

APPENDIXES

Appendix I

ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control

Source: American Society of Hospital Pharmacists: ASHP technical assistance bulletin on hospital drug distribution and control. *Am J Hosp Pharm* 37:1097–1103, 1980. Reprinted with permission.

ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control

Drug control (of which drug distribution is an important part) is among the pharmacist's most important responsibilities. Therefore, adequate methods to assure that these responsibilities are met must be developed and implemented. These guidelines will assist the pharmacist in preparing drug control procedures for all medication-related activities. The guidelines are based on the premise that the pharmacy is responsible for the procurement, distribution, and control of all drugs used within the institution. In a sense, the entire hospital is the pharmacy, and the pharmacy service is simply a functional service extending throughout the institution's physical and organizational structures.

It should be noted that, although this document is directed toward hospitals, much of it is relevant to other types of health-care facilities.

Pharmacy Policies, Procedures, and Communications

Policy and Procedure Manuals.¹ The effectiveness of the drug control system depends on adherence to policies (broad, general statements of philosophy) and procedures (detailed guidelines for implementing policy). The importance of an up-to-date policy and procedure manual for drug control cannot be overestimated. All pharmacy staff must be familiar with the manual; it is an important part of orientation for new staff and crucial to the pharmacy's internal communication mechanism. In addition, preparing written policies and procedures requires a thorough analysis of control operations; this review might go undone otherwise.

Drug control begins with the setting of policy. The authority to enforce drug control policy and procedures must come from the administration of the institution, with the endorsement of the medical staff, via the pharmacy and therapeutics (P&T) committee and/or other appropriate committee(s). Because the drug control system interfaces with numerous departments and professions, the P&T committee should be the focal point for communications relating to drug control in the institution. The pharmacist, with the cooperation of the P&T committee, should develop media such as newsletters, bulletins, and seminars to communicate with persons functioning within the framework of the control system.

Inservice Training and Education. Intra- and interdepartmental education and training programs are important to the effective implementation of policies and procedures and the institution's drug control system in general. They are part of effective communication and help establish and maintain professional relationships among the pharmacy staff and between it and other hospital departments. Drug control policies and procedures should be included in the pharmacy's educational programs.

Standards, Laws, and Regulations

The pharmacist must be aware of and comply with the laws, regulations, and standards governing the profession. Many of these standards and regulations deal with aspects of drug

control. Among the agencies and organizations affecting institutional pharmacy practice are those described below.

Regulatory Agencies and Organizations. The U.S. government, through its Food and Drug Administration (FDA), is responsible for implementing and enforcing the federal Food, Drug, and Cosmetic Act. The FDA is responsible for the control and prevention of misbranding and of adulteration of food, drugs, and cosmetics moving in interstate commerce. The FDA also sets label requirements for food, drugs, and cosmetics; sets standards for investigational drug studies and for marketing of new drug products; and compiles data on adverse drug reactions.

The U.S. Department of the Treasury influences pharmacy operation by regulating the use of tax-free alcohol through the Bureau of Alcohol, Tobacco and Firearms. The U.S. Department of Justice affects pharmacy practice through its Drug Enforcement Agency (DEA) by enforcing the Controlled Substances Act of 1970 and other federal laws and regulations for controlled drugs.

Another federal agency, the Health Care Financing Administration, has established Conditions of Participation for hospitals and skilled nursing facilities to assist these institutions to qualify for reimbursement under the health insurance program for the aged (Medicare) and for Medicaid.

The state board of pharmacy is the agency of state government responsible for regulating pharmacy practice within the state. Practitioners, institutions, and community pharmacies must obtain licenses from the board to practice pharmacy or provide pharmacy services in the state. State boards of pharmacy promulgate numerous regulations pertaining to drug dispensing and control. (In some states, the state board of health licenses the hospital pharmacy separately or through a license that includes all departments of the hospital.)

Standards and guidelines for pharmaceutical services have been established by the Joint Commission on Accreditation of Hospitals (JCAH)² and the American Society of Hospital Pharmacists (ASHP).³ The United States Pharmacopeial Convention also promulgates certain pharmacy practice procedures as well as official standards for drugs and drug testing. Professional practice guidelines and standards generally do not have the force of law but rather are intended to assist pharmacists in achieving the highest level of practice. They may, however, be employed in legal proceedings as evidence of what constitutes acceptable practice as determined by the profession itself.

In some instances, both federal and state laws may deal with a specific activity; in such cases, the more stringent law will apply.

The Medication System

Procurement: Drug Selection, Purchasing Authority, Responsibility, and Control.⁴⁻⁶ The selection of pharmaceuticals is a basic and extremely important professional function of the hospital pharmacist who is charged with making decisions regarding products, quantities, product specifica-

tions, 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 only 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 P&T 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.

Although 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 recordkeeping 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 that 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 general 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 must be 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.

In-House Manufacturing, Bulk Compounding, Packaging, and Labeling.^{7,8} As with commercially marketed drug products, those produced by the pharmacy must be accurate in identity, strength, purity, and quality. Therefore, there must be adequate process and finished product controls for all manufacturing/bulk compounding and packaging operations. Written master formulas and batch records (including product test results) must be maintained. All technical personnel must be adequately trained and supervised.

Packaging and labeling operations must have controls sufficient to prevent product/package/label mixups. A lot number to identify each finished product with its production and control history must be assigned to each batch.

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The Good Manufacturing Practices of the FDA is a useful model for developing a comprehensive control system.

The pharmacist is encouraged to prepare those drug dosage forms, strengths, and packagings that are needed for optimal drug therapy but that are commercially unavailable. Adequate attention must be given to the stability, palatability, packaging, and labeling requirements of these products.

Medication Distribution (Unit Dose System).⁹⁻¹¹ Medication distribution is the responsibility of the pharmacy. The pharmacist, with the assistance of the P&T committee and the department of nursing, must develop comprehensive policies and procedures that provide for the safe distribution of all medications and related supplies to inpatients and outpatients.

For reasons of safety and economy, the preferred method to distribute drugs in institutions is the *unit dose* system. Although the unit dose system may differ in form depending on the specific needs, resources, and characteristics of each institution, four elements are common to all: (1) medications are contained in, and administered from, single unit or unit dose packages; (2) medications are dispensed in ready-to-administer form to the extent possible; (3) for most medications, not more than a 24-hour supply of doses is provided to or available at the patient-care area at any time; and (4) a patient medication profile is concurrently maintained in the pharmacy for each patient. Floor stocks of drugs are minimized and limited to drugs for emergency use and routinely used “safe” items such as mouthwash and antiseptic solutions.

(1) *Physician's drug order: writing the order.* Medications should be given (with certain specified exceptions) only on the *written* order of a qualified physician or other authorized prescriber. Allowable exceptions to this rule (i.e., telephone or verbal orders) should be put in written form immediately and the prescriber should countersign the nurse's or pharmacist's signed record of these orders within 48 (preferably 24) hours. Only a pharmacist or registered nurse should accept such orders. Provision should be made to place physician's orders in the patient's chart, and a method for sending this information to the pharmacy should be developed.

Prescribers should specify the date and time medication orders are written.

Medication orders should be written legibly in ink and should include

- Patient's name and location (unless clearly indicated on the order sheet).
- Name (generic) of medication.
- Dosage expressed in the metric system, except in instances where dosage must be expressed otherwise (i.e., units, etc.).
- Frequency of administration.
- Route of administration.
- Signature of the physician.
- Date and hour the order was written.

Any abbreviations used in medication orders should be agreed to and jointly adopted by the medical, nursing, pharmacy, and medical records staff of the institution.

Any questions arising from a medication order, including the interpretation of an illegible order, should be referred to the ordering physician by the pharmacist. It is desirable for the pharmacist to make (appropriate) entries in the patient's

medical chart pertinent to the patient's drug therapy. (Proper authorization for this must be obtained.¹²) Also, a duplicate record of the entry can be maintained in the pharmacy profile.

In computerized patient data systems, each prescriber should be assigned a unique identifier; this number should be included in all medication orders. Unauthorized personnel should not be able to gain access to the system.

(2) *Physician's drug order: medication order sheets.*

The pharmacist (except in emergency situations) must receive the physician's original order or a direct copy of the order before the drug is dispensed. This permits the pharmacist to resolve questions or problems with drug orders before the drug is dispensed and administered. It also eliminates errors which may arise when drug orders are transcribed onto another form for use by the pharmacy. Several methods by which the pharmacy may receive physicians' original orders or direct copies are

1. Self-copying order forms. The physician's order form is designed to make a direct copy (carbon or NCR) which is sent to the pharmacy. This method provides the pharmacist with a duplicate copy of the order and does not require special equipment. There are two basic formats:
 - a. Orders for medications included among treatment orders. Use of this form allows the physician to continue writing his orders on the chart as he has been accustomed in the past, leaving all other details to hospital personnel.
 - b. Medication orders separated from other treatment orders on the order form. The separation of drug orders makes it easier for the pharmacist to review the order sheet.
2. Electromechanical. Copying machines or similar devices may be used to produce an exact copy of the physician's order. Provision should be made to transmit physicians' orders to the pharmacy in the event of mechanical failure.
3. Computerized. Computer systems, in which the physician enters orders into a computer which then stores and prints out the orders in the pharmacy or elsewhere, are used in some institutions. Any such system should provide for the pharmacist's verification of any drug orders entered into the system by anyone other than an authorized prescriber.

(3) *Physician's drug order: time limits and changes.*

Medication orders should be reviewed automatically when the patient goes to the delivery room, operating room, or a different service. In addition, a method to protect patients from indefinite, open-ended drug orders must be provided. This may be accomplished through one or more of the following: (1) routine monitoring of patients' drug therapy by a pharmacist; (2) drug class-specific, automatic stop-order policies covering those drug orders not specifying a number of doses or duration of therapy; and (3) automatic cancellation of all drug orders after a predetermined (by the P&T committee) time interval unless rewritten by the prescriber. Whatever the method used, it must protect the patient, as well as provide for a timely notification to the prescriber that the order will be stopped *before* such action takes place.

(4) *Physician's drug order: receipt of order and drug profiles.* A pharmacist must review and interpret every medication order and resolve any problems or uncertainties

with it before the drug is entered into the dispensing system. This means that he must be satisfied that each questionable medication order is, in fact, acceptable. This may occur through study of the patient's medical record, research of the professional literature, or discussion with the prescriber or other medical, nursing, or pharmacy staff. Procedures to handle a drug order the pharmacist still believes is unacceptable (e.g., very high dose or a use beyond that contained in the package insert) should be prepared (and reviewed by the hospital's legal counsel). In general, the physician must be able to support the use of the drug in these situations. It is generally advisable for the pharmacist to document actions (e.g., verbal notice to the physician that a less toxic drug was available and should be used) relative to a questionable medication order on the pharmacy's patient medication profile form or other pharmacy document (not in the medical record).

Once the order has been approved, it is entered into the *patient's medication profile*. A medication profile must be maintained in the pharmacy for all inpatients and those outpatients routinely receiving care at the institution. (Note: Equivalent records also should be available at the patient-care unit.) This essential item, which is continuously updated, may be a written copy or computer maintained. It serves two purposes. First, it enables the pharmacist to become familiar with the patient's total drug regimen, enabling him to detect quickly potential interactions, unintended dosage changes, drug duplications and overlapping therapies, and drugs contraindicated because of patient allergies or other reasons. Second, it is required in unit dose systems in order for the individual medication doses to be scheduled, prepared, distributed, and administered on a timely basis. The profile information must be reviewed by the pharmacist *before* dispensing the patient's drug(s). (It also may be useful in retrospective review of drug use.)

Patient profile information should include

- Patient's full name, date hospitalized, age, sex, weight, hospital I.D. number, and provisional diagnosis or reason for admission (the format for this information will vary from one hospital to another).
- Laboratory test results.
- Other medical data relevant to the patient's drug therapy (e.g., information from drug history interviews).
- Sensitivities, allergies, and other significant contraindications.
- Drug products dispensed, dates of original orders, strengths, dosage forms, quantities, dosage frequency or directions, and automatic stop dates.
- Intravenous therapy data (this information may be kept on a separate profile form, but there should be a method for the pharmacist to review both concomitantly).
- Blood products administered.
- Pharmacist's or technician's initials.
- Number of doses or amounts dispensed.
- Items relevant or related to the patient's drug therapy (e.g., blood products) not provided by the pharmacy.

(5) *Physician's drug order: records.* Appropriate records of each medication order and its processing in the pharmacy must be maintained. Such records must be retained in accordance with applicable state laws and regulations. Any changes or clarifications in the order should be written in the chart. The signature(s) or initials of the person(s) verifying the transcription of medication orders into the

medication profile should be noted. A way should be provided to determine, for all doses dispensed, who prepared the dose, its date of dispensing, the source of the drug, and the person who checked it. Other information, such as the time of receipt of the order and management data (number of orders per patient day and the like) should be kept as desired. Medication profiles also may be useful for retrospective drug use review studies.

(6) *Physician's drug order: special orders.*^{5,6,13,14} Special orders (i.e., "stat" and emergency orders and those for nonformulary drugs, investigational drugs, restricted use drugs, or controlled substances) should be processed according to specific written procedures meeting all applicable regulations and requirements.

(7) *Physician's drug order: other considerations.* The pharmacy, nursing, and medical staffs, through the P&T committee, should develop a schedule of standard drug administration times. The nurse should notify the pharmacist whenever it is necessary to deviate from the standard medication schedule.

A mechanism to continually inform the pharmacy of patient admissions, discharges, and transfers should be established.

(8) *Intravenous admixture services.*¹⁵ The preparation of sterile products (e.g., intravenous admixtures, "piggy-backs," and irrigations) is an important part of the drug control system. The pharmacy is responsible for assuring that all such products used in the institution are (1) therapeutically and pharmaceutically appropriate (i.e., are rational and free of incompatibilities or similar problems) to the patient; (2) free from microbial and pyrogenic contaminants; (3) free from unacceptable levels of particulate and other toxic contaminants; (4) correctly prepared (i.e., contain the correct amounts of the correct drugs); and (5) properly labeled, stored, and distributed. Centralizing all sterile compounding procedures within the pharmacy department is the best way to achieve these goals.

Parenteral admixtures and related solutions are subject to the same considerations presented in the preceding sections on "physician's drug order." However, their special characteristics (e.g., complex preparation or need for sterility assurance) also mandate certain additional requirements concerning their preparation, labeling, handling, and quality control. These are described in Reference 15.

It is important that the pharmacy is notified of any problems that arise within the institution pertaining to the use of intravenous drugs and fluids (infections, phlebitis, and product defects).

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

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Important labeling considerations are

1. The metric system should be given prominence on all labels when both metric and apothecary measurement units are given.
2. The names of all therapeutically active ingredients should be indicated in compound mixtures.
3. Labels for medications should indicate the amount of drug or drugs in each dosage unit (e.g., per 5 ml and per capsule).
4. Drugs and chemicals in forms intended for dilution or reconstitution should carry appropriate directions.
5. The expiration date of the contents, as well as proper storage conditions, should be clearly indicated.
6. The acceptable route(s) of administration should be indicated for parenteral medications.
7. Labels for large volume sterile solutions should permit visual inspection of the container contents.
8. Numbers, letters, coined names, unofficial synonyms, and abbreviations should not be used to identify medications, with the exception of approved letter or number codes for investigational drugs (or drugs being used in blinded clinical studies).
9. Containers presenting difficulty in labeling, such as small tubes, should be labeled with no less than the prescription serial number, name of drug, strength, and name of the patient. The container should then be placed in a larger carton bearing a label with all necessary information.
10. The label should conform to all applicable federal, state, and local laws and regulations.
11. Medication labels of stock containers and repackaged or prepackaged drugs should carry codes to identify the source and lot number of medication.
12. Nonproprietary name(s) should be given prominence over proprietary names.
13. Amount dispensed (e.g., number of tablets) should be indicated.
14. Drug strengths, volumes, and amounts should be given as recommended in References 11 and 16.

(10) *Medication containers, labeling, and dispensing: inpatient medications.*^{11,16} Drug products should be as ready for administration to the patient as the current status of pharmaceutical technology permits. Inpatient medication containers and packages should conform to applicable *USP* requirements and the guidelines in References 11 and 16.

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

(11) *Medication containers, labeling, and dispensing: outpatient medications.*¹⁷ Outpatient medications must be labeled in accordance with state board of pharmacy and federal regulations. As noted, medications given to patients as "discharge medication" must be labeled in the pharmacy (not by nursing personnel) as outpatient prescriptions.

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

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

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

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

(12) *Delivery of medications.* Couriers used to deliver medications should be reliable and carefully chosen.

Pneumatic tubes, dumbwaiters, medication carts, and the like should protect drug products from breakage and theft. In those institutions having automatic delivery equipment, such as a pneumatic tube system, provision must be made for an alternative delivery method in case of breakdown.

All parts of the transportation system must protect medications from pilferage. Locks and other security devices should be used where necessary. Procedures for the orderly transfer of medications to the nurse should be instituted; i.e., drug carts or pneumatic tube carriers should not arrive at the patient-care area without the nurse or her designee acknowledging their arrival.

Medications must always be properly secured. Storage areas and equipment should meet the requirements presented in other sections of these guidelines.

(13) *Administration of medications.* The institution should develop detailed written procedures governing medication administration. In doing so, the following guidelines should be considered:

1. All medications should be administered by appropriately trained and authorized personnel in accordance with the laws, regulations, and institutional policies governing drug administration. It is particularly important that there are written policies and procedures defining responsibility for starting parenteral infusions, administering all intravenous medications, and adding medications to flowing parenteral fluids. Procedures for drug administration by respiratory therapists and during emergency situations also should be established. Exceptions to any of these policies should be provided in writing.
2. All medications should be administered directly from the medication cart (or equivalent) at the patient's room. The use of unit dose packaged drugs eliminates the need for medication cups and cards (and their associated trays), and they should not be used. A medication should not be removed from the unit dose package until it is to be administered.
3. Medications prepared for administration but not used must be returned to the pharmacy.
4. Medications should be given as near the specified time as possible.
5. The patient for whom the medication is intended should be positively identified by checking the patient's identification band or hospital number or by other means as specified by hospital policy.
6. The person administering the medication should stay with the patient until the dose has been taken. Exceptions to this rule are specific medications which may be left at the patient's bedside upon the physician's written order for self-administration.
7. Parenteral medications that are not to be mixed together in a syringe should be given in different injection sites on the patient or separately injected into the

- administration site of the administration set of a compatible intravenous fluid.
8. The pharmacy should receive copies of all medication error reports or other medication-related incidents.
 9. A system to assure that patients permitted to self-medicate do so correctly should be established.

(14) *Return of unused medication.* All medications that have not been administered to the patient must remain in the medication cart and be returned to the pharmacy. Only those medications returned in unopened sealed packages may be reissued. Medications returned by outpatients should not be reused. Procedures for crediting and returning drugs to stock should be instituted. A mechanism to reconcile doses not given with nursing and pharmacy records should be provided.

(15) *Recording of medication administration.* All administered, refused, or omitted medication doses should be recorded in the patient's medical record according to an established procedure. Disposition of doses should occur immediately after administering medications to each patient and before proceeding to the next patient. Information to be recorded should include the drug name, dose and route of administration, date and time of administration, and initials of the person administering the dose.

Drug Samples and Medical Sales Representatives.¹⁸ The use of drug samples within the institution is strongly discouraged and should be eliminated to the extent possible. They should never be used for inpatients (unless, for some reason, no other source of supply is available to the pharmacy). Any samples used must be controlled and dispensed through the pharmacy.

Written regulations governing the activities of medical sales representatives within the institution should be established. Sales representatives should receive a copy of these rules and their activities should be monitored.

Investigational Drugs.¹³ Policies and procedures governing the use and control of investigational drugs within the institution are necessary. Detailed procedural guidelines are given in Reference 13.

Radiopharmaceuticals. The basic principles of compounding, packaging, sterilizing, testing, and controlling drugs in institutions apply to radiopharmaceuticals. Therefore, even if the pharmacy department is not directly involved with the preparation and dispensing of these agents, the pharmacist must ensure that their use conforms to the drug control principles set forth in this document.

"Bring-In" Medications. The use of a patient's own medications within the hospital should be avoided to the extent possible. They should be used only if the drugs are not obtainable by the pharmacy. If they are used, the physician must write an appropriate order in the patient's medical chart. The drugs should be sent to the pharmacy for verification of their identity; if not identifiable, they must not be used. They should be dispensed as part of the unit dose system, not separate from it.

Drug Control in Operating and Recovery Rooms.¹⁹ The institution's drug control system must extend to its operating room complex. The pharmacist should ensure that all drugs used within this area are properly ordered, stored, prepared, and accounted for.

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

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

Pharmacy Service When the Pharmacy Is Closed. Hospitals provide services to patients 24 hours a day. Pharmaceutical services are an integral part of the total care provided by the hospital, and the services of a pharmacist should be available at all times. Where around the clock operation of the pharmacy is not feasible, a pharmacist should be available on an "on call" basis. The use of "night cabinets" and drug dispensing by nonpharmacists should be minimized and eliminated wherever possible.

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

Drugs should not be dispensed to emergency room patients by nonpharmacist personnel if the pharmacy is open. When no pharmacist is available, emergency room patients should receive drugs packaged, to the extent possible, in single unit packages; no more than a day's supply of doses should be dispensed. The use of an emergency room "formulary" is recommended.²⁰

Adverse Drug Reactions. The medical, nursing, and pharmacy staffs must always be alert to the potential for, or presence of, adverse drug reactions. A written procedure to record clinically significant adverse drug reactions should be established. They should be reported to the FDA, the involved drug manufacturer, and the institution's P&T committee (or its equivalent). Adverse drug reaction reports should contain

- Patient's age, sex, and race.
- Description of the drug reaction and the suspected cause.
- Name of drug(s) suspected of causing the reaction.
- Administration route and dose.
- Name(s) of other drugs received by patient.
- Treatment of the reaction, if any.

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These reports, along with other significant reports from the literature, should be reviewed and evaluated by the P&T committee. Steps necessary to minimize the incidence of adverse drug reactions in the facility should be taken.

Medication Errors. If a medication error is detected, the patient's physician must be informed immediately. A written report should be prepared describing any medication errors of clinical import observed in the prescribing, dispensing, or administration of a medication. This report, in accordance with hospital policy, should be prepared and sent to the appropriate hospital officials (including the pharmacy) within 24 hours.

These reports should be analyzed, and any necessary action taken, to minimize the possibility of recurrence of such errors. Properly utilized, these incident reports will help to assure optimum drug use control. Medication error reports should be reviewed periodically by the P&T committee. (It should be kept in mind that, in the absence of an organized, independent error detection system, most medication errors will go unnoticed.)

The following definitions of medication errors are suggested. A *medication error* is broadly defined as a dose of medication that deviates from the physician's order as written in the patient's chart or from standard hospital policy and procedures. Except for errors of omission, the medication dose must actually reach the patient; i.e., a wrong dose that is detected and corrected before administration to the patient is not a medication error. Prescribing errors (e.g., therapeutically inappropriate drugs or doses) are excluded from this definition.

Following are the nine categories of medication errors:

1. *Omission error:* the failure to administer an ordered dose. However, if the patient refuses to take the medication, no error has occurred. Likewise, if the dose is not administered because of recognized contraindications, no error has occurred.
2. *Unauthorized drug error:* administration to the patient of a medication dose not authorized for the patient. This category includes a dose given to the wrong patient, duplicate doses, administration of an unordered drug, and a dose given outside a stated set of clinical parameters (e.g., medication order to administer only if the patient's blood pressure falls below a predetermined level).
3. *Wrong dose error:* any dose that is the wrong number of preformed units (e.g., tablets) or any dose above or below the ordered dose by a predetermined amount (e.g., 20%). In the case of ointments, topical solutions, and sprays, an error occurs only if the medication order expresses the dosage quantitatively, e.g., 1 inch of ointment or two 1-second sprays.
4. *Wrong route error:* administration of a drug by a route other than that ordered by the physician. Also included are doses given via the correct route but at the wrong site (e.g., left eye instead of right).
5. *Wrong rate error:* administration of a drug at the wrong rate, the correct rate being that given in the physician's order or as established by hospital policy.
6. *Wrong dosage form error:* administration of a drug by the correct route but in a different dosage form than that specified or implied by the physician. Examples of this error type include use of an ophthalmic ointment when a solution was ordered. Purposeful alteration (e.g., crushing of a tablet) or substitution (e.g., substituting liquid for a tablet) of an oral dosage form to facilitate administration is generally not an error.
7. *Wrong time error:* administration of a dose of drug greater than $\pm X$ hours from its scheduled administration time, X being as set by hospital policy.
8. *Wrong preparation of a dose:* incorrect preparation of the medication dose. Examples are incorrect dilution or reconstitution, not shaking a suspension, using an expired drug, not keeping a light-sensitive drug protected from light, and mixing drugs that are physically/chemically incompatible.
9. *Incorrect administration technique:* situations when the drug is given via the correct route, site, and so forth, but improper technique is used. Examples are not using Z-track injection technique when indicated for a drug, incorrect instillation of an ophthalmic ointment, and incorrect use of an administration device.

Special Considerations Contributing to Drug Control

Pharmacy Personnel and Management.²¹⁻²⁴ Adequate numbers of competent personnel and a well-managed pharmacy are the keys to an effective drug control system. References 21-24 provide guidance on the competencies required of the pharmacy staff and on administrative requirements of a well-run pharmacy department.

Assuring Rational Drug Therapy: Clinical Services.^{21,25} Maximizing rational drug use is an important part of the drug control system. Although all pharmacy services contribute to this goal in a sense, the provision of drug information to the institution's patients and staff and the pharmacy's clinical services are those that most directly contribute to rational drug therapy. They are, in fact, institutional pharmacists' most important contributions to patient care.

Facilities. Space and equipment requirements relative to drug storage have been discussed previously. In addition to these considerations, space and equipment must be sufficient to provide for safe and efficient drug preparation and distribution, patient education and consultation, drug information services, and proper management of the department.

Hospital Committees Important to Drug Control.^{26,27} Several hospital committees deal with matters of drug control, and the pharmacist must actively participate in their activities. Among these committees (whose names may vary among institutions) are the P&T committee, infection control committee, use review committee, product evaluation committee, patient care committee, and the committee for protection of human subjects. Of particular importance to the drug control system are the formulary and drug use review (DUR) functions of the P&T committee (although DUR in many institutions may be under a use review or quality-assurance committee).

Drug Use Review.²⁸ Review of how drugs are prescribed and used is an important part of institutional quality-assurance and drug control systems. DUR programs may be performed retrospectively or, preferably, concurrently or prospectively. They may utilize patient outcomes or therapeutic processes as the basis for judgments about the appropriateness of drug

prescribing and use. Depending on the review methodology, the pharmacist should be involved in

1. Preparing, in cooperation with the medical staff, drug use criteria and standards.
2. Obtaining quantitative data on drug use, i.e., information on the amounts and types of drugs used, prescribing patterns by medical service, type of patient, and so forth. These data will be useful in setting priorities for the review program. They also may serve as a measure of the effectiveness of DUR programs, assist in analyzing nosocomial infection and culture and sensitivity data, and help in preparing drug budgets.
3. Reviewing medication orders against the drug use criteria and standards.
4. Consulting with prescribers concerning the results of 3 above.
5. Participating in the followup activities of the review program, i.e., educational programs directed at prescribers, development of recommendations for the formulary, and changes in drug control procedures in response to the results of the review process.

It should be noted that the overall DUR program is a joint responsibility of the pharmacy and the organized medical staff; it is not unilaterally a pharmacy or medical staff function.

Quality Assurance for Pharmaceutical Services.²⁹ To ensure that the drug control system is functioning as intended, there should be a formalized method to (1) set precise objectives (in terms of outcome and process criteria and standards) for the system; (2) measure and verify the degree of compliance with these standards, i.e., the extent to which the objectives have been realized; and (3) eliminate any noncompliance situations. Such a *quality-assurance program* will be distinct from, though related to, the DUR activities of the department.

Drug Recalls. A written procedure to handle drug product recalls should be developed. Any such system should have the following elements:

1. Whenever feasible, notation of the drug manufacturer's name and drug lot number should appear on outpatient prescriptions, inpatient drug orders or profiles, packaging control records, and stock requisitions and their associated labels.
2. Review of these documents (prescriptions, drug orders, and so forth) to determine the recipients (patients and nursing stations) of the recalled lots. Optimally, this would be done by automated means.
3. In the case of product recalls of substantial clinical significance, a notice should go to the recipients that they have a recalled product. The course of action they should take should be included. In the case of outpatients, caution should be exercised not to cause undue alarm. The uninterrupted therapy of the patients must be assured; i.e., replacement of the recalled drugs generally will be required. The hospital's administration and nursing and medical staffs should be informed of any recalls having significant therapeutic implications. Some situations also may require notifying the physicians of patients receiving drugs that have been recalled.

4. Personal inspection of all patient-care areas should be made to determine if recalled products are present.
5. Quarantine of all recalled products obtained (marked "Quarantined—Do Not Use") until they are picked up by or returned to the manufacturer.
6. Maintenance of a written log of all recalls, the actions taken, and their results.

Computerization.³⁰ Many information handling tasks in the drug control system (e.g., collecting, recording, storing, retrieving, summarizing, transmitting, and displaying drug use information) may be done more efficiently by computers than by manual systems. Before the drug control system can be computerized, however, a comprehensive, thorough study of the existing manual system must be conducted. This study should identify the data flow within the system and define the functions to be done and their interrelationships. This information is then used as the basis to design or prospectively evaluate a computer system; any other considerations, such as those of the hospital accounting department, are subordinate.

The computer system must include adequate safeguards to maintain the confidentiality of patient records.

A backup system must be available to continue the computerized functions during equipment failure. All transactions occurring while the computer system is inoperable should be entered into the system as soon as possible.

Data on controlled substances must be readily retrievable in written form from the system.

Defective Drug Products, Equipment, and Supplies. The pharmacist should be notified of any defective drug products (or related supplies and equipment) encountered by the nursing or medical staffs. All drug product defects should be reported to the USP-FDA-ASHP Drug Product Defect Reporting Program.

Disposal of Hazardous Substances. Hazardous substances (e.g., toxic or flammable solvents and carcinogenic agents) must be disposed of properly in accordance with the requirements of the Environmental Protection Agency or other applicable regulations. The substances should not be poured indiscriminately down the drain or mixed in with the usual trash.

Unreconstituted vials or ampuls and unopened bottles of oral medications supplied by the National Cancer Institute (NCI) should be returned to the NCI's contract storage and distribution facility.

Other intact products should be returned to the original source for disposition.

Units of anticancer drugs no longer intact, such as reconstituted vials, opened ampuls, and bottles of oral medications, and any equipment (e.g., needles and syringes) used in their preparation require a degree of caution greater than with less toxic compounds to safeguard personnel from accidental exposure. The National Institutes of Health recommends that all such materials be segregated for special destruction procedures. The items should be kept in special containers marked "*Danger—Chemical Carcinogens.*" Needles and syringes first should be rendered unusable and then placed in specially marked plastic bags. Care should be taken to prevent penetration and leakage of the bags. Excess liquids should be placed in sealed containers; the original vial is satisfactory. Disposal of all of the above materials should be by incineration to destroy organic material.

100 Drug Distribution and Control: Distribution—*Technical Assistance Bulletins*

Alternate disposal for BCG vaccine products has been recommended by the Bureau of Biologics (BOB). The BOB suggests that all containers and equipment used with BCG vaccines be sterilized prior to disposal. Autoclaving at 121 °C for 30 minutes will sterilize the equipment.

At all steps in the handling of anticancer drugs and other hazardous substances, care should be taken to safeguard professional and support services personnel from accidental exposure to these agents.

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Developed by the ASHP Council on Professional Affairs. Approved by the ASHP Board of Directors, March 20, 1980. Revised November 1981.

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The bibliographic citation for this document is as follows: American Society of Hospital Pharmacists. ASHP technical assistance bulletin on hospital drug distribution and control. *Am J Hosp Pharm.* 1980; 37:1097-103.