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Pharmacy Communications

It is a well-documented fact that the majority of the hospitals in this country lack a good method of communicating with the staff and patients. The methods employed to disseminate interdepartment information are usually well prototyped, namely, bulletins, memoranda, bulletin board notices and committee meetings. In most instances, this form of communication is adequate even though it is limited in its scope.

The department of pharmacy, because its method of operation brings it into close contact with the major hospital services, departments and the entire medical staff, is in a position to alleviate that portion of the problem that relates to the dissemination of data concerning drugs and related supplies.

As has been stated earlier, one of the duties of the Pharmacy and Therapeutics Committee is to assist the pharmacist in conducting a teaching program within the hospital via a pharmacy publication. The membership of this committee can be extremely helpful by preparing brief lead articles concerning the latest therapeutic advances in their specialty and by reviewing the materials by the pharmacist for publication.

With today's emphasis on clinical pharmacy, the publication may be edited by the clinical pharmacist members of the department and therefore the direction of the effort will be in the area of therapeutics, pharmacokinetics, toxicology and drug interactions. Also of importance is the fact that the nursing service constitutes a large segment of the readership and therefore the editor should invite contributions from the nursing group as well as to include articles of interest to them.

The individual assigned the reponsibility for pharmacy communications must be alert to the fact that other groups in the hospital have an interest in drugs and drug therapy. A good example would be the interest of the therapeutic dietician in food-drug interactions.

Another interested party with whom the clinical pharmacist comes into daily contact is the patient. Since no two patients are alike, it is the pharmacist's duty to devise different methodologies for disseminating drug information.[1] After developing these, it is of great impor-

tance to ascertain the patient's evaluation of the method and its content.[2]

The preparation of a worthwhile pharmacy publication requires a great deal of time and forethought. The purpose of this chapter is to provide some ideas relative to possible contents, format, duplication, and distribution of such an educational and informative medium.

SELECTION OF A TITLE

The title selected for the publication should be specific, short and of such a nature that it identifies the publication as well as its contents.

Too often, a title is selected which imparts the impression that the publication is a collegiate gossip paper rather than a professional journal.

Examples of good titles are: Pharmacy Bulletin, Pharmacy News, Therapeutic Notes, Pharmacy Review, and Pharmacy Newsletter.

Examples of titles which are not acceptable are: The Mortar and Pestle, The Pill Roller News, Drug Store News, News Capsules, etc.

CONTENTS

Since the purpose of this publication is to educate as well as to inform, it is imperative that its contents be of such a nature.

In general, the publication should be divided into five categories. They are as follows:

A. Editorial.
B. New Drug Section.
C. Abstract of the Pharmacy and Therapeutics Committee Meeting.
D. Lead articles by prominent members of the medical staff.
E. General.

The *editorial,* prepared by the Pharmacist-in-Chief or other interested member of the Pharmacy and Therapeutics Committee, should be a means whereby new procedures relative to ordering, prescribing, storage or administration of drugs within the hospital are introduced and publicized. It may also be used to focus attention on infractions of established procedures and to editorialize therapeutic trends and opinions.

The *new drug section* should contain the major data on each drug accepted for use within the hospital by the Pharmacy Committee. Major information in this instance includes a brief description of the drug, its range of usefulness indications, side effects, administration and dosage and how supplied by the pharmacy. The format employed in the presentation of this information may be in a number of forms.

The *abstract of the minutes* of the Pharmacy and Therapeutics Committee meeting is a worthy inclusion in the publication in that it keeps

the entire staff aware of the constantly changing trend of therapeutics within the institution. In addition, it allows those members of the staff who have had reason to communicate with the Pharmacy and Therapeutics Committee to note that their recommendations have received attention.

Each issue should have a *lead article* by a prominent member of the staff. The article should not be lengthy and should be restricted to an evaluation of current pharmaceuticals or trends of therapy within the author's field of specialization or to topics of current interest to the staff.

The section categorized as "General" may include anything the editor feels is of interest to the medical staff, nursing service or laboratory staff. Samples of the type of information that might well be placed in this category are abstracts of releases from the state department of public health, abstracts of articles of interest on current situations such as the recurrence of an outbreak of Asian influenza and abstracts from the various journals relative to unusual sources of poisoning in humans, drug research news or drug warnings.

This section can be particularly helpful to the medical and nursing staffs, when, due to a change of suppliers, medications arrive on the floor in new colors, shapes, sizes and packages. By planning ahead, nurses can be alerted to the proposed changes and can be assured that although medication appearances and brands may change as new suppliers are integrated into the system, drug content and quality remain constant.

FORMAT AND DUPLICATION

The format of the publication will vary with the originality of the pharmacist; therefore, the following description is provided as a basis for further development by the individual concerned.

The paper should be a good quality paper measuring 8½" × 11". In view of the fact that the first page should be inviting to the potential reader, it is recommended that the heading be preprinted. By so doing, you will have the advantage of being able to use stock cuts of pharmaceutical symbols which the printer can obtain for you in order to decorate the publication. In addition, you will be able to have the heading of each issue printed in a different colored ink on the white or colored paper stock. Neither of the above suggestions would cost much, but would serve to draw the attention to the potential reader (Fig. 20).

Some authors have suggested that the page be longitudinally split in half and the data typed in columns. The advantage of this being that many of the readers like to clip out the data on a new drug and affix

PHARMACY

℞ **BULLETIN** ℞

PETER BENT BRIGHAM HOSPITAL BOSTON, MASS.

Fig. 20

it to a page in their Formulary or, in the case of the nursing service, 3" × 5" cards in their new drug file.

DISTRIBUTION

The completed issue should be distributed to the following areas and individuals, provided they exist in the particular hospital:

A. Every member of the medical staff and to the staff library.
B. Administration.
C. Nursing Service.
   1. A copy to each station
   2. Several copies to Nursing School Office
   3. Nursing School Faculty
   4. Nurses' Library
D. Laboratories.

ADVANTAGES

The preparation of a pharmacy publication requires the time, effort and imagination of the pharmacist who undertakes such a project. On the other hand, a well-prepared issue can save the pharmacy a great deal of time by reducing the number of telephone calls concerning new drugs or newly instituted procedures.

In addition, it will add to the professional stature of the pharmacist within the institution and give him the satisfaction of having made a contribution towards better self communication between his department and the professional staff.

The ASHP, in recognition of the pharmacist's role in teaching patients about their drug therapy, has caused to be prepared and distributed a series of guidelines[3] to assist hospital pharmacists in this endeavor.

ASHP GUIDELINES ON PHARMACIST-CONDUCTED PATIENT COUNSELING[a]

It is well-documented that safe and effective drug therapy most frequently occurs when patients are well-informed about medications and their use. Knowledgeable patients exhibit increased compliance with drug regimens, resulting in improved therapeutic outcomes. Therefore pharmacists, as well as other health professionals, have a responsibility to properly inform patients about their drug therapy.

Pharmacists' drug consultations with patients should be aimed at improving therapeutic outcomes by maximizing proper use of medications. Pharmacists, in conjunction with other health team members whenever possible, must make appropriate value judgments to determine the specific information and counseling required in each patient care situation.

Using suitable verbal, written or audio-visual communication techniques and methods, the pharmacist should inform, educate and counsel patients (or their representative or guardian) about the following items for each medication in the patient's drug regimen:

1. Name [trademark, generic, common synonym or other descriptive name(s)];
2. Intended use and expected action;
3. Route, dosage form, dosage and administration schedule;
4. Special directions for preparation;
5. Special directions for administration;
6. Precautions to be observed during administration;
7. Common side effects that may be encountered, including their avoidance and action required if they occur;
8. Techniques for self-monitoring of drug therapy;
9. Proper storage;
10. Potential drug-drug or drug-food interactions or other therapeutic contraindications;
11. Prescription refill information;
12. Action to be taken in the event of a missed dose; and
13. Any other information peculiar to the specific patient or drug.

These thirteen points are applicable to nonprescription drugs as well as those ordered by a physician or other prescriber. In addition, pharmacists must counsel patients in the proper selection of nonprescription drugs as well as when and if they should be used.

[a]Approved by the ASHP Board of Directors at its meeting of November 17–18, 1975, and by the ASHP House of Delegates on April 7, 1976.

AUDIOVISUAL COMMUNICATIONS

Pharmacy communications should not be limited to printed materials. Today, most major teachng hospitals have on their staff individuals who are well versed in the science and art of audio and audiovisual educational materials. Slides, film strips and sound movies are an excellent means to communicate new techniques in drug administration, treatments and to highlight special reactions attributable to drug therapy. These educational materials can then be distributed by the pharmacy to the house staff, school of nursing, college of pharmacy and to small pharmacies in neighboring hospitals. These hospitals that do not have this in-house capability might give consideration to contracting for such service with an outside firm specializing in this type of work.

With the advent of the concept of the prescription package insert (PPI) hospitals might very well consider the preparation of a set of audio-visual materials on these drugs. By so doing patients will be able to study the material on the scene and thereby ask any questions that they may have prior to leaving.

SELECTED READING

Baker, David: A Study Contrasting Different Modalities of Medication Discharge Counseling. Hosp. Pharm., *19*:8:545, (Aug.) 1984.

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2. Stefani, E.: Consumer's Evaluation of Available Drug Information. Drug Inf. J., *11*:158–163, (July–Sept.) 1977.
3. ASHP Guidelines on Pharmacist-Conducted Patient Counseling. Am. J. Hosp. Pharm., *33*:644–645, (July) 1976.

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Investigational Use Drugs

By definition, research or investigational use drugs are those compounds or mixtures which have not been released by the Federal Food and Drug Administration for general distribution and use. These drugs usually bear the following statement on their labels:

Caution: New Drug—Limited by Federal Law to Investigational Use

They are released only to physicians who sign the proper Federal Food and Drug Release form for the manufacturer.

With the increased use of the clinical facilities of teaching hospitals for the therapeutic evaluation of investigational use drugs, it has become necessary to define the responsibility for the use of these products and to centralize pertinent information concerning them.

A lack of control and information relative to investigational use drugs in a hospital obviously can lead to chaos. This can induce drug administration "accidents" as well as deter suit-conscious, yet competent, clinical investigators from carrying out this important phase of medicine within the hospital.

Prior to 1950, the literature describing methods of controlling this class of preparations was sparse. As the tempo for the clinical evaluation of new drugs increased, so too did the literature describing methods employed by various hospitals to control the drugs and disseminate information concerning them to the proper personnel.

THE U.S. PUBLIC HEALTH SERVICE POLICY

The U.S. Public Health Service now requires assurance that the rights, privacy and welfare of human beings involved as subjects in research or training activities are protected, and that their informed consent has been obtained before subjecting them to any research procedure, and that any protocol involving human subjects has received *a priori* review and approval by a committee of the staff of the hospital.[1]

Thus each hospital has found it necessary to establish a Committee on Human Use in Research.

The Committee on Human Use in Research, a standing committee of the hospital, is charged with the responsibility of considering the problems associated with the use of human subjects for clinical research and other biomedical (including psychological) investigations, to establish guiding principles with respect to these matters, and to advise the Administrative officers with respect to policy issues that may arise. In accordance with the recommendations of this Committee, mechanisms are established to assure that every proposal for clinical research or investigation involving human subjects will receive the best possible review and guidance.

Any investigation that proposes to apply to human subjects a procedure of protocol potentially hazardous or uncomfortable (or which may invade his rights of privacy) and is not clearly for the individual's benefit, is to be reviewed prior to its initiation by the Committee on Human Use in Research at the hospital with reference to (1) the risks and potential medical benefits of the investigation, (2) the rights and welfare of the individuals involved, and (3) the appropriateness of the methods used to obtain informed consent. The committee's comments and any recommended changes in protocol or procedure should be reported to or discussed with the principal investigator and his chief of service. Appropriate written records should be maintained. A signed and dated report of the committee's recommendation on each application submitted by the hospital to outside sources of support for research or training should be forwarded to the proper administrative office and kept on file.

All research involving the use of human subjects must be approved by the appropriate chief of service, who is responsible for maintaining over-sight as the investigation proceeds. Any significant changes in protocol or emergent problems which would alter the experimental situation or adversely affect the rights or welfare of the subjects should be promptly referred to the Committee on Human Use in Research for Review and advice.

In order to ensure continuing surveillance of the research project by the Committee of Human Use in Research, each principal investigator should prepare a Continuing Surveillance Report, on a quarterly basis, and forward it to the Secretary of the Committee on Use of Humans in Research.

FDA Amendments of 1966

The Federal Food, Drug and Cosmetic Act was amended in 1966 by the addition of a new statement of policy as follows.

Consent for use of investigational new drugs on humans: statement of policy.[2]

(a) Section 505(i) of the act provides that regulations on use of investigational new drugs on human beings shall impose the condition that investigators "obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interest of such human beings."

(b) This means that the consent of such human beings (or the consent of their representatives) to whom investigational drugs are administered primarily for the accumulation of scientific knowledge, for such purposes as studying drug behavior, body processes, or the course of a disease, must be obtained in all cases and, in all but exceptional cases, the consent of patients under treatment with investigational drugs must be obtained.

(c) "Under treatment" applies when the administration of the investigational drug for either diagnostic or therapeutic purposes constitutes responsible medical judgment, taking into account the availability of other remedies or drugs and the individual circumstances pertaining to the person to whom the investigational drug is to be administered.

(d) *"Exceptional cases,"* as used in paragraph *(b)* of this section, which exceptions are to be strictly applied, are cases where it is not feasible to obtain the patient's consent or the consent of his representative, or where, as a matter of professional judgment exercised in the best interest of a particular patient under the investigator's care, it would be contrary to that patient's welfare to obtain his consent.

(e) "Patient" means a person under treatment.

(f) *"Not feasible"* is limited to cases where the investigator is not capable of obtaining consent because of inability to communicate with the patient or his representative; for example, where the patient is in a coma or is otherwise incapable of giving informed consent, his representative cannot be reached, and it is imperative to administer the drug without delay.

(g) *"Contrary to the best interest of such human beings"* applies when the communication of information to obtain consent would seriously affect the patient's disease status and the physician has exercised a professional judgment that under the particular circumstances of this patient's case, the patient's best interest would suffer if consent were sought.

(h) *"Consent" or "informed consent"* means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of an affirmative decision by such person the investigator should make known to him the nature, duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; all inconveniences and hazards reasonably to be expected, including the fact, where applicable, that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effects upon his health or person that may possibly come from the administration of the investigational drug. Said patient's consent shall be obtained in writing by the investigator. (See Figures 25 and 26, pp. 175 and 176, for sample Consent Forms.)

The Office of Grant Administration Policy

The Office of Grant Administration Policy, Department of Health and Human Services has issued its Manual, Chapter 1–40, entitled "Protection of Human Subjects." The stated purpose of the new manual is to establish uniform policies for the protection of human subjects involved in research, demonstration and other activities supported by the Department's grants and contracts.

Chapter 1–40 attributes broad definitions to the terms "subject" and "at risk" to include anyone exposed to the possibility of physical, psychologic, sociologic, or other adverse effect as a consequence of any activity which goes beyond the application of standard and accepted methods to meet individual needs. The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question.[3]

Emphasized in the policy is the responsibility of the grantee or contractor to safeguard the rights and welfare of human subjects. To provide for the proper discharge of this responsibility, the Department of Health and Human Services will not require the grantee or contractor to carry out initial and continuing committee review of all activities involving human subjects. The review must establish that the rights and welfare of the subject are adequately protected, that the risks to him are outweighed by the activity's potential benefit, and that informed consent is to be obtained by methods that are adequate and appropriate.[4]

This review is expected to take into consideration such matters as local standard of professional practice, applicable laws, practical aspects of community acceptability, and to benefit from the committee's knowledge of the personnel involved and of the conditions under which the study is to be carried out. The policy also requires a review of the grant application by a committee of the Department of Health and Human Services.[4]

The manual chapter further spells out procedures for certifying institutional review of applications, for institutional review of cooperative activities, for documentation of institutional committee actions, and for Department of Health and Human Services administration of policy. Responsibility for administration of the policy has been delegated to the Division of Research Grants, National Institute for Health because of its experience in the administration of a similar Public Health Service Policy.

Principles Involved in the Use of Investigational Drugs in Hospitals

The following *"Guidelines for the Use of Investigational Drugs in Hospitals"* was approved by the Board of Directors of the American

Hospital Association and has been published in the February 1979 issue of the *Journal of the American Society of Hospital Pharmacists* and is reprinted here for convenient reference.[5]

ASHP GUIDELINES FOR THE USE OF INVESTIGATIONAL DRUGS IN INSTITUTIONS[a]

Hospitals and related health care facilities, the primary centers for clinical studies on investigational drugs,[b] must ensure that policies and procedures for the safe use of these drugs are established and followed. This document is designed to help institutions to develop these policies and procedures and evaluate those presently in use.

Basic Principles

Procedures in the use of investigational drugs should be built around these basic principles:[c]

1. An institution that is the setting for investigational drug studies must assure that such studies contain adequate safeguards for itself, its staff, the scientific integrity of the study and, especially, the patient. In doing so, the institution must have written policies and procedures for the approval, management and control of investigational drug studies. Equally important, all involved staff must be fully informed about, and comply with, these policies and procedures.
2. All investigational drug studies must meet accepted ethical, legal and scientific standards and be conducted by appropriately qualified investigators.
3. All patients who participate in investigational drug studies must freely consent[d], in writing, to treatment with the drugs. This consent must be obtained from the patient or his legally authorized representative before treatment is begun, and only after the patient has been fully informed about the study objectives and the risks and benefits associated with the study drugs. No exhorbitant inducements should be offered to patients to encourage their participation in the study.

Guidelines for Institutions

The following recommendations will serve as a guide to develop investigational drug procedures in keeping with the aforementioned basic principles.

1. As required by federal regulation, institutions in which clinical research is conducted must have an Institutional Review Committee (IRC), often titled a "Committee on Human Investigations" or "Clinical Research

[a]Approved by the ASHP Board of Directors, December 12, 1978; revised November 18, 1982, based on the recommendation of the ASHP Council on Clinical Affairs. Originally developed by the ASHP Council on Professional Affairs.

[b]In this document, investigational drugs are defined as those which are being considered for, but have not as yet received, approval by the federal Food and Drug Administration for human use.

[c]It should be noted that the principles and procedures described here are applicable to *all* clinical drug studies, not just those involving investigational drugs.

[d]There are certain emergency situations in which a priori consent may be waived.

Committee." This committee must evaluate each proposed clinical research study in terms of its compliance with recognized ethical, legal and scientific standards. No clinical study may be initiated unless approved, in writing, by the committee. The committee must also monitor approved studies to ensure they are carried out appropriately. The Director of Pharmacy or the director's designee should be a member of the IRB or be consulted by the committee whenever drug studies are involved.

2. Investigational drugs must be used only under the supervision of the principal investigator or authorized co-investigators, all of whom must be members of the institution's professional staff.
3. The principal investigator is responsible for obtaining the written, informed consent of the patient to participate in the study. The informed consent process must conform to current federal and state regulations. Approval of the consent document by the IRB is required; review by the institution's legal counsel may be desirable also. The following items must be addressed, either in the document or its accompanying oral explanation by the investigator:
   a. A fair representation of the nature and purpose of the study, the expected benefits, and the risks or discomfort (or both) involved. The name of the person(s) to contact for answers to questions about the study or drug should be provided. Any compensation or treatment that will be furnished in the event of injury should be described.
   b. A balanced description of the alternative treatments available (including their respective risks and benefits).
   c. A general description of the study procedures and the expected length of therapy with the drug.
   d. A statement to the effect that: (1) the patient may withdraw from the study at any time without penalty; and (2) the principal investigator may remove the patient from the study if circumstances warrant.
   e. The name of the drug(s), name and signature of the patient and name and signature of the principal or co-investigator.
   f. A statement of who will have access to any study records that contain the patient's name.

   The consent form should be as detailed as is practical, minimizing the amount of information that must be presented orally. For non-English speaking patients, the consent form should be in the patient's own language when feasible or adequate interpretation provided. The patient (or his representative) must have adequate time to read the consent form before signing it and should receive a copy of the signed form.
4. The principal investigator is responsible for the proper maintenance of the case report forms and all other records required in the study by the drug sponsor, institution or Food and Drug Administration.
5. The institution's drug control system must contain the following elements regarding investigational drugs:
   a. Drugs must be properly packaged in accordance with all applicable standards and regulations (e.g., FDA, USP, Poison Prevention Packaging Act).
   b. Drugs must be labeled properly so as to ensure their safe use by the nursing staff and patient (see item 4 under "Guidelines for Pharmacists").
   c. There must be a mechanism to assure that sufficient supplies of the drugs are always available in the institution for the duration of the studies.

d. Nurses called upon to administer investigational drugs must have adequate written information about their pharmacology (particularly adverse effects), storage requirements, method of dose preparation and administration, precautions to be taken, authorized prescribers, patient monitoring guidelines and any other material pertinent to the safe and proper use of the drugs. They also should be informed about the overall study objectives and procedures.
e. Bulk supplies of the drug must be properly stored.
f. There must be a method to assure that only authorized practitioners prescribe the drug and that all patients who receive it have provided the necessary consent.
g. Records of the amounts of drug received from the sponsor and of its disposition (amounts dispensed to patients, returned to sponsor, etc.) must be maintained. These records should be retained for two years or as required by regulation.
h. If the patient is to receive the drug at another facility, suitable arrangements for its transfer must be made. Sufficient information for safe use of the drug (see item d above), including a copy of the patient's signed consent form and the study protocol, must accompany the drug. The facility to which the drug is transferred should have written procedures governing the proper handling of investigational drugs.
i. The institution's records on investigational drug studies should be designed so that various statistical reports (e.g., the names of all drugs under study, the names of those patients who have received a drug, etc.) may be generated conveniently and expeditiously.

The pharmaceutical services standards of the Joint Commission on Accreditation of Hospitals[a] and the ASHP Minimum Standard For Pharmacies in Institutions[b] note that the pharmacy is the area to which the drug control responsibilities described above should be assigned. This is to the advantage of the principal investigator, who will be relieved of many of the technical aspects of drug control, and therefore will have more time for the clinical concerns of the study. In addition, the pharmacy may be able to assist in protocol development, drug procurement, preparation of codes for blinded studies, patient monitoring, education of nursing and personnel, data collection and analysis, and special dosage form and packaging development.

GUIDELINES FOR PHARMACISTS

The pharmacist is reponsible to the institution and the principal investigator for seeing that procedures for the control of investigational drug use as described above are developed and implemented. Suggestions to accomplish this are as follows; however, each facility must develop procedures specific to its own needs and organization.

[a]Joint Commission on Accreditation of Hospitals. Accreditation manual for hospitals. Chicago, IL: Joint Commission on Accreditation of Hospitals; 1982.
[b]American Society of Hospital Pharmacists. ASHP minimum standard for pharmacies in institutions. *Am. J. Hosp. Pharm.* 1977; *34*:1356–8.

1. A copy of the IRB-approved research protocol should be kept in the pharmacy.
2. Using the protocol and additional information (if needed) supplied by the principal investigator, the pharmacy should prepare an Investigational Drug Data Sheet which concisely summarizes for the medical, nursing and pharmacy staffs information pertinent to use of the drug. This form should contain, at the minimum: (a) drug designation and common synonym(s); (b) dosage form(s) and strength(s) available; (c) usual dosage range, including dosage schedule and route of administration; (d) indications; (e) expected therapeutic effect; (f) expected and potential untoward effects (including symptoms of toxicity and their treatment); (g) contraindications; (h) storage requirements; (i) instructions for dosage preparation and administration; (j) instructions for disposition of unused doses; (k) names and telephone numbers of principal and authorized co-investigators. The drug data sheet should be reviewed by the principal investigator and included with the study protocol submitted to the IRC. Copies should be distributed to the appropriate pharmacy staff and all patient care units where the drug will be used. It is the responsibility of the involved staff to become familiar with the information on these data sheets.
3. Investigational drug supplies must be kept only in the pharmacy. The pharmacy should maintain an Investigational Drug Inventory Record where a perpetual inventory of the drug is kept. This form[a] should contain the drug's name, dosage form and strength, lot number and the name, address and telephone number of the sponsor and any other information needed for ordering the drug. It should provide for recording data on the disposition of the drug (amounts dispensed, data, names of patients and prescribers) and the amount currently on hand.
4. The dispensing of investigational drugs should be integrated with the rest of the drug distribution system with respect to packaging, labeling, order review, profile maintenance, delivery and so forth. However, prescription labels for investigational drugs should be distinguishable from other labels by an appropriate legend (e.g., "investigational drug"). There must be a method to verify that a valid, signed consent form has been received from the patient prior to dispensing the initial supply of drug. The drug must be dispensed only upon the order of an authorized investigator.
5. Patient education and monitoring of therapy are two clinical functions which are particularly important and applicable to investigational drugs. These functions should be provided in a coordinated fashion by the pharmacy and nursing staffs and the authorized investigator(s).
6. At the conclusion of the study, the pharmacy should return all unused drugs to the principal investigator or sponsor.
7. The pharmacy should prepare for the institution's administrator an annual or semiannual statistical summary of investigational drug use, including such information as the number of drug studies in progress and a listing of all drugs studied during the previous year.
8. Drug costs and other expenses associated with investigational drug studies (e.g., costs of record-keeping, drug administration) should be properly allocated and reimbursed.

[a]Stolar, M.H., ed.: Pharmacy-coordinated investigational drug services. Bethesda, MD: American Society of Hospital Pharmacists; 1982.

Elaboration on these guidelines and further information on investigational drug studies is in the book *Pharmacy-Coordinated Investigational Drug Services.*

Classification of Drugs

Summarized, the *Statement of Principles Involved in the Use of Investigational Use Drugs in Hospitals* espouses four distinct purposes:

1. To establish a drug classification.
2. To centralize pertinent information concerning drugs available for research use.
3. To define the availability of such drugs to staff members.
4. To establish a single stocking and dispensing unit within the hospital.

In order to attain the above goals, it is necessary for the Pharmacy and Therapeutics Committee to establish a drug classification system within the hospital. By establishing drug categories, a more definitive approach to the control, distribution and utilization of drugs, within each category, may be realized.

One simple classification which can be adapted to any hospital research program is to categorize all drugs in the institution into four classes: Classes A, B, C, and D.

Class A should contain all investigational use drugs that are in a preliminary experimental stage. The use of drugs in this category is usually restricted to the principal investigator. With regard to the storage and dispensing of drugs in Class A, there are two schools of thought. One group believes that products in this category should be stocked and dispensed by the principal investigator; the other group firmly holds that all drugs should be stored and dispensed through the pharmacy by pharmacists. The advantages of the latter are obvious; however, both systems will work if the interested parties, the clinical investigator and the pharmacist, will cooperate in a united endeavor.

Class B should consist of investigational use drugs which have passed through the preliminary research stage. Usually, drugs in this category are supplied to the department of pharmacy by the principal investigator and are dispensed only upon his written prescription or those of his duly designated co-investigators.

Class C is limited to drugs approved by the United States Pharmacopeia, National Formulary, or passed by the Federal Food and Drug Administration for commercial distribution.

Drugs in this category may be used within the hospital or its clinics if the physician complies with the following procedure:

If the product is to be used by a single patient, the prescriber must obtain the consent of the Chief-of-Service or his duly designated alter-

nate (usually the Chairman of the Pharmacy and Therapeutics Committee) before the product may be obtained by the pharmacist.

A Class C preparation, which various members of the Staff feel has therapeutic promise, may be introduced into the hospital on a six-month trial. A request for such drug must be made to the Pharmacy and Therapeutics Committee which may then authorize the pharmacist to purchase, stock, and dispense the product. Pertinent data, concerning this special drug, are to be gathered and filed in the pharmacy office. At the completion of the trial period, the clinical experience is reviewed by the Pharmacy and Therapeutics Committee along with the clinician. If the results are favorable, the product is accepted into the hospital formulary; if the evidence is not favorable, the product is barred from further use within the hospital.

Class D drugs are preparations which have been accepted for use in the hospital and are listed in the hospital formulary.

Information concerning these products is to be kept in the general literature file in the pharmacy library.

Preparations in this class may be precribed routinely by any licensed physician on the hospital staff.

Another simple classification which can be adapted to any hospital pharmacy operation again classifies each drug into three categories: General, Conditional and Investigational.

1. **General**—An FDA-approved drug which as recommended as essential for good patient care with a well established usage, once accepted, may be prescribed by all members of the attending and house staff.
2. **Conditional**—Certain drugs may be approved for a conditional period of trial. A drug approved by the FDA for general use, but which the Committee wishes to evaluate for a given period before final consideration, may be prescribed by all members of the attending and house staff.
3. **Investigational**—Drugs which are not approved by the FDA for use other than under controlled clinical settings must be approved by the Research Advisory/Human Subjects Committees. Radioisotopes must also be approved by the Radiation Safety Committee. A protocol of any study involving drugs must be submitted to the Pharmacy.

CONTROL OF INVESTIGATIONAL USE DRUGS

All investigational use drugs should be registered with the Pharmacy and Therapeutics Committee. This may be accomplished by a letter from the principal investigator which provides the following information on each drug.

1. New Drug Number
2. Generic Name
3. Manufacturer
4. Proprietary Name (if any)
5. Chemical Name
6. General Chemistry
7. Pharmacology
8. Toxicology
9. Dose Range
10. Method of Administration
11. Antidote (if known)
12. Therapeutic Uses

The above data are usually found in the brochure prepared by the manufacturer and supplied to each investigator. Therefore, the brochure may be sent to the Pharmacy and Therapeutics Committee with a letter indicating the investigator's intent to use such a product.

Many pharmacists have developed various forms which may be used to disseminate the above information on an investigational use drug to the various staff doctors and nurses. These forms are usually titled *"Physician's Data Sheet on Investigational Drugs," "Nurse's Data Sheet on Investigational Drugs"* and *"Pharmacist's Data Sheet on Investigational Drugs."* Figures 21, 22 and 23 illustrate these various data sheets which have been used by the Pharmacy Service of the Veterans Administration Hospital in Albany, New York.[6] Under this system, the pharmacist completes the necessary form or portion of a form and sends it to the appropriate physician or pavilion each time a new investigational drug is prescribed. Although this method does offer control and proper dissemination of information, it is burdensome upon the phar-

PHYSICIAN'S DATA SHEET ON INVESTIGATIONAL DRUGS

1. Name of Investigational Drug _____
2. Manufacturer or Other Source _____
3. Strength and Form of Investigational Drug _____
4. Amount Received _____
   Date Received _____
   Control or Batch No. _____
5. *Pharmacologic and Therapeutic Properties, Dosage, Precautions:*
6. *Arrangements Which Have been Made for its Administration:*

_____
Investigator

Registered:

_____
Date

Fig. 21

NURSE'S DATA SHEET ON INVESTIGATIONAL DRUGS

1. Name of Investigational Drug: _____
2. Manufacturer or Other Source: _____
3. Strength and Form of Investigational Drug: _____
4. Pharmacologic, Therapeutic Properties and Precautions to be Observed:
5. *Arrangements Which Have Been Made for its Administration:*

_____
Chief Pharmacist

Fig. 22

macist since three different forms bearing similar information must be prepared.

Figure 24 illustrates a *New Drug Report Form*. This form, as designed, provides all of the data required for the proper handling of the investigational use drug by physician, pharmacist and nurse.

The *New Drug Report Form* may be placed on each pavilion, where it is readily available to any investigator. Each time a clinician desires to prescribe an investigational use drug, he must complete the *New Drug Report Form* in duplicate, place the original in the patient's medical record folder, and have the carbon copy sent to the pharmacy with the drug order slip appended. By so doing, the pharmacist is aware that the new drug is being used on a particular patient in a specific area, the nurses have the necessary information, and physicians on the pavilion also have all the necessary data. This same procedure should be followed irrespective of the number of patients using the drug on

PHARMACIST'S DATA SHEET ON INVESTIGATIONAL DRUGS

Investigational Drug: _____ Manufacturer: _____

Chief Investigator: _____

DATE	PHYSICIAN	PATIENT	R No.	AMOUNT	WARD

Fig. 23

PETER BENT BRIGHAM HOSPITAL

NEW DRUG FORM

Addressograph Use Only

New Drug No.: _____

Generic Name: _____ Date & Time of 1st Dose: _____

Trade Name (If Any): _____

Chemical Name: _____

Chemistry:

Pharmacologic Action:

Dose: _____ Method of Administration: _____

Toxicity: Antidote(s):

Therapeutic Uses: Names of physicians from whom drug is available:

Fig. 24

the same pavilion. In order to save the clinician's time in such a situation, he may complete one form in detail and permit either the medication nurse or resident to complete similar forms for each of the other patients on the same pavilion.

In hospitals where the research load may not be quite so heavy, the pharmacist may undertake to complete each set of *New Drug Report Forms* each time he receives an order for an investigational use drug.

The fact that carbon copies are used saves time and provides the identical information to both clinician and nurse. A separate file for prescriptions for each investigational use drug readily serves the purpose of tracing the drug and accounting for each dose consumed.

Identification of Investigational Use Drugs

Whenever Class A or Class B drugs are dispensed from the pharmacy, they should be labeled in such a manner as to differentiate them from routine prescription drugs. In some hospitals, investigational use drug

labels are printed in red ink on white paper stock. In addition to the commonly required label information of patient's name, date, prescription number, doctor's name and directions for use a space for the research drug number is provided. This double set of numbers, the prescription number and the manufacturer's research drug number, provides a two-day control relative to the identity of the product dispensed.

Charge Policy for Handling and Dispensing

Because it is usually difficult to convince drug investigators that investigational use drugs should be stored and dispensed from the pharmacy, many hospital pharmacists waive a charge for this service, the consensus being that it serves as an inducement to the investigator to avail himself of the pharmacist's service. In these institutions a charge is made when a special dosage form is prepared in the pharmacy. The basis of the charge is arrived at by determining the cost of materials and labor involved.

In hospitals where there is a potent Pharmacy and Therapeutics Committee, a routine nominal charge is made for handling and dispensing research drugs. This charge is usually passed on to the patient but, where sufficient funds are available to the investigator, he may wish to assume the total cost of the project and accordingly requests the pharmacy not to charge the patient but to bill his research grant or fund on a monthly basis.

Personnel in the department of pharmacy at Ohio State University Hospital have studied the administrative aspects of a pharmacy coordinated investigational drug service and its related cost.[7] It was demonstrated that an average of 5 hours is required to coordinate pharmacy participation in a drug study. A drug information specialist spends about 1.5 hours developing a data sheet on the investigational drug and recordkeeping consumes 11 hours per study. After ascertaining personnel and space charges, the director of pharmacy services should institute a departmental fee for the pharmacy's involvement in investigational drug studies.

Authorization for Treatment with Drug Under Clinical Investigation

The Law Department of the American Medical Association[8] states that drugs under clinical investigation should be administered only where:

1. the informed consent of the patient or his authorized representative has been obtained;
2. the physician is convinced of the reasonable accuracy of his di-

agnosis and, if necessary, has confirmed it by adequate consultation; and
3. existing methods of treatment have proven unsatisfactory.

The voluntary participation of the patient will not excuse a deviation from the physician's obligation to exercise his best skill in rendering the care required of a reasonable practitioner. Furthermore, the physician is advised to confine his clinical investigations of new drugs to those furnished by reputable sources who have supplied him with comprehensive written information concerning:

1. animal experimentation;
2. previous clinical investigations, if any;
3. recommended dosages;
4. contraindications;
5. possible side effects to be watched for, and
6. the safety and possible usefulness of the drug from existing data.

Since oral consent is not sufficient, the American Medical Association has developed medicolegal form number 29 (Fig. 25).

Another example of a consent form which does not limit itself to the use of investigational use drugs is that used on the Clinical Center of the Harvard Medical School at the Peter Bent Brigham Hospital (Fig. 26).

Since this text material is not intended to offer legal advice due to the fact that state laws vary from state to state, the hospital pharmacist is urged to consult the hospital's legal counsel for the law applicable to the area in which the hospital is located.

Role of the Pharmacist in the Clinical Evaluation of a Drug

Once the pharmacologist has demonstrated a new compound to be effective and safe in animal tests, clinical trials are invariably commenced. These trials usually proceed in two steps—preliminary and extended.

During the preliminary stage, the principal investigator cautiously administers the drug to a limited number of selected patients and closely follows the results. After having gained experience and confidence in its use, the investigator is generally ready to conduct an extended comprehensive evaluation of its efficacy.

It is during this stage that the pharmacist can play an important role by assisting in the development of the protocol and the control of a double blind study. Such tests are devised by having the experimental drug and the placebo prepared in exactly the same dose form. The

AUTHORIZATION FOR TREATMENT WITH DRUG
UNDER CLINICAL INVESTIGATION

Date _____ Time _____ A.M. P.M.

I authorize Dr. _____, the attending physician, to treat _____ with the drug presently
(Name of Patient)
identified as _____ for the following condition:

_____

_____

_____

(Describe symptoms of disease to be treated)

It has been explained to me that the safety and usefulness of the drug in the treatment of patients for the above condition are now being investigated and that the manufacturer or distributor has supplied the drug for the purpose of providing further evidence of its safety and usefulness.

I voluntarily consent to treatment with the drug and release the attending physician from liability from any results that may occur.

Signed _____
(Patient or person authorized to consent for patient)

Witness _____

Fig. 25

identified products are then entrusted to the pharmacist to dispense according to a predetermined pattern and to maintain an exact record of which patient received the true drug and which received the placebo. Neither the patient nor the physician is informed as to whether the placebo or potent article is being tried in any individual patient. All information for breaking double blind codes must be kept in the pharmacy. Should an emergency arise requiring the breaking of the code, the pharmacist on duty or on call is authorized to provide the necessary information.

In addition to the above role, the hospital pharmacist can render a valuable service to the new drug researcher by formulating new dosage forms from the pure chemical. A word of caution should be interjected at this point—since time is of the essence in a research project, many investigators will attempt to speed up the pharmacist by waiving certain control tests. The pharmacist should insist upon the time necessary to

CONSENT FORM

Patient's Name: _____ Date: _____

Project Title:

Description of procedure to be undertaken:

I have fully explained to the patient _____ the nature and purpose of the procedure described above and such risks as are involved in its performance.

_____
Physician's signature

I have been fully informed of the risks and possible consequences involved in the peformance of the procedure described above, have been advised that unforeseen results may occur and, nevertheless, hereby authorize Dr. _____ and such assistants as he may designate to perform the procedure upon me and hereby release and forever discharge him, such assistants, the Peter Bent Brigham Hospital, its officers, agents and employees, and all persons on its medical and surgical staff who are in any way connected with the procedure from liability from injury which may result directly or indirectly from the performance of the procedure.

_____
Patient's signature

_____
Witness

Fig. 26

develop a scientifically sound formulation as well as for the performance of chemical and bacteriological tests for potency and sterility.

As the Colleges of Pharmacy train more and more clinical pharmacists, these individuals become available to participate in the clinical evaluation of new drug products. Because of their training in biopharmaceutics, pharmacokinetics and in the use of modern instrumentation techniques of analysis, clinical pharmacists can monitor the blood and tissue levels of the new drugs as well as their excretion rates and thereby advise the clinical pharmacologist relative to the need for dosage adjustment, mode of administration or product formulation.

CLINICAL TESTING FOR SALE AND EFFECTIVE DRUGS

Investigational Drug Procedures[9]

Before 1962, there was no requirement that the Food and Drug Administration by notified that drugs were being tested on humans.

The 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act greatly strengthened the Government's authority over clinical (human) testing of new drugs.

With this new regulatory authority, the Food and Drug Administration has taken steps to:

1. Provide added safeguards for those on whom drugs are tested.
2. Improve reports by drug investigators.
3. Establish investigative procedures to supply substantial scientific evidence that a drug is safe and effective.

First Steps

Before a new drug may be tested on humans, the sponsor (usually a pharmaceutical firm, sometimes a physician) must give the FDA the information specified as a "Notice of Claimed Investigational Exemption for a New Drug" (Forms FD 1571, 1572, and 1573), known as an "IND." Copies of these IND forms may be obtained from:

Document and Records Service Section
(HFD-106)
Bureau of Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

The IND should include the following information:

a. Complete composition of the drug, its source, and manufacturing data, to show that appropriate standards exist to insure safety.
b. Results of all preclinical investigations, including animal studies. Initially, these should be directed toward defining the drug's safety, rather than its efficacy. The data must demonstrate that there will not be unreasonable hazard in initiating studies in humans. Further animal studies may be conducted concurrently with clinical studies. The Bureau of Drugs will, on request, comment on the adequacy of the proposed animal studies. The FDA generally requires as a minimum: (i) pharmacological profile, (ii) acute toxicity be determined in several species of animals and that the route of administration be that which will be used in the animal trials, (iii) short term studies ranging from two weeks to three months depending upon the proposed use to evaluate toxicity. Additional animal studies are frequently necessary.

c. A detailed outline (protocol) of the planned investigation.
d. Information regarding training and experience of the investigators. (See "Qualifications of Investigators.") Investigators are responsible to the sponsor and are required to submit, to the sponsor (not the FDA), either Form FD 1572 for clinical pharmacology or Form FD 1573 for clinical trials.
e. Copies of all informational material supplied to each investigator. (The type of information is listed in Form 1571.)
f. An agreement from the sponsor to notify the FDA and all investigators if any adverse effects arise during either the animal or human tests.
g. The investigator's agreement to obtain the consent of the person on whom the drug is to be tested before the test is made.
h. Agreement to submit annual progress reports and commitments regarding disposal of the drug when studies are discontinued.

Physician-Sponsored IND

When an investigator wishes to act as sponsor for the use of a drug solely as a research tool or for early clinical investigation of a drug of therapeutic or diagnostic potential (clinical pharmacology—phases 1 and 2) a simpler abbreviated form of submission is acceptable. An example would be the study of a drug that no manufacturer is interested in sponsoring. An outline of such a study should provide the following information:

1. The identity of the compound or compounds, together with the facts that satisfy the investigator that the agent may be justifiably administered to man as intended.
2. The purpose of the use and the general protocol.
3. Appropriate background information, including a brief statement of the investigator's scientific training and experience and the nature of the facilities available to him.

The physician sponsoring this form of IND deals directly with the FDA. The FDA has no authority over the practice of medicine and cannot require a physician to prescribe or not to prescribe for a drug for a particular illness. But physicians are encouraged to submit an IND when they use a drug for purposes other than those approved by the FDA, when the drug was marketed. This enables the FDA to accumulate data on the safety and efficacy of the drug for that kind of treatment and to share the information with other physicians.

The Clinical Investigation

The kind and extent of the investigational drug tests are crucial to producing the substantial scientific evidence of safety and effectiveness needed to approve the drug for marketing. This evidence is obtained in three phases:

Phase I

Pharmacology studies are used to determine toxicity, metabolism absorption and elimination, and other pharmacological actions; preferred route of administration, and safe dosage range. These studies involve a small number of persons and are conducted under carefully controlled circumstances by persons trained in clinical pharmacology.

Phase II

Initial trials are conducted on a limited number of patients for a specific disease treatment or prevention. Additional pharmacological studies performed concurrently on animals may be necessary to indicate safety.

Phase III

Proposals for this phase, involving extensive clinical trials, are in order if the information obtained in the first two phases demonstrates reasonable assurance of safety and effectiveness, or suggests that the drug may have a potential value outweighing possible hazards. The phase III studies are intended to assess the drug's safety, effectiveness and most desirable dosage in treating a specific disease in a large group of subjects. The studies should be carefully monitored, no matter how extensive.

The FDA receives constant reports on the progress of each phase. If the continuation of the studies appears to present an unwarranted hazard to the patients, the sponsor may be requested to modify or discontinue clinical testing until further preclinical work has been done.

30-Day Delay

After the sponsor submits his IND, he must wait 30 days before beginning clinical tests. This delay enables the FDA to review the protocol to make certains it contain all of the necessary information and to assure that patients are not exposed to unwarranted risks. The 30-day period may be extended if the FDA feels additional time is needed for the sponsor to correct deficiencies in the protocol. The FDA also may waive the delay requirement if it feels such action is justified.

Sponsors may discuss their protocols at any time either before or during the tests with the Office of Scientific Evaluation, Bureau of Drugs.

Test in Institutions

Drug tests on persons in hospitals, prisons, research facilities, and other institutions must be carefully supervised by institutional review committees.

The committees must be composed of persons with varying backgrounds, such as lawyers, clergymen or laymen, as well as scientists. They are appointed by the institution involved in the study. The FDA inspects the institutions periodically to determine if the committees are operating properly.

Qualifications of Investigators

The sponsor of an investigational new drug (usually the manufacturer) will ask the clinical investigator to supply the following information on Form FD 1572 (for the clinical pharmacologist engaged in

phase 1 or 2 trials) or Form FD 1573 (for the physician engaged in phase 3 clinical trials):

1. A statement of his education, training and experience.
2. Information regarding the hospital or other medical institution where the investigations will be conducted; special equipment and other facilities.

The training and experience needed will vary, depending upon the kind of drug and the nature of the investigation. In phase 1, the investigator must be able to evaluate human toxicology and pharmacology. In phase 2, the clinicians should be familiar with the conditions to be treated, the drugs used in these conditions and the methods of their evaluation. In phase 3, in addition to experienced clinical investigators, physicians not regarded as specialists in any particular field of medicine may serve as investigators. At this stage, a large number of patients may be treated by different physicians to get a broad background of experience.

Obligations of Investigators

The investigator must keep careful records of his study and retain them for at least two years after the NDA is approved. The records must be made available promptly to the drug sponsor and to the FDA when required. Regular progress reports must be sent to the sponsor.

Reports must be sent to the sponsor immediately when dangerous adverse effects are observed, so the FDA and the other investigators can be notified, and the study stopped if the hazard warrants.

The regulations regarding consent of human beings given investigational drugs must be observed.

Patient Consent

The law requires that before using investigational drugs on human beings, the physician must "obtain the consent of such human beings or their representatives except when it is not feasible or when in his professional judgment it is contrary to the best interest of such human beings."

The consent for use of an investigational new drug in phase 1 and phase 2 must be in writing. In phase 3, it is the responsibility of the investigator, taking into consideration the physical and mental state of the patient, to decide when it is necessary or preferable to obtain consent in other than written form.

If written consent is not obtained, the investigator must obtain oral consent except as provided above, and record that fact in the medical record of the person receiving the drug.

Causes for Termination of Investigation

The FDA may direct the sponsor to terminate an investigation at any stage under certain conditions. These include:

Evidence of significant hazard.
Convincing evidence that the drug is ineffective.
Submission of false data.
Omission of material information.
Unsatisfactory manufacturing practices.
Failure to conduct the investigation in accordance with the plan submitted by the sponsor and approved by the FDA.

Commercialization of the drug. The IND regulations are not intended to provide a way of marketing a drug for profit without an approved NDA.
Failure to submit progress reports at intervals not exceeding one year.
Failure to report serious or potentially serious adverse reactions.
Failure to meet requirements for patient consent.

The Commissioner may notify the sponsor of any of the above conditions and invite immediate correction. A conference may be arranged. If the corrections are not effected immediately the Commissioner may require the sponsor to terminate the investigation and recall unused supplies of the drug. The drug in question may not be reintroduced into clinical testing in man until additional data have been submitted to the FDA and the Commissioner has approved the proposed resumption of the study.

The Investigator and "Promotion"

The regulations forbid manufacturers or any persons acting for or on their behalf to disseminate any promotional material concerning a new drug prior to completion of the investigation.

This is not intended to restrict the full exchange of scientific findings in scientific or other communications media. Its purpose is to restrict promotional claims by the sponsor until the safety and effectiveness of the investigational drug have been established. Violation of the regulations by an investigator may result in FDA action to deny him further supplies of the drug. The manufacturer may also jeopardize his right to sponsor the investigation.

Special Preclearance before Human Trials

Before starting an investigation in any of the following categories, FDA approval is required for:

a. Substances controlled under Schedule I of the Controlled Substances Act (PL 91–513).
b. Investigations of drugs so toxic that their use may be justified only under special conditions.
c. Substances proposed for treatment of drug dependence.
d. Reinstitution of drug investigations which have been terminated by the Commissioner.

Use of Drugs for Laboratory Procedures

New drugs used only for studies in vitro (test tubes) or in laboratory animals are being exempted from the new-drug provisions of the Act provided they are labeled "Caution—Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans."

The exemption does not apply, however, for a new drug used in vitro when this use will influence the diagnosis or treatment of disease in a human patient—for example, discs to determine the sensitivity to antibiotics of bacteria in culture, or a stick or strip of paper incorporating a reagent to test for sugar in the urine. Apparent ineffectiveness of an antibiotic sensitivity disc or a false negative test for glycosuria might well lead to an incorrect diagnosis and deprive the patient of appropriate treatment.

Before such a preparation can be marketed there must be certification (in the case of antibiotics) or approval of a New Drug Application (in the case of other drugs). For that reason, it is necessary to submit adequate proof of the effectiveness of these preparations before they can be marketed.

INVESTIGATIONAL USE DRUGS AND THE PHARMACY AND THERAPEUTICS COMMITTEE

In view of the fact that all drugs used in the hospital are subject to review by the Pharmacy and Therapeutics Committee, it is this group's responsibility to develop procedures for the introduction of investigational drugs into the institution. The following policies are in force in one major teaching hospital.[10]

Investigational drugs are defined as those which have been filed with the Food and Drug Administration (FDA) in the form of a Notice of Claimed Investigational Exemption for a New Drug (IND) under the provisions of Section 505 of the Federal Food, Drug and Cosmetics Act and paragraphs 312.1 of Title 21 of the Code of Federal Regulations. Such drugs must be approved by the FDA and assigned an IND number. An investigaitonal drug must be approved by the Human Subjects Committee, the Pharmacy and Therapeutics Committee, and, if applicable, the Isotope Committee before it can be administered to Peter Bent Brigham Hospital patients.

In emergency situations, for the use of investigational drugs or an approved drug for a non-approved indication which has not been assigned an IND number by the FDA, the policy is as follows:

a. The physician must notify the Chairpersons of the Human Subjects and Pharmacy & Therapeutics Committees for their approval. When the Chairpersons cannot be reached, (holidays, nights or weekends) the physician may contact the Hospital administrator on call.
b. The physician shall be informed that neither the hospital nor other hospital personnel will be reponsible for any legal liabilities which may result from the use of the drug(s). Further, the physician shall hold these persons harmless and indemnify them against any legal action or payments made in connection therewith.
c. Patient, or legally responsible person, must sign a hospital approved consent form.
d. The physician is responsible to register the drug(s) in the Pharmacy and provide all pertinent drug information such as pharmacological action, contraindications, adverse reactions, dosage range and route of administration, who may administer the drug, where the drug will be stored and the name of the principal investigator.

Hospital pharmacists should know that there are a number of ways in which a physician may introduce an investigational drug into the institution. They are:

a. Obtain an IND individually
b. Become a co-investigator under another physician's IND and
c. Become an investigator for a pharmaceutical or chemical company under that firm's IND.

In those situations where a physician wishes to prescribe an investigational drug in one hospital but the drug is under a IND in another, the physician may be granted an emergency IND after telephoning the FDA and presenting the case for such special consideration.

INVESTIGATIONAL DRUG CIRCULAR

Because hospital pharmacists have great interest in investigational use drugs, it is suggested that they subscribe to the *Investigational Drug Circular*. This publication is issued by the Bureau of Medicine of the Food and Drug Administration. It is stated that the purpose of this *Circular* ". . . is to answer questions asked by drug sponsors and clinicians regarding requirements of the Food, Drug and Cosmetic Act. . . ."

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8

Developing the Budget

One of the most important tasks in the fiscal operation of the department is the preparation of the annual budget. Too often, many administrators and chief pharmacists take the development of the budget too lightly and thereby arrive at a document which does not serve its true purpose.

Hahn[1] describes the budget as an instrument

"... through which hospital administration, management at departmental levels, and the governing board can review the hospital's services in relationship to a prepared plan in a comprehensive and integrated form expressed in financial terms."

In order that the over-all hospital budget complies with the above definition, each and every departmental budget must be accurately prepared and submitted.

Hahn[1] further states that—

"A properly developed and used budget should have as its goals (1) development of standards of performance, (2) comparison of actual results with these standards thus identifying deviations, and (3) subsequent analysis of deviations to determine whether they are controllable or uncontrollable."

Larson[2] in writing on the political aspects of budgeting in hospitals believes that, the pharmacist, in order to participate more effectively in the budgetary process, must be cognizant of the political aspects of the process. Among these political considerations are

1. Personal considerations,
2. Development of confidence among other officials,
3. Institutional-philosophical pressures, and
4. Demographic pressures.

Each of these factors affects the power base of a department and, consequently, the strength of its bargaining position in the budgetary process.

Personal considerations, in the form of individual reputations, are important in any political process. An individual who has acquired a reputation for having submitted previous budgets that have been thor-

oughly researched and supported by substantial justification stands a better chance of having his budget submittal approved.

Since most pharmacy programs affect other hospital departments, it is important for the Director of Pharmacy Services to obtain their collaboration and support. This support from the other departments provides the clout necessary to win administrative approval of the proposed program.

The institutional-philosophical considerations in the budgetary process consist of the goals and objectives of the hospital and its divisions. Since many state planning agencies require hospitals to submit 1- and 5-year plans outlining the institution's short- and long-range programs, it is of vital importance that the programs of the pharmacy service coincide with the overall plan of the institution.

In view of the fact that most hospitals are community based, the consumer public has made inroads into the decision making process of the institution. Today, many boards of trustees have consumer representatives from the local community serving on them. With a knowledge of the demographic, epidemiologic and attitudinal characteristics of the communities they serve, pharmacists are able to delineate the services desired and needed by the people.[2]

A budget is a short-range plan for future operations. The meaning and appropriate use of a budget must be clearly understood by those in managerial positions since their participation is required in its preparation and their cooperation is essential if it is to serve the function of a control device over operations. Prior to embarking upon a plan, management must first define the purpose of the unit, establish policies for its operation, and project the hospital's growth.

The plan should be reasonable and, through the concientious efforts of all personnel, attainable. It should not forecast results that are not possible under current and anticipated conditions. Students must not be misled when first exposed to the jargon "estimated results" during a discussion of a budget. This does not mean guesswork but rather carefully determined values based upon a knowledge of current financial and operating conditions and their relationship to future periods. The budget must not be construed as a tool to restrict initiative or to be impervious to the effects of changing conditions.

Between 1976 and 1979, hospital costs rose at an average annual rate of 14.1%, which turned out to be higher than the total inflation rate of all cost indicators.[3] Health-related expenditures in 1980 accounted for approximately 10% of the gross national product, compared with 8.5% in 1975.[4]

Supplies and other expenses usually comprise 60 to 70% of a pharmacy department's operating budget; drugs and intravenous solutions account for more than 95% of the category. The remainder of the op-

erating budget is assigned to salaries (approximately 27%) and capital equipment.[5]

In 1978, the federal government began giving serious consideration towards price control and cost containment legislation in an effort to control spiraling health care costs. Not desirous of further governmental intrusions into an already over-regulated industry, a coalition of business, industry, labor, insurance and health care associations was formed and identified as "The Voluntary Effort to Contain Health Care Costs" commonly referred to as the "VE" program. Among the organizations joining to form the coalition were the American Hospital Association, American Medical Association, Federation of American Hospitals, Health Industry Manufacturers Association, Health Insurance Association of America and the Blue Cross and Blue Shield Associations.

The purpose of the "VE" program was to decelerate the rapidly rising cost of health care by instructing all providers to redouble their commitment to cost containment and to specifically request institutions to keep their operating and capital budgets at the lowest possible level.

The type of reimbursement that a hospital operates under is of great importance. Knowing the potential for increasing revenue over costs will affect the type of budget developed. For example, if the hospital is basically cost-reimbursed with little charge reimbursement, budgeting increased revenue is meaningless. On the other hand, projections showing expenditures that are within the cost restraints of the institution, or which actually decrease costs are desirable.[6]

In the preparation of the budget, it is important to consider the impact of reimbursement under the Tax Equity and Fiscal Responsibility Act (TEFRA), Diagnostic Related Groupings (DRGs) and Health Maintenance Organizations (HMOs) amongst others. For example, with the inplementation of Social Security's Prospective Payments for Medicare Inpatient Hospital Services, hospitals must conform to a prospective payment system to replace the former cost-based reimbursement system for short-term acute care hospitals. The prospective payment system provides for a fixed price for DRG's that will be paid to hospitals.[6]

SECTIONS OF THE BUDGET

Every budget consists of three separate parts, *(a)* Revenue Accounts, *(b)* Expense Accounts and *(c)* Capital Equipment Requests.

The Revenue Account

The *Chart of Accounts and Definitions for Hospitals*[7] provides as follows.

PHARMACY

Account Number	
Revenue	Expense
4070	7070

"This department produces, preserves, stores, compounds, manufactures, packages, controls, assays, dispenses, and distributes medications (including intravenous solutions) for inpatients and out-patients under the direction of a licensed pharmacist. Pharmacy services include the maintenance in designated areas of separate stocks of commonly used items. Additional activities can include, but are not limited to: development and maintenance of formularies established by the medical staff, consultation with and advice to medical and nursing staff on drug therapy, adding drugs to intravenous solutions, determining incompatibility in drug combinations, and stocking floor drugs and dispensing machines.

This responsibility center should be credited or charged with all the direct revenues and expenses incurred in maintaining a pharmacy under the direction of a licensed pharmacist. Appropriate subaccounts should be established to accumulate the expenses of this center under the natural classification—salaries and wages, supplies, and so forth. The cost of supplies and equipment that are not billed to patients and are issued at invoice cost to other areas represented by responsibility centers should be transferred to the accounts of the consuming responsibility centers on a monthly basis."

A commonly used method is whereby either the department of pharmacy or the accounting department maintains a daily, weekly, monthly or annual total of the cost of the pharmaceuticals issued to the various patient services as well as to the special service departments. This total, when added to that obtained from the processing of patient prescriptions and requisitions, represents the true income of the department.

In addition, there are other statistics that are of value in assisting management to accurately predict the volume of activity of the department of pharmacy. They are:

a. Number of prescriptions according to subcategories.
b. Number of prescriptions dispensed per pharmacist.
c. Hours of service.
d. Prescription volume per hour of service.
e. Medication cost per patient day.
f. Medication cost per clinic visit.
g. Average drug cost per prescription.
h. Average salary cost per prescription.
i. Average supply cost per requisition.

Although, "income" is considered as a single figure by the beginner, it is important to understand the derivation of the figure. Generally, income in the hospital pharmacy is limited to the sale of drugs to inpatients, ambulatory patients and departments of the hospital. However, the sale of drugs to patients may be sub-divided further based

upon the patients' ability to pay or to their employment status if they are employed by the hospital. The following sub-division is but one example:

a. Full pay.
b. Part pay.
c. Non-pay
d. Physicians
e. General employee.

If income is generated from a combination of the above, it is desirable to separate the data so as to lead to more accurate appraisal and evaluation.

In some hospitals, the Controller may choose to treat income from the sale of drugs to other hospital departments as a "deduction" from the Purchase Account rather than added to the Income Account on the premise that such a maneuver enables a better evaluation of drug purchase costs for patient use.

THE EXPENSE ACCOUNTS—GENERAL INFORMATION

Expense accounts may be divided into four general categories—*Administration and General; Professional Care of Patients' Out-Patient and Emergency* and *Other Expenses.*

The department of pharmacy is listed under the category of Professional Care of Patients and is assigned code number 4070 for revenue and 7070 for expenses. (This code need not be used by all hospitals.) Each subdivision under this expense code number is coded by the addition of a dot and another digit, *e.g.*, 7070.1 is the code for Salaries and Wages; 7070.2 for Supplies and Expenses.

Although the hospital pharmacist will not be involved with the establishing of expense codes for his department (this being the prerogative of the comptroller), he should have a general understanding of what expenses belong under each section expense code.

Accordingly, the following is a sample categorization and contents.[8]

Salaries and Wages

Salaries and wages of pharmacists, assistants, clerks and other employed in the hospital pharmacy department.

Supplies and Expense

Drugs and Pharmaceuticals

Drugs and pharmaceuticals dispensed by prescription or otherwise from the hospital pharmacy department. Drugs and pharmaceuticals used in the outpatient and emergency departments should be charged there and not to this account.

Purchaed Services

This account should include the cost of prescriptions (excluding those in-

tended for out-patients) purchased from an outside pharmacy in the event the hospital does not have its own pharmacy.

Miscellaneous Supplies and Expense

Bottles, labels, glassware, narcotic and alcoholic permit fees, printed forms and stationery, pharmacists' uniforms, reference books, etc. Parts required to repair and maintain equipment used by this department and repairs made by outside concerns to such equipment also should be charged to this account, to separate sub-accounts if significant in amount.

It should be clearly understood that the above codes and designations are not intended to provide the ideal system of segregating costs. At most, it is a guide and should be modified by the individual hospital to meet its particular need.

EXPENSE ACCOUNT—SALARIES AND WAGES

In order to arrive at an accurate determination of the salaries and wages, it is recommended that the Pharmacist-in-Chief prepare a breakdown of the personnel in the department of pharmacy into the following categories:

a. Authorized permanent full-time positions—filled.
b. Authorized permanent full-time positions—vacant.
c. Authorized permanent part-time positions—filled.
d. Authorized permanent part-time positions—vacant.
e. Authorized temporary positions.
f. Proposed new positions.
g. Overtime requested.

It may also be of value to the Pharmacist-in-Chief if he further subdivided the above positions into three sub-categories, *i.e.*, administrative, professional and non-professional staff. It may be useful to prepare a table of all full-time administrative, professional and non-professional pharmacy staff and a similar table for the part-time employees in each category. Once the proposed annual salary for each employee is determined, the cost of new positions is added and finally any overtime which, according to past experience may be necessary, is also added. This, then, represents the total anticipated salary and wage expenditure for the next fiscal year.

EXPENSE ACCOUNT—SUPPLIES AND MATERIAL

In developing the supplies and expense portion of the budget, it is important for the department head to have available the dollar amount budgeted for each expense code for the fiscal year. It is also necessary to have available the latest financial statement showing the present

actual cost of materials and supplies. From this, it is a relatively simple mathematical process to estimate what the actual expense will be for the present fiscal year. If the budgeted figure and the estimated actual figure agree, then the previously prepared budget was well done. On the other hand, if these two figures are too far apart, it indicates that either there was an error in the calculation of the previous year's expense budget or something has occurred or is occurring in the present fiscal year which was not anticipated and, therefore, needs investigation and evaluation.

If the department is to be involved in an expansion program of service, *i.e.*, dispensing to new clinics, opening of a new wing, etc., then the Pharmacist-in-Chief should ascertain the cost of the materials and supplies to be consumed by the new program and so provide for it in the new budget.

From the above discussion, it would appear that the department of pharmacy is required to keep rather detailed records in order to arrive at the figures requested by the budget. Although it is highly desirable to accumulate one's own statistical data, it is common practice for the pharmacist to rely upon the accounting department for many of his base figures. Therefore, there should be developed a close rapport between the Pharmacist-in-Chief and the Comptroller.

EQUIPMENT AND CONSTRUCTION BUDGET

In hospitals where funding of the depreciation of physical plant and equipment is practiced, the actual cash for replacement or remodeling is usually readily available. In those hospitals where funding is not a policy, then construction and purchase of equipment creates a major financial burden requiring the development of a comprehensive and detailed budget.

However, irrespective of the policy with regard to funding, an equipment and construction budget must be prepared. Many hospitals require that any price of equipment with a unit cost of $500 or more is considered to be "capital equipment" and must be included in this portion of the budget. By the same reasoning, any construction with a total cost which exceeds $500 is considered "major" and must also be included in this section of the budget. Although the figure of $500 appears to be quite low, it is usually intentionally set at this level in order to exert greater control.

For the convenience of the reader, the following is a check list of depreciable equipment commonly found in the department of pharmacy[8] and which provides an indication of the "life" of the item.

DEPRECIABLE EQUIPMENT CHECK LIST

Professional Equipment	*Life in Years*	*Professional Equipment*	*Life in Years*
Balances	10	Meters, conductivity	25
Cabinets		Mixers, electric	10
Metal	20	Prescription cases, cabinets	15
Wood	15	Pumps, vacuum and pressure	10
Capsule machines	15	Refrigerators	10
Chemical hoods	10	Rinsers	10
Cleaners, pressure	15	Safe, Narcotic	25
Distilling apparatus	15	Scales	15
Drum hoists	15	Sterilizers	20
Filters (except glass)	10	Tanks	15
Homogenizers	15	Typewriters	5
Hot plates	10	Worktables	10
Labels, cabinet	15		

Administrative Equipment	*Life in Years*		
Adding machines	10	Clocks	15
Bookcases, metal	20	Desks, wood	15
Bulletin Boards	10	Filing Cabinets, metal	20
Calculators	10	Lockers, metal	20
Cash Registers	10	Worktables	10

During the budget preparation process, it is essential to prepare work papers that can be used to eliminate confusion and provide a good set of reference documents for later use. One way is to produce simple work sheets, for example, the supplies and expenses detail sheet (below). While there are far too many items to be listed individually, the central storeroom listing of inventory items will provide useful groupings, i.e., instruments, office supplies etc. for which an average cost and approximate usage can be determined.

SUPPLIES & EXPENSE DETAIL

Department _____ Account Code _____ Date _____

Item	Unit Cost ×	Inflation = Index	Projected × Unit Cost	Projected = Ann. Usage	Projected Ann. Cost

Another example is the travel budget request form which provides an accurate record of this type of activity for use by the department after it has ceased to be useful in the budget preparation.

TRAVEL BUDGET REQUEST

Department _____ Account No. _____ Date _____

Prepared By: _____

Name and Position of Traveler	Destination	Purpose of Trip	Days Away	Budget Request

SELECTED READINGS

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9

Purchasing and Inventory Control

The purchase and inventory control of pharmaceuticals is a special and important phase of the operation of a successful hospital pharmacy.

A portion of the purchases, controlled drugs and alcohol, is rigidly controlled by Federal regulations which in reality provide the means for accurate purchase and inventory control. These two classes of products, however, constitute a relatively small portion of the over-all purchases of an institutional pharmacy. Therefore, the purchase and control of the largest segment of the inventory is left to the administrative staff of the hospital or its duly authorized delegates.

In most general hospitals with an out-patient clinic operation, a pharmacy inventory of $100. to $200. per bed may be considered reasonable. However, many pharmacies, particularly those associated with the large teaching hospitals, include in their inventory parenteral and irrigating fluids, surgical dressings, rubber goods, sutures, surgical instruments, syringes and laboratory supplies. Clearly then, the dollar value of the inventory when expressed in dollars per bed may vary depending upon the variety of the inventory as well as the activity of the institution. In general, the pharmacy inventory should be adapted to the individual hospital's needs taking into consideration its distance from a source of supply, storage facilities, and rapidity of inventory turn-over.[1]

In view of the fact that, throughout this discussion, three words "purchase," "inventory" and "control" will be in constant use, it is felt that these terms should be defined.

The word *purchase*, as defined in the dictionary, has numerous meanings, the most appropriate being—"to obtain by paying money or its equivalent; to buy for a price."

The word *inventory* is defined as—"an itemized list of goods with their estimated worth; specifically an annual account of stock taken in any business."

The word *control* is defined as follows—"to exercise, directing, guiding, or retraining of power over."

Purchasing Agent vs. Pharmacist

The hospital literature is replete with articles dealing with the question, "Should pharmaceutical and related products be purchased by the purchasing agent or the pharmacist?"

One school believes that all institutional purchasing should be centralized under the aegis of the purchasing agent. According to this system the pharmacist, like all other department heads, requests, on a special form, the item to be purchased. The selection of the brand and vendor is thereby left to the discretion of the purchasing agent, unless the pharmacist has prepared a list of specifications which may or may not restrict the selection to the product of a particular manufacturer. This system has certain control and economic merits and can function within the hospital. It must, however, depend upon the close cooperation between the pharmacist and purchasing agent. Each must be aware of the definite contribution which he can make to such a specialized purchase.

The other school believes that pharmaceuticals and related items constitute specialties which require the technical skills of a formally trained individual for their proper selection and purchase.[2]

A leading advocate of this school was Dr. Malcolm T. MacEachern who in his text[3] stated:

"... the purchase of drugs and pharmaceuticals is a specialty which can be carried out to the best advantage by a pharmacist trained in managing a hospital pharmacy. ... This is the only department in the hospital in which it is usually *not* advisable to have purchasing done by a general purchasing agent."

One of the principles enunciated in the American Society of Hospital Pharmacist' *Minimum Standard for Pharmacies in Hospitals*[4] is that "... the pharmacist in charge shall be responsible for specifications both as to quality and source for purchase of all drugs, chemicals, antibiotics, biologicals and pharmaceutical preparations used in the treatment of patients. . . "

This same document under the section on *Elaboration of Responsibilities* goes on to state that

.... "The pharmacist should furnish specifications for the purchase of all drugs, chemicals and pharmaceutical preparations even though a purchasing agent may do the actual procurement through a centralized department.

Since the pharmacist has the responsibility for the compounding, dispensing and manufacture of the drugs used in the hospital he should also have the authority to specify the drugs to be purchased. In large institutions with centralized purchasing, the pharmacist and the purchasing agent should work hand-in-hand, each recognizing the importance of the function of the other. In such a system it is essential that the pharmacist state the specifications for drugs to be purchased and to have authority to reject any article below standard or not complying with specifications so that the purchasing agent may be guided

and assisted in his function. The pharmacist will also, in certain instances, wish to consult with the Pharmacy and Therapeutics Committee concerning specifications for drugs."

Franck[5] writing editorially states that "in the application of this principle, the pharmacist is made, in effect, the agent of the medical staff and of the hospital for the specification of medicinal agents. Justification for this lies in the fact that since the pharmacist has the responsibility for the compounding, dispensing and manufacturing of drugs in the hospital, he should also have the authority for the specifications of drugs to be purchased."

The hospital may follow the intermediate plan whereby the actual function of purchasing is retained by the purchasing department, and yet utilize the benefits of the technical knowledge of the pharmacist by permitting him to develop the necessary specifications for the purchase of the drugs and allied products.

The importance of a policy governing the procurement, drug selection and purchasing authority are clearly stated in the following excerpt from the ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control.[6]

PROCUREMENT: DRUG SELECTION, PURCHASING AUTHORITY, RESPONSIBILITY AND CONTROL

The selection of pharmaceuticals is a basic and extremely important function of the hospital pharmacist, who is charged with making decisions regarding products, quantities, product specifications and sources of supply. It is the pharmacist's obligation to establish and maintain standards assuring the quality, proper storage, control, and safe use of all pharmaceuticals and related supplies (e.g., fluid administration sets); this responsibility must not be delegated to another individual. Although the actual purchasing of drugs and supplies may be performed by a nonpharmacist, the setting of quality standards and specifications requires professional knowledge and judgment and must be performed by the pharmacist.

Economic and therapeutic considerations make it necessary for hospitals to have a well-controlled, continuously updated formulary. It is the pharmacist's responsibility to develop and maintain adequate product specifications to aid in the purchase of drugs and related supplies under the formulary system. The *USP-NF* is a good base for drug product specifications; there also should be criteria to evaluate the acceptability of manufacturers and distributors. In establishing the formulary, the pharmacy and therapeutics committee recommends guidelines for drug selection. However, when his knowledge indicates, the pharmacist must have the authority to reject a particular drug product or supplier.

Though the pharmacist has the authority to select a brand or source of supply, he must make economic considerations subordinate to those of quality. Competitive-bid purchasing is an important method for achieving a proper balance between quality and cost when two or more acceptable suppliers market a particular product meeting the pharmacist's specifications. In selecting a vendor, the pharmacist must consider price, terms, shipping times, dependability,

quality of service, returned goods policy, and packaging; however, prime importance always must be placed on drug quality and the manufacturer's reputation. It should be noted that the pharmacist is responsible for the quality of all drugs dispensed by the pharmacy.

Records. The pharmacist must establish and maintain adequate record-keeping systems. Various records must be retained (and be retrievable) by the pharmacy because of governmental regulations; some are advisable for legal protection; others are needed for JCAH accreditation, and still others are necessary for sound management (evaluation of productivity, workloads and expenses, and assessment of departmental growth and progress) of the pharmacy department. Records must be retained for at least the length of time prescribed by law (where such requirements apply).

It is important the pharmacist study federal, state, and local laws to become familiar with their requirements for permits, tax stamps, storage of alcohol and controlled substances, records, and reports.

Among the records needed in the drug distribution and control system are:

- Controlled substances inventory and dispensing records.
- Records of medication orders and their processing.
- Manufacturing and packaging production records.
- Pharmacy workload records.
- Purchase and inventory records.
- Records of equipment maintenance.
- Records of results and actions taken in quality assurance and drug audit programs.

Receiving Drugs. Receiving control should be under the auspices of a responsible individual, and the pharmacist must ensure that records and forms provide proper control upon receipt of drugs. Complete accountability from purchase order initiation to drug administration must be provided.

Personnel involved in the purchase, receipt, and control of drugs should be well-trained in their responsibilities and duties and must understand the serious nature of drugs. All nonprofessional personnel employed by the pharmacy should be selected and supervised by the pharmacist.

Delivery of drugs directly to the pharmacy or other pharmacy receiving area is highly desirable; it should be considered mandatory for controlled drugs. Orders for controlled substances must be checked against the official order blank (when applicable) and against hospital purchase order forms. All drugs should be placed into stock promptly upon receipt, and controlled substances must be directly transferred to safes or other secure areas.

Drug Storage and Inventory Control. Storage is an important aspect of the total drug control system. Proper environmental control (i.e., proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored in the institution. Storage areas must be secure; fixtures and equipment used to store drugs should be constructed so that drugs are accessible only to designated and authorized personnel, such personnel must be carefully selected and supervised. Safety also is an important factor, and proper consideration should be given to the safe storage of poisons and flammable compounds. Externals should be stored separately from internal medications. Medications stored in a refrigerator containing items other than drugs should be kept in a secured, separate compartment.

Proper control is important wherever medications are kept, whether in gen-

eral storage in the institution or the pharmacy or patient care areas (including satellite pharmacies, nursing units, clinics, emergency rooms, operating rooms, recovery rooms, and treatment rooms). Expiration dates of perishable drugs must be considered in all of these locations and stock rotated as required. A method to detect and properly dispose of outdated, deteriorated, recalled, or obsolete drugs and supplies should be established. This should include monthly audits of all medication storage areas in the institution. (The results of these audits should be documented in writing.)

Since the pharmacist must justify and account for the expenditure of pharmacy funds, he must maintain an adequate inventory management system. Such a system should enable the pharmacist to analyze and interpret prescribing trends and their economic impacts, and appropriately minimize inventory levels. It is essential that a system to indicate subminimum inventory levels be developed to avoid "outages," along with procedures to procure emergency supplies of drugs when necessary.

ROLE OF PURCHASING AGENT IN DRUG PROCUREMENT

The role of the purchasing agent in drug procurement may vary markedly from small to large hospitals. In the small hospital, the purchasing function may be a part-time one and may be handled by the administrator, an administrative assistant or the storekeeper. This, therefore, means that lack of time or pressure from other duties will cause the individual to restrict his activities in this function to a minimum.

In a large hospital, where the purchasing function is of such magnitude that it is a full-time position for one or more individuals, the purchasing agent may assume the following duties in relation to drug purchases:

1. issues purchase orders
2. maintains purchase records
3. follows-up on delayed orders
4. initiates competitive bidding procedures
5. obtains quotations from specified sources

ROLE OF PHARMACIST IN DRUG PROCUREMENT

The National Survey of Hospital Pharmacy Services[7] shows that in 87% of the hospitals surveyed pharmacists had the authority to select the brand supplier of the drugs dispensed; this is about 20% higher than in the 1975 survey. In addition, 72% of the hospitals were involved in group purchasing. This is nearly double the percentage in 1975.

Pharmaceuticals for hospital use may be purchased in one of the following ways:

1. by direct purchase from the manufacturer
2. by direct purchase from a wholesaler
3. by bid from either manufacturer or wholesaler[8]

4. by purchase from a local retail pharmacy (emergency purchases only)
5. by a contract purchase arrangement with the manufacturer (*e.g.* ampul contract or solutions contract)
6. by a contract purchase through a hospital purchase bureau or corporation.

The hospital pharmacist should acquaint the purchasing agent with the above avenues of drug purchasing. The choice of one over the other may be made by the pharmacist or left to the discretion of the purchasing agent.

With regard to bid purchasing, a word of caution needs to be interjected. If the bids for drugs are released to a select group of reputable manufacturers, then the lowest bidder should receive the purchase order and the hospital may be assured of receiving first-quality merchandise. If, on the other hand, the bids are released to all vendors requesting them, the lowest price does not always mean quality merchandise. Therefore, if this type of bid release program is to be employed, it is strongly recommended that some arrangement be made for the analytical and clinical testing of samples of the product. This testing program may be carried out by a local laboratory or by the hospital.

In addition to the above, the hospital pharmacist should, in collaboration with the purchasing agent, assume the following duties:

1. maintain a list of the names, addresses and telephone numbers of drug manufacturers, wholesalers, and their local representatives
2. prepare detailed specifications for drugs, chemicals and biologicals
3. prepare Request for Purchase Forms
4. prepare Receiving Memo if drugs are received directly by the pharmacy
5. prepare Return Goods Memo, whenever applicable.

With regard to the development of drug specifications, the hospital pharmacist should make liberal use of the latest editions of the *United States Pharmacopeia*, the *National Formulary* and their supplements. These compendia are officially referred to as the "U.S.P." and the "N.F."

PURCHASING PROCEDURE

The plan of purchasing procedures herein described assumes that there exist in the hospital a qualified pharmacist and a hospital purchasing agent who have been instructed to cooperate in the purchasing of pharmaceuticals and allied products. The plan further assumes that

specifications have been drawn and that all supplies ordered will be received and stored either in the pharmacy or in the storeroom exclusively controlled by the pharmacist.

The pharmacist, or a person authorized by him, should complete a **Purchase Request Form** (Fig. 27) for the product desired. Drugs coming from the same vendor may be grouped upon a single form. This form provides the purchasing department with the data concerning the description, specification, packaging, price, quantity needed as well as information concerning the inventory balance and anticipated monthly use. In addition, this form also is the source document for information which is of importance to the accounting office, namely the cost center to be charged and the discount which may or may not be earned upon payment for the merchandise. The original of this form should be forwarded to the administrative officer responsible for the department. Upon his approval, the form is then forwarded to the purchasing agent. The copy is retained by the pharmacist as a record of the fact that the merchandise is in the process of being procured.

Upon the receipt of the approved Purchase Request, the purchasing agent should then prepare the official **Purchase Order** (Fig. 28). This form utilizes the data from the source document, the Purchase Request. The purchase order may take the form of any number of different types—it may consist of a two-page or a many page snap-out form. The majority of institutions prefer the multi copy snap-out form since it provides a copy for the vendor, accounts payable department of the

DATE TODAY

PURCHASE OR REPAIR REQUEST

PETER BENT BRIGHAM HOSPITAL

Nº 0605

☐ REPAIR OF EQUIPMENT
☐ PURCHASE

DEPARTMENT NAME | Account NAME - Charge to:

CHARGE CODE | SUGGESTED VENDOR

DATE NEEDED

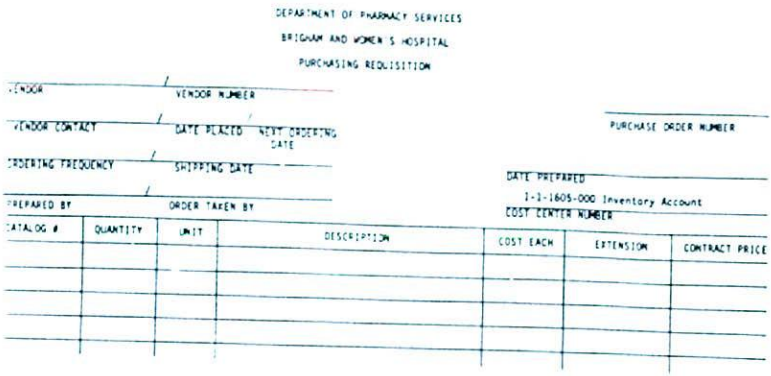
PURCHASE DEPARTMENT USE ONLY
TERMS | PURCHASE ORDER NO. NO.

COMMODITY NO.	DESCRIPTION — SPECIFICATIONS — PACKAGING	PRICE PER UNIT	UNITS NEEDED	TOTAL PRICE	QUANTITY ON HAND DATE	QUANTITY USED PER MONTH

REQUESTED BY _____ APPROVED BY _____

Form 90 FORWARD WHITE COPY TO PURCHASING/MAINTENANCE. RETAIN PINK COPY.

Fig. 27. Purchase Request Form.



DEPARTMENT OF PHARMACY SERVICES
BRIGHAM AND WOMEN'S HOSPITAL
PURCHASING REQUISITION

VENDOR _____ VENDOR NUMBER _____

VENDOR CONTACT _____ DATE PLACED _____ NEXT ORDERING DATE _____

ORDERING FREQUENCY _____ SHIPPING DATE _____

PURCHASE ORDER NUMBER _____

DATE PREPARED _____

PREPARED BY _____ ORDER TAKEN BY _____

1-1-1605-000 Inventory Account

COST CENTER NUMBER _____

CATALOG #	QUANTITY	UNIT	DESCRIPTION	COST EACH	EXTENSION	CONTRACT PRICE

Fig. 28. Purchase Order Form.

hospital, purchasing number file, initiating department, two receiving reports and a history copy.

The vendor's copy is either mailed or given to the vendor's representative.

The accounts payable copy is forwarded to the accounting office where it is held until the invoice is received from the vendor and the completed receiving reports from the initiating department. Then and only then may the invoice be processed for payment.

Copy 3 is retained by the purchasing agent for his "number file." This will serve as a source of information to him whenever a question is raised relative to the issuance of the order.

Copy 4 is returned to the initiating department, in this case, the pharmacy. This copy should be matched with the Request for Purchase to check for accuracy.

Copies 5 and 6 serve as receiving reports and are sent to the receiving department. If the order is received in full, only copy 5 is required to be completed and forwarded to the accounting office. Should merchandise be back ordered, the second receiving report (copy 6) is utilized.

Copy 7 is known as the history copy and is retained by the purchasing agent for use in ascertaining rates of use, etc.

Some hospitals prefer to use a separate purchase order form and a separate Receiving Notice. The disadvantage in the use of this system is that the individual receiving the merchandise must record by hand the name of each item. This may cause error and, if rushed by the load of work, a delay in receiving the completed memo in the accounting office, thereby causing a loss of the discount for prompt payment.

This form also provides for copies for the accounting department, purchasing agent, initiating department, and storeroom files.

Whenever merchandise that has been received by the hospital is to

be returned to the vendor for any cause, a Returned Goods Memorandum must be prepared, for it is by this means that the hospital can be assured of receiving credit for the merchandise. This form is of the snap-out type and provides for copies for the accounting department, purchasing agent, storeroom, initiating department and the vendor.

Once the merchandise is received, it is the duty of the pharmacist to record upon a **Purchase Record** (Fig. 29) the transaction for each item purchased. By so doing, he will have available a source of reference for determining rate of use, cost of drug, source, etc. Some pharmacists feel that this card should be maintained by the purchasing agent and made available to them whenever necessary. Whichever way the situation is to be handled is irrelevant so long as the card is prepared and kept up to date. The final decision as to whose responsibility it is rests with the desires of the administrator.

On occasion, merchandise may be ordered from the pharmacy at a time when it is out of stock. This may happen quite frequently in pharmacy departments handling surgical and laboratory supplies as well as drugs. When this happens, an **Out-of-Stock Form** (see Chapter 15, Fig. 62) should be prepared in duplicate and one copy sent to the initiating pavilion or laboratory. The other copy is retained in the pharmacy. This form serves a dual purpose in that it speeds the delivery of merchandise to the floor upon its arrival and it prevents the pavilion or laboratory from reordering and creating a false sense of heavy demand which could result in over ordering by the pharmacy.

CONTROLS ON PURCHASES

Many administrators attempt to exercise a power of control over the volume of purchases by the pharmacist by placing a dollar limitation on the purchase order. This method is archaic and is easily circumvented by the issuance of multiple small orders which in the long run is more costly for the hospital.

A more modern and reliable means is the *computation* of *inventory turnover.* Inventory turnover is computed by dividing the cost of goods

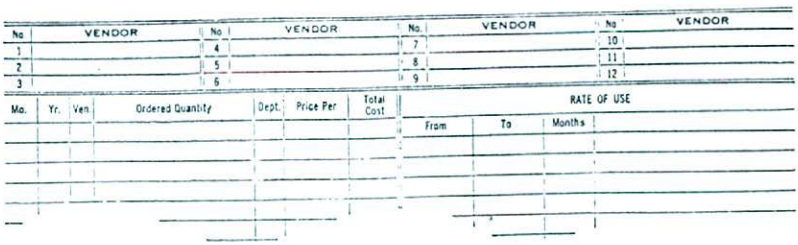


Fig. 29. A sample of a Purchase Record Form.

sold during the fiscal period by the average of opening and closing inventories. This gives the number of times the inventory has been "turned" during the fiscal period.[9]

A low turnover indicates:

1. duplication of stock
2. large purchases of slow-moving items
3. dead inventory

A high turnover of inventory may be due to small volume purchasing which is indicative of a failure to take advantage of the maximum quantity discounts.

A turnover of six to eight times a year is considered satisfactory for most institutions. However, those in short supply of cash reserves may wish to increase their turnover rate. This is a policy decision and should be arrived at by discussion with the administrator.

The Lilly Hospital Pharmacy Survey for 1984 revealed the following:[10]

a. the estimated turnover rate increased from 6.6 to 7.2 times.
b. hospital pharmacy managers have improved their turnover rate more than two full turns since 1977 (from 5.1 to 7.2 in 1983) suggesting that managers are continuing to exercise more control over inventory.
c. inventory investment rose 47.4% for an annual growth rate of about 6% for the recent 8-year period.
d. purchases grew at an annual rate of 15%.

Hospital pharmacists might well try to control purchase volume and inventory by the time of the EOQ (Economic Order Quantity) and RQL (Reorder Quantity Level).

The RQL is stated to be the inventory level that must be reached before additional stock can be ordered. Ideally, the remaining inventory should be almost depleted before the arrival of the new shipment. Obviously, zero stock level must be avoided because it can cause serious problems. This can usually be avoided by building into the system safety factors for various vendor lead times. Sapp[11] makes utilization of the following table:

SAFETY FACTORS FOR VARIOUS VENDOR LEAD TIMES

Vendor Lead Time (VLT)	*Safety Factor*
0 to 2 weeks	1.0
2 to 5 weeks	1.5
5 to 8 weeks	2.0
8 to 11 weeks	2.5
11 to 15 weeks	3.0

To determine the RQ, divide the **average usage** rate per month in units of issue (AU) by thirteen weeks; then multiply this figure by the average **vendor lead time** (VLT) plus the safety factor.

In the application of the above formula, Sapp[11] stressed the following points:

(1) Unanticipated large increases in usage.
(2) Shelf life of the items involved.
(3) Unusual delays in delivery caused by strikes or storms.
(4) Necessity for rechecking the RQL periodically to allow for a change in usage rate.

The determination of how much to order is the EOQ factor. In determining the EOQ factor it is important to ascertain the *cost of ordering* and the *cost* of *carrying inventory.*

The following must be considered in arriving at the *cost* of *ordering.*[11]

(1) All labor in purchasing except the purchasing manager.
(2) The labor cost in supporting areas such as the stockroom, receiving and material control.
(3) The cost applicable to payment of invoices generated by the purchasing section should apply to ordering cost.
(4) Cost of general operating supplies such as pencils, paper, forms etc.
(5) Freight and telephone costs.

After all of the above are applied to total cost, divide the resulting figure by the total number of purchase orders to obtain the *ordering cost* in *dollars per order.* Ordering cost per order can vary from $5.00 to $8.00.

To obtain item cost, divide average number of line items on purchase order into total ordering cost.

To determine carrying charges consideration must be given to the following.[11]

(1) Interest on the dollar value of the inventory.
(2) Space charge (rent) for the storage area.
(3) Labor costs for storage operations.
(4) Cost of supplies for storage operations.
(5) Insurance.
(6) Taxes (if applicable).
(7) Obsolescence.
(8) Deterioration.
(9) Pilferage.

Dividing the value of the average inventory by the total of the above costs results in the *inventory holding* or *carrying cost* for the particular inventory item. Thus, it may be advantageous to order expensive items

on a monthly basis and inexpensive items annually. In general, carrying charges may range from 18 to 30%.

Thus the formula for determining Economic Order Quantity is the following:

$$EOQ = \sqrt{\frac{2 \times 12 \times \text{monthly usage} \times \text{cost of ordering}}{\text{Unit cost} \times \text{Holding Cost}}}$$

On the basis of the above equation, purchasing agents have developed nomographs to simplify figuring the EOQ.

QUALITY OF DRUGS

As has been stated above, the pharmacist should draw freely upon the specifications detailed in the *United States Pharmacopeia*, the *National Formulary* and their supplements.

Both the U.S.P. and the N.F. are designated as official compendia by the terms of the Federal Food and Drug Law and the Federal Food, Drug, and Cosmetic Act.

The *Pharmacopeia* and the *National Formulary* render "a distinct service to pharmacists and pharmaceutical manufacturers by providing specifications for the procurement of drugs used in dispensing, prescription compounding, and manufacturing, and supplying formulas and working directions for the preparation of dosage forms."[12]

During recent years, there has been a move towards the acceptance and use of the initials A.R.B. (Any Reliable Brand). Certainly, if there exists a situation where the prescriber believes in the use of these initials, well and good; however, these symbols should never be used by a hospital pharmacist or a hospital purchasing agent as a specification for quality merchandise. What one individual considers to be "reliable" may oftentimes be far from the truth. If any symbols are to be used as a means of specification then those of U.S.P. and N.F. are the safest and most reliable.

Oftentimes a hospital pharmacist may desire assistance in the selection of a product for use by the hospital. If the hospital has an active Pharmacy and Therapeutics Committee, this committee may serve as an advisor to the pharmacist. Because of the background and experience of the membership, it behooves the hospital pharmacist to give a great deal of weight to their suggestions.

Certain large hospitals in this country feel that it is more economical to purchase drugs from manufacturers who might not be listed in the "Class A group." The consensus being that these small firms do not have to support expensive research and large sales staffs, the savings can be passed along to the purchaser. This premise can be dangerous

and should not be followed unless the hospital is in a position to establish a small control laboratory for the purpose of analyzing products purchased from these firms. Oftentimes the cost of operating such a laboratory will far exceed the cost of purchasing under tight specifications from a reliable manufacturer.

Some pharmacists utilize a *Qualified Suppliers List* which is based upon their personal knowledge and experience with the manufacturer and his products.[9]

Other pharmacists make use of a *Suppliers Application Form* to obtain information about prospective suppliers. The information requested includes the company's annual sales, a list of other accounts, the number of employees, type of operation, description of quality control procedures and the company's location and facilities. The use of this form is stated to discourage marginal suppliers and serves as a screening technique for the hospital pharmacist.[13]

DISCOUNTS

There are three ways in which merchandise may be purchased at a discount or savings: (1) volume contract, (2) "deals," and (3) discounts.

Volume contracts are usually offered by a majority of the manufacturers and include contracts to cover total purchases of parenteral solutions, ampoules, tablets or even gallon goods. Under this system, the institution approximates its annual consumption of the particular class of product and signs an agreement with the company to purchase this amount. At the end of the contract period, usually a year, if the goal has been reached, the manufacturer will issue a rebate check based on a percentage of the value of the total purchase. A hidden benefit of this type of purchase is the fact that the contract price is usually protected from an increase yet any reduction in price is passed on to the hospital.

"Deals" represent that type of transaction that involves the purchase of a specified volume and receiving certain merchandise at no additional cost (*e.g.* "Three free with the purchase of a dozen"). There is nothing wrong with this type of purchase if the "free goods" remain in the pharmacy inventory. In order that the inventory not be understated, the entry into the hospital inventory records should indicate that fifteen units were received for the price paid.

"Deals" which are created by the representative and the pharmacist without the full sanction of the manufacturer should be either avoided or carefully scrutinized by the Administrator or Comptroller since these offer a great temptation for dishonesty.

Discounts may accrue to the institution for the prompt payment of its drug bills. Because of the large volume of drug consumption, these discounts amount to a sizeable sum of money at the end of a year.

Other types of discounts are also available from the manufacturers,

e.g., discounts to government institutions or to educational institutions. Obviously, the hospital pharmacist should immediately investigate the discount policy of every new firm with which he deals.

CENTRAL STORAGE VS. PHARMACY STORAGE

The dichotomous storage arrangements of supplies is prevalent in many hospitals, although it is common knowledge that central storage is ideal.

The proponents of centralized storage facilities are quick to demonstrate the reduction in labor and record keeping, as well as the tight control afforded by centralization.

In contrast, it should be pointed out that the responsibility for the storage of drugs should be placed with competent individuals who have been educated, trained and licensed to handle pharmaceuticals. These individuals are the pharmacists.

In order that the pharmacist may properly supervise the storage of drugs, they should be stored in an area directly under his control. This allows him the freedom of stock arrangement, instituting of inventory controls, the adjustment of inventory based upon his knowledge of the prescribing trends of the staff and the preparation of inventory cost reports to management.

Therefore, all merchandise ordered by or for the pharmacy should be shipped directly to the pharmacy receiving area. Should the merchandise be received by the hospital post office or central storeroom, it should immediately be forwarded to the pharmacy in the unopened state.

Upon the receipt of the merchandise in the pharmacy receiving area, the department personnel then process it in the routine manner, namely, checking the receiving slip with the copy of the purchase order and preparing a receiving memorandum.

STOREROOM ARRANGEMENT

There is no definite rule specifying how a pharmacy storeroom should be arranged. Each individual may so arrange the area to meet both his and the institution's needs.

In general hospitals handling a variety of supplies, the storeroom is divided into the following areas.

1. Alcohol and Liquors
2. Capsules and Tablets
3. Chemicals
4. Gallon Goods
5. Narcotic Vault
6. Ointments
7. Biologicals and other cold room inventory
8. Laboratory Instruments
9. Surgical Instruments
10. Rubber Goods
11. Sutures
12. Medical and Surgical Supplies

Alphabetical arrangement is followed, where possible, within the section. Each shalf, drawer, or bin within the section is numbered to facilitate location of the item during the taking of a physical inventory as well as to locate the item for new personnel.

"SHELF-STRIPPING" AND "FLOOR-MARKING"

"Shelf-stripping" consists of applying a strip of tape to the front run of the shelf and marking upon it pertinent information relative to the product being stored. The usual information placed on the tape consists of the name and strength of the product, unit size, maximum level and minimal level, the re-order point being the minimal level.

Where adequate funds are available plastic or metallic strips may be applied to the shelving which will permit the insertion of a card bearing the essential data.

Another means of accomplishing the same goal is to attach the data card to the wooden shelf by means of a thumbtack or stapler.

"Floor-marking" consists of preparing a stencil with the necessary information and painting it on the storeroom floor. This is best done on concrete or wooden floors. In areas where the floor is tiled or marking the floor is not desirable, a good quality tape with adherability may be employed.

By so marking and identifying the storage areas, one provides a definite space for the storage of a particular product, induces orderliness and provides another means of checking inventory to prevent shortages.

MARKING OF MERCHANDISE

Management consultants all agree that money invested in drug inventories should have a turnover of four to five times a year. A turnover of less than four indicates overstocking and a turnover of more than five may indicate understocking.

One means of sound inventory control is to date and price each item when it is received into inventory. This may be accomplished by the utilization of a marking machine to print small adhesive-backed tags that contain the following information: date received, cost price, and the selling price.

The date is placed on the first line and consists of the month and year. This is usually numerically indicated as "6/80."

The second line represents the cost price of the particular unit. This figure is usually coded in order to preserve confidential price quotations. This figure is of great value in institutions where supplies are sent to areas at cost for it enables the dispensing pharmacist to immediately price the charge slips. In addition, the availability of this figure is of great value in taking and pricing a physical inventory.

The third line represents the retail price to the patient. By placing this figure on the tag, it is possible to save a great deal of time by having the dispensing pharmacist price the charge ticket without having to refer to a charge or rate book.

CONTROL OF DATED OR PERISHABLE INVENTORY

Dated inventory such as biologicals or antibiotics requires special control in order to insure potency at the time of dispensing and to be sure that the pharmacy is not carrying in inventory worthless stock.

This can be accomplished by the use of a form such as the **Record of Dated Pharmaceuticals** (Fig. 30).

Each dated product is entered on this sheet which provides the name of the product, the date of purchase, the manufacturer, the control number and the expiration date. By placing a check mark in the box of the appropriate month, the pharmacist can tell at a glance which product is expiring and should be replaced or returned for credit.

Some pharmacists prepare a separate sheet for each dated product. This modified sheet eliminates the need for re-writing the name of the product each time it is purchased. The remaining information and format remains the same.

HOSPITAL PHARMACY

RECORD OF DATED PHARMACEUTICALS

PRODUCT	DATE OF PURCHASE	MFG.	CONTROL NUMBER	MONTH EXPIRATION DATE 1965												MISC.
				1	2	3	4	5	6	7	8	9	10	11	12	

Fig. 30.

TAKING OF A PHYSICAL INVENTORY

The taking of a total physical inventory in the pharmacy is usually required by the auditing firm employed to audit the hospital's fiscal operation. Since the pharmacy inventory usually is the largest in dollar value, it receives a great deal of attention.

On the other hand, some auditing firms will require only a spot check type of inventory on 10 or 20% of the high-cost, fast-moving items.

The actual taking of a physical inventory cannot be undertaken without a great deal of planning and attention to detail. Anything less than one's maximum effort will lead to a faulty inventory and thus to a repeat performance.

Approximately 2 months before the taking of an inventory, the pharmacist should review his stock and remove from it all merchandise which has not moved since the last inventory. In addition, any merchandise should be removed which has been purchased during the year but has not moved appreciably during the preceding three months. These items should be returned for credit whenever possible; if such a move is not feasible, they should be written off the inventory via an adjustment in the books of account in the business office.

Once this has been accomplished, the inventory should be recorded on the inventory sheets. This recording should consist of only the name of the item, or other identification. The sheets upon which the recording is to take place should be in duplicate, and should have proper spaces to show the date, location, recorder and caller (Fig. 31).

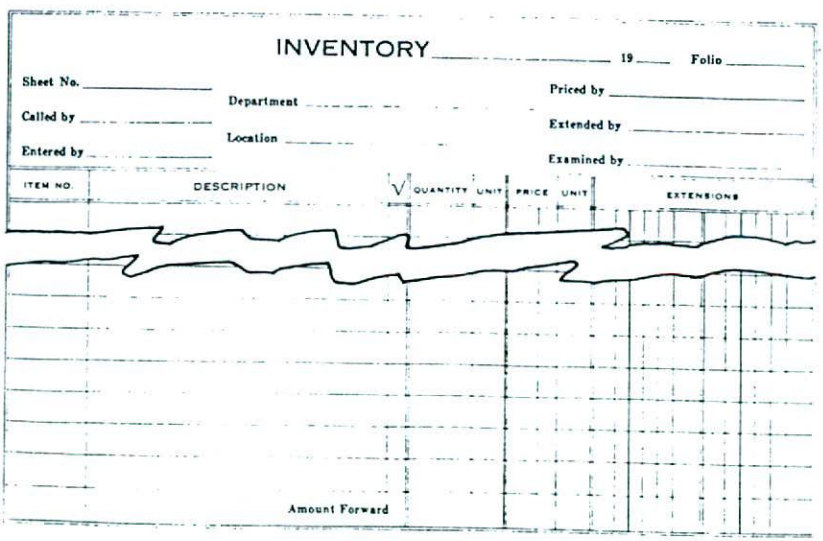


Fig. 31. Sample form for the recording of the inventory.

The actual taking of the inventory may start at the close of a business day or at a time when there is no movement of merchandise. At this time the pharmacy staff and its helpers may arrange themselves into teams of two—one to record and the other to call out the name of the item, price, and count. As each sheet is completed, it is handed to the auditor supervising the inventory. It is the prerogative of the supervising auditor as to how many entries he wishes to check out. The usual procedure is to check all large dollar volume items and to random check the less valuable entries.

At the close of the inventory, the sheets may be turned over to the comptroller for extension, or this operation may be delegated to the pharmacist.

Any merchandise ordered prior to the date of inventory and received on the day of inventory or shortly thereafter need not be counted. The invoices pertaining to these purchases should be clearly marked with the fact that they were received "post inventory." The accounting office will make the appropriate adjustment in the final inventory figure to account for this merchandise.

THE PERPETUAL INVENTORY

The maintaining of a perpetual inventory is, of course, an ideal situation if the record-keeping can be kept up to date. In many small hospital pharmacies, the pharmacist, at the end of each day, summarizes all drug charge slips and makes the proper posting in the perpetual inventory file. The process of tabulation may be accomplished by either the pegboard method or the use of punched cards.

The pegboard method merely requires a pegboard and requisition forms with holes evenly spaced and punched along the top. The forms are then aligned on the board so that the first sheet is entirely visible and subsequent sheets covering all but the section showing the quantities ordered. The forms are then summarized across into one master requisition form which is used for posting the inventory records.

The larger and more complex operations require mechanized equipment such as that provided by the International Business Machine Corporation or the Remington Rand Corporation. The basic operations performed on this specialized equipment are key punching, verifying, sorting, collating, interpreting, calculating, tabulating and reproducing. These systems may utilize a punched card whereby the data are punched in the various fields in the body of the card.

By using this type of system it is possible to have purchase orders, receiving reports and disbursement requisitions forwarded to the tabulating department daily, where transaction cards are punched. These cards are then fed into calculators and tabulators which issue a com-

prehensive stock status report. This report may be produced on a daily, weekly or monthly basis.

The latest and most sophisticated system for electronic data processing is the computer.

With one of these systems, a hospital can readily obtain a record of all inventory items, and their balances in quantity and dollar value is maintained. Using item numbers already in use, the inventory record can show the following:

1. item number
2. description
3. unit size
4. quantity on hand
5. receipts
6. disbursements
7. vendor number
8. price
9. general ledger number

The installation of either of these mechanized systems is highly technical as well as costly and therefore the institutional officers, comptroller and pharmacist should avail themselves of the counsel and advice of the various reputable manufacturers or consulting services before embarking upon such a program.

MATERIALS MANAGEMENT

To this point, purchasing and inventory control have been discussed from the viewpoint of the department of pharmacy—that is, complete control over the drugs by the pharmacist from purchase to disposition. In the operation of a modern hospital, it is still possible to provide the control feature even though part of the responsibility may rest in another person—the Director of Materials Management. In some hospitals, the Department of Materials Management has operational responsibility over purchasing, receiving, inventories, print shop, central sterile supply, laundry, distribution, messenger service, traffic and disposal activities.

Simply defined, materials management encompasses all materials and their movement from point of origin to point of use, and then to their final breakdown back into the environment.[14]

In those hospitals utilizing the materials management concept, it is not uncommon to find that the hospital pharmacist plays an important role in developing the program associated with the acquisition, storage, distribution and disposition of biologicals, radioisotopes, drugs and chemicals.

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10

Medical Service Representative-Pharmacist Relationship

Each year the pharmaceutical industry budgets millions of dollars for the purpose of promoting their products. A sizeable portion of this allocation is devoted to providing the profession with well-trained detailmen or medical service representatives. One of the duties of these people is to carry on a large-scale educational program relative to the use of the latest therapeutic agents. This is usually achieved in hospitals through the media of drug exhibits and "detailing" of the chief of the pharmacy service and physicians.[1]

In a recent survey, it was shown that 92% of the physicians interviewed stated that they saw "some" or "all" detailmen.[2] Of interest to the hospital pharmacist is the further statistic that in answer to the question—Has the Detailman's Contribution Increased or Lessened in the Past Five Years?—30 physicians answered "increased," 29 answered "lessened" and 28 answered "same."[2]

By the same token, there must be rapport between the pharmacist and the detailman. That this does not always exist is supported by such derogatory opinions as—"nothing but order takers"; "detailmen have generally poor attitude"; and "not told what is being detailed."[3]

Although it behooves the manufacturer to exercise extreme care in the selection of his field representative, it is imperative that the hospital pharmacist develop appropriate rapport with the detailman in order that the hospital and medical staff might benefit from his specialized knowledge.

Hospital displays are desirable since they offer a convenient means of contacting a large number of staff physicians in a minimal amount of time. Furthermore, there is, by this approach, a saving of the physician's valuable time when compared to an office visit by the same medical representative.

Many hospital administrators frown upon drug exhibits on the grounds that they promote an aura of commercialism in an otherwise highly professional atmosphere. To avoid the "taunt of commercial-

ism," it behooves the hospital pharmacist to develop basic policies for the conduct of detailmen within the hospital and guiding principles for scheduling drug exhibits.

The relationship between the hospital and the manufacturer can be enhanced if the pharmacist responsible for the purchasing function will take the time to review with the marketing representative the following ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Distributors.[4]

ASHP GUIDELINES FOR SELECTING PHARMACEUTICAL MANUFACTURERS AND DISTRIBUTORS[a]

Preamble

Pharmacists are responsible for selecting, from the hundreds of manufacturers and suppliers of drugs, those that will enable them to fulfill an important obligation: assuring that their patients receive pharmaceuticals and related supplies at the lowest cost consistent with high quality. These guidelines are offered as an aid to the pharmacist in achieving this goal.

Obligations of the Supplier

Pharmacists may purchase with confidence the products of those companies meeting the critera presented below. It should be noted that other factors such as credit policies, delivery times, and the breadth of a company's product line must also be considered in selecting a supplier.

Technical Considerations

1. Upon request of the pharmacist (via the ASHP Drug Product Information Request Form[b]), the supplier should furnish analytical control, sterility testing and bioavailability data, descriptions of testing, procedures for raw materials and finished products, or any other information which may be indicative of the quality of a given finished drug product. This information should be supplied at no charge.
2. There should be no history of recurring product recalls indicative of deficient quality control procedures.
3. The company should permit visits (during normal business hours) by the pharmacist to inspect its manufacturing and control procedures.

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[a]Approved by the ASHP Board of Directors at its meeting of November 17–18, 1983. Supersedes an earlier version approved by the Board of Directors in 1975. Developed initially and revised by the ASHP Council on Clinical Affairs.

0002-9289/84/Q201-0331$00.50.

[b]Available from the American Hospital Formulary Service, 4630 Montgomery Avenue, Bethesda, MD 20814.

4. All drug products shipped to the hospital should conform to the requirements of the most recent USP-NF unless otherwise specified by the pharmacist. Items not recognized by the USP-NF should meet the specifications set forth by the pharmacist.
5. All single unit packages of drugs should conform to the ASHP Technical Assistance Bulletin on Single Unit Packages of Drugs.
6. The name and address of the fabricator of the final dosage form should be present on the product labeling.
7. Expiration dates shall be clearly indicated on the package label and, unless stability properties warrant otherwise, should be dated January or July.
8. Therapeutic, biopharmaceutic, and toxicologic information should be available to the pharmacist upon request. Toxicity information should be available around the clock.
9. Patient and staff educational materials that are important for proper use of the product should be routinely available.

Distribution Policies

1. Whenever possible, delivery of a drug product should be confined to a single lot number.
2. Unless otherwise specified or required by stability considerations, not less than a 12-month interval between a product's time of delivery and its expiration date shall be present.
3. The supplier should accept for full credit (based on purchase price), without prior authorization, any unopened packages of goods returned within 12 months of the expiration date. Credits should be in cash or applied to the institution's account.
4. The supplier should ship all goods in a timely manner, freight prepaid, and enclose a packing slip with each shipment. All items "out of stock" should be noted and the anticipated availability of the item should be clearly indicated. There should be no extensive recurrence of back orders.
5. The supplier should warrant title to commodities supplied by him, warrant them free from defects and imperfections, and fit for any rational use of the product, and indemnify and hold the purchaser harmless against any and all suits, claims and expenses, including attorneys' fees, damages and injuries or any claims by third parties relating to his product.

Marketing and Sales Policies

1. The supplier should furnish, upon written request of the pharmacist, proof of any claims made regarding the efficacy, safety, and superiority of its products.
2. The supplier shall not, without the written consent of the pharmacist and administrator, use the pharmacist's or institution's name in any advertising or other promotional materials or activities.
3. A reasonable quantity of the supplier's products should be available, for evaluative purposes, upon request of the pharmacist, at no cost to the institution.
4. The supplier's sales representatives shall comply with the institution's regulations governing their activities if such regulations are in force at the institution.
5. The supplier shall not offer cash, equipment, or merchandise to the institution or its staff as an inducement to purchase its products.

6. Discounts should be in cash, not merchandise, and should be clearly indicated on invoices and bills, rather than consisting of end-of-year rebates or similar discount practices.
7. In entering into a contract to supply goods to the institution, the supplier should guarantee to furnish, at the price specified, any minimum amount of products so stated. If the supplier is unable to meet the supply commitment, he should reimburse the institution for any excess costs incurred in obtaining the product from other sources. If, during the life of the contract, a price reduction is announced, the lower price shall prevail.
8. All parties to the bidding process should respect the integrity of the process and the contracts awarded thereby.

Responsibilities of the Purchaser

It may be desirable to purchase drugs or other commodities on a competitive bid basis. The pharmacist should insure that competitive bidding procedures conform to the guidelines below:

1. Invitations to bid should be mailed to the companies' home offices with copies to their local representatives (if any), unless the company specifies otherwise.
2. Potential bidders should be given no less than three weeks to submit a bid.
3. The opening date for the bids shall be specified and adhered to by the institution.
4. The language of the invitation to bid form should be clear and concise, and the form should include the specific name and phone number of the person the bidder should contact in the event of questions or problems. Specifications should be complete with respect to products, packagings, and quantities desired.
5. If the bidder is to return the form to the institution, it should contain adequate space for the bidder to enter the information requested.
6. The winning bidder should be notified in writing and the unsuccessful bidders may be informed of who won the award and at what price, if they so request.
7. The quantities specified in the invitation to bid should be a reasonable estimate of the institution's requirements.
8. If the invitation to bid is offered on behalf of a group of institutions, the individual members should not engage in bidding procedures of their own and should purchase the goods in question from the winning bidder.

APPOINTMENTS

In order to carry on a successful professional relations program and to service hospital inventory requirements, it is necessary for the manufacturer's representative to make periodic visits to the pharmacy. Faced with a heavy work-load, a shortage of staff, or an unforeseen event, the pharmacist is prone to dismiss him with an "I'll see you the next time around." In other instances, the visit of the detailman is taken

too lightly and the time devoted to the interview is rapidly utilized with needless "chit-chat."

After consideration of the above, it should be clear that the direct loser is the hospital pharmacist and the indirect loss is shared by the entire hospital staff. The hospital pharmacist must avail himself of the opportunity to draw upon the specialized knowledge of the detailman.

There are many ways in which this can be accomplished. Those most commonly employed are to arrange the detailman's visit on an "appointment only" basis, the use of a product information sheet, and the development of a controlled method of allowing demonstration and sales promotional displays within the hospital.

While it is relatively easy for the pharmacist to schedule appointments, it may place an undue hardship upon the detailman unless the scheduling is given some forethought.

One method of scheduling appointments is to divide the list of detailmen into three categories: (1) Those on a monthly basis, (2) Those on a bi-weekly basis, and (3) Those to be interviewed whenever they are in the territory.

For each representative in categories 1 and 2, a definite time should be assigned which coincides with the hours he expects to be in the particular section of the community in which the hospital is located. Once the schedule is established, it behooves each party to be prompt, and when necessary to cancel the appointment in advance.

Representatives in the third category must realize that they are being accorded a special privilege. They, therefore, have special obligations which are relatively simple. These entail the courtesy of notifying the pharmacist in advance of the approximate date and hour of the intended visit, and, conversely, the pharmacist should inform the representative of his ability to keep the appointment. Either of the above can be easily accomplished by postcard or telephone.

PROPER UTILIZATION OF APPOINTMENT TIME

Having established the routine for visitation, the pharmacist should use the time to best advantage. The nature of the division of time and the topics to be discussed rests with the pharmacist. As a guide, the allocated time may be divided into two units: (1) to discuss inventory needs, and (2) new products. It is in connection with the latter that the greatest amount of time can be saved. This can be accomplished through the use of a *Product Information Sheet* (Fig. 32). The required information can be recorded by the pharmacist while he is being "detailed" by the representative. Since the data on the sheet are concise, it serves as a valuable quick reference for pharmacists and medical staff. It may also serve the worthy purpose of providing the members of the Pharmacy and Therapeutics Committee with an "abstract" of a new product.

PRODUCT INFORMATION SHEET

Name _____ Mfg. _____

Generic Name _____

Chemical Name _____

Synonyms _____

Composition (if a combination) Therapeutic Uses

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Contraindications and Cautions Toxicology and Antidote

_____

_____

_____

Dosage and Administration Forms Available Similar Products

_____ _____ _____

_____ _____ _____

_____ _____ _____

Package Sizes and Prices Literature ____Yes ____No

_____ _____ Samples ____Yes ____No

_____ _____ Date: _____

This Space Reserved for Pharmacy and Therapeutics Committee.

Fig. 32

PROMOTIONAL DISPLAYS

The sponsoring of sales promotional displays within the hospital by pharmaceutical and medical supply representatives can be an interesting and worthwhile venture if properly controlled and supervised. One way to regulate these exhibits is to prepare a set of guiding principles governing displays; develop an application form which requests permission to conduct an exhibit; and finally place the total responsibility for the notification of the clinical and nursing staff of the exhibit as well as the supervision of the display upon the hospital pharmacist.

The rules for conducting the exhibit may vary with each institution, therefore, the following guiding principles are suggested as a model:

1. Demonstration and sales promotional displays by pharmaceutical and hospital supply representatives may be arranged by completing and having approved the "Request for Display Form" available from the pharmacy.
2. Displays or exhibits, for which application is made in the pharmacy, must be of a professional and ethical nature and must be related to hospital function.
3. All displays, not to exceed one per week, are presented in the staff room. Special group meetings, including film presentations, require arrangement through the executive offices.
4. Sales representatives and exhibitors are not permitted entrance to the various hospital departments without administrative approval: this includes the clinics, nursing stations, pavilions and operating suite.
5. Exhibitors must remain by their displays, and shall not solicit orders or approach persons who do not wish to view the displays.
6. Distribution of advertising in the form of samples and brochures must be confined to the display area, and only during the time reserved for the display or exhibit. Distribution of prescription legend items is allowed to physicians only.
7. Notices of any kind are not to be posted throughout the hospital by an exhibitor.
8. Displays and exhibits of each supplier are limited to two annually, and each to one-half day from 9:00 a.m. to 1:00 p.m.
9. Pharmaceutical products to be displayed are limited to those officially included in the latest revisions and supplements of the hospital formulary or those products accepted by the therapeutics committee for clinical trial in the hospital.
10. Representatives should have available a supply of reprints of clinical studies by qualified investigators of each product displayed.

The Request for Display forms (Fig. 33) should always be used because they serve a number of valuable control purposes. From the completed form, the pharmacist may determine exactly what is to be displayed and who is going to conduct the exhibit. In addition, reference to the copy of the Request for Display form will enable the pharmacist to determine whether or not the display of any particular product coincided with its increased use; the frequency of displays by any particular firm; and the frequency which an individual therapeutic category was featured.

Once the display is scheduled, the pharmacist should notify all clin-

REQUEST FOR DISPLAY

I, (We) do hereby agree to abide by the rules and regulations covering displays in the hospital, and request the following date to feature the items listed below in a display.

Date of Application: _____

Company: _____

Representative(s) Covering Display: _____

_____

_____

Display Date Requested:

1st Choice _____ 2nd Choice _____

Do You Need Display Equipment? ____Yes ____No

Products to be Displayed:

_____ _____ _____

_____ _____ _____

Display Approved By _____ Date: _____

Please prepare in duplicate. Return *both* copies to the Pharmacy. The approved copy will be returned to you and is your authorization to conduct the display.

Fig. 33

ical and nursing personnel of the date, hour and products to be exhibited. This notification can be accomplished in any number of ways.

1. General memo to clinical and nursing staffs.
2. Posting of a list of displays for the month or season in the Nursing Office and Staff Room.
3. Publication of the display dates in the Pharmacy Bulletin.
4. Specific letter to the Chief-of-Staff and to the Director of Nursing.

On occasion, the question arises as to whether or not the hospital should charge the manufacturer for the right to conduct displays on the hospital premises. The argument advanced is that a certain amount of administrative time is utilized in the scheduling and announcing of displays; guard services are utilized to deter unauthorized personnel or visitors from entering the display area; parking facilities are utilized; and hospital equipment such as tables or small trucks are used by the representative.

There is no single answer to the question. Certainly the above reasons are valid and if it is the policy of the hospital to rent space for various

functions, then a rental for a pharmaceutical display is warranted. On the other hand, the donation of the above services and the space for a display provides a return to the hospital in the form of a well-informed staff on the latest developments in pharmacology and therapeutics.[1]

DEFINITION OF DRUG SAMPLES

The words "drug sample" would appear to be clearly self-explanatory, however, in order that there be no misunderstanding, the following definition is presented.

A drug sample may be considered as a quantity of any form of a chemical, drug or drug product which is made available by the manufacturer to an individual legally qualified to receive it. It makes no difference whether the drug is made available in an original trade package, or in a clearly identifiable sample package.

USE OF SAMPLES IN THE HOSPITAL

Any discussion governing the use of drug samples must, of necessity, be divided into two parts—for their use by the hospital and secondly, the use of samples by the manufacturer or his representative.

The use of drug samples in the hospital may be as varied as the imagination of the pharmacist in charge. One type of program that falls into this category and is worthy of mention is the pharmacist and the student nurse association "adopt" a hospital located in some remote part of the world and undertake to accumulate and ship the samples of its medical staff for distribution to their indigent patients.

In some hospitals, sample drugs are used in the care of the intern and resident staff as well as the students enrolled in the various nursing, dietary or technician training programs.

One pharmacist has gone on record[5] as recommending the availability of drug samples as a means of inducing widespread clinical use. Another[6] has described a method whereby drug samples are utilized in the care of the indigent ill irrespective of whether they were ambulatory clinic patients or admitted to the hospital.

Insofar as the manufacturer is concerned, drug samples are used as a means of introducing the physician to a new product and to induce him to try it clinically.

USE OF SAMPLES IN COMPETITIVE BUYING

Some manufacturer's representatives have used drug samples as a means of offsetting the company's higher price for a particular product, especially when competitive prices are lower. Whether or not this is ethical conduct on the part of the medical service representative and

the hospital pharmacist is a difficult point to debate. Certainly those pharmacists who do not permit such transactions are to be commended and those who are prone to permit this practice under the guise that they are doing their job—namely, obtaining the best drugs available for the lowest net cost—should be cautioned to make every aspect of the negotiation open to the scrutiny of those in authority lest their individual integrity became the object of question.

CONTROL OF DRUG SAMPLES

Hospital mail rooms are deluged with drug samples. Often these samples are addressed to doctors no longer on the staff, and unfortunately the samples are often carelessly handled by the mail room personnel or the physician himself. It should be clear that any unsolicited drug sample entrusted to the general mail has a good chance of being discarded by the physician in such a manner that it unintentionally creates a hazard.

The hazard can be of many different types. (1) By disposing of the drug material into a wastebasket, it becomes readily available to cleaning personnel who may salvage it for the purpose of self-medication or for the illegitimate drug traffic. (2) Improper disposition of the baskets may mean that they could fall into the hands of children with disastrous results and (3) if incinerated by housekeeping personnel an explosion hazard is incurred, particularly if many vials or sealed containers of various drugs have been discarded.

The best place to control sample distribution in the hospital is at the source of the sample's entry into the institution—the detailman, drug displays and in the mail receiving room.

All detailmen or medical service representatives whether on private calls to physicians in the hospital or conducting displays should be fully informed of the hospital's policy governing the distribution of drug samples. Although a conscientious medical service representative will acquaint himself with the rules, it behooves the hospital pharmacist to call them to the attention of the representatives prior to each display request.

In brief, a good drug sample control policy would dictate that no samples may be left in the clinics, on the pavilions or nursing stations, nor may large quantities be left with physicians for the purpose of being dispensed by him for clinical trial.

Any physician desirous of using sample drugs for clinical trial should arrange to have the material deposited in the pharmacy from whence his prescriptions for the material will be honored. In this case the hospital may or may not collect a small handling fee from the patient.

Furthermore, the policy should also prohibit the distribution of drug

products to hospital personnel even though the particular product to be distributed may have an over-the-counter status.

Some manufactureres have adopted an excellent policy in requiring the physician to write a prescription for the material requested, whereas others do not distribute samples during a display but will mail samples of the requested products directly to the physician.

Mass mailings to physicians in hospitals create problems in drug control, as these samples are or may be carelessly discarded and thereby fall into the wrong hands, or they are easily pilfered which awaiting distribution.

One way of mastering this problem is to have all mass handlings of drugs delivered directly to the pharmacy. Here, under the control of pharmacists,[7] the samples may be sorted and properly stored or, if necessary, adequately destroyed or discarded. Any physician desiring the sample material may obtain a reasonable supply from the pharmacy.

CATALOGUING OF DRUG SAMPLES

Once the packages of drug samples are delivered to the pharmacy, they should be sorted, exterior mailing cartons removed, catalogued and properly stored in a sample section. The pharmacist is reminded that sample drugs, like their purchased counterpart, should not have their control number identification removed as it may be the only means of identifying a particular batch of drug being recalled due to untoward side effects or reactions or possible error in preparation.

The cataloguing procedure should be reasonably detailed and accurate if it is to serve its purpose. The recording may be done on cards for storage in a card file or punched paper suitable for storage in a binder. Irrespective of the choice, the following data should be recorded for each drug sample received:

(a) Trade Name
(b) Generic Name
(c) Manufacturer
(d) Strength
(e) Pharmaceutical Form
(f) Control Number
(g) Expiration Date (if any)
(h) Date Received
(i) Quantity Received
(j) Location: Shelf #_: Drawer #_

Once catalogued and stored, any pharmacist removing a portion or the entire supply of sample must then record on the back of the page or card the following information concerning its disposition:

(a) Date
(b) Amount Dispensed
(c) To Whom
(d) Signature of dispensing pharmacist.

If the sample material is given to a physician his name is placed in the space after "*(c)* To Whom;" if a patient on a physician's prescription,

then the prescription serial number is entered; if to a house patient, his name and hospital number should be entered.

EFFECT OF SAMPLES ON FISCAL OPERATIONS

Drug samples that are not obtained in the process of competitive buying are not usually considered a part of the pharmacy inventory.

However, if a relatively large volume of sample material is solicited and dispensed from the pharmacy, two obvious results may be immediately noted: *(a)* there will usually be a reduction in pharmacy income and *(b)* the volume of purchases will decline. The long range effect will invariably manifest itself by a reduction in the "turn-over rate" of the inventory.

On the other hand, if the drug samples are being dispensed to indigent patients, there should be a corresponding decrease in the allowances associated with the patient's inability to pay the hospital's bills for drugs.

Both aspects of the effect of the use of large amounts of drug samples on income, inventory and allowances have been briefly presented in order that the pharmacist may be forewarned of these possible repercussions.

CONTROLLED SUBSTANCES ACT OF 1970 ON SAMPLES

The Controlled Substances Act of 1970 amends the Federal Food, Drug and Cosmetic Act by placing additional controls over *stimulant and depressant drugs* through increased record keeping and inspection requirements providing control over intrastate traffic in these drugs, and making possession of them illegal except under certain specified conditions. (See Chapter 16.)

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