 60 days, then the quantity of drug, if the therapy warrants it, should be sufficient to last until the date of the subsequent appointment. Failure to do this will result in burdening the patient by forcing him to return to the hospital for an unscheduled appointment for the purpose of obtaining authorization for a refill. Thus quantities of 50, 75 and 100 unit doses may be prepackaged for clinic dispensing.

As has been previously stated, no set rule can be provided which will be of universal value in determining the total volume of material to be prepackaged. Some hospital pharmacists have developed a routine whereby items are prepackaged in a volume estimated to last for a period of 60 days, whereas others vary from as little as 30 days to as much as 120 days. In this regard, a word of caution must be interjected—

namely, an extremely large volume of prepackaging of a single item may be quite risky should the use fall off or be jeopardized by reports of adverse reactions resulting from its use. The prepackaged items may not be returned to the manufacturer for credit and may become a total loss to the hospital.

PREPACKAGING OPERATION

In the small hospital, the prepackaging operation is usually accomplished by the staff pharmacist with the assistance of a part-time helper. This is a practical approach to the problem when the volume is not great for it permits the pharmacist to remain busy throughout the work week. Under these circumstances, no special area need be set aside nor is there the need for any special counting equipment other than manual tablet counters or moderately sensitive scales for weighing.

Hospitals requiring large scale prepackaging operations have found it feasible to establish a separate unit for this facet of the total operation. Here, a separate lay work force is marshalled under the supervision of a pharmacist, and the monumental task is undertaken with the assistance of automatic filling machines for liquid preparations, automatic tablet and capsule counters and automatic labeling machines.

In between these two extremes lies the majority of the hospitals. That is, the volume is too great for a total hand operation, yet too small for a separate automated division within the department proper. Here, the pharmacy staff usually rotates the responsibility for maintaining a supply of prepackaged goods. Oftentimes, the pharmacist may have available the assistance of lay personnel already on the pharmacy payroll, other staff pharmacists during off-peak hours, or members of the volunteer staff in the hospital.

The prepackaging of drugs in this type of operation usually makes use of some semi-automatic packaging aids such as the various types of automatic and electronic tablet and capsule counters, automatic filling and capping machines, pipetting machines, and semi-automatic labeling equipment. Figure 71 demonstrates one such piece of equipment—the King "Dispensa" electronic tablet and capsule counter.

Although the above-mentioned equipment is intended for use in the larger hospital, there is on the market a number of units intended for use in the small hospital. This is particulary true with the various tablet counters.

TYPES OF CONTAINERS

The literature is amply documented[1,2] with the pros and cons associated with the choice of container for dispensing pharmaceuticals. This controversy was made possible by the advent of the plastic con-

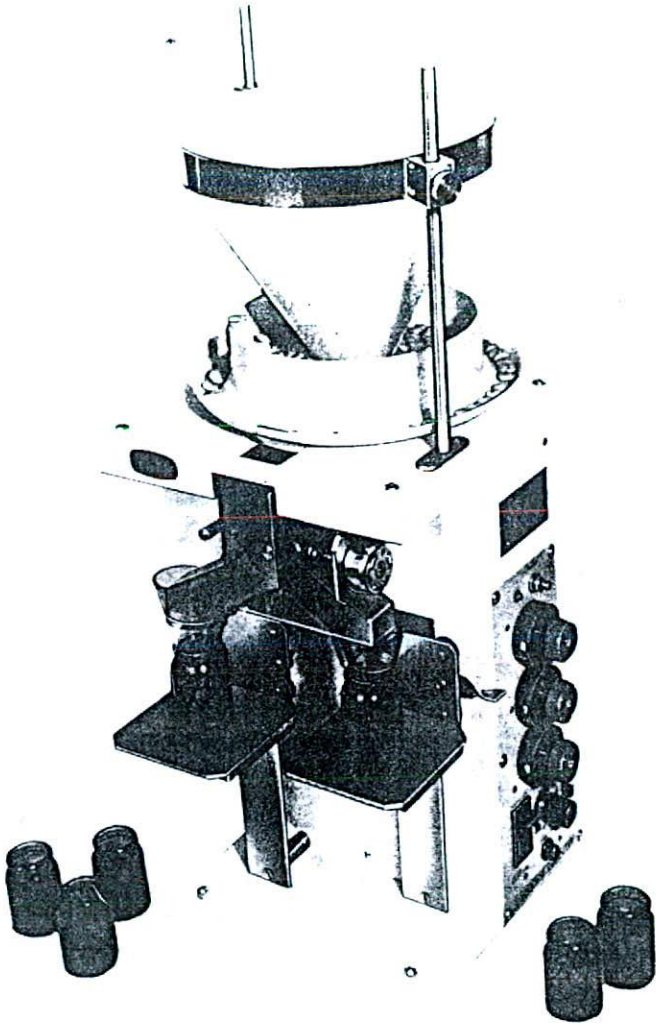


Fig. 71. The King "Dispensa." (Courtesy of Modular Packaging Systems, Inc., E. Hanover, N.J.)

tainer, the plasticized paper or cardboard package, and the strip package. Those opposed to the use of these modern packaging aids often cite the requirements of the *United States Pharmacopeia* and *National Formulary* which direct that the official preparations be packaged, stored and preserved in air-tight, light-resistant containers.

The general claim is usually based upon the observation that some plastic containers do not meet the standards of moisture vapor trans-

mission set for well-closed containers, that volatile oils and certain dyes migrate through the walls of polyethylene containers, and that "plastic containers" do not withstand heat sterilization.

A sophisticated study of the literature will quickly dispel many of these observations for, in fact, high density polyethylene containers do protect against migration of volatile oils, do measure up to high standards in the moisture vapor transmission tests, and can be subjected to heat sterilization.

Although plastic materials do all these things, it is the considered opinion of many that they still do not fully meet the requirements of the official compendia.

Despite these generally divergent views, the ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs provides the following information:[3]

ASHP TECHNICAL ASSISTANCE BULLETIN ON SINGLE UNIT AND UNIT DOSE PACKAGES OF DRUGS[a]

Drug packages must fulfill four basic functions: (1) identify their contents completely and precisely; (2) protect their contents from deleterious environmental effects (e.g., photodecomposition); (3) protect their contents from deterioration due to handling (e.g., breakage, contamination); (4) permit their contents to be used quickly, easily, and safely. Modern drug-distribution systems use single unit packages to a great extent and, in fact, such packages are central to the operation of unit dose systems, intravenous admixture services, and other important aspects of pharmacy practice. These guidelines have been prepared to assist pharmaceutical manufacturers and pharmacists in the development and production of single unit and unit dose packages, the use of which has been shown to have substantial benefits.

A *single unit* package is one which contains one discrete pharmaceutical dosage form, i.e., one tablet, one 2-ml volume of liquid, one 2-g mass of ointment, etc. A *unit dose* package is one which contains that particular dose of the drug ordered for the patient. A single unit package is also a *unit dose* or *single dose* package if it contains the particular dose of the drug ordered for the patient. A unit dose package could, for example, contain two tablets of a drug product.

[a]Approved by the ASHP Board of Directors, November 14–15, 1984. Revised by the ASHP Council on Clinical Affairs. Supersedes the previous version, which was approved on March 31–April 1, 1977.

General Considerations

Packaging Materials. Packaging materials (and the package itself) must possess the physical characteristics required to protect the contents from (as required) light, moisture, temperature, air, and handling. The material should not deteriorate during the shelf life of the contents. Packages should be of lightweight, nonbulky materials that do not produce toxic fumes when incinerated. Materials that may be recycled or are biodegradable, or both, are to be preferred over those that are not.' Packaging materials should not absorb, adsorb, or otherwise deleteriously affect their contents. Information should be available to practitioners indicating the stability and compatibility of drugs with various packaging materials.

Shape and Form. Packages should be constructed so that they do not deteriorate with normal handling. They should be easy to open and use, and their use should require little or no special training or experience. Unless the package contains a drug to be added to a parenteral fluid or otherwise used in compounding a finished dosage form, it should allow the contents to be administered directly to the patient (or IPPB apparatus or fluid administration set) without any need for repackaging into another container or device (except for ampuls).

Label Copy. Current federal labeling requirements must be adhered to, with attention also given to the items below. The desired copy and format are as follows:

Nonproprietary Name
(and propietary name, if to be shown)
Dosage Form (if special or other than oral)
Strength
Strength of Dose and Total Contents
Delivered
(e.g., no of tablets and their total dose)
Special Notes (e.g., refrigerate)
Expiration Date
Control Number

1. *Nonproprietary and Proprietary Name(s).* The nonproprietary name and the strength should be the most prominent part of the package label. It is not necessary to include the proprietary name, if any, on the package. The name of the manufacturer or distributor should appear on the package. In addition, the name of the manufacturer of the finished dosage form should be included in the product labeling. The style of type should be chosen to provide maximum legibility, contrast, and permanence.
2. *Dosage Form.* Special characteristics of the dosage form should be a part of the label, e.g., extended release. Packages should be labeled as to the route of administration if other than oral, e.g., topical use. In a package containing an injection, the acceptable injectable route(s) of administra-

tion should be stated on both outer and inner packages, i.e., both on the syringe unit and carton (if any).

3. *Strength.* Strength should be stated in accordance with terminology in the *American Hospital Formulary Service.* The metric system should be used, with dosage forms formulated to provide the rounded-off figures in the USP table of approximate equivalents and expressed in the smallest whole number.

   Micrograms should be used through 999, then milligrams through 999, then grams. Thus, 300 mg, *not* 5 gr, nor 325 mg, nor 0.3 g; 60 mg, *not* 1 gr. nor 0.06 g, nor 64.5 mg, nor 65 mg; 400 μg, *not* 1/150 gr, nor 0.4 mg, nor 0.0004 g; ml (milliliters) should be used instead of cc (cubic centimeters).
4. *Strength of Dose and Total Contents Delivered.* The total contents *and* total dose of the package should be indicated. Thus, a unit dose package containing a 600-mg dose as two 300-mg tablets should be labeled: "600 mg (as two 300-mg tablets)." Likewise, a 500-mg dose of a drug in a liquid containing 100 mg/ml should be labeled: "Delivers 500 mg (as 5 ml of 100 mg/ml)."
5. *Special Notes.* Special notes such as conditions of storage (e.g., refrigerate), preparation (e.g., shake well, moisten), and administration (e.g., not to be chewed) that are not obvious from the dosage form designation are to be included on the label.
6. *Expiration Date.* The expiration date should be prominently visible on the package. If the contents must be reconstituted prior to use, the shelf life of the final product should be indicated. Unless stability data warrant otherwise, all expiration dates should fall during January and July to simplify product recall procedures.
7. *Control Number (Lot Number).* The control number should appear on the package.

Product Identification Codes. The use of product identification codes, appearing directly on the dosage form, is encouraged.

Evidence of Entry. The package should be so designed that it is evident, when the package is still intact, that it has never been entered or opened.

Specific Considerations

Oral Solids.

1. *Blister Package.* A blister package should
   a. Have an opaque and nonreflective backing (flat upper surface of package) for printing,
   b. Have a blister (dome or bubble) of a transparent material that is, preferably, flat bottomed,
   c. Be easily peelable, and
   d. If it contains a controlled substance, be numbered sequentially for accountability purposes.
2. *Pouch Package.* A pouch package should
   a. Have one side opaque and nonreflective for printing,
   b. Be easily deliverable, i.e., large tablets in large pouches, small tablets in small pouches,

c. Tear from any point or from multiple locations, and
d. If it contains a controlled substance, be numbered sequentially for accountability purposes.

3. The packages should be such that contents can be delivered directly to the patient's mouth or hand.

Oral Liquids.

1. The packages should be filled to deliver the labeled contents. It is recognized that overfilling will be necessary, depending on the shape of the container, the container material, and the formulation of the dosage form.
2. The label should state the contents as follows: Delivers _____mg (or g or μg) in _____ml.
3. If reconstitution is required, the amount of vehicle to be added should be indicated. These directions may take the form of "fill to mark on container" in lieu of stating a specific volume.
4. Syringe-type containers for oral administration should not accept a needle and should be labeled "For Oral Use Only."
5. Containers should be designed to permit administration of the contents directly from the package.

Injectables.

1. The device shall be appropriately calibrated in mililiters and scaled from the tip to the fill line. Calibrated space may be built into the device to permit addition of other drugs. The label should state the contents as follows: Delivers _____mg (or g in μg) in _____ml.
2. An appropriate-size needle may be an integral part of the device. The needle sheath should not be the plunger. The plunger should be mechanically stable in the barrel of the syringe.
3. The device should be of such a design that it is patient-ready and assembly instructions are not necessary.
4. The sheath protecting the needle should be a nonpenetrable, preferably rigid material, to protect personnel from injury. The size of the needle should be indicated.
5. The device shall be of such a design that easy and visible aspiration is possible. It should be as compact as possible and to such a size that it can be easily handled.

Pareteral Solutions and Additives

1. The approximate pH and osmolarity of parenteral solutions should be stated on the label. The amount of overfill also should be noted. Electrolyte solutions should be labeled in both meq (or millimole) and mg concentrations. Solutions commonly labeled in terms of percent concentrations, e.g., dextrose, should also be labeled in w/v terms.
2. Parenteral fluid container labels should be readable when hanging and when upright or in the normal manipulative position.
3. Drugs to be mixed with parenteral infusion solutions should be packaged into convenient sizes that minimize the need for solution transfers and other manipulations.
4. Partially filled piggyback-type containers should
   a. Be recappable with a tamperproof closure,
   b. Have a hanger,
   c. Have volume markings,

d. Be designed to minimize the potential for contamination during use, and
e. Contain a partial vacuum for ease of reconstitution.

5. If an administration set is included with the container, it should be compatible with all large-volume parenteral delivery systems.

Other Dosage Forms—Ophthalmics, Suppositories, Ointments, etc. Dosage forms other than those specifically discussed above should be adequately labeled to indicate their use and route of administration and should adhere to the above and other required package labeling and design criteria.

The following excerpts from ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control[10] are useful to the student:

ASHP TECHNICAL ASSISTANCE BULLETIN ON HOSPITAL DRUG DISTRIBUTION AND CONTROL

(10) *Medication Containers, Labeling and Dispensing: Inpatient Medications.* Drug products should be as ready for administration to the patient as the current status of pharmaceutical technology permits. Inpatient medication containers and packages should conform to applicable USP requirments and the ASHP guidelines.

Inpatient self-care and "discharge" medications should be labeled as outpatient prescriptions (see below).

(11) *Medication Containers, Labeling and Dispensing: Outpatient Medications.* Outpatient medications must be labeled in accordance with state board of pharmacy and federal regulations. As noted, medications given to patients as "discharge medication" must be labeled in the pharmacy (not by nursing personnel) as outpatient prescriptions.

The source of the medication and initials of the dispenser should be noted on the prescription form at the time of dispensing. If feasible, the lot number also should be recorded.

An identifying check system to ensure proper identification of outpatients should be established.

Outpatient prescriptions should be packaged in accordance with the provisions of the Poison Prevention Packaging Act of 1970 and any regulations thereunder. They must also meet any applicable requirements of the USP.

Any special instructions to or procedures required of the patient relative to the drug's preparation, storage, and administration should be either a part of the label or accompany the medication container received by the patient. Counseling of the patient sufficient to ensure understanding and compliance (to the extent possible) with his medication regimen must be conducted. Nonprescription drugs, if used in the institution, should be labeled as any other medication.

LABELING

The ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control states the following:[10]

(9) *Medication Containers, Labeling and Dispensing: Stock Containers.* The pharmacist is responsible for labeling medication containers. Medication labels should be typed or machine-printed. Labeling with pen or pencil and the use of adhesive tape or china marking pencils should be prohibited. A label should not be superimposed on another label. The label should be legible and free from erasures and strikeovers. It should be firmely affixed to the container. The labels for stock containers should be protected from chemical action or abrasion and bear the name, address, and telephone number of the hospital. Medication containers and labels should not be altered by anyone other than pharmacy personnel. Prescription labels should not be distributed outside the pharmacy. Accessory labels and statements (shake well, may not be refilled, and the like) should be used as required. Any container to be used outside the institution should bear its name, address, and phone number.

Important labeling considerations are:

1. The metric system should be given prominence on all labels when both metric and apothecary measurement units are given.
2. The names of all therapeutically active ingredients should be indicated in compound mixtures.
3. Labels for medications should indicate the amount of drug or drugs in each dosage unit (e.g., per 5 ml., per capsule).
4. Drugs and chemicals in forms intended for dilution or reconstitution should carry appropriate directions.
5. The expiration date of the contents, as well as proper storage conditions, should be clearly indicated.
6. The acceptable route(s) of administration should be indicated for parenteral medications.
7. Labels for large-volume sterile solutions should permit visual inspection of the container contents.
8. Numbers, letters, coined names, unofficial synonyms, and abbreviations should not be used to identify medications, with the exception of approved letter or number codes for investigational drugs (or drugs being used in blinded clinical studies).
9. Containers presenting difficulty in labeling, such as small tubes, should be labeled with no less than the prescription serial number, name of drug, strength, and name of the patient. The container should then be placed in a larger carton bearing a label with all necessary information.
10. The label should conform to all applicable federal, state, and local laws and regulations.

11. Medication labels of stock containers and repackaged or prepackaged drugs should carry codes to identify the source and lot number of medication.
12. Nonproprietary name(s) should be given prominence over proprietary names.
13. Amount dispensed (e.g., number of tablets) should be indicated.

The labeling of the various prepackaged drugs must be considered as one of the most important steps in the entire operation, yet, unfortunately, too many hospital pharmacists take this step for granted. Consider the following implications which may result from improperly labeled units.

1. If the preparation of the label to be applied to a particular batch of prepackaged drug is wrong, then every container in the lot, whether it be 50 units or 500 units, is also improperly labeled. This could lead to innumerable incidents on the pavilions and thereby cast reflections upon the accuracy of the pharmacy staff.
2. Insufficient information on the label may cause the nurse or physician or even the patient to make unnecessary and time-consuming telephone calls to the pharmacy.
3. Improperly or inaccurately labeled containers are an indication that the safety controls and checks are not functioning adequately.
4. In case of a drug recall by the manufacturer, it may be difficult to remove the affected containers from circulation due to the insufficient data on the label.
5. Labels which are ambiguous may lead to medication errors or may mislead the prescriber as to its contents.

One hospital pharmacist[4] utilizes a ¼ × 2-inch pressure sensitive label upon which is printed the following information:

Proprietary name	Pharmaceutical classification
Generic name	Description of the product
Strength	Control number

The finished label in this instance is quite informative and in itself has a number of built-in checks against improper package contents and the possible administration of the wrong medication to a patient. Figure 72 is an example of this type of label.

Labeling a medication container with the generic name of the product is considered to be proper. However, the use of a brand or proprietary name other than the one which actually describes the contents is never proper; as a matter of fact it may be considered to be fraudulent. It is also considered to be improper if the proprietary name is used in such a manner as to imply that the contents are the same, although every one concerned knows that they are of a different make.

The format in Figure 73 has been recommended for the labeling of

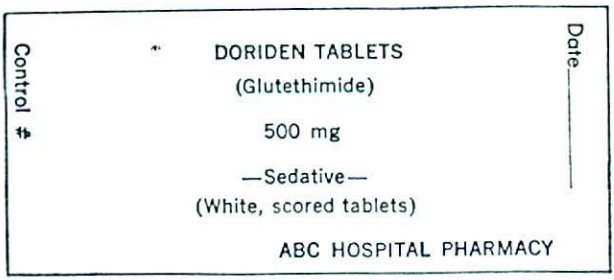


Fig. 72

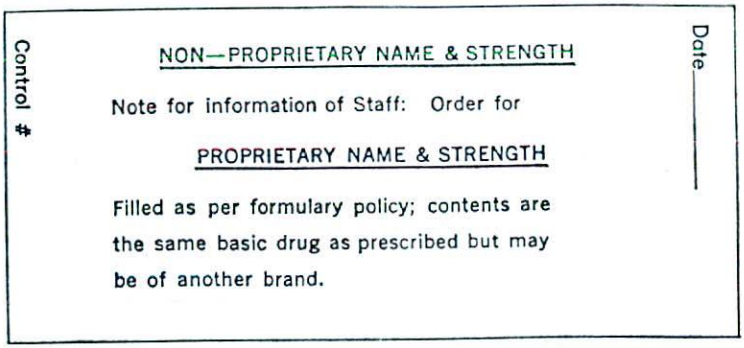


Fig. 73

medication containers in the hospital in order to overcome the above situations.

Because many drugs which are prepackaged in the hospital bear an expiration date, it is advisable to include this on an ancillary label. Although some hospital pharmacists feel that this is not needed because of the rapid consumption of drugs in the hospital and the fact that the proper control record will provide this information, it is suggested that the hospital prepackaging operation should comply with the rules set for manufacturers or other prepackagers of drugs.

In this regard, it is of interest to note that the regulations governing the location of expiration dates on labels of drug packages appeared in the *Federal Register of July 16, 1958* and reads as follows:

"3.507 *Location of Expiration Date in Drug Labeling.* Drugs which require an expiration date should show the expiration date on the immediate container. When the immediate container is packaged in an individual carton, the expiration date should also be placed on the carton. When single dose containers are packed in single cartons, the expiration date may properly appear on the carton only. . . ."

For the benefit of the student or those who wish to, for the first time, establish a prepackaging program, the following is a program of labeling which when pursued will provide the safety and control needed in a successful operation.

Step One.—Using a marking or printing machine, prepare the proper number of self-adhering labels bearing the following information:

a. Date of prepackaging by month and year.
e.g. 8/79.

b. On the next line insert the name of the manufacturer.

c. On the third line insert the control number assigned by the manufacturer.

d. If the item is a dated product, place the expiration date on the far right of the first line, *e.g.* 8/79 (on left), 9/80 (on right).

Thus the completed tag will appear as shown in Figure 74.

This tag is then affixed to the container and is not to be removed by nursing or pharmacy personnel. Whenever dry goods are packaged, the label is placed on the inside of the cap of the capsule or tablet vial thus reducing the temptation to remove it.

Step Two.—Again using a marking or printing machine prepare the proper number of self-adhering labels bearing the following information:

a. Date of prepackaging by month and year.
b. Name and strength of the drug.
c. Unit cost—coded if desirable.
d. Unit selling price.
e. Number of capsules on far right of the first line.

Thus, the finished tag appears as shown in Figure 75 and is affixed to the outside of the container.

Step Three.—Affix any ancillary labels which are required, *e.g.* for the Eye; for the Nose; Refrigerate, etc.

Step Four.—When the unit is dispensed, the tag described in Step Two is removed from the container and affixed to the prescription or to the medication order slip.

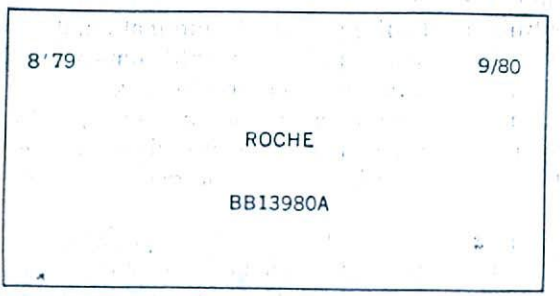


Fig. 74

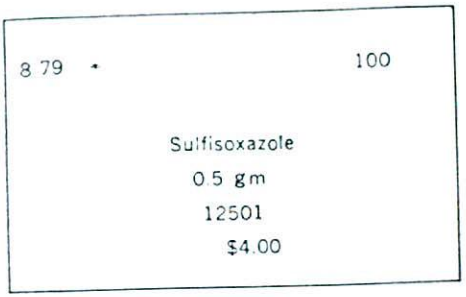


Fig. 75

Many pharmacists have expressed the opinion that this final step is unnecessary and is burdensome; however it serves the purpose of affording the checking pharmacist another visible means (in addition to the characterstic color or shape of the dispensed product) of ascertaining accuracy.

Recently a national survey[11] was conducted to determine the policies of hospital pharmacies regarding expiration dates for repackaged pharmaceuticals. The results were that less than one third of the responding institutions followed the current FDA recommendations for dating oral solids repackaged from bulk. Almost one quarter used the manufacturer's date. Only 5.6% of the hospitals used more conservative dating. Similar percentages were found for the dating of oral liquids. One third of the hospitals used 30 to 90 days to date repackaged injectables.

The Control Record

Besides accurate and comprehensive labeling practices, it is essential that the pharmacist maintain a written control record. Many different varieties of records may be kept; that is, sheets, cards, books, etc. What is important is the information which appears on these records.

Miller[5] recommends the use of a control card upon which is transcribed the following information:

a. Item packaged
b. Manufacturer's control number
c. Total number of units
d. Size of each unit
e. Identity of the prepacker
f. Identity of the checker
g. Type of container and closure

Figure 76 is an example of one type of prepackaging record. Of interest here is the fact that a separate sheet is used for each product prepackaged and should be retained for a period of one year after the last entry.

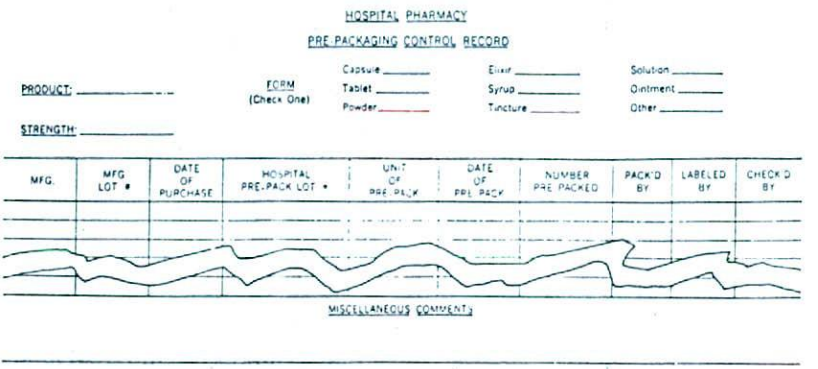


Fig. 76

Strip Packaging

In discussing the various methods of drug distribution in the hospital (Chap. 13), reference was made to the commercial availability of many drug products in strip packages. The pharmaceutical industry has made many drugs available to the hospital pharmacy in prepackaged strips of 5 tablets or capsules, rolls of 25 and rolls of 100. Each strip of 5 is then placed in a bulk dispensing carton, whereas the rolled strips are packaged in cardboard reel-type dispensing packages.

In spite of industry's good intentions, there still remains a large number of drugs, in common hospital use, that are not strip packaged. Thus, some hospital pharmacists have, in cooperation with industrial packagers, sought to develop a practical yet inexpensive means of strip packaging within the hospital. One such study at the University of Kentucky Medical Center[6] has resulted in the development of both a machine and a program.

In describing the project, the authors state that the operational principles of the machine are basic:

> Two strips of packaging material are fed through the machine from reels mounted on each side. As this packaging material is pulled into the meshing crimp rollers: (1) the packaging material is labeled where the pocket is to be formed; (2) the tablet or capsule is placed in position to be entrapped in the pocket; (3) the two strips of packaging material are sealed around the tablet or capsule to form the pocket and are then pulled from the heated crimp rollers. Thus, the three phases of the packaging operation are completed.

The packaging machine is known as the Una-Strip Packer.

Prior to undertaking such a program, the hospital pharmacist should undertake studies to ascertain the volume of drugs which must be prepackaged. He must develop a satisfactory label to comply with all

legal requirements, and finally he must select the proper packaging material to protect the product against air, moisture, and light.

A comparison of five hospitals to determine labor savings if single unit packaged medications replaced those now prepared and dispensed from bulk containers revealed the following figures:[7]

(a) Estimated labor cost per dose in the pharmacy for existing methods averaged 1.61 cents while the unit dose average was 1.33 cents. For nurses, the figures were 14.6 cents and 14 cents respectively. This represents a cost of 16.2 cents per dose for existing methods as opposed to 14.3 cents for unit dose.
(b) There was a direct labor savings of two cents per unit with single-dose dispensing over existing bulk-methods, versus an average cost increase of one cent per single-unit of medications over conventional bulk containers.

Because many hospital pharmacists operating in a large medical center prefer for reasons of availability and economy to repackage oral solids and liquids in single unit and unit dose packages, it is important that certain precautions be undertaken to assure the integrity of the final package. In a collaborative effort the American Society of Hospital Pharmacists and the American Society of Consultant Pharmacists developed a set of guidelines for repackaging oral medications in single unit and unit dose packages. The following is a verbatim, presentation of these **Guidelines.**[8]

ASHP TECHNICAL ASSISTANCE BULLETIN ON REPACKAGING ORAL SOLIDS AND LIQUIDS IN SINGLE UNIT AND UNIT DOSE PACKAGES[a]

To maximize the benefits of a unit dose drug distribution system, all drugs must be packaged in single unit or unit dose packages.[b] However, not all drugs are commercially available in single unit (or unit dose) packages. Therefore, the institutional pharmacist must often repackage drugs obtained in bulk containers (e.g., bottles of 500 tablets) into single unit packages so that they may be used in a unit dose system.

[a]Revised by the ASHP Board of Directors, November 16–17, 1978. This document was developed originally by a joint working group of the American Society of Hospital Pharmacists and the American Society of Consultant Pharmacists and representatives of the drug packaging industry. The original document subsequently was approved officially by the boards of directors of ASHP and ASCP. The Food and Drug Administration reviewed the original document and commended ASHP and ASCP for developing the Guidelines.

[b]A *single unit* package is one which contains one discrete pharmaceutical dosage form, e.g., one tablet, one 5-ml volume of liquid, etc. A *unit dose* package is one which contains the particular dose of drug ordered for the patient. A *single unit* package is a *unit dose* (or *single dose*) package if it contains that particular dose of drug ordered for the patient.

Certain precautions must be taken if the quality of drugs repackaged by the pharmacist is to be maintained. The guidelines presented herein will assist the pharmacist in developing procedures for repackaging drugs in a safe and acceptable manner.

1. The packaging operation should be isolated, to the extent possible, from other pharmacy activities.
2. Only one drug product at a time should be repackaged in a specific work area. No drug products other than the one being repackaged should be present in the immediate packaging area. Also, no labels other than those for the product being packaged should be present in the area.
3. Upon completion of the packaging run, all unused stocks of drugs and all finished packages should be removed from the packaging area. The packaging machinery and related equipment should then be completely emptied, cleaned and inspected before commencing the next packaging operation.
4. All unused labels (if separate labels are utilized) should be removed from the immediate packaging area. The operator should verify that none remain in the packaging machine(s). If labels are prepared as part of the packaging operation, the label plate (or analogous part of the printing apparatus) should be removed or adjusted to "blank" upon completion of the run. This will help assure that the correct label is printed during any subsequent run. There should be a procedure to reconcile the number of packages produced with the number of labels used (if any) and/or destroyed (if any) and the number of units or volume of drug set forth to be packaged.
5. Before beginning a packaging run, an organoleptic evaluation (color, odor, appearance and markings) of the drug product being repackaged should be made. The bulk container should also be examined for evidence of water damage, contamination or other deleterious effects.
6. All packaging equipment and systems should be operated and used in accordance with the manufacturer's or other established instructions. There should be valid justification and authorization by the supervisor for any deviation from those instructions on the part of the operator.
7. The pharmacist should obtain data on the characteristics of all packaging materials used. This information should include data on the chemical composition, light transmission, moisture permeability, size, thickness (alone or in laminate), recommended sealing temperature and storage requirements.
8. Unit dose packages and labels should, to the extent possible, comply with the American Society of Hospital Pharmacists' "Guidelines for Single Unit and Unit Dose Packages of Drugs."[1]
9. Whenever feasible, a responsible individual, other than the packaging operator, should verify that: (a) the packaging system (drug, materials, machines) is set up correctly and (b) all procedures have been performed properly. Ultimate responsibility for all packaging operations rests with the pharmacist.
10. Control records of all packaging runs must be kept. These records should include the following information: (1) complete description of the product, i.e., name, strength, dosage form, route of administration, etc.; (2) the product's manufacturer or supplier; (3) control number; (4) the pharmacy's control number if different from the manufacturer's; (5) expiration dates of the original container and the repackaged product; (6) number

of units packaged and the date(s) they were packaged; (7) initials of the operator and checker (if any); (8) a sample of the label and, if feasible, a sample of the finished package which should not be discarded until after the expiration date and which should be examined periodically for signs of deterioration; (9) description (including lot number) of the packaging materials and equipment used.

11. It is the responsibility of the pharmacist, taking into account the nature of the drug repackaged, the characteristics of the package, and the storage conditions to which the drug may be subjected, to determine the expiration date to be placed on the package. This date must not be beyond that of the original package.[a]
12. All drugs should be packaged and stored in a temperature- and humidity-controlled environment to minimize degradation caused by heat and moisture. A relative humidity of 75% at 23° C should not be exceeded. Packing materials should be stored in accordance with the manufacturer's instructions and any applicable regulations.
13. Written procedures (both general and product-specific) governing repackaging operations should be prepared and updated as required. Any deviation from these procedures should be noted and explained on the control record. Operators must understand the procedures (and operation of all packaging equipment) before commencing the run.
14. Applicable FDA and USP requirments concerning the type of package required for specific drug products must be followed.
15. Drugs and chemicals with high vapor pressures should be stored separately from other products in order to minimize cross contamination.

REFERENCES

1. American Society of Hospital Pharmacists. ASHP guidelines for single unit and unit dose packages of drugs. Am. J. Hosp. Pharm., 1977; *34*:613–4.
2. Stolar, M.H.: Expiration dates of repackaged drug products. Am. J. Hosp. Pharm., 1979; *36*:170. Editorial.

QUALITY CONTROL GUIDELINES FOR SINGLE PACKAGING OF PARENTERALS

The primary manufacturer of a product is liable for the quality and safety of his product until such time as another party assumes the responsibility from him. In the hospital pharmacy, the manufacturer may be relieved of his responsibility for the product whenever the hospital pharmacist undertakes to repackage it. Thus, to repackage and store these products without an adequate quality control program may result in a lawsuit for the hospital.

A good quality control program should concern itself with the details involved in container selection in order to eliminate stability and compatibility programs arising from a reaction with capping material or even the plunger tip. Contamination of the parenteral solution must be

[a]For specific recommendations on expiration-date policy, see reference 2.

guarded against from such sources as personnel, environment, and containers. Vials and syringes should be checked for accuracy of calibration in order that the amount of overfill be ascertained.

The filling process should be performed under a laminar airflow hood and detailed records should be maintained.[9]

SELECTED READINGS

Turco, S.J.: Chairman's Overview—National Coordinating Committee on Large Volume Parenterals. Infusion, *2*:4–7, (Jan.–Feb.) 1979.

———: Recommendations for the Labeling of Large Volume Parenterals. Infusion, *1*:2:50, (Nov.–Dec.) 1977.

REFERENCES

1. Archambault, G.F.: Plastics and the U.S.P. Requirements for Tight, Light-Resistant Containers. Am. J. Hosp. Pharm., *15*:877, 1958.
2. ———: Standards for Prescription Containers. Am. J. Hosp. Pharm., *20*:538, 1952.
3. ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs. Am. J. Hosp. Pharm., *42*:378–379, 1985.
4. Benya, Theodore J.: Labeling Pre-packaged Medication. Am. J. Hosp. Pharm., *19*:1:20, 1962.
5. Webb, John W.: Methods of Promoting Safety and Control in Hospital Pharmacy. Am. J. Hosp. Pharm., *15*:11:977, 1958.
6. Samuels, Tom M. and Guthrie, Don L.: Unit Dose Packaging—a New Machine for Strip Packaging Tablets and Capsules. Am. J. Hosp. Pharm., *23*:1:4, 1966.
7. Blasingame, W.G., Drevno, Harold, Godley, Leo F., Kratz, Richard L., Vona, Joseph P., and Minott, Paul: Some Time and Motion Considerations with Single-Unit Packaged Drugs in Five Hospitals. Am. J. Hosp. Pharm., *26*:6:310, (June) 1969.
8. ASHP Guidelines fo Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages. Am. J. Hosp. Pharm., *40*:451–452, (Mar.) 1983.
9. Patel, J.A., Curtis, E.G., and Phillips, G.L.: Quality Control Guidelines for Single Unit Packaging of Parenterals in the Hospital Pharmacy. Am. J. Hosp. Pharm., *29*:11:947, (Nov.) 1972.
10. ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control. Am. J. Hosp. Pharm., *37*:1097–1103, (Aug.) 1980.
11. Chaney, R.F. and Summerfield, M.: Survey of Expiration Dating Policies for Repackaged Pharmaceuticals. Am. J. Hosp. Pharm., *41*:1150–1152, 1984.