CHAPTER 111

Laws Governing Pharmacy

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Pharmacists—whether community practitioners, employed by an institution or working for a pharmaceutical manufacturer—must be aware of the legal requirements that apply to their daily professional activities. The laws pertaining to the practice of pharmacy arise from a variety of different sources, including statutory laws such as the Food Drug and Cosmetic Act (FD&CA), the Controlled Substances Act (CSA), the Poison Prevention Packaging Act (PPPA), at the federal level and Pharmacy Practice Acts or Codes at the state level. In addition, several regulatory agencies in the federal government including the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC) and the Drug Enforcement Administration (DEA) have the authority to promulgate regulations that have the force of law. State agencies such as a Board of Pharmacy also adopt rules or regulations that have the force of law. Another source of law comes from court decisions the either interpret statutory and regulatory laws or make new laws based on judicial decisions; the later type of rulings are often called "judge made" or "common" laws derived for the English court system.

Beside the various *sources* of laws, there are a multitude of *types* of law. Civil law governs the relationship between individuals within society, whereas criminal law governs the relationship of the individual to society as a whole. Two important subdivisions of civil law are the law of contracts and tort law. The former concerns relationships that the individuals enter into voluntarily, while the latter embodies relationships that exist automatically by virtue of law. Each *type* and *source* of law is applicable to pharmacists and pharmacy practice.

LAWS GOVERNING THE PRACTICE OF PHARMACY

Relationship between State and Federal Laws

Differentiating between state and federal laws governing the practice of pharmacy can be a daunting task because some areas of the law are reserved exclusively to state governments while other topics are governed exclusively by federal authorities. Complicating the subject even more, there are numerous issues that both the state and federal laws address. In the later case, when both federal and state laws speak to the same issue, the governing bodies are said to have "concurrent jurisdiction." Determining which of the two sets of laws to apply to any given situation is sometimes difficult, especially in cases where the two laws differ in their obligations or prohibitions. As a general rule, when there is a "conflict of laws" it is usually safer to apply and follow the stricter law. An example will help illustrate the point. DEA regulations require pharmacies to keep controlled substances records, including prescriptions for at least two years. Several states have laws that all prescriptions be stored in a pharmacy for a longer period. In Michigan, for example, pharmacies must retain prescriptions a minimum of five years from the date of last refill. Because record retention is a subject of "concurrent jurisdiction" between state and federal governments, a pharmacist would follow the "stricter" law and, at least in Michigan, keep all prescriptions, including those for controlled substances, for a minimum of five years from the date of the last refill. Another area of "concurrent jurisdiction" that has sparked over a decade of controversy involves the compounding of drugs by pharmacists. Historically, compounding was thought to be exclusively in the realm of state jurisdiction. In the early 1990s, the FDA began an aggressive approach to regulate pharmacies that were engaging in large scale compounding more akin to manufacturing. Viewed another way, the FDA was attempting to regulate pharmacies that were manufacturing, and therefore subject to federal laws, under the guise of state regulated compounding practices. The furor over the subject led to an amendment to the FD&CA that gave the FDA some regulatory authority over compounding while leaving other aspects of compounding subject to state law. This in turn led the National Associations of Boards of Pharmacy (NAPB) to adopt model guidelines for states to enact. Animosities between the FDA and compounding pharmacies finally cumulated in a Unites States Supreme Court decision in April, 2002 that should have settled the issue in favor of state authority to regulate compounding. Undaunted by the Supreme Court decision, within days, the FDA reissued guidelines to its field officers to distinguish between acceptable compounding activities and unlawful manufacturing by pharmacies without a federally issued manufacturing license. The topic is addressed in more detail under the *Compounding* subsection below.

The authority for states to regulate pharmacy originates in the Tenth Amendment to the United States Constitution, which reserves most "police powers" to the states. The terminology could be misleading if "police power" were thought to refer to law enforcement officers only. In fact, as the term is used in the law, the "police power" reserved exclusively to the states means that the states have the authority to pass laws designed to protect the health, safety and welfare of its citizens. Note that the Constitution reserves *most* "police powers" to the states. As might be expected, there are exceptions that permit the federal government to "preempt" inconsistent state laws if the federal government determines it will "occupy the field" of

a particular subject matter. Another example is offered to clarify the point. Every state has laws regarding the labeling and packaging of drugs dispensed pursuant to a prescription. Some states even have laws regarding the type of container used to contain prescription drugs. The Consumer Product Safety Commission (CPSC), a federal agency, acting under the auspices of the federal Poison Prevention Packaging Act (PPPA) has "preempted" inconsistent state laws dealing with the packaging of "household substances," which include prescription drugs. Under the applicable regulations, every drug dispensed by prescription must be in a child resistant container unless the patient or prescriber requests otherwise. Because of the preemption, any state law not consistent with the demands of the CPSC regulations would have no force of law and pharmacists are required to follow the federal mandates.

Perhaps it is too simplistic to put it this way, but another general rule to use in determining which jurisdictional body controls a subject matter is to think of state laws as regulating the *practice of pharmacy* and the federal government as regulating *pharmaceuticals* including their marketing, production and distribution. As with all laws, there are exceptions to this general rule. Nonetheless, it should help readers better comprehend the scope of the jurisdictional authority of the different governmental bodies.

STATE LAWS

As mentioned, the regulation of the *practice of pharmacy* is primarily a function of the states and not of the federal government. Accordingly, states are relatively free to enact laws and Board of Pharmacy rules independent of the federal government (so long as the regulations are not in conflict or inconsistent with federal law). While pharmacy laws of the different states do vary among themselves, they are in agreement with respect to the fundamental principles, purposes, aims and objectives of pharmacy practice. In a Chapter of this magnitude, it is impossible to consider the vast array and nuances of every state pharmacy practice law. Therefore, the focus will be on the commonalities among state laws.

Like every profession, the practice of pharmacy is a privilege bestowed by the state. However, this is a privilege available only to a class of persons who satisfy stated minimal qualifications. No one may practice pharmacy without a license, except for those who are licensed according to state law. However, anyone may achieve such licensure by successfully completing the statutory pattern of qualification that the state has established and as administered by an agency given the regulatory authority. Not every state has a Board of Pharmacy as the regulatory agency with this authority; however because that is the term used by the majority of states, hereafter the governing administrative agency will be referred to as the Board of Pharmacy. In some instances the Board of Pharmacy is a sub-agency that exists as part of a larger state agency, such as a department of health or licensing.

Once licensure is gained it may not be easily revoked. The state may suspend, revoke or terminate it but only after due process and for just cause as set out in the appropriate legislation. At the same time, the state undertakes to protect the public and the licensed pharmacists from practice by unlicensed (hence, unqualified) parties in its jurisdiction. As to licensed pharmacists, they have gained what constitutes a "monopoly" to practice pharmacy safeguarded by the Federal and state constitutions as a property right. While they must abide by the legislation to preserve it, pharmacists must pay fees required to accomplish initial and continuing licensure, and must satisfy the legal, moral and ethical standards of their peers, as set out in law and regulations. They do have the right to legal redress against any who would seek unjustifiably to deprive them of the benefits and prerogatives of licensure. Pharmacy practice acts specifically must identify the conduct for which sanctions can be imposed.

State pharmacy laws generally provide for:

1. The educational and experiential qualifications that pharmacists must meet at the time of an examination for licensure (or "registration"). The vast majority of states require that applicant for licensure to have graduated from an "accredited" school or collage of Pharmacy or take a "foreign licensure" exam to show that the applicants knowledge and credentials match graduates of an accredited institution.
2. Establishment of an administrative agency (Board of Pharmacy) charged with enforcement and administration of the pharmacy practice laws. This agency will have powers delegated by the legislature in pharmacy practice statutes to promulgate rules or regulations to implement the statutes. A certain amount of enforcement discretion will be vested in a Boards of Pharmacy. While the board is authorized to make rules and regulations for the enforcement and administration of the pharmacy law, such rules and regulations must be strictly in accord with the expressed or implied purposes of the law. The board is an administrative, not a legislative, agency. It may not exercise any power or authority not clearly delegated to it. The Board of Pharmacy will grant licenses to qualified pharmacists and pharmacies, and also have the power to impose sanctions against those who do not follow the applicable laws. The conditions under which licensure or registration may be canceled, revoked, suspended, or put on probation must be specified in a statute or regulation. Many Boards of Pharmacy have other disciplinary sanctions available including civil fines and the imposition of a community service requirement. Some state laws specify that violations of the pharmacy act are punishable as a criminal misdemeanor.
3. The granting of licenses for the conduct of a community and institutional pharmacy. In most states permits are issued for one or two years and application must be made for renewal at a specified time.
4. Periodic re-licensure of pharmacists. In most states, certificates of licensure or registration are granted for the period of one or two years.
5. The prominent display of the certificate of licensure or registration in the pharmacy in which the holder is employed.
6. Reciprocal registration whereby a pharmacist licensed by examination in one state may, by conforming to more or less nominal rules, becomes registered in another state without full licensure examination. In almost all states and jurisdictions within the United States, reciprocating pharmacists must take the pharmacy law exam in the state they wish to become licensed in.

Every state has a pharmacy practice act that regulates the profession, but there is significant variation in the detail of these acts from state to state. Many of the states statutes are antiquated, with amendments being added in a haphazard manner. Many of these early acts regulated an older and traditional profession that was primarily product-oriented and involved in the preparation and delivery of drugs.

Nuclear pharmacy, clinical pharmacy, pharmaceutical care, mandated counseling and drug-product selection are just some of the developments impacting upon regulation of pharmacy since most of the laws were originally developed. These changes, along with the need to provide more uniformity among the states, caused the National Associations of Boards of Pharmacy (NABP) to develop a *Model State Pharmacy Practice Act* (MSPPA). The Model Act is intended to provide both uniformity and flexibility to the states that adopt it. Many states have adopted some of the Model Act's provisions while formulating unique regulations to address issues of particular concern in individual states.

The NABP's MSPPA is online at http://nabp.net and is available for downloading without fee. Readers who are interested in seeing how a model act is organized and the suggested topics that should be covered in a state act are advised to visit the NABP site or contact the NABP (700 Busse Hwy., Oak Ridge, IL 60068; Phone: 847-698-6227). Because there are so many variations in the pharmacy laws between states, readers should consult the laws of the particular state in interest.

One of the more common sections contained in nearly every state pharmacy act is a definition of the "practice of pharmacy." The MSPPA includes a broad interpretation of the term:

> The Practice of Pharmacy means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug

Orders; participation in Drug and Device selection, Drug Administration, Drug Regimen Reviews, and drug or drug-related research; provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care including Primary Care; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of proper records for them.

In contrast, many state statutes are so out of date in that they limit the practice of pharmacy to the preparation and distribution of a dosage form. The MSPPA adopts very broad language to allow boards of pharmacy to promulgate rules and regulations with considerable flexibility as the profession changes to meet future needs.

Definitions

No matter which state laws are being considered, the best place to start is with definitions contained within the statutes or acts. Many words in laws are used in ways that differ from common everyday usage. Basic definitions are essential to the clarity, administration and enforcement of any law. For example, comments to the MSPPA indicate that the *practice of pharmacy* includes the selection of therapeutic agents in accord with institutional protocols or some other legal authority. The definition also encompasses the concept of consulting with, or providing information to, both the prescriber and the patient regarding drug therapy. Patient counseling and pharmaceutical care are further defined in the model rules.

The following definitions from the MSPPA are provided as examples of important terms often included in pharmacy acts:

(a) *Administer* means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(b) *Automated Pharmacy Systems* include, but are not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and that collect, control, and maintain all transaction information.

(c) *Beyond-Use Date* means a date determined by a Pharmacist and placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(d) *Compounding* means the preparation, mixing, assembling, packaging, or Labeling of a Drug or Device (i) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding also includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

(e) *Confidential Information* means information accessed, maintained by, or transmitted to the Pharmacist in the patient's records or that is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, as the patient directs, to those Practitioners, other authorized health care professionals, and other Pharmacists where, in the Pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other Persons or governmental agencies authorized by law to receive such Confidential Information, regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

(f) *Dispense* or *Dispensing* means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.

(g) *Distribute* means the Delivery of a Drug or Device other than by Administering or Dispensing.

(h) *Drug* means:
- (1) Articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
- (3) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and
- (4) Articles intended for use as a component of any articles specified in clause (1), (2), or (3) of this subsection.

(i) *Emergency Situations*, for the purposes of authorizing an oral Prescription Drug Order of a Schedule II controlled substance, means those situations in which the prescribing Practitioner determines (1) that immediate Administration of the controlled substance is necessary for proper treatment of the patient, (2) that no appropriate alternative treatment is available, including Administration of a drug that is not a Schedule II controlled substance, and (3) that it is not reasonably possible for the prescribing Practitioner to provide a written Prescription Drug Order to be presented to the person Dispensing the substance, prior to the Dispensing.

(j) *Equivalent Drug Product* means a Drug product that has the same established name, active ingredient(s), strength or concentration, dosage form, and route of Administration and that is formulated to contain the same amount of active ingredient(s) in the same dosage form and to meet the same compendial or other applicable standards (ie, strength, quality, purity, and identity), but that may differ in characteristics such as shape, scoring, configuration, packaging, excipients (including colors, flavors, preservatives), and expiration time.

(k) *Intern* means an individual who is:
- (1) currently licensed by this State to engage in the Practice of Pharmacy while under the personal supervision of a Pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or
- (2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or
- (3) a qualified applicant awaiting examination for licensure; or
- (4) an individual participating in a residency or fellowship program.

(l) *Labeling* means the process of preparing and affixing a label to any Drug container exclusive, however, of the labeling by a Manufacturer, packer, or distributor of a Non Prescription Drug or commercially packaged Legend Drug or Device. Any such label shall include all information required by federal and state law or rule.

(m) *Non Prescription Drug* means a drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this State and the Federal Government.

(n) *Patient Counseling* means the oral communication by the Pharmacist of information, as defined in the rules of the Board, to the patient or caregiver, to ensure the proper use of Drugs and Devices.

(o) *Person* means an individual, corporation, partnership, association, or any other legal entity including government.

(p) *Pharmaceutical Care* is the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the Rules of the Board.

(q) *Pharmacist* means an individual currently licensed by this State to engage in the Practice of Pharmacy.

(r) *Pharmacist-in-Charge* means a Pharmacist currently licensed in this state who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the distribution of Drugs, and who is personally in full and actual charge of such pharmacy and personnel.

(s) *Pharmacy* means any place within this State where Drugs are Dispensed and Pharmaceutical Care is provided and any place outside of this State where Drugs are Dispensed and Pharmaceutical Care is provided to residents of this State.

(t) *Practice of Telepharmacy Across State Lines* means the provision of Pharmaceutical Care through the use of telecommunications and information technologies that occurs when the patient is physically located within the jurisdiction and the Pharmacist is located outside the jurisdiction.

(u) *Practitioner* means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.
(v) *Preceptor* means an individual who is currently licensed as a Pharmacist by the Board of Pharmacy, meets the qualifications as a Preceptor under the Rules of the Board, and participates in the instructional training of pharmacy Interns.
(w) *Prescription Drug* or *Legend Drug* means a Drug that is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered: (i) *Caution: Federal law prohibits dispensing without prescription or Rx Only*; or (ii) *Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian*; or (iii) a Drug that is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.

The definitions of a device or a drug in state law are often similar to those included in the FD&CA, but their application will be different under state law as the Board of Pharmacy is interested primarily in the dispensing aspects of such drugs or devices as opposed to the Federal orientation to the purity, strength and appropriate labeling of drugs.

The various states will also include a variety of individuals within the definition of a "practitioner" who is permitted to prescribe prescription only drugs. Such provisions anticipate that those persons other than pharmacists who are permitted to prescribe and administer drugs will be specifically authorized in other legislation.

Each state pharmacy practice act, as well as state controlled substances legislation, must be examined carefully to determine the legality of pharmacists filling prescription orders written by practitioners or prescribers in other states. The majority of the states do not prohibit the dispensing of prescription orders that originate out-of-state, but some states prohibit the dispensing of prescriptions from all out-of-state prescribers except those living in *border states*. Pharmacists should consult state statutes carefully and with the board of pharmacy to determine the legal status of prescription orders originating in another state.

Rules and Regulations

There are vast differences in the rules (or "regulations" as they are called in some states) between the states. Fortunately, the NABP, through its MSPPA, has provided some basic rules that every state should follow. The following is a restatement from Article II of the MSPPA:

"The Board of Pharmacy shall make, adopt, amend, and repeal such rules as may be deemed necessary by the Board from time to time for the proper administration and enforcement of this Act. Such rules shall be promulgated in accordance with the procedures specified in the Administrative Procedures Act of this State.

(a) The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following:
  (1) The licensing by examination or by license transfer of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;
  (2) The renewal of licenses to engage in the Practice of Pharmacy;
  (3) The establishment and enforcement of compliance with professional standards and rules of conduct of Pharmacists engaged in the Practice of Pharmacy;
  (4) The determination and issuance of standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including internship;
  (5) The enforcement of those provisions of this Act relating to the conduct or competence of Pharmacists practicing in this State, and the suspension, revocation, or restriction of licenses to engage in the Practice of Pharmacy;
  (6) The licensure and regulation of the training, qualifications, and employment of Pharmacy Interns and Pharmacy Technicians;
  (7) The collection of professional demographic data;
  (8) The right to seize any such Drugs and Devices found by the Board to constitute an imminent danger to the public health and welfare;
  (9) Establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, Compounding and/or Dispensing of such Drugs or Devices, and for the monitoring of drug therapy;
  (10) Establishing minimum standards for the purity and quality of such Drugs, Devices, and other materials within the Practice of Pharmacy;
  (11) The issuance and renewal of licenses of all Persons engaged in the manufacture and distribution of Drugs and Devices;
  (12) Inspection of any licensed Person at all reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of Drugs or Devices or the Practice of Pharmacy are being violated. The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with the enforcement of the laws of the US, of this State, and of all other states relating to Drugs, Devices, and the Practice of Pharmacy; and
  (13) Establishing minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health-care information.
(b) The Board of Pharmacy shall have such other duties, powers, and authority as may be necessary to the enforcement of this Act and to the enforcement of Board rules made pursuant thereto, which shall include, but are not limited to, the following:
  (1) The Board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the Practice of Pharmacy for the protection of the health and welfare of the public and/or whose activities assist and facilitate the work of the Board.
  (2) The Board may receive and expend funds, in addition to its [annual/biennial] appropriation, from parties other than the State, provided:
    (i) Such funds are awarded for the pursuit of a specific objective that the Board is authorized to accomplish by this Act, or that the Board is qualified to accomplish by reason of its jurisdiction or professional expertise;
    (ii) Such funds are expended for the pursuit of the objective for which they are awarded;
    (iii) Activities connected with or occasioned by the expenditures of such funds do not interfere with the performance of the Board's duties and responsibilities, and do not conflict with the exercise of the Board's powers as specified by this Act;
    (iv) Such funds are kept in a separate, special account; and
    (v) Periodic reports are made concerning the Board's receipt and expenditure of such funds.
  (3) The Board may establish a Bill of Rights for patients concerning the health-care services a patient may expect in regard to Pharmaceutical Care.
  (4) Any investigation, inquiry, or hearing that the State Board of Pharmacy is empowered to hold or undertake may be held or undertaken by or before any member or members of the Board and the finding or order of such member or members shall be deemed to be the order of said Board when approved and confirmed as noted in Section 210(d).
  (5) Embargo
    (i) Notwithstanding anything in this Act to the contrary, whenever a duly authorized representative of the Board finds, or has probable cause to believe, that any Drug or Device is adulterated or misbranded within the meaning of the (State) Food and Drug Act, he shall affix to such Drug or Device a tag or other appropriate marking giving notice that such article is or is suspected of being adulterated or misbranded, has been detained or embargoed, and warning all Persons not to remove or dispose of such article by sale or otherwise until provision for removal or disposal is given by the Board, its agent, or the Court. No Person shall remove or dispose of such embargoed Drug or Device by sale or otherwise without the permission of the Board or its agent or, after summary proceedings have been instituted, without permission from the Court.
    (ii) When a Drug or Device detained or embargoed under Paragraph (i) of this subsection (5) has been declared by such representative to be adulterated or mis-

branded, the Board shall, as soon as practical thereafter, petition the Judge of the Court in which jurisdiction the article is detained or embargoed for an order for condemnation of such article. If the judge determines that the Drug or Device so detained or embargoed is not adulterated or misbranded, the Board shall direct the immediate removal of the tag or other marking.

(iii) If the court finds the detained or embargoed Drug or Device is adulterated or misbranded, such Drug or Device, after entry of the decree, shall be destroyed at the expense of the owner under the supervision of a Board representative and all court costs and fees, storage, and other proper expense shall be borne by the owner of such Drug or Device. When the adulteration or misbranding can be corrected by proper Labeling or processing of the Drug or Device, the Court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond has been posted, may direct that such Drug or Device be Delivered to the owner thereof for such Labeling or processing under the supervision of a Board representative. Expense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of the Drug or Device on representation to the Court by the Board that the Drug or Device is no longer in violation of the embargo and the expense of supervision has been paid.

(iv) It is the duty of the Attorney General [State's Attorney] to whom the Board reports any violation of Section 213(b)(5) to cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law. Nothing in this subparagraph (iv) shall be construed to require the Board to report violations whenever the Board believes the public's interest will be adequately served in the circumstances by a suitable written notice or warning.

(6) The Board may place under seal all Drugs or Devices that are owned by or in the possession, custody, or control of a licensee at the time his license is suspended or revoked or at the time the Board refuses to renew his license. Except as otherwise provided in this section, Drugs or Devices so sealed shall not be disposed of until appeal rights under the Administrative Procedures Act have expired, or an appeal filed pursuant to that Act has been determined. The court involved in an appeal filed pursuant to the Administrative Procedures Act may order the Board, during the pendency of the appeal, to sell sealed Drugs that are perishable. The proceeds of such a sale shall be deposited with that court.

(7) Except as otherwise provided to the contrary, the Board shall exercise all of its duties, powers, and authority in accordance with the State Administrative Procedures Act.

(8) In addition to the fees specifically provided for herein, the Board may assess additional reasonable fees for services rendered to carry out its duties and responsibilities as required or authorized by this Act or Rules adopted hereunder. Such services rendered shall include, but not be limited to, the following:

(i) Issuance of duplicate certificates or identification cards;
(ii) Mailing lists, or reports of data maintained by the Board;
(iii) Copies of any documents;
(iv) Certification of documents;
(v) Notices of meetings;
(vi) Licensure transfer;
(vii) Examination administration to a licensure applicant; and
(viii) Examination materials.

(9) Cost Recovery

(i) If any order issues in resolution of a disciplinary proceeding before the Board of Pharmacy, the Board may request the to direct any licensee found guilty of a charge involving a violation of any drug laws or rules, to pay to the Board a sum not to exceed the reasonable costs of the investigation and prosecution of the case and, in any case, not to exceed twenty-five thousand dollars ($25,000).

(ii) In the case of a Pharmacy or Wholesale Distributor, the order may be made as to the corporate owner, if any, and as to any Pharmacist, officer, owner, or partner of the Pharmacy or Wholesale Distributor who is found to have had knowledge of or have knowingly participated in one or more of the violations set forth in this section.

(iii) The costs to be assessed shall be fixed by the and shall not be increased by the Board; where the Board does not adopt a proposed decision and remands the case to a(n) _____, the _____, shall not increase any assessed costs.

(iv) Where an order for recovery of costs is made and timely payment is not made as directed in the Board's decision, the Board may enforce the order for payment in the Court in the county where the administrative hearing was held. This right of enforcement shall be in addition to any other rights the Board may have as to any Person directed to pay costs.

(v) In any action for recovery of costs, proof of the Board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment."

Licensure Exams

Passing an examination is a necessary prerequisite prior to licensure. Each state administers two exams, one dealing with the clinical and practice knowledge of the licensure applicant and the other dealing with state and federal law. The later test is often referred to as the "pharmacy jurisprudence" exam. All but a few states (at the time of publication, the two exceptions are California and Hawaii) administer the NAPLEX that was developed by the NABP to test clinical and practice-based knowledge skills. The NAPLEX consists of a combined format that determines a candidate's competency to practice through an integrated test, rather than dividing the material into separate subject areas. Most states now administer the NABP's Multistate Pharmacy Jurisprudence Exam (MPJE) to test the applicant's knowledge of individual state and federal laws. The MPJE provides flexibility to permit each state to test on its unique state laws while incorporating the federal laws common across the country. Detailed information about the MPJE is available in the NABP Registration Bulletin and at the NABP website: www.nabp.net. The MPJE has several questions involving federal laws pertinent to the practice of pharmacy. For this reason, applicants must know both federal and state laws. Applicants should take special care to learn both federal and state controlled substances laws because these are usually emphasized in the examinations. It is important to understand that there is no distinction between federal and state laws in the questions. Applicants are advised to answer all questions according to prevailing state law unless there is a stricter or preemptive federal law on point.

The MPJE is administered over a two-hour period in the computer-adaptive format similar to the NAPLEX. Each examination is unique to the individual applicant. One of the most important things to realize when sitting for this exam is that answers cannot be changed once they are entered. Unlike the traditional pencil and ink exam, the applicant cannot review questions and change answers later. Likewise, it is important to understand that a question cannot be skipped and referred to at later time. These factors make taking this test very different from the experiences of most pharmacy students.

While the test consists of 90 questions, only 60 are graded. A score of 75% or higher on the graded questions is needed to earn a passing mark. There is no distinction in the exam between graded and ungraded questions so the applicant has no way of knowing which of the 90 questions actually counts towards the final score.

Applicants should also be aware that the state MPJE scores may only be used for obtaining a pharmacist license in the state where the applicant is applying for a pharmacist license. Each state that uses the MPJE has its own separate version of the

exam. However, applicants for a license in another state may actually take the exam for that state in another sate and have the results reported to the state where licensure is sought. Applicants are not allowed to take the examination before graduation.

Reciprocity

As an alternative to licensure by examination, some applicants also may seek licensure by the reciprocal or license transfer process. Such an applicant must:

(1) Have submitted a written application in the form prescribed by the Board of Pharmacy;

(2) Have attained the age of majority;

(3) Have good moral character;

(4) Have possessed at the time of initial licensure as a Pharmacist all qualifications necessary to have been eligible for licensure at that time in this State;

(5) Have engaged in the Practice of Pharmacy for a period of at least one (1) year or have met the internship requirements of this State within the one (1) year period immediately previous to the date of such application;

(6) Have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;

(7) Have presented to the Board proof that any other license granted to the applicant by any other state has not been suspended, revoked, or otherwise restricted for any reason except non-renewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed but not engaged in the Practice of Pharmacy; and

(8) Have paid the fees specified by the Board.

(9) No applicant is be eligible for license transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.

At the time of publication only California and Hawaii do not reciprocate with any of the other 48 states. In the past Florida was also a non-reciprocating state but it was removing some of the reciprocity restrictions at press time and is expected to participate in the reciprocity process in the near future.

The NABP acts as a clearinghouse for the reciprocation process. The applicant provides information to the NABP that in turn verifies these facts relating to licensure and provides that information to the reciprocating state. The reciprocating state reviews the application, and it is highly likely that before it will issue a license it will require the applicant to pass a jurisprudence examination (either the MPJE or its own jurisprudence exam) on the state laws where licensure is sought.

Interstate Practice

One of the more recent developments in pharmacy regulation involves practices that cross state borders such as in mail-order and internet dispensing where a pharmacist in one state may be dispensing prescriptions and counseling patients in another state. This presents a challenge to Boards of Pharmacy that do not have any legal authority or jurisdiction over the pharmacist located out of state. The MSPPA has a provision to address this situation:

(a) An applicant applying for registration to engage in the Practice of Telepharmacy Across State Lines shall:
  (1) present to the Board proof of licensure in another jurisdiction and proof that such license is in good standing;
  (2) submit a written application in the form prescribed by the Board of Pharmacy;
  (3) pay the fee(s) specified by the Board of Pharmacy for the issuance of the license; and
  (4) comply with all other requirements of the Board of Pharmacy.

(b) Application
  (1) The written application required under Section 304(a)(1) of the Act shall request of the applicant, at a minimum, the following information:
    (i) Name, address, and current pharmacist licensure information in all other jurisdictions, including jurisdiction(s) of licensure and license number(s);
    (ii) Name, address, phone number, and (if applicable) jurisdiction of licensure and license number of the site where the Practice of Telepharmacy will originate;
    (iii) A statement of the scope of patient services that will be provided;
    (iv) A description of the protocol or framework by which patient care will be provided, including any collaborative practice arrangements with other health-care practitioners; and
    (v) A statement attesting that the applicant will abide by the pharmacy laws and regulations of the jurisdiction in which the patient is located.

A few states have adopted the model act language and others have taken a different approach. One example involves the "long arm jurisdiction" approach in which a state requires any out of state pharmacy that sends prescription drug into the state be licensed and comply with that state's laws. In either event, states still have jurisdictional and practical limits on seeking to discipline pharmacists and pharmacies located out of the state. This could be an area where the federal government may have to intervene to set up some uniform enforcement laws.

Institutional Pharmacy

The NABP also has developed model rules for institutional pharmacy. These regulations may be applied to facilities such as a hospital, nursing home, psychiatric center, health maintenance organization and others. These regulations include special provisions for the distribution of drugs when the institutional pharmacy is unattended by a licensed pharmacist. The model rules include provisions for night cabinets, emergency kits, investigational drugs, quality assurance and other items that particularly are applicable to the institutional practice of pharmacy.

Central to the issue of regulating institutional pharmacy practice is the definition of *institution*. The Model Rules for Institutional Pharmacy (MRIP) veloped by NAPB provides:

(a) *Institutional Facility* means any organization whose primary purpose is to provide a physical environment for patients to obtain health-care services, including but not limited to a(n):
  (1) Hospital;
  (2) Convalescent Home;
  (3) Nursing Home;
  (4) Extended Care Facility;
  (5) Mental Health Facility;
  (6) Rehabilitation Center;
  (7) Psychiatric Center;
  (8) Developmental Disability Center;
  (9) Drug Abuse Treatment Center;
  (10) Family Planning Clinic;
  (11) Penal Institution;
  (12) Hospice;
  (13) Public Health Facility;
  (14) Athletic Facility.

(b) *Institutional Pharmacy* means that physical portion of an Institutional Facility where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as Drugs) are Dispensed, Compounded, and distributed and Pharmaceutical Care is provided; and that is registered with the State Board of Pharmacy pursuant to Article V of the Pharmacy Practice Act.

The MRIP contemplates that a *Pharmacist-in-Charge* will direct pharmacy practice in the institution. Absences are addressed in another provision:

(a) During such times as an Institutional Pharmacy may be unattended by a Pharmacist, arrangements shall be made in advance

by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be *on call* during all absences.

(b) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and that is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:
  (1) Drugs are properly Labeled;
  (2) Only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
  (3) Whenever access to the cabinet occurs, written Practitioner's orders and proofs-of-use are provided;
  (4) All Drugs therein are inventoried no less than once per week;
  (5) A complete audit of all activity concerning such cabinet is conducted no less than once per month; and
  (6) Written policies and procedures are established to implement the requirements of this Section 4.

(c) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of this Section 4. One supervisory nurse in any given 8-hr shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of Drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

(d) For an Institutional Facility that does not have an Institutional Pharmacy, Drugs may be provided for use by authorized personnel by emergency kits located at such Facility, provided, however, such kits meet the following requirements:
  (1) Emergency kit drugs are those Drugs that may be required to meet the immediate therapeutic needs of patients and that are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources;
  (2) All emergency kit drugs shall be provided and sealed by a Pharmacist;
  (3) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits;
  (4) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them;
  (5) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist;
  (6) Drugs shall be removed from emergency kits only pursuant to a valid Prescription Drug Order;
  (7) Whenever an emergency kit is opened, the supplying Pharmacist shall be notified and the Pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients; and
  (8) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist shall replace the expired Drug. (MSPPA)

Drug distribution and control are also to be assigned responsibility of the Pharmacist-in-Charge:

(a) The Pharmacist-in-Charge shall establish written procedures for the safe and efficient distribution of Drugs and for the provision of Pharmaceutical Care. An annual updated copy of such procedures shall be on hand for inspection by the Board of Pharmacy.

(b) Drugs brought into an Institutional Facility by a patient shall not be Administered unless they can be identified and the quality of the Drug assured. If such Drugs are not to be Administered, then the Pharmacist-in-Charge shall, according to procedures specified in writing, have them turned into the Pharmacy, which shall package and seal them and return them to an adult member of the patient's immediate family, or store and return them to the patient upon discharge.

(c) Investigational Drugs shall be stored in and Dispensed from the Pharmacy only. All information with respect to investigational Drugs shall be maintained in the Pharmacy.

Licensing of Facilities

In most states community, as well as institutional, pharmacies may be operated only under permits issued by the board of pharmacy. State law normally will require an annual fee, provisions for inspection of the premises, proper prescription records and the maintenance of certain minimums of equipment or stock. The licensure of facilities provides a Board of Pharmacy with knowledge of all premises involved in the storage, distribution and sale of drugs and devices within the state and those located outside the state that are shipping drugs into the state. These requirements permit a Board of Pharmacy to better to insure against drug diversion from legitimate channels of commerce.

Nuclear Pharmacy

Nuclear pharmacy, recognized as the first specialty area in the profession, also may have special regulations at the state level. Most regulations make it unlawful for any person to provide nuclear pharmaceutical services unless under the supervision of a qualified nuclear pharmacist. The MSPPA defines *a Qualified Nuclear Pharmacist* as a currently licensed pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for *authorized user status* of radioactive material.
(2) Completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas:
  (i) Radiation physics and instrumentation;
  (ii) Radiation protection;
  (iii) Mathematics of radioactivity;
  (iv) Radiation biology; and
  (v) Radiopharmaceutical chemistry.
(3) Attain a minimum of 500 hr of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

Pharmaceutical Care

The NABP has developed comprehensive model rules to implement the patient-care concepts embodied in the definition of the practice of pharmacy. The rules provide for the age-old requirements of a prescription- drug order with provisions for the electronic transmittal of the prescription to the pharmacist. The transfer of prescriptions between unrelated pharmacies also is addressed in these rules.

The model rules include provisions for drug-product selection, prescription labeling and patient records. These sections provide an important background for the central focus of the pharmaceutical care rules—the requirement for patient counseling and prospective drug review by the pharmacist. Following a review of the patient's records for therapeutic duplication, drug interactions, over- or under-use and a number of other considerations, the pharmacist personally must initiate discussion with the patient or the patient's caregiver regarding the prescription.

Minimum Requirements for a Pharmacy

The physical facilities housing a pharmacy are addressed in the Model Rules for Pharmaceutical Care:

(1) Each Pharmacy shall be of sufficient size to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.
(2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy.
(3) Each Pharmacy shall maintain on file at least one current reference in each of the following categories:
  (a) State and Federal drug laws relating to the Practice of Pharmacy and the legal distribution of Drugs and any rules or regulations adopted pursuant thereto;
  (b) pharmacology;
  (c) dosage and toxicology;
  (d) general.
(4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper drug usage.
(5) All areas where Drugs and Devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures that will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the USP/NF and/or the Manufacturer's or distributor's Labeling unless otherwise indicated by the Board.
(6) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.
(7) Security
  (a) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.
  (b) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use.
  (c) Prescription and other patient health-care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the Board.
(8) Equipment/Supplies
  (a) The Pharmacy shall carry and use the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.
(9) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the delivery of Pharmaceutical Care other than as authorized by law or rules of the Board. (MSPPA)

Duties of the pharmacist and pharmacy personnel are also delineated:

Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.
(2) The Pharmacist-in-Charge has the following responsibilities:
  (a) Developing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion.
  (b) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he is in charge. He shall supervise a training program conducted pursuant to the Pharmacy Technician Training Manual for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall be responsible for maintaining a record of all technicians successfully completing the Pharmacy's Technician training program and shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.
  (c) Establishing policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices.
  (d) Establishing policies and procedures for the provision of pharmacy services.
  (e) Assuring that the Automated Pharmacy System is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.
  (f) Implementing an ongoing quality assurance program that monitors performance of the Automated Pharmacy System, which is evidenced by written policies and procedures developed by the pharmacy.
  (g) Assuring that all Pharmacists and Interns employed at the Pharmacy are currently licensed and that all Pharmacy Technicians employed at the Pharmacy are currently registered with the Board of Pharmacy.
  (h) Notifying the Board of Pharmacy immediately of any of the following changes:
    (i) Change of employment or responsibility as the Pharmacist-in-Charge;
    (ii) Change of ownership of the Pharmacy;
    (iii) Change of address of the Pharmacy; or
    (iv) Permanent closing of the Pharmacy.
  (i) Making or filing any reports required by State or Federal laws and rules.
  (j) Responding to the Board of Pharmacy regarding any minor violations brought to his/her attention.
  (k) Establishing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health-care information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with the established policies and procedures.
  (l) Assuring that the means provided for as stipulated in Section 1.A.(9) have been established and implemented.
  (m) Providing the Board with prior written notice of the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:
    (i) The name and address of the pharmacy;
    (ii) The location of the automated equipment; and
    (iii) The identification of the responsible pharmacist.
(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists and Pharmacy Technicians as may be required to competently and safely provide pharmacy services.
  (a) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Pharmacy Technicians assisting in the provision of pharmacy services.
  (b) The Pharmacist-in-Charge shall develop and implement written policies and procedures to specify the duties to be performed by Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that Pharmacy Technicians are to be personally and directly supervised by a Pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of Pharmacy Technicians, and that Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist.
(4) The Pharmacist-in-Charge shall develop and implement a procedure for proper management of Drug recalls that may include, where appropriate, contacting patients to whom the recalled Drug product(s) have been Dispensed. (MSPPA)

Processing of prescription orders are described in detail:

A. *Prescription Drug Order.* A Prescription Drug Order shall contain the following information at a minimum:
  (1) Full name and street address of the patient;
  (2) Name, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;

(3) Date of issuance;
(4) Name, strength, dosage form, and quantity of Drug prescribed;
(5) Directions for use;
(6) Refills authorized, if any; and
(7) If a written Prescription Drug Order, prescribing Practitioner's signature.

B. *Manner of Issuance of a Prescription Drug Order.* A Prescription Drug Order, to be effective, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.
(1) A Prescription Drug Order must be communicated directly to a Pharmacist in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or by way of Electronic Transmission.
(2) If communicated orally or by way of Electronic Transmission, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist that may be maintained for the time required by laws or rules. . . .

C. *Transfer of a Prescription Drug Order.* Pharmacies using automated data processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted in subsection (4) below. The transfer of original Prescription Drug Order information for the purpose of refill dispensing is permissible between Pharmacies subject to the following requirements:
(1) The information is communicated directly between two Pharmacists and the transferring Pharmacist records the following information:
(a) Write the word *VOID* on the face of the invalidated Prescription Drug Order;
(b) Record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist receiving the Prescription Drug Order;
(c) Record the date of the transfer and the name of the Pharmacist transferring the information; and
(d) The computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.
(2) The Pharmacist receiving the transferred Prescription Drug Order information shall reduce to writing the following:
(a) Write the word *TRANSFER* on the face of the transferred Prescription Drug Order;
(b) Provide all information required to be on a Prescription Drug Order pursuant to State and Federal laws and rules, and include:
(i) Date of issuance of original Prescription Drug Order;
(ii) Original number of refills authorized on original Prescription Drug Order;
(iii) Date of original Dispensing;
(iv) Number of valid refills remaining and date of last refill;
(v) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
(vi) Name of transferring Pharmacist.
(c) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmaceutical Care.
(3) Both the original and transferred Prescription Drug Order shall be maintained for a period of 5 yr from the date of last refill.
(4) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed, and, further, that a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order or to which the Prescription Drug Order is transferred.

D. *Drug Product Selection by the Pharmacist.*
(1) A Pharmacist Dispensing a Prescription Drug Order for a Drug product prescribed by its brand name may select any Equivalent Drug Product provided that the Manufacturer or distributor holds, if applicable, either an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA), unless other approval by law or from the FDA is required.
(2) The Pharmacist shall not select an Equivalent Drug Product if the Practitioner instructs otherwise, either orally or in writing, on the Prescription Drug Order.
(3) The Pharmacist shall notify the patient or patient's agent if a Drug other than the brand name Drug prescribed is Dispensed.
(4) Whenever Drug Product Selection is performed by a Pharmacist, the Pharmacist shall Dispense the Equivalent Drug Product in a container Labeled in accordance with Section 3.E (Labeling).

E. *Labeling.*
(1) All Drugs Dispensed for use by inpatients of a hospital or other health-care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:
(a) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:
(i) The nonproprietary or proprietary name of the Drug;
(ii) The route of Administration, if other than oral;
(iii) The strength and volume, where appropriate, expressed in the metric system whenever possible;
(iv) The control number and expiration date;
(v) Identification of the re-packager by name or by license number shall be clearly distinguishable from the rest of the label; and
(vi) Special storage conditions, if required.
(b) When a multiple-dose Drug distribution system is used, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:
(i) Identification of the Dispensing Pharmacy;
(ii) The patient's name;
(iii) The date of Dispensing;
(iv) The nonproprietary and/or proprietary name of the Drug Dispensed; and
(v) The strength, expressed in the metric system whenever possible.
(2) All Drugs Dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such Drug is dispensed including:
(a) The name and address of the Pharmacy Dispensing the Drug;
(b) The name of the patient for whom the Drug is prescribed; or, if the patient is an animal, the name of the owner and the species of the animal;
(c) The name of the prescribing Practitioner;
(d) Such directions as may be stated on the Prescription Drug Order;
(e) The date of Dispensing;
(f) Any cautions that may be required by Federal or State law;
(g) The serial number of the Prescription Drug Order;
(h) The name or initials of the Dispensing Pharmacist;
(i) The proprietary or generic name of the Drug Dispensed and its strength, if more than one strength of the Drug is marketed;
(i) When Dispensing an Equivalent Drug Product, the word *INTERCHANGE* or letters *IC* must appear on the label affixed to the container in which such Drug is Dispensed, followed by the generic name and Manufacturer, or reasonable abbreviation, and/or distributor of the chosen product.
(ii) The requirements of (i) only apply to single-entity, multiple-source Drugs.
(iii) When Dispensing a single-entity, single-source Drug, the trade name of the prescribed Drug may also appear on the label, and the generic name of the prescribed Drug may also appear on the label.
(iv) When Dispensing a fixed combination product, the USP's publication of Pharmacy Equivalent Names

(PEN) for fixed combination products is the official list of abbreviations for such Labeling, and will be the approved abbreviation for identifying the combination product Dispensed. If no PEN has been officially issued by the USP, the Practitioner or Pharmacist will label the medication secundum artem.

(v) Subsection (i) - (iv) apply in all cases of Dispensing by Practitioners or Pharmacists.

(j) The name of the Manufacturer or distributor of the Drug;

(k) The Beyond-Use Date. . . .

F. *Patient Records.*

(1) A patient record system shall be maintained by all Pharmacies for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(a) Full name of the patient for whom the Drug is intended;

(b) Street address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all Prescription Drug Orders obtained by the patient at the Pharmacy maintaining the patient record during the (number) years immediately preceding the most recent entry showing the name of the Drug, prescription number, name and strength of the Drug, the quantity and date received, and the name of the Practitioner; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or Drug.

(2) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient that may relate to Prospective Drug Review.

(3) A patient record shall be maintained for a period of not less than 5 years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Confidential Information or personally identifiable information may be released to the patient or the patient's authorized representative, the prescriber or other licensed Practitioner then caring for the patient, another licensed Pharmacist, the Board or its representative, or any other person duly authorized by law to receive such information. Confidential Information or personally identifiable information in the patient medication record may be released to others only on written release of the patient.

G. *Prospective Drug Review.* A Pharmacist shall review the patient record and each Prescription Drug Order presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease contraindications;

(4) Drug-Drug interactions;

(5) Incorrect Drug dosage or duration of Drug treatment;

(6) Drug-allergy interactions;

(7) Clinical abuse/misuse.

Upon recognizing any of the above, the Pharmacist must take appropriate steps to avoid or resolve the problem and if necessary, include consultation with the Prescriber.

H. *Patient Counseling.*

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters that will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

(a) The name and description of the Drug;

(b) The dosage form, dose, route of Administration, and duration of Drug therapy;

(c) Intended use of the Drug and expected action;

(d) Special directions and precautions for preparation, Administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring Drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(2) A Pharmacist providing Telepharmacy services across state lines shall:

(a) Identify himself or herself to patients as a *licensed pharmacist*;

(b) Notify patients of the jurisdiction in which he or she is currently licensed to Practice Pharmacy and registered to Practice Telepharmacy Across State Lines; and

(c) Provide patients with that jurisdiction's board of pharmacy address and/or phone number.

(4) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health-care professionals are authorized to Administer the Drug(s).

(5) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

The Model Rules for Pharmaceutical Care also address unprofessional conduct.

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(1) The publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy.

(2) Unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists.

(3) Attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders.

(4) Divulging or revealing to unauthorized Persons patient or Practitioner information or the nature of professional Pharmacy services rendered without the patient's express consent, or without order or direction of a court. The following are considered authorized Persons:

(a) Patient or patient's agent, or another Pharmacist acting on behalf of a patient;

(b) Practitioner who issued the Prescription Drug Order;

(c) Certified/licensed health-care personnel who are responsible for the care of the patient;

(d) A member, inspector, agent, or investigator of the Board of Pharmacy or any Federal, State, county, or municipal officer whose duty is to enforce the laws of this State or the US relating to Drugs and/or Devices and who is engaged in a specific investigation involving a designated Person or Drug; and

(e) An agency of government charged with the responsibility of providing medical care for the patient, upon a written request by an authorized representative of the agency requesting such information.

(5) Selling, giving away, or otherwise disposing of accessories, chemicals, or Drugs or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities.

(6) Engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct that substantially departs from the standards of care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established.

(7) Selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug.
(8) Willfully and knowingly failing to maintain complete and accurate records of all Drugs received, Dispensed, or disposed of in compliance with the Federal laws and regulations and State laws and rules.
(9) Obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's Pharmaceutical Care, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

All states that intend to remain in compliance with Federal Medicaid requirements need to adopt some form of patient counseling. The Omnibus Budget Reconciliation Act (OBRA) of 1990 provides that pharmacists must offer to counsel, in person or by telephone, all Medicaid recipients who receive prescription drugs. The model rules provide a framework for the states to adopt so that the concepts of pharmaceutical care might be extended to all patients, not just those on Medicaid.

Computer Regulations

Computerization has become an important component of the profession as more and more pharmacies keep a wide variety of records on computers. Model rules have been developed by the NABP for states who wish to use them to facilitate the inspection of pharmacies employing computers. These computer systems must have adequate security and systems safeguards to maintain the confidentiality of patients and to prevent unauthorized access or manipulation of patient-profile data.

The computer system must provide for on-line retrieval of original information for those prescription orders that are currently authorized for refilling. The MSPPA states:

The computerized system shall have the capability of producing a printout of any prescription-drug order information. The systems should provide a refill-by-refill audit trail for any specified strength and dosage form of any drug. Such an audit trail must be by printout, and include name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, date of dispensing of each refill, name or identification code of the dispensing pharmacist and unique identifier of the prescription.

The model rules also provide for special backup procedures when the automated system becomes temporarily inoperative. This auxiliary system must insure that all refills are authorized and that the maximum number of refills is not exceeded, and it must! be maintained until the automated system becomes operational. The proposed model rules provide that nothing shall preclude the pharmacist from using professional judgment for the benefit of the patient's health and safety when the computerized system is not working. When the computer returns to operation, all information regarding prescriptions filled and refilled during the inoperative period must be entered into the computer within 96 hours.

Pharmacy Ownership

Few states have ownership restrictions on pharmacies. Some states have attempted to legislate against physician-owned pharmacies or any other type of non-pharmacist owned pharmacies. The US Supreme Court in 1928 held that laws restricting pharmacy ownership only to pharmacists violated the Fourteenth Amendment of the US Constitution. Forty-four years later, the same issue again was raised in the North Dakota courts. The North Dakota Pharmacy Act required that the majority of stock of a pharmacy corporation be owned by registered pharmacists in good standing in North Dakota. The statute was challenged by an out-of-state chain operation, and the case eventually was appealed to the US Supreme Court. The nation's highest court reversed its earlier decision and held that pharmacy-ownership laws were constitutionally sound if such a requirement could be related reasonably to the public's health and welfare. The case was returned to the North Dakota Supreme Court and that court identified seven possible reasons for ownership restrictions:

1. The professional and ethical standards of pharmacy demand the pharmacist's concern for the quantity and quality of stock and equipment. A drug that has deteriorated because of improper storage can be a detriment to public health. A drug not in stock poses a threat to the individual who needs it now. Decisions made in conjunction with the quantity and quality of stock and equipment by non-registered pharmacist-owners could be detrimental to the public health and welfare.
2. Supervision of hired pharmacists by registered-pharmacist-owners would be in the best interests of public health and safety.
3. Responsibility for improper action could be pinpointed more readily when supervision is in registered pharmacist-owners.
4. The dignity of a profession, and the morale and proficiency of those licensed to engage therein, is enhanced by prohibiting the practitioner from subordinating himself to the direction of untrained supervisors.
5. If control and management is vested in laymen unacquainted with pharmaceutical service, who are untrained and unlicensed, the risk is that social accountability will be subordinated to the profit motive.
6. The term pharmacy was intended to identify a particular type of establishment within which a health profession is practiced, and thus was intended to be more than a mere means of making a profit. He who holds the purse strings controls the policy.
7. Doctor-owned pharmacies with built-in conflict-of-interest problems could be restricted.

Although this case cleared the way for state legislatures to develop restrictions on the ownership of pharmacies, there has not been a great deal of momentum in this area. Consumer groups and large national pharmacy corporations have lobbied successfully against such proposals.

Hypodermic Needles and Syringes

Some states restrict the sale of hypodermic needles and syringes to a pharmacist on an over-the-counter (OTC) basis. The pharmacist of course must use good professional discretion to ensure that the devices are not to be used illegally. Other states will require that these devices be sold only upon a physicians order. Other states restrict the sale of these devises to prescription only status but make exception to permit their sale without a prescription order when they are to be used by diabetics, for the administration of adrenaline or for veterinary use. In these latter cases a registry is often required as evidence of the OTC sale.

Compounding

As mentioned in the *Relationship Between State and Federal Laws* section in the introductory remarks to this chapter, the issue of states rights versus federal rights on the issue of which government controls the practice of pharmacy compounding has been controversial since the early 1990s. Before that period of time, compounding was considered to be part of the practice of pharmacy and therefore regulated exclusively bt the states. Policy makers at the FDA began rethinking the issue when some of the large, brand name drug manufacturers that belong to the Pharmaceutical Research and Manufacturers of America (PhRMA) group decided that community pharmacists should not be permitted to compound drugs that are available in commercial preparations. In public, the FDA claimed that many retail pharmacies were purchasing large quantities of bulk drug substances and combining those

substances into specific drug products before ever receiving any valid prescriptions. The FDA speculated that these pharmacies engaged in this large-scale compounding to circumvent the drug, adulteration, and misbranding provisions of the Food, Drug, and Cosmetic Act (FD&CA), discussed further below, that regulate the manufacture of drugs.

The mechanism chosen for this newly developed attempt to regulate pharmacy practice was to declare compounded preparations to be unapproved new drugs even when all of the ingredients in the compounded product had pre-approval from the FDA. There was no consideration given to the fact that first half century after enactment of the FDCA, the FDA left regulation of compounding to state governments. During those approximately 50 years, pharmacists regularly compounded products without applying to the FDA for an NDA (new drug approval). The FDA justified its authority by claiming unapproved compounds could be a dangerous threat to public health. It also reasoned that the availability of commercial products that had been through a rigorous NDA process could satisfy the needs of the vast majority of patients, and pharmacist compounding was no longer necessary.

To give field agents some standards for searching out pharmacists engaged in this illegal public endangerment, the FDA developed Compliance Policy Guide (CPG) 7132.16 in 1992. The guideline contained nine "factors" that agents were to take into account before deciding if a pharmacist was engaged in illegal manufacturing under the pretext of normal compounding. One of the factors was whether the pharmacy advertises compounding services or solicits prescriptions requiring compounding from physicians for commercially available products. It may only be a historical quirk, but 1992 was also the year that Congress passed the Prescription Drug User Fee Act (PDUFA). This law changed the FDA from being a exclusive taxpayer supported agency to one that is funded, at least in part, by the commercial manufacturers who are subject to its regulations. The FDA did not take into consideration that some patients might have unique needs that commercial preparations could not address. Several enforcement actions were taken against small pharmacies taking care of one patient at a time. The FDA also took enforcement actions against some of the larger operations that solicited prescriptions from across state lines and compounded large batches of medications in anticipation of receiving prescriptions.

Soon after the guideline went into effect, a group representing pharmacies that engaged in widespread compounding activities known as Professionals and Patients for Customized Care (P2C2) sought to prevent its enforcement. They claimed that the FDA violated federal rulemaking procedures because the Compliance Policy was really a new rule that affected substantive rights and therefore should have been subject to formal procedures and public comment under the federal Administrative Procedures Act. They claimed that this was a new attempt by the federal government to regulate the practice of pharmacy. In 1995, a federal court of appeals affirmed a lower court finding that the FDA was well within its authority to use the guidelines in the manner it choose. In doing so, the court noted that the FDA had some limitations imposed on it by Congress. The law has been that pharmacists who dispense drugs upon prescriptions of practitioners for their patients, and do not manufacture or compound drugs for sale other than in the regular course of their business of dispensing or selling drugs, are exempt from FDA registration requirements for manufacturing and the misbranding provisions of the FD&CA. The court also noted that although the FD&CA does not expressly exempt "pharmacies" or "compounded drugs" from the new drug, adulteration, or misbranding provisions, the FDA as a matter of policy had not historically brought enforcement actions against pharmacies engaged in traditional compounding. In the court's view the Compliance Policy does not change that law; it simply announces factors for deciding when pharmacies have overstepped the authority to compound.

Despite that governmental victory, the acrimony between compounding pharmacies and the FDA continued. At the time, Congress was engaged in hearings to reform other FDA practices. This effort culminated in the Food and Drug Administration Modernization Act of 1997 (FDAMA), which, among other things, added a new section to the FD&CA. This new part, §503a, attempted to accommodate the FDA's need to prevent unsafe products from being marketed and at the same time prevent the agency from overreaching into the normal practice of pharmacy. A majority of the factors contained in the Compliance Policy were incorporated into FDAMA. The statute stated, in essence, that pharmacist-compounded drugs are exempt from the FD&CA's standard drug-approval requirements as long as the pharmacies refrain from advertising or promoting particular compounded drugs.

Before the law was scheduled to take effect, another group of pharmacies specializing in compounding services sought an injunction to prevent its enforcement. They claimed that the advertising ban violates the Constitution's free speech guarantee in the First Amendment. Both the district court and the court of appeals found the statute unconstitutional.

Supreme Court Decision

The US Supreme Court agreed to hear the FDA's appeal. The high court rendered its decision in *Thompson v. Western States Medical Center*, 70 USLW 4275 on April 30, 2002. With a narrow majority of five justices agreeing over the vigorous opposition of the four justices in the minority, the Supreme Court agreed that the entire statute (§503a) is unconstitutional and must be stricken because it infringes on commercial speech rights. The decision rebuked the unsound position of the FDA that average pharmacists working in the community cannot be trusted to safely compound drug products. It also questioned the integrity of the FDA when it claimed the ban on the advertising of these products is necessary to prevent the public from demanding drugs they do not otherwise need and pressuring doctors who cannot resist prescribing them.

While there are a number of salient points in the majority opinion, one of the more striking is the court's focus on the fact that the attempted restrictions on pharmacy compounding only applies to products that are otherwise commercially available. The FDA attempted to justify this application by claiming the new drug approval process that manufacturers are subject to results in scientifically sound conclusions about the safety and efficacy of commercial products. The FDA also complained that the impressions of the individual doctors who think a patient might benefit from a compounded alternative to a commercial product cannot be relied upon because these physicians are incapable of compiling sufficient safety data. Ignoring the irony of the situation, the FDA claimed in the same breath that it did not want to end all compounding for individual patients by pharmacists because compounding is "sometimes critical to the care of patients with drug allergies, patients who cannot tolerate particular drug delivery systems, and patients requiring special drug dosages." Apparently those doctors who cannot be trusted to make adequate safety assessments if a product is commercially available can be trusted when a commercial product is not as desirable. What is so striking about the attempted distinction is that it is exactly when a physician thinks there is an alternative to the commercially available product that a compounded product is called for. A majority of the justices concluded that this argument puts the FDA into an untenable position. Preserving the integrity of the new drug approval process is an important governmental interest, but no more important than its interest in encouraging a system that permits patients access to the particular drugs needed to treat individual conditions.

The majority of the justices also rejected the FDA's argument that advertising, or the lack thereof, is somehow tied to

the quality of the product produced by compounding pharmacies. Justice O'Connor seemed especially perplexed by the FDA's position that it is perfectly fine for compounded drugs that have not undergone safety and efficacy testing to be sold by compounding pharmacies that do not advertise, but not all right if the products or services are advertised. The government justified its position by claiming that advertising is not necessary for traditional small scale compounding legally performed by pharmacists for individual patients where commercial products are not available. It claimed that pharmacies that do advertise are the ones engaged in the large-scale operations that look more like manufacturing than compounding. In other words, the FDA used advertising as proxy for the large-scale production of compounded drugs to meet marketplace needs as opposed to individual needs determined on a case-by-case basis. According to the FDA, the ban on advertising closes a loophole that would allow unlicensed manufacturing under the notion that the pharmacy was merely compounding. Justice O'Connor did not buy into the claim that without advertising it would not be possible to market a drug on a large scale to make safety and efficacy testing economically feasible. Nor did she accept the idea that conditioning an exemption from the FDA approval process on refraining from advertising is an acceptable way to permit compounding and yet also guarantee that compounding is not conducted on such a scale as to undermine the FDA approval process.

She went on to complain that the amount of beneficial speech prohibited by the FDAMA is forbidding enough to hold it unconstitutional. Her concern centered around the intimidation effect the ban would have on pharmacists wanting to advertise legitimate compounding services. She noted that forbidding the advertisement of compounded drugs altogether would prevent pharmacists with no interest in mass-producing medications, but who serve clienteles with special medical needs, from telling the doctors treating those clients about the alternative drugs available through compounding. She set forth an example involving a pharmacist serving a children's hospital, where many patients are unable to swallow pills, would be prevented from telling the children's doctors about a new development in compounding that allowed the drug to be administered another way. In her opinion, the ban would also prohibit a pharmacist from posting a notice informing customers that if their children refuse to take medications because of the taste, the pharmacist could change the flavor. The net result of the *Thompson* decision is to render §503a unconstitutional and unenforceable.

Despite that holding, within days of the *Thompson* decision by the Supreme Court, the FDA "re-issued" its 1992 Compliance Policy Guidance (Guidance) (CPG Ch. 4 § 460.200 (May, 2002) with minor alterations to give the FDA and pharmacists notice of what factors will be taken into account to determine whether the pharmacy is engaged in legal compounding as opposed to unlawful manufacturing of drugs under the guise of compounding. It is noteworthy that the Guidance was published as FDA policy without any advance public notice or comment period. The irony of that action is that it was the original 1992 Guidance on compounding issued by the FDA (CPG Ch. 4 § 7132.16 (March, 1992) renumbered to § 460.200) that underlies the Thompson decision. Taking these developments into account, it should be clear the pharmacies may advertise compounding services but still not "manufacture" large quantities of drugs under the guise of compounding.

Both the current 2002 and original 1992 versions of the Guidance are presented below in the hope that comparing the "current thinking" of the FDA with its thought process over a decade ago may be instructive in determining the agency's priorities. Although there are places that the two versions do not line up exactly, the 1992 version has been reordered with its original factor number to match the 2002 version as close as possible. In both versions, the preamble states that in deciding whether the FDA will initiate an enforcement action, it will consider whether the pharmacy engages in *any* of the following acts (emphasis added):

2002 COMPLIANCE POLICY GUIDE	1992 COMPLIANCE POLICY GUIDE (REORDERED)
1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.	6. Compounding inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons.	
3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND).	
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.	3. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-approved facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.	4. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.	5. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.	7. Offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.	2. Compounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of commercially available, FDA-approved drug products.

At approximately the same time that the federal Congress was considering the FDAMA amendment to the FDCA that added the compounding statute, the NAPB was adopting language for its MSPPA that could serve as the basis for states to adopt regulations that would compliment the federal provisions. In that spirit, the NAPB developed *Good Compounding Practices* guidelines to assist pharmacists who engage in the practice of compounding drugs. Given the legal developments surrounding the issue, it is difficult to predict how much applicability it will have in influencing FDA inspectors equipped with the 2002 FDA Guidance on compounding. A few of the relevant portions of the NABP's are reproduced here so that readers can view a slightly different approach than used by the FDA. The following definitions are excerpted from the NABP *Good Compounding Practices* section of the MSPPA:

Compounding—the preparation, mixing, assembling, packaging, or Labeling of a Drug or Device (i) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding also includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

Manufacturing—the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or Labeling or re-labeling of its container, and the promotion and marketing of such Drugs or Devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, Practitioners, or other Persons.

Component—any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

THE FEDERAL FOOD, DRUG AND COSMETIC ACT

Regulation of Pharmaceuticals

Congress has the authority to regulate drugs pursuant to its powers under the "commerce clause" (Article 1, Section 8) of the US Constitution, which grants Congress authority to regulate commerce among the states. This type of transaction is known as "interstate commerce." Transactions occurring within only one state are called "intrastate commerce." The federal government's control over interstate commerce extends to control over intrastate commerce in many instances. For example, the FD&CA regulates the distribution of drugs between states, but it also regulates the distribution of drugs within a state (eg, the selling and dispensing of drugs by a neighborhood pharmacist whose transactions are entirely intrastate). The federal intrastate regulation is constitutional because the courts have decided that intrastate transactions may have a significant effect on interstate commerce.

In the introductory remarks, it was mentioned that the basic focus of federal regulations affecting pharmacy practice are laws that deal with the safety and efficacy of drugs, their production, labeling and distribution. The history of federal regulation of pharmaceuticals makes the understanding of current laws significantly easier to understand.

Summary of Important Points About the FD&CA

The FD&CA is designed to protect the public health by requiring that:

Only safe, effective, and properly labeled drugs may be introduced into interstate commerce.

The food and cosmetic preparations subject to the Act be safe and properly labeled.

The manufacturing, processing, packaging, and holding of drugs comply with the Current Good Manufacturing Practices (CGMP) set by the FDA.

The FD&CA be enforced by the FDA.

OTC (nonprescription) drugs be labeled for safe use by consumers in self-medication.

Prescription drugs be dispensed to an individual only pursuant to a prescription or administered directly by the physician or other authorized prescriber.

Drug prescriptions be refilled only as authorized by a physician or other authorized prescriber.

Specific labeling be used for both prescription and nonprescription drugs.

Dispensing a drug for distribution in violation of the Act's labeling requirements is "misbranding" the drug.

Drugs containing filthy, putrid, and decomposed substances and drugs packed and held under unsanitary conditions be deemed "adulterated."

Seizures of misbranded or adulterated drugs can be made by the FDA.

Interpretations of the Act show that lack of knowledge or lack of criminal intent will not excuse a violation.

An employer or other responsible person may be prosecuted for violations of the Act committed by an employee.

FDA has broad inspection powers over factories, warehouses, and establishments where drugs, food, medical devices, and cosmetics are made or processed.

The FDA is authorized to perform limited inspection of pharmacies in certain circumstances.

Manufacturers or re-packagers of drugs must register with the FDA.

Historical Background of the Act

The first federal statute designed to protect US citizens from harmful drugs was the Import Drug Act of 1848 (9 Stat. 237), which prohibited the importation of adulterated drugs. It was passed because anti-malarial medication for US troops in Mexico was found to be grossly adulterated and lacking in potency.

The next federal legislation concerning adulterated articles was enacted on August 30, 1890, when Congress adopted a law to prevent importation of dangerously adulterated articles for food and drink. The law worked by permitting the President of the United States to issue a proclamation prohibiting importing of adulterated articles. In 1902, Congress passed a law (32 Stat. 632) prohibiting the introduction of falsely labeled dairy products into interstate commerce (21 U.S.C §16).

The primary forerunner of today's FD&CA was enacted on June 30, 1906, with the passing of the Wiley-Heyburn Act, or the Federal Pure Food and Drug Act of 1906, which took effect in 1907. The Act was prompted, in part, by public concern over unsanitary practices in the drug and food industries, resulting in lack of purity. The 1906 Act was a major advancement in prohibiting adulteration and misbranding of food and drugs in interstate commerce. Drug adulteration was defined in the 1906 Act to prohibit the marketing of drugs of substandard strength or purity (below United States Pharmacopoeia (USP) or National Formulary (NF) standards unless the drugs were labeled to show how their strength, quality, and purity differed from those of the formulary standard). This concept of adulteration is carried through to present law (see §501(b) of the Act). The 1906 Act, with several minor amendments, lasted until 1938 (shortly after what has become known as the sulfanilamide tragedy, described below) when Congress adopted new legislation.

The Sulfanilamide Tragedy

In 1937, the S.E. Massengill Company marketed Sulfanilamide Elixir, which contained 40 grains of sulfanilamide per fluid ounce in a solution with diethylene glycol. The diethylene glycol solvent was suggested by the firm's chief chemist in response to its marketing department's demand for a liquid preparation of sulfanilamide, a "sulfa" drug used to treat

hemolytic streptococcal infections. Toxicity tests of the product were not conducted and very little was known about the inherent toxicity of diethylene glycol (a deadly poison now used as a type of permanent automotive antifreeze). More than 100 individuals reportedly died from ingesting Sulfanilamide Elixir before the FDA removed it from the market under a technical labeling violation under the 1906 Act. This incident propelled the passage of the 1938 FD&CA.

The FD&CA (21 U.S.C. §301 et seq.) is divided into 9 chapters, many of which are not discussed here because they deal exclusively with food and cosmetics. Only specific provisions of the Act concerning pharmacists and pharmacy practice are provided here. Further, only a few select portions of the Act are reproduced. For those interested, the entire Act may be found online at http://www.gpo.gov.

The 1938 Federal FC&C Act remains as the basis of today's law. It requires anyone who wishes to market a drug product to prove its safety to the FDA before it could be marketed. This was the beginning of the "pre-market approval process" for drugs in the United States—requiring the submission of a New Drug Application (NDA). Any compound that falls within the definition of a "new drug" under the act requires an NDA to be submitted to the FDA. The Act, as it was originally passed, did not require a manufacturer to prove the efficacy of the drug product. That requirement came about in a later amendment to the Act.

Definition of Drug

The definition of a "drug" as set forth in Section 201 (g)(1) of the FD&CA (21 U.S.C. §321(g)(1)) does not differentiate between prescription and nonprescription drugs, nor does it distinguish legal or lawful drugs from illicit ones:

The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to Sections 403(r)(1)(B) and 403(r)(3) or Sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of Section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with Section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

Intended Use

Often, a key element in determining whether a particular item is a drug is the "intended use" of the manufacturer or distributor of the article. The classifications under the FD&CA are not mutually exclusive. For example, an item may meet the criteria to be classified as both a drug and a cosmetic under the legal framework of this statute.

The Grandfather Clause

The 1938 Act contains a loophole known as the "grandfather clause." This provision exempts certain drugs that were on the market the day prior to the effective date of the Act (in 1938) from having to meet the FDA's pre-approval marketing requirements. Although few of those drugs are still marketed, today, many of them have now obtained "approval" via an NDA or an Abbreviated New Drug Application (ANDA).

Before the 1938 FD&CA, there was very limited federal or state control over the retail sale of non-narcotic and non-poisonous drugs. The 1914 Harrison Narcotic Act regulated the distribution of narcotics, and there were various state laws restricting the retail sale of poisons. However, there was no federal comprehensive law that regulated the dispensing of controlled substances or other drugs. Community pharmacists were at liberty to dispense all manner of non-narcotic and nonpoisonous drugs without a prescription.

In the 1930s, sensational drug abuse cases contributed to the enactment of the FD&CA. The Act restricted certain drugs to be dispensed only by the pharmacist, and dispensed pursuant to a prescription only. The prescriptions were non-refillable. However, some pharmacists did not take the Act seriously, especially in light of their history of relatively free dispensing powers. Furthermore, it was believed that the Act's labeling requirements only applied to *interstate* drug distribution as opposed to *intrastate* distribution.

The 1948 US Supreme Court case of *United States v. Sullivan*, 332 U.S. 689 (1948), helped to clarify the real effect of the Act. That case involved a community pharmacist who sold sulfathiazole tablets over-the-counter, labeled with only the drug name and dispensed in the pharmacist's own container. The Court held that his action, which in effect constituted dispensing a drug without a prescription, violated a misbranding (§301(k)) of the FD&CA. More importantly, the Act was applied judicially to an intrastate transaction, which extended the powers of the Federal Act over intrastate as well as interstate commerce.

The Durham-Humphrey Amendment Provision

After the *Sullivan* case, pharmaceutical organizations worked for an amendment to the Act to clarify the dispensing obligations of pharmacists. The new provision, enacted in 1951, as the Durham-Humphrey Amendment was named for Carl Durham, a pharmacist representing North Carolina in the US House of Representatives, and Hubert Humphrey, a pharmacist representing Minnesota in the US Senate. The Durham-Humphrey Amendment (FD&CA §503(b)(1); 21 U.S.C. §353(b)(1)) took effect in 1952. The amendment distinguished drugs requiring a prescription from Over the Counter (OTC) drugs. The amendment accomplished this goal by defining the kinds of drugs that cannot be used safely without medical supervision. The amendment restricted the sale of such drugs by requiring a prescription from a practitioner licensed by state law to prescribe drugs and dispensing pursuant to only a prescription. In addition to requiring a prescription for specific drugs, the Durham Humphrey Amendment also provided statutory provisions for the receipt of oral prescriptions as well as provisions allowing for the refilling of prescriptions. Refilling the prescription is allowed only if it specifically is authorized in the prescription or if authorization is obtained subsequently from the prescribing practitioner or from another licensed practitioner. If the original prescription does not contain an indication of refills, it is by law deemed to be a "no refill."

The terms "physician," "prescriber," and "practitioner," when used in this discussion, refer to the individual who is permitted by the jurisdiction or state in which he or she practices to prescribe or administer drugs in the course of professional practice. The determination of who may prescribe/administer is made by the state, not by the federal government.

The Thalidomide Tragedy

In late 1961, the "thalidomide disaster" began to unfold. Thalidomide was marketed in 1958 and was sold without prescription as a tranquilizer in the West German Federal Republic until April 1961, when the drug was recognized as causing polyneuritis in adults. In November 1961, the drug first was believed to cause the severe birth defect phocomelia, or "seal

limbs." By that time thousands of infants had been born in West Germany without one or both arms or legs or with only partially formed extremities. The manufacturer withdrew the drug from the West German market on November 26, 1961.

A number of drug firms had obtained licenses to market thalidomide worldwide. In the United States, the William S. Merrell Company had distributed the drug experimentally in 1960 under the trade name Kevadon, but the FDA never gave final approval to the NDA the company had submitted.

The FDA's timely action in withholding Kevadon approval was because an FDA medical officer refused approval while seeking data on further proof of safety. Even so, 29,413 patients in the United States had been involved in the human clinical trial testing of Kevadon. When the evidence that thalidomide was teratogenic (causing harm to the human fetus) was established, the FDA agents seized almost all of the Kevadon on the market. Consequently, only a very small number of phocomelia cases were reported in the United States. Thalidomide had been widely tested around the world as a sedative and tranquilizer. It was later found to act as an anti-nauseant in pregnancy, and its widespread use for that indication brought the horrible side effect to the surface. The lesson of the thalidomide tragedy is that serious side effects caused by certain new drugs, or caused by new uses for old drugs, may not be discovered until the drug has had very wide clinical use—after some damage already has occurred.

Kefauver-Harris Amendment

The thalidomide tragedy was the impetus for the Kefauver-Harris Amendment, otherwise known as the 1962 Drug Amendments, to the FD&CA. In the late 1950s and early 1960s, Senator Estes Kefauver of Tennessee led Congressional hearings concerning antitrust legislation and drug pricing. The Kefauver-Harris Amendment, which became effective in 1963, required substantiation to the FDA of both the *safety and efficacy* of all drugs introduced after 1962 and of drugs for which NDAs had been approved between 1938 and 1962. Any compound falling under the revised definition of a "new drug" as defined in §201(p) of the Act required this substantiation. The amendments required a positive act of approval by the FDA (as opposed to automatic approval if not disapproved by the FDA under the previous version of the Act). The amendments also contained a typical grandfather clause exempting from both safety and efficacy requirements the drugs on the market from 1906 to the day prior to the effective date of the 1938 Act, as those drugs were never subject to NDAs.

Drug Approval Process

NEW DRUGS—New drugs simply refer to those that have not yet received general recognition by medical experts as being both safe and effective for the intended use. A new drug may not be commercially marketed in the United States unless it has been approved as safe and effective. Such approval is based upon an NDA, which must contain acceptable scientific data, including the results of tests, to evaluate its safety. There must be substantial evidence of effectiveness for the conditions for which the drug is to be sold. Often, the question of whether a drug is recognized as "safe and effective" is a question of fact that must be decided in a legal action.

Newly discovered chemicals are not the only subjects of NDAs. A drug may be legally regarded as a "new drug" if it is an old, established drug (pre-1938 FD&C) which is offered in a new dosage form, with new medical claims, in new dosage levels, or if the drug is to be used on a different patient population. An NDA may also be required if a new combination of old drugs is used.

SYNOPSIS OF NEW DRUG APPLICATION PROCEDURES—Before a new drug can be marketed, federal law requires the submission and approval of form FDA-356h. Before the NDA is filed, an Investigational New Drug (IND) form (form FDA-1571) for the drug must be filed. The specific FDA regulations regarding INDs and NDAs are contained in 21 CFR §§312 and 314. The FDA also has provided for the electronic submission of NDAs. A Guidance Document entitled Guidance for Industry Providing Regulatory Submissions in Electronic Format-NDAs may be found on the Internet at: http://www.fda.gov/cder/guidance/index.htm. In addition, copies of forms required for such submissions may also be found on the Internet at http://aosweb.psc.dhhs.gov/forms/fdaforms.htm. If the FDA does not reject the IND request within 30 days of submission, clinical testing of the investigational drug on humans may begin by the IND sponsor. The IND application must include proof of preclinical testing of the new drug on animals to substantiate the safety of clinical testing in humans.

The sponsor of the IND can be a drug manufacturer, hospital, pharmacy, physician, pharmacist, or anyone who submits the application. However, the individuals (investigators) who conduct the clinical trials must be trained and experienced, and a statement of their respective qualifications must be attached to the IND. The investigators submit to the IND sponsor a completed and signed "Statement of Investigator" Form FDA-1572.

Phase 1 of clinical investigation involves a small number of patients in carefully controlled studies of the drug toxicity, metabolism, absorption, and elimination, to determine the preferred route of administration and safe dosage.

Phase 2 involves use of the investigational drug on a limited number of patients for specific disease treatment or prevention, along with additional pharmacology studies on animals to further determine the drug's safety.

Phase 3 trials evaluate whether information obtained from phase 1 and 2 studies can reasonably ensure the safety and efficacy of the drug or if the drug has a potential value outweighing its possible hazards.

"Phase 4," as it is unofficially termed, involves post-marketing surveillance of approved drugs to detect adverse effects or other problems not encountered in the 3 prior phases of drug testing due to the limited number of patients using the medication (see 21 CFR §314.80).

Before a human being may be involved as a subject in research, the investigator must obtain legally effective "informed consent" of the patient or his or her representative (21 CFR Part 50).

In April 1996, the FDA released a Guidance Document entitled Guidance for Industry Good Clinical Practice: Consolidated Guidance that may be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm or from the Drug Information Branch CDER, 5600 Fishers Lane, Rockville, MD 20857, telephone 301-827-4573. This guidance discusses the informed consent process of "trial subjects" in depth.

If, during the clinical testing of a new drug, the data furnished to the FDA indicate that the drug is too toxic under the criteria of the FDA's risk/benefit ratio, the FDA will terminate the IND approval. In this instance, the FDA's action is not subject to court review or appeal and, as such, it is one of the rare examples in the law in which administrative action is not judicially reviewable. If all goes well with the clinical testing, the sponsor of the drug (usually the manufacturer or supplier at this point) submits a voluminous NDA (form FD-356H) to the FDA wherein the proposed labeling (package insert) is contained. If approved by the FDA, the package insert will accompany the marketed drug product in its package.

After the NDA is approved by the FDA, the drug is marketed, but the drug manufacturer's reporting does not end there. The 1962 amendment to the Act requires that the manufacturer submit periodic reports to the FDA, containing samples of current labeling and advertisements, summaries of medical journal articles on the drug, and information on adverse reactions.

EFFICACY AND THE DEFINITION OF A "NEW DRUG"—Disputes arose between pharmaceutical firms and the FDA as to how the 1962 Drug Amendments affected the

efficacy requirement for new drugs approved by the FDA between 1938 and 1962. The issue was determined somewhat in three separate United States Supreme Court cases all decided on the same day—June 18, 1973. In the first case, the Court ruled that the 1962 efficacy proof requirement (well-controlled and adequate clinical studies) retrospectively applied to all NDAs approved from 1938 to 1962. The Court also held that the FDA had the power to decide whether a drug is a new drug as defined in §201(p) of the FD&CA. Thus, the Court held that the FDA had the authority to withdraw the NDA of any drug on the market. In the second case, the court held that generic drugs are subject to the FDA's requirements for proof of safety and efficacy. In the third case, the Court concluded that the FDA has authority to determine what comprises a "new drug" under the Act.

GENERIC DRUG APPROVALS—In the late 1970s and early 1980s, a series of cases arose that challenged the FDA's authority to determine the "new drug" status of generic versions of brand name drugs. FDA policy at the time allowed the marketing of generic products as long as an Abbreviated New Drug Application (ANDA) had been filed. Although it had not been "officially" approved the "paper NDA," as it was called at the time, required only data on labeling and manufacturing, but not data relating to safety and efficacy. This policy was based on the theory that the active ingredients in such products had become generally recognized as safe and effective and therefore, the FDA need only require assurance of proper labeling and manufacturing. However, there was concern by some about bioavailability and bioequivalence of these generic drugs. In 1975, a district court judge ruled that the FDA could not permit drugs to be marketed unless an NDA or ANDA had been approved. Two Court of Appeals cases split on the issue of whether a generic version of an approved pioneer drug is considered a "new drug" under the Act and therefore subject to the NDA or ANDA approval process. Because of this split among the circuits, the issue ended up in the United States Supreme Court. The landmark Supreme Court case of *United States v. Generix Drug* (1983) resolved the issue. The Court held that the definition of "drug" under the Act included inactive as well as active ingredients, and, therefore, a generic version of a pioneer drug would require its own NDA or ANDA if it differed in any significant respect from the pioneer drug.

Drug Efficacy Study

As mentioned above, the 1962 Kefauver-Harris Amendment to the Act required proof of efficacy in addition to proof of safety before a drug product could be introduced into interstate commerce. The issue of how these provisions should be applied to drugs approved between 1938 and 1962 was controversial.

In 1966, the FDA commissioned the National Academy of Sciences/National Research Council to evaluate drug products introduced between 1938 and 1962. Some 16,000 claims for 4000 drug products were reviewed. Approximately 15% were reported to be ineffective (ie, lack of substantial evidence of effectiveness), 34.9% were reported to be possibly effective, 7.3% were reported to be probably effective, 19.1% were reported to be effective, and 24% were reported to be "effective but….". The FDA initiated an action to remove from the market those drug products that lacked proof of efficacy. This process was known as the Drug Efficacy Study Implementation (DESI) project. The process of removing ineffective drugs from the market took several years. The DESI project in now concluded.

Current Good Manufacturing Practices (CGMP)

The FDA's CGMP regulations apply to a pharmacy only if it is engaged in repackaging and re-labeling drugs beyond the usual conduct of dispensing and selling them at retail. Such activities, outside the usual scope of pharmacy practice, would subject the pharmacy to FDA registration (FDCA §510) and to FDA inspection at regular intervals.

The FDA, in its introductory comments to the CGMP regulations, gave 3 situations in pharmacy practice that require the pharmacy to comply with FDA registration, inspections, and CGMPs:

> If the pharmacy in hospital repackages drug products for its own use as well as for that in other hospitals;
> if a pharmacy chain repackages and re-labels quantities of drug products from the manufacturer's original commercial containers for shipment to an individual chain location; and
> if similar repackaging and re-labeling are conducted by individual pharmacists as members of an informal buying group (43 Fed. Reg. 45028).

If a hospital pharmacy confines repackaging of drug products to those used solely within the hospital, the hospital would not be subject to the FDA registration, regular inspections or the CGMP compliance requirements. Similarly, the usual type of repackaging and re-labeling of drug products done for on-premises dispensing or retail sale would not subject a pharmacy to FDA registration, regular inspections, and CGMP compliance requirements.

The FDA has also stated that CGMP requirements apply to shared service operations servicing HMOs and hospital groups. FDA Guideline 7356.002B states:

For the purposes of differentiating whether an establishment is acting as a pharmacy or as a re-packager/re-labeler, the repackaging of drug products by licensed pharmacists, (ie, filling prescriptions for identified patients), is within the regular practice of pharmacy. The repackaging of drug products by pharmacists, or any other entity, for resale or distribution to hospitals, other pharmacies, nursing homes, health care facilities, etc., are beyond the practice of pharmacy, and these repackaging/re-labeling facilities are thus required to register and list all such products with the FDA. Thus, hospitals packaging drugs provided to other hospitals, nursing homes, or other entities are subject to the FDA's CGMP requirements.

The FDA's authority for its position on manufacturing practices can be found in the FD&CA. §501(a)(2)(B) of the Act (21 U.S.C. §351(a)(2)(B) which provides that a drug will be deemed adulterated if the methods used in or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to CGMP regulations. This section of the law is applicable to wholesalers, retailers, pharmacies, and hospitals as well as to drug manufacturers. However, the FDA states the CGMP regulations only apply to organizations engaged in the preparation of a drug product and, therefore, do not apply to wholesalers, retailers, pharmacies, and hospitals engaged in activities that are traditional to them. Pharmacies are exempt from FDA manufacturer registration only if they do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of dispensing and selling drugs at retail (21 U.S.C. §510(g)(1). The exemption from regular FDA factory inspection is given to pharmacies by 21 U.S.C. §704(a)(2)(A); again, the pharmacy may engage only in the regular business of dispensing and selling drugs at retail. Consequently, repackaging and re-labeling of drugs for off-premises sale can be interpreted as out of the regular course of the pharmacy's business and, hence, nullify the exemptions in §§510(g) and 704(a) and the FDA exemption of the pharmacy from CGMP compliance.

The Drug Price Competition and Patent Term Restoration Act of 1984

The legislation known as the Hatch-Waxman Act (Pub. L. No. 98-417, and 98-427, 98 Stat 1585 (1984) (21 U.S.C. §355 (j), FD&CA §505 (j) was a congressional effort to strike a balance between the competing forces of generic firms and innovator (pioneer or brand name) drug firms. Title I of the Act extended

the ANDA process to generic versions of drugs first approved and marketed after 1962. It required the FDA to approve generic drugs shown to be "bioequivalent" to a previously approved drug. This eliminated the requirement for generic manufacturers to duplicate expensive clinical and animal research to demonstrate the safety and efficacy of the products. In essence, this act codified the "paper NDA" process that the FDA had been using for several prior years. Title II of the Act compensated pioneer companies for losses caused by competition from the generic companies by extending the patent terms of some pioneer drugs.

The Prescription Drug User Fee Act of 1992

The Prescription Drug User Fee Act of 1992 (PDUFA), (Pub. L. 102-571; 106 Stat. 4491) authorized the FDA to charge fees to cover the costs incurred for review of human drug applications and supplements, inspection of prescription drug establishments, and other activities. The intent of this legislation was to make additional funds available to the FDA to expedite the review of human drug applications. The PDUFA authorized three different types of user fees: drug application fees, annual establishment fees, and annual product fees. Fees are assessed at different rates depending on whether an application requires a review of clinical data on safety and efficacy as opposed to review of only bioavailability or bioequivalence studies. All or part of the fees may be waived at the FDA's discretion. While this Act has been vital to the economic survival of the FDA and has been renewed several times, it has not been without controversy. Consumer advocate groups have noted that the Act turned the FDA into a manufacturer-funded group as opposed to a taxpayer supported agency. This has led to complaints that the FDA is now more oriented to manufacturer's interests instead of an agency designed to protect the public health and safety.

The Food and Drug Administration Modernization Act of 1997 (FDAMA)

The first major overhaul of the Food, Drug, and Cosmetic Act in over 30 years occurred with the passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. No. 105-115, 111 Stat. 2296). FDAMA made major changes in the regulation of foods, drugs, and devices. Documents related to FDAMA implementation can be found on the Internet as part of FDA's Web site, http://www.fda.gov or http://www.fda.gov/cder/fdama. Some of the major changes of FDAMA that impact pharmacy include:

PEDIATRIC STUDIES OF DRUGS—§111 of FDAMA (§505A FD&CA) authorized the FDA to determine that a particular drug may produce health benefits in a pediatric population. The first step in this process required that the FDA, after consultation with experts in pediatric research, develop, prioritize, and publish a list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. If such a determination was made, the FDA could then request pediatric studies of the drug from the manufacturer. Once the manufacturer completed these studies and they were accepted by the FDA, the FDA had the ability to grant an additional 6 months of marketing exclusivity for the drug. The additional 6 months of marketing exclusivity did not apply to drugs for which an NDA was submitted after January 1, 2002.

The FDA began to implement these provisions on May 20, 1998 ((63 Fed. Reg. 27733) when it announced the availability of a "List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population." On June 1998, the FDA made available a "Guidance for Industry Qualifying for Pediatric Exclusivity" However, at the time that this publication was going to press, the federal government ordered a halt to the Pediatric testing program. Readers are urged to consult the web sites listed above to determine the current status to this program.

PHARMACY COMPOUNDING—As detailed in the **Compounding** subsection above, FDAMA also contained §127 (21 U.S.C. §503a) that attempted to clarify that compounding of pharmaceutical products was appropriately regulated by the states and exempted pharmacies from requirements for compliance with NDAs and current good manufacturing requirements when compounding drugs for an identified individual patient. As noted, the United States Supreme Court held that provision unconstitutional because there is no rational relationship between the ban on advertising compounding services as a condition for exemption from the NDA mandates.

ELIMINATION OF CERTAIN LABELING REQUIREMENTS—Section 126 of FDAMA changed the requirement for the "prescription legend" that commercial containers had to bear on the label for prescription drugs packaging. A drug is now required to bear, at a minimum, the symbol "Rx only." In addition, this provision repealed Section 502(d) of the FDC Act, which required the labels of certain habit-forming drugs to bear the statement, "Warning—May Be Habit Forming."

DISSEMINATION OF OFF-LABEL TREATMENT INFORMATION—Section 551 of FDAMA provides incentives for manufacturers to conduct research on new uses of drugs and to file supplemental NDAs (SNDAs) for these uses by allowing manufacturers to disseminate limited information on unapproved uses of drugs. It required that information on an unapproved use must be in the form of a peer-reviewed article, and the information must include a statement disclosing, among other things, that the information concerns a use that has not been approved or cleared by the FDA. In addition, it required that notice was to be provided to the FDA 60 days before any information was disseminated under these provisions. A manufacturer could not disseminate information under this section unless the it had submitted a supplemental NDA for the new use or certified that studies to support the new use had been done or were going to be done, and an application submitted. The application was to be filed no later than 6 months after the date of the initial dissemination of the information if the studies had already been completed and no later than 36 months if studies had yet to be completed. These provisions have been found to be unconstitutional by the courts under the First Amendment right to commercial speech.

Liability Under The FD&CA

The FD&CA imposes a form of strict liability (liability without fault) on all who are affected by its provisions. (The specific prohibited acts involving misbranding and adulteration of drugs are discussed in the next section.) This concept is illustrated in the case of *United States v. Vitamin Industries*, 130 F.Supp. 755 (D Neb 1955), which indicated that criminal intention is not essential for one to violate the Act. In other words, it is not a defense for the accused to claim lack of knowledge or lack of intent to violate the law. Although this may seem rather harsh, if lack of knowledge or specific intent were an acceptable defense, every violator would avail himself or herself of this claim and the Act would become unenforceable *United States v. Dotterweich*, 320 U.S. 277 (1943) and *United States v. Park*, 421 U.S. 658 (1975).

Doctrine of Respondeat Superior

Under the FD&CA, an employer can be convicted for a violation committed by an employee. The legal term for this doctrine is *Respondeat Superior*. There are several situations where this doctrine applies:

(1) The employer know or should know of the employee's illegal action;
(2) the employer participated in or willfully authorized or consented to the employee's illegal act; or
(3) the employer has a responsible share in the employee's illegal act.

Any one of these situations will impute liability to the employer; all three need not be present.

Strict liability of a proprietor under the FD&CA exists if it is proven in court the defendant is the sole proprietor of a business, and the offense committed was committed by an employee of that business during the course of business duties. Although the proprietor may not have violated the law personally, he or she may still be found guilty. Responsibility for the acts of the employee rests with the proprietor. Strict liability of the member of a partnership under the FD&CA exists if it can be proven in court the defendant is a member of a partnership and is responsible, in part, for the conduct of its activities. If it can be proven that an employee of the partnership, during the course of business duties, violated the law, the defendant will be found guilty, although he or she did not personally commit the offense.

Recordkeeping under the FD&CA

Recordkeeping for the pharmacist under the FD&CA is similar to the recordkeeping required under the Controlled Substances Act (CSA) (discussed in detail below) but is not so precisely defined or detailed. Probably the most important distinction between the recordkeeping under the CSA as opposed to that under the FD&CA is, for the pharmacist, the required documents for the CSA are more quantitative while those for the FD&C Act are more qualitative. The recordkeeping under the CSA is concerned with accountability for the receipt and disposition of drugs, whereas recordkeeping under the FD&CA is concerned with the ability to trace a specific drug product, usually in response to drug recall.

Nonetheless, the basic type of records is the same under the two Acts. For example, purchase invoices are considered records of drug receipt, prescriptions are records of drug disposition, and inventories furnish a record of drugs on hand. Sales or other disposals of drugs to physicians or pharmacists, returns to wholesalers or manufacturers, drug destruction, and thefts should be documented by some type of written or other reliable memorandum.

Drug records should be kept at least for the running of state or federal statute of limitations on crimes. In most cases, this is a period of 5 or 6 years from the date of the alleged felony offense. Although federal or state drug control laws often provide for a lesser period of time (usually 3 years) for retention of drug records, the reason for preserving the records for the length of the statute of limitations is that they furnish proof of the transactions involved in a lawsuit, some of which may provide a valid defense to a prosecution arising out of an alleged drug law violation.

Prescription Drug Labeling

LABELS ON COMMERCIAL CONTAINERS—FDA regulations require that the following information appear on the manufacturer's or distributor's container of prescription drugs (21 CFR §§201.1 to 201.55):

The name and address of the manufacturer, packager, or distributor;
ingredient information;
a statement of identity (ie, the generic and the proprietary names);
quantity in terms of weight or measure applicable to drug (eg, 0.5 g);
the net quantity of the package contents (eg, 100 tablets);
a statement of dosage or a reference to the package insert for dosage information;
the expiration date of the drug;
the lot number; and
the National Drug Code (NDC) number (requested, not required, by FDA regulations).

PACKAGE INSERTS/PROFESSIONAL PRODUCT LABELING—The package insert is the part of a prescription drug product's approved labeling directed to health care professionals. It is the primary mechanism by which the FDA and drug manufacturers communicate essential, science-based prescribing information to health care practitioners.

Historically, the contents and format of package insert labeling are imposed by FDA regulations (21 CFR §201.56). FDA regulations §§201.56 and 201.57, as they affect the prescription drug labeling described in FDA regulation 201.100 (d) (21 CFR §201.100 (d), were revised in June 1979. Under the regulations, the package insert labeling must contain a summary of essential scientific information that is needed for the safe and effective use of the drug. The labeling must be informative, accurate, and neither promotional in tone nor false or misleading. The labeling must be based, whenever possible, on data derived from human experiments. Implied claims and suggestions for drug use may not be made if there is inadequate evidence of safety or lack of substantial evidence of effectiveness. Conclusions that are based on animal data are permitted if they are necessary for safe and effective use of the drug in humans; however, they must be identified as animal data. There is no law or regulation that prohibits the pharmacist from giving a package insert to a patient.

21 CFR §201.56 requires that the package insert for a prescription drug product contain the following specific information under the following section headings and in the following order:

Description (proprietary and generic names);
Clinical pharmacology;
Indications and usage (the use of the drug in the treatment, prevention, or diagnosis of a recognized disease or condition);
Contraindications;
Warnings;
Precautions;
Adverse reactions;
Drug abuse and dependence;
Overdosage;
Dosage and administration; and
How supplied.

Other FDA Regulations

On December 22, 2000, the FDA proposed new regulations that would significantly change the "labeling" (ie, the package insert) of prescription drugs. The proposal may be found at 65 FR 81082 and at http://www.fda.gov/OHRMS/DOCKETS/98fr/122200a.pdf.

The FDA's intent in making this proposal is to "make it easier for health care practitioners to access, read, and use" the package insert information, and to "enhance the safe and effective use of prescription drug products." By making the information easier to find, read, and use, the FDA hopes to reduce medical errors caused by inadequate communication. The labeling change would require the addition (at the beginning of the insert) of a "Highlights of Prescribing Information" section. This section is intended to be a concise extract of the most important information that is contained in the Comprehensive Information" section that would follow. The Highlights section would contain the following categories:

boxed warnings;
recent substantive labeling changes;
indications and usage;
dosage and administration;
how supplied;
contraindications;
warnings/precautions, including a subsection for the most common adverse reactions;
drug interactions; and
use in specific populations.

In addition, "R_x" should be present to indicate the product is sold only by prescription. A triangular icon appears for drugs that have been approved for marketing within the past 3 years. In addition to proposing changes to the package insert, the rule also provides for some changes to the label of the prescription drug itself. The agency hopes that by reducing the amount of required information on product labels and simplifying them, the number of medications errors will be reduced.

Patient Package Inserts

HISTORICAL BACKGROUND OF PATIENT PACKAGE INSERTS—The first patient warning of a prescription drug was in 1968 when the FDA required that the following statement appear on the dispensing package of an isoproterenol inhalation drug product (21 CFR §201.306): "Warning: Do not exceed the dose prescribed by your physician. If difficulty in breathing persists, contact your physician immediately." Isoproterenol aerosols and nebulizer solutions (eg, Aerolone Solution, Isuprel HCl Solution, Medihaler-Iso) are prescription-only drugs. The package warnings were required because repeated use of isoproterenol inhalation preparations occasionally causes airway resistance or a refractory state (commonly known as "concrete of the nasal passages"). Cardiac arrest and death also were noted in several instances of excessive use of the drug therapy.

In 1970, the FDA issued a regulation (21 CFR §310.501) requiring that certain information about oral contraceptive drugs be included in each package of the prescription drug dispensed to the patient. Again, the patient labeling informed the patient of the possible adverse effects (eg, thrombophlebitis, pulmonary embolism, retinal artery thrombosis, MI, benign hepatic adenomas, induction of fetal abnormalities, gallbladder disease). In 1977, a regulation (21 CFR §310.515) was issued requiring that information regarding the newly discovered hazards of estrogen be provided for estrogenic drug products (eg, diethylstilbestrol, Premarin, Tace, and Estinyl tablets) and for combination preparations containing estrogens. Essentially, the PPI listed the risk of estrogens leading to endometrial carcinoma and risks encountered when estrogens are taken during pregnancy. Similar labeling requirements were promulgated for contraceptive intrauterine devices (IUDs), which were regulated as prescription drugs or medical devices, and for progestational drug products (see 21 CFR §310.516). (When diethylstilbestrol or progestational drug products are intended for contraceptive use, labeling requirements under 21 CFR §310.501 apply.)

It is required that the manufacturer of a drug requiring a PPI provide the pharmacist with a sufficient amount of PPIs to provide one to each patient to whom the drug is dispensed. Sample forms of PPIs are provided by the FDA, and the manufacturer is, additionally, obligated to provide a PPI in Spanish upon the request of the distributor or dispenser.

The FDA requires the pharmacist to provide the PPI to the patient upon dispensing of the drug that is subject to the PPI requirements. PPIs for products dispensed in acute care hospitals or long-term care facilities are considered to have been provided if given to the patient before the first administration of the drug and every 30 days thereafter. Outpatient prescriptions are subject to the same requirements as are applicable to those dispensed by the community pharmacist.

UNIT-DOSE LABELING—Unit-dose (or individual-dose) packaging of drug products is done routinely, especially in the institutional setting. Individually wrapped and labeled single doses of drug products in tablet or capsule form have resulted in an efficient institutional drug distribution system. The main advantages of the unit-dose system are: it reduces errors because each dose is labeled with the drug identity and strength, and it permits the return and recycling of unused doses provided the sealed package has not been opened. However, the unit-dose system is more expensive than multi-dose drug distribution systems.

The FDA, in Compliance Policy Guide 7132b.10, specifies its requirements for unit dose labeling for solid and liquid oral dosage forms of both prescription and nonprescription drugs. For prescription drugs, the label of the actual unit-dose container must contain:

The established name of the drug and the quantity of active ingredient per dosage unit;
The expiration date (21 CFR §§201.17, 211.137)
The lot or control number (see 21 CFR §§201.100(b), 211.130);
The name and place of business of the manufacturer, packer, or distributor as provided for in 21 CFR §201.1;
For official drugs, any statement required by the compendia; for unofficial drugs, any pertinent statement bearing on special characteristics of the dosage form.

The Compliance Policy Guide (CPG) does not require, but strongly recommends, that the label contain:

Any pertinent statement bearing on the need for special storage conditions;
Information to alert a health professional that a procedure(s) is necessary prior to patient administration;
If more than one dosage unit is contained, the number of dosage units per container and the strength per dosage unit.

Because most commonly prescribed drugs are available in commercially marketed unit-dose packaging, it is prudent the pharmacist use the commercial unit-dose drug product, rather than repackaging the drug.

LABELING OF CUSTOMIZED MEDICATION PACKAGES—In lieu of dispensing 2 or more drug products in separate containers, a pharmacist may, with the consent of the patient, his or her caregiver, or prescriber, provide a customized medication package (Patient Med Pak).

Regulation of Dietary Supplements

Traditionally, the FDA considered dietary supplements to be foods and regulated them accordingly. The focus of the agency was on ensuring safety and wholesomeness as well as ensuring the labeling was truthful and not misleading.

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994—In 1994 Congress enacted the Dietary Supplement Health and Education Act (DSHEA), amending several portions of the FD&CA pertaining to dietary supplements and ingredients of dietary supplements. The most important point for pharmacists to understand about dietary supplements is that they are not regulated as "drugs" by the FDA and are exempt from the safety and efficacy requirements for drugs as well as the Current Good Manufacturing Practices (CGMPs) applicable to drugs. The CGMP exemption may be coming to an abrupt halt for dietary supplements. On March 7, 2003 the FDA issued a 527 page proposed rule that would bring dietary supplements under most, but not all, of the CGMP regulations. The proposed regulations contained a 90 day comment period. As such, at the time that this publication was going to press, the future of the proposed regulation was not finalized. Readers who are interested in the final regulation are urged to consult to FDA's web site at http://www.fda.gov for updated information.

DSHEA defines "dietary supplements" and treats them as a special class that falls somewhere in between foods and drugs. The legislation prohibits Congress from regulating "dietary supplements" as food additives or as drugs. It places the burden on the FDA to prove a dietary supplement is unsafe before it can be removed from the market. The intent of Congress in passing this legislation was to protect "the right of access of consumers to safe dietary supplements" and to remove "unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." The passage of this legislation has had a significant impact on the marketing of dietary supplements in this country. Under DSHEA (§201(ff)), a "dietary supplement" is defined as:

A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

A vitamin;
A mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake;
A concentrate, metabolite, constituent, extract, or combination of any ingredient above;
A product intended for ingestion in tablet, capsule, powder, softgel, gel cap, or liquid form; or if not intended for ingestion in such a form, is

not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and
Labeled as a dietary supplement.

Probably the most significant result of DSHEA is that it allows dietary supplement manufacturers to make certain claims on their products' labels. These claims cannot constitute a "disease claim" (ie, the type of claim made for a drug that claims it is effective to treat a disease). However, certain "structure/function" claims are allowed under the law. This type of claim describes, for example, the role the nutrient or dietary supplement plays in affecting the normal structure or function of the human body (as opposed to affecting the structure or function of the human body in a disease state). When such a claim is made on the label, the following "disclaimer" must also appear: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." The manufacturer must have substantiation that such a statement is truthful and not misleading, and must notify the FDA within 30 days of the marketing of the dietary supplement with such a statement.

DSHEA also modified the law with regard to what constitutes "labeling" of a dietary supplement. Scientific publications and other types of information marketed along with dietary supplements are not defined as "labeling" as long as certain conditions are met.

Under DSHEA, a dietary supplement manufacturer may place a claim that the product affects the "structure/function" of the body on its product without pre-approval of the FDA. On January 6, 2000, the FDA issued final regulations regarding types of "structure/function" claims allowed to be made under DSHEA (65 FFR 1000). In general, claims that a product affects the normal structure or function of the human body are allowed. Any claim that explicitly or implicitly says the product can be used to "prevent, treat, cure, mitigate, or diagnose disease" are considered "disease claims" and would subject the product to the drug requirements under the Act. The rule clarifies that such prohibited express or implied claims are made through the name of a product, through a statement about the formulation of a product (contains aspirin) or through the use of pictures, vignettes, or symbols (EKG tracings). The rule allows for claims that do not relate to disease, including health maintenance claims ("maintains a healthy circulatory system"), other non-disease claims ("for muscle enhancement," "helps you relax"), and claims for common, minor symptoms often associated with life stages ("for common symptoms of PMS," "for hot flashes"). A detailed Continuing Education article on the subject may be accessed at: http://www.uspharmacist.com/ce/healthclaims/default.cfm.

Drug Recalls

There are essentially 3 classifications of FDA drug recall:

Class I exists where there is a reasonable possibility that the use of or exposure to a product will cause either serious adverse effects on health or death.
Class II exists where the use of or exposure to a product may cause temporary or medically reversible adverse effects on health or where the probability of serious adverse effects on health is remote.
Class III exists where the use of or exposure to a product is not likely to cause adverse health consequences.

Note that no statutory provision expressly authorizes the FDA to order a drug product recall. Manufacturers do know, however, that if the FDA requests or suggests a drug product recall, and the manufacturer does not comply, the product is subject to the ultimate FDA sanction: withdrawal of the product's NDA and seizure of all products on the market.

LABELING OF OTC AND DISPENSED DRUGS—The regulations for drug labeling are contained in§§502 and 503 of the FD&C (21 U.S.C. §§352 and 353). Labeling of controlled substances is discussed in detail in the Controlled Substances section. The emphasis in this section is on the basic labeling required for both prescription and OTC drugs.

The FDA regulations differentiate between the terms "label" and "labeling." Label means the printed, written, or graphic material that is literally affixed to the container of the drug (21 CFR §1.3(b)). Labeling means the printed, written, or graphic material that is enclosed with or accompanies the drug once it enters interstate commerce and is put up for sale after shipment (21 CFR §1.3(a)).

Much of the authority of the FD&C over the manufacture and distribution of food, drugs, medical devices, and cosmetics is through the labeling requirements of the FDA regulations implementing the statute.

The FDA promulgates regulations dealing with specific labeling requirements authorized by the FD&CA. In addition, the FDA issues labeling requirements pursuant to the authority of the Fair Packaging and Labeling Act (15 U.S.C. §1047 et seq.), which concern truthfulness in labeling as applicable to consumer packaging (eg, defining "economy size," "king size," etc.).

Of importance to the pharmacist are those FDA regulations relating to the general labeling of drugs and to specific labeling of prescription and nonprescription drugs. The FDA also has specific labeling requirements applicable to veterinary drugs. Applicable FDA regulations on labeling can be found at 21 CFR §201.

"Adequate *directions* for use" refers to the labeling of nonprescription drugs. The directions must be written clearly so the layperson can use a drug safely for the purposes for which it is intended (see 21 CFR §201.5). "Adequate *information* for its use" differs from the term previously discussed. It is defined in 21 CFR §201.100(c)(1) in reference to prescription drugs and applies to the promotional labeling and the package inserts accompanying the drugs in commercial containers. The labeling must include the medical indication, effects, and dosage; the route, method, frequency, and duration of administration; and any relevant hazards, contraindications, side effects, and precautions.

SPECIAL LABELING—Special labeling for certain drugs is contained in 21 CFR Part 201 Subpart G. These include specific requirements for certain prescription and certain OTC drugs. One example is the statement required by 21 CFR §201.314 for salicylate preparations that says: "Warning: Keep out of reach of children."

LABELING OF NONPRESCRIPTION DRUGS—On March 17, 1999, the FDA issued final regulations regarding the labeling of OTC drug products. The latest regulation is based on the FDA's success with standardizing food labeling. The General Requirements for the OTC label are contained in 21 CFR Part 210 Subparts A and C. Generally, the label of an OTC drug must contain:

a principal display panel, including a statement of identity of the product (21 CFR §201.60 and 201.61);
the name and address of the manufacturer, packager, or distributor (21 CFR §201.1);
the net quantity of contents (21 CFR §201.62);
the National Drug Code number is requested, but not required, to be on the label (21 CFR §201.2);
cautions and warnings that are needed for the protection of the user (this requirement varies by the type of product);
adequate directions for safe and effective use (21 CFR §201.5);
content and format of OTC product labeling in "Drug Facts" panel format (21 CFR §201.66).

The regulations are designed to simplify OTC drug product labeling to enable consumers to make informed decisions about the medications they use and give their families. The regulations require the labeling to be in a standardized format that clearly shows the drug's active ingredients, uses, warnings, directions, and inactive ingredients. The FDA also recommends that manufacturers include a phone number for consumers to call for more information. The regulations set requirements for minimum type sizes and other graphic features for the standardized format, including options for modifying the format for various package sizes and shapes.

The Drug Facts panel must contain the following information in the following order:

Drug Facts—title
Active ingredient(s)—including amount in each dosage unit
Purpose—pharmacologic class
Use(s)—indications
Warnings
- Do not use—absolute contraindications, when the product should not be used under any circumstances
- Ask a doctor before use if you have—warnings for persons with certain pre-existing conditions and for persons experiencing certain symptoms
- Ask a doctor or pharmacist before use if you are—drug-drug and food-drug interactions
- When using this product—side effects that could occur and substances or activities to avoid
- Stop use and ask a doctor if—signs of toxicity and other serious reactions that would require consumers to stop using the product immediately
- Pregnancy/breast-feeding warning
- Keep out of reach of children/Accidental overdose warnings
- Direction—dosage when, how, or how often to take

Other information
Inactive ingredients
Questions? (Optional)—followed by telephone number

On December 1, 1999, the FDA announced the availability of a Guidance Document entitled "Draft Guidance for Industry on Labeling of Over-the-Counter Human Drug Products Using a Column Format" (21 CFR §201.5). It can be found on the Internet at http://www.fda.gov/cder/guidance/index.htm. By way of a "negative prohibition," it requires OTC drug labeling to contain the following information:

statements of all cases, conditions, and purposes for which the drug is intended, except those restricted under medical supervision;
the normal dose for each intended use of the drug and the doses for individuals of different ages and different physical conditions;
both the frequency and duration of administration or application;
the administration or application in relation to meals, onset of symptoms, or other time factors;
the route or method of administration or application; and
the preparation for use (ie, shaking, dilution, etc.).

When adequate directions for common use of an OTC drug are known to the ordinary individual (which would be unlikely) there is an exemption under 21 CFR §201.116 from both the adequate directions for use requirement of labeling and from the prescription-only requirement, although not from the other labeling requirements of law, such as ingredient information and the manufacturer's name.

The individual who repackages or re-labels an OTC drug from bulk supply must comply with all of the FDA labeling regulations that are applicable to labeling OTC drugs. Failure to do so will render the product misbranded. 21 CFR §201.66(e) provides a mechanism to request an exemption or deferral from the standardized format. It requires documentation of why a particular requirement is inapplicable or contrary to public health and requires a copy of the proposed labeling also be submitted.

Because a pharmacist is licensed, he or she is considered an expert on drugs and, as such, must be able to professionally answer all queries that his or her patients may have concerning the active ingredients and the labeling of the OTC drugs sold in the pharmacy. The patient is ultimately responsible for reading and following the drug labeling; however, the pharmacist should draw attention to the directions for and warnings on use of the drugs.

While the pharmacist may not legally diagnose or prescribe in most states, he or she may recommend a nonprescription drug product in response to the patient's request for a remedy. When recommending a drug product, the pharmacist must be careful not to give an express warranty or guarantee for the preparation so as not to be involved in a civil liability suit should the "guaranteed remedy" prove ineffective.

When nonprescription drugs are dispensed pursuant to a prescription, the prescription label satisfies the FDA labeling requirements applicable to consumer self-medication labeling.

Prescription Drug Marketing Act

The Prescription Drug Marketing Act of 1987 (PDMA), which became law in 1988 (P.L. 100-293), amended the FD&CA to reduce the potential public health risks that may result from diversion of prescription drugs from legitimate commercial channels (see 21 U.S.C. §353[c]-[e]). Congress found the reintroduction of these drugs into commercial channels could lead to the distribution of mislabeled, adulterated, and subpotent or counterfeit drugs to the American public. The PDMA requires that states license wholesale distributors of prescription human drugs in conformance with federal guidelines that provide minimum standards for prescription drug storage, handling, and recordkeeping. It also requires wholesale distributors who are not authorized manufacturers' distributors to provide a written statement to the purchaser identifying each prior sale.

The PDMA, sometimes known as the Drug Diversion Act, amended several sections of the FD&CA to:

Ban the reimportation of federal legend human drugs manufactured in the United States, except when reimported by the manufacturer or for emergency medical care with permission of the Secretary;
prohibit, with certain exceptions, the sale, purchase, or trade (including the offer to sell, purchase, or trade) federal legend human drugs by hospitals or health care entities;
prohibit, with certain exceptions, the sale, trade, or purchase (including the offer to sell, purchase, or trade) federal legend human drugs donated or sold at reduced cost to charitable institutions;
ban the sale, purchase, or trade, and the counterfeiting of drug coupons;
ban the sale, purchase, or trade (including the offer to sell, purchase, or trade) of drug samples;
require practitioners to request samples in writing;
mandate storage, handling, and recordkeeping requirements for drug samples;
require state licensing of wholesale distributors of federal legend human drugs under federal guidelines that include minimum standards for storage, handling, and recordkeeping;
require unauthorized drug distributors to provide a statement of origin ("pedigree") as part of certain sales of drugs; and
set forth criminal and civil penalties for violations of these provisions.

The re-importation of prescription human drugs produced in the United States is banned, except when re-imported by the manufacturer or, after FDA approval, for emergency use. The PDMA also bans sale, trade, or purchase of drug samples and the trafficking in and counterfeiting of drug coupons (forms that may be redeemed for a prescription drug at no cost or reduced cost). For purposes of this legislation, a drug sample is defined as "a unit of drug, which is not intended to be sold, that is intended to promote the sale of the drug." The PDMA requires all requests for drug samples be made in writing by licensed practitioners. It also requires drug samples be properly stored and handled, and certain recordkeeping be followed. With certain specific exceptions, the resale of prescription drugs purchased by hospitals or health care facilities or donated or supplied to charitable institutions is prohibited.

On December 3, 1999, the FDA issued its final regulations implementing this legislation (see 64 Fed. Reg. 67720-67731). The final rule set forth requirements for re-importation and wholesale distribution of prescription drugs, the offer of, or the sale, purchase, or trade of prescription drugs purchased by hospitals or health care entities, or donated to charitable organizations, and the distribution of prescription drug samples. In this rulemaking, the FDA also amended certain sections of the regulations entitled "Guidelines for State Licensing of Wholesale Prescription Drug Distributors." However, on May 3, 2000, at 65 FR 25639, the FDA announced it was delaying the effective date for certain requirements related to wholesale distribution of prescription drugs by distributors who were not au-

thorized distributors of record. Another portion of the final regulation being stayed was one prohibiting blood centers functioning as "health care entities" to act as wholesale distributors of blood derivatives. The PDMA provision prohibits wholesale distribution of drugs in interstate commerce unless the wholesaler is licensed by a state in accordance with the guidelines.

Key points with regard to the PDMA and its final implementing regulations with regard to samples and pharmacies are:

A "drug sample" is defined as "a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug."

The FDA's position is that starter packs, which are distributed free to pharmacies, are not samples because they are intended to be sold by the pharmacy. Also, vouchers or other similar systems for indigent patients filled out of pharmacy's stock at the manufacturer's expense are not considered samples.

Samples only may be distributed by a practitioner licensed to prescribe, or to the pharmacy of a hospitals or health care entity (at the written request of a prescriber).

The proposed rule stated that drug samples found in a retail pharmacy would be considered evidence that the sample was obtained by the pharmacy in violation of the Act. The final rule excludes this provision, but if the pharmacy is not part of a health care entity, the presumption probably can still be made.

Drug Price Competition and Patent Term Restoration Act of 1984

When President Ronald Reagan signed the Drug Price Competition and Patent Term Restoration Act (DPCPTRA) into law on September 24, 1984, he stated "this legislation will speed up the process of federal approval of inexpensive generic versions of many brand-name drugs, make the generic versions more widely available to consumers, and grant pharmaceutical firms added incentives to develop new drugs." The law converts the drug approval process that had been used for pre-1962 generic drugs and makes that process a formal requirement for moving post-1962 drugs to ANDA status. All generic drugs approved under this process must be bioequivalent to the brand name reference drug. The DPCPTRA provides pioneer drug firms 5 years of patent restoration or at least 5 years of exclusive marketing once their drug is approved. Generic companies may not submit an application until 5 years after the approval of the brand-name product.

Some pharmacists and consumers have raised concerns about the equivalence of generic copies marketed under the new law. Particular concerns have been raised regarding substituting generic drug products for brand name products that still have exclusivity over certain indications. Another concern is that the FDAs criteria for bioequivalence may not be sufficient to guarantee safety and efficacy for a class of drugs commonly called Narrow Therapeutic Index (NTI) drugs.

Misbranding and Adulteration

§§501 and 502 of the Act prohibit the introduction into interstate commerce of any article that is "misbranded" or "adulterated," as those terms are defined under the FD&CA. The misbranding and adulteration provisions apply to action taken after shipment in interstate commerce.

The United States Pharmacopoeia and National Formulary

The majority of drugs marketed in the United States have monographs in The United States Pharmacopeia/National Formulary (USP/NF). The FD&CA recognizes the USP/NF as an "official compendia." If a drug product that appears in a monograph in the USP/NF fails to meet the standards for strength, quality, purity, packaging, or labeling contained in the monograph, the drug may be deemed "misbranded" or "adulterated" under the Act. For example, USP's monograph for nitroglycerin tablets requires that prescriptions be labeled for sublingual use and that they be dispensed in the original unopened container. In addition, the USP/NF's standards for packaging and storage of prescription drugs are widely recognized by individual state Food, Drug, and Cosmetic acts as well as by state pharmacy practice acts and regulations.

Adulterated Drugs

In most instances, adulteration violations would be committed by the pharmaceutical manufacturer. For example, if a drug is manufactured under conditions that do not conform to Current Good Manufacturing Practices, the drug is deemed adulterated under the Act. Section 502(a)-(d) states that:

A drug or device shall be deemed to be adulterated:

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not opeerated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug, and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of Section 721(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of Section 721(a); or (5) if it is a new animal drug which is unsafe within the meaning of Section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of Section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therfore.

Misbranded Drugs

Misbranded or mislabeled drugs are those that are sold, dispensed, or distributed in violation of the labeling requirements of the FD&CA. The courts have held that when a pharmacist sells a prescription drug at retail without a prescription or refills a prescription without the prescriber's authorization, he or she has in effect "misbranded" the drug. *United States v. Carlisle*, 234 F.2d 196 (5th Cir. 1956).

Section 502 (a)-(p) of the Act provides that:

A drug or device shall be deemed misbranded—

(a) If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under Section 505 or under Section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in Section 505(a) or in Section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term "health care economic information" means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed theron with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) (Repealed by Pub. L. 105-115, November 21, 1997.)

(e)(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name; (ii) the established name and quantity, or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and (iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name" with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to Section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharamcopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to Section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States

Pharmacopeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) (Repealed by Pub. L. 105-115, November 21, 1997.)

(l) (Repealed by Pub. L. 105-115, November 21, 1997.)

(m) If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under Section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in Section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under Section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations

which shall be issued by the Secretary in accordance with the procedure specified in Section 701(e) of this Act, except (A) in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of Sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52-57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in Section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.

If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under Section 510, if it was not included in a list required by Section 510(j), if a notice or other information respecting it was not provided as required by such section or Section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under Section 510(e) as the Secretary by regulation requires.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 3 and 4 of the Poison Prevention Packaging Act of 1970.

To understand the meaning of the term "misbranded," the term must be read in light of the requirement of §502(f)(1) of the FD&CA (21 U.S.C. §352(f)(1) stating that the labeling of a drug contain "adequate directions for use." That is to say, prescription drugs are such because medical experts agree adequate directions for consumer self-medication cannot be provided for these drugs. Regardless of what directions a pharmacist or other dispenser might give when a legend drug is dispensed in absence of a prescription, the directions are, by law, not adequate for consumer use. Only the practitioner licensed to prescribe drugs is allowed to give directions adequate for the patient's safe and effective use of the federal legend drug product.

The Prescription Label

The directions and supervision of the prescribing or administering prescriber suffice in lieu of the adequate directions for use requirements of §502(f)(1) of the FD&CA. However, this does not mean a drug may be dispensed without labeling by the pharmacist. Section 503(b)(2) of the Act (21 U.S.C. §353[b][2]) requires the prescription label have the following information:

The name and address of the dispenser (pharmacy);
the serial number of the prescription;
the date of the prescription or the date of its filling (or refilling)—state law often determines which date is to be used;
the name of the prescriber;
the name of the patient, if stated in the prescription; and
directions for use, including precautions, if any, as indicated on the prescription.

State law may require the following further information including:

The name and address of the patient;
the initials or name of the dispensing pharmacist;
the telephone number of the pharmacy;
the drug name, strength, and manufacturer's lot or control number;
the beyond-use date, if any; and
the name of the manufacturer or distributor.

Receipt of Misbranded or Adulterated Drugs

If a pharmacy receives a misbranded or adulterated drug from a manufacturer or drug wholesaler, there is protection from federal penalty if the drug is then sold to a consumer. The FD&CA provides a number of exemptions from prosecution for the sale of misbranded or adulterated products that are received from outside sources, although civil liability may not be avoided because of implied warranty under state laws.

Section 303(c) of the Act states that a retail dealer can escape criminal penalty for receipt and subsequent delivery (sale) of misbranded or adulterated drugs if the delivery is in good faith and if, on request, he or she furnishes the FDA with records of the source of the interstate shipment. When the pharmacist purchases drugs from a wholesaler or manufacturer, he or she should look for a guaranty that the drugs are not adulterated or misbranded on the invoice. Consequently, a pharmacy may obtain protection from its drug suppliers by obtaining a "continuing guaranty" (as part of its original purchase contracts). Again, if the guaranty is not obtained, the retailer has some protection under §303(c)(1). The drug wholesaler generally is limited to obtaining a guaranty from its suppliers since the §303(c)(1) exemption usually does not apply because the wholesaler puts drugs into interstate commerce.

Prescription Drugs

FDA regulations define "prescription drugs" as drugs subject to the requirement of §503(b)(1) of the FD&CA, which states:

A drug intended for use by man which (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited by an approved application under Section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner, which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

and as those exempt from the requirement of §502(f)(1), which states that drugs must bear adequate directions for use or be considered misbranded and subject to seizure under certain conditions. A drug is limited by the Act to dispensing by or upon a prescription because it is habit-forming, toxic, or has a potential for harm, or the NDA limits it to use under a physician's supervision. 21 CFR Part 201 Subpart D.)

Previously, one of the conditions of the FDA regulations for exempting a prescription-only drug from the §502(f)(1) requirement of adequate directions for safe use was that the label of the prescription drug, prior to dispensing, required the statement: "Caution: Federal law prohibits dispensing without a prescription." (This phrase is known as the "federal legend," and, hence, prescription drugs have historically been known as "legend" drugs.) Section 126 of the FDAMA amended Section 503(b)(4) of the FD&CA to require, at a minimum, that prior to dispensing, the label of prescription products contain the phrase "Rx only." The intent of this change was to simplify the labeling of prescription drug products in an effort to help reduce the incidence of medication errors in which product labeling and package design had been identified as a contributing factor. While the new requirement does not prohibit manufacturers from including other language on the label (ie, the "old" federal legend), the FDA believes that in the interest of simplification, it is preferable to have only the "Rx only" statement. The FDA has published a Guidance for Industry addressing the implementation of Section 126 of FDAMA. The Guidance Document, which may be accessed at http://www.fda.gov/cder/guidance/index.htm states the FDA intends to exercise its enforcement discretion and not object if a manufacturer does not comply with the labeling provisions until the next revision of its labels, or by February 19, 2003, whichever comes first.

Nonprescription (Over-the-Counter) Drugs

Nonprescription drugs (OTCs)are defined as drugs recognized among experts to be safe and effective for use (21 CFR §330.10). These drugs must be manufactured in accordance with the FDA's current good manufacturing standards and be labeled with directions for the layperson that indicate their safe and effective use.

POISONS

A poison has been defined as any drug known to the pharmaceutical or medical profession that is liable to be destructive to adult human life if taken in quantities of 60 grains or less. This general definition is helpful in indicating the substances customarily regarded as poisonous, but it is not followed in many of the state poison laws. Regulation of the sale of poisons usually falls within the jurisdiction of the state governments and governmental limits in this area may vary widely from state to state.

State statutes regulating the sale of poisons usually require that the purchaser be of a certain minimum age and that he know, or be informed, that the substance being purchased is a poison. Moreover, the pharmacist frequently has a responsibility to determine that the substance will be used for a lawful purpose. Recordkeeping requirements usually are specified in state statutes. For example, the pharmacist may be required to record the date of sale, name and address of the purchaser, name or initials of the seller, name and quantity of the poison and purpose for which it is intended. Some states require that the purchaser sign the record book to form a receipt and impress upon the purchaser the dangerous nature of the substance. The book in which this information is recorded frequently is referred to as the Poison Register and there may be a requirement that the book be used exclusively for recording sales of poisons. Most states specify a time period during which the sales records must be preserved and made available for inspection by appropriate state authorities.

Special labeling requirements for poisons frequently are encountered. The usual minimum requirement is that the container bear the name of the substance, the word poison, and the name and place of business of the seller. Such state requirements may be supplemented by federal requirements concerning labeling with information about toxicity, cautionary statements and information about treatment. Poisons are not permitted to be mailed without specific authorization from the US Postal Service.

Poison Prevention Packaging Act

The Poison Prevention Packaging Act was enacted by Congress during 1970 and authorizes the Consumer Product Safety Commission (CPSC) to establish standards for child-resistant packaging. The agency also enforces the statute at the pharmacy level.

Under this statute, prescription drugs, and some nonprescription medications, are considered to be hazardous household substances and, consequently, must be dispensed with a child-resistant closure. However, there are some exceptions to this requirement under the Act.

Most nonprescription medications are not required to be packaged in a child-resistant fashion. However, the CPSC has ordered, for example, that aspirin and products containing more than 500 mg of iron per package must be in safety packages. Yet manufacturers of aspirin products may produce one size of a package containing the drug that has a standard closure. Such non-safety packages are required to bear the warning statement, *This package for households without young children*. Other nonprescription products may be added to the list of drugs requiring safety packaging and pharmacists should watch for such developments.

Some prescription drugs are not required to be dispensed in child-resistant packages either. For example, the CPSC has stated that safety packaging is not required for sublingual dosage forms of nitroglycerin as well as sublingual and chewable dosage forms of isosorbide dinitrate in strengths of 5 mg or less. Other prescription drugs may be considered for exemption from the requirements of the Act and, while under consideration, child-resistant packaging is not required.

The prescriber may request that a drug, which otherwise would be required to be in a child-resistant package, be dispensed with a standard closure. The patient also has this option under the Act. The legislation does not require any specific fashion for communicating this waiver, ie, it is not required to be in writing. For example, a prescriber transmitting a prescription by telephone could indicate orally that standard packaging is requested. Nonetheless, the pharmacist may desire to have requests by prescribers or patients for noncomplying packaging in writing to document the transaction; this could prove to be invaluable in case of an adverse occurrence.

At the outset of the enforcement of this statute, the CPSC took the position that the pharmacist could not advise the patient of the option of standard packaging. This position was taken in furtherance of the agency's view that non-safety packaging should be the rare exception, not the rule, and a feeling that if pharmacists were to advise patients of their options widely, the Act would be undermined. The APhA challenged this position of the agency and the CPSC now adopts the position that pharmacists may advise patients of their right to request non-safety packaging.

Drugs dispensed for use by inpatients, be they in a hospital or a nursing home, are not required to be in child-resistant containers because the patients usually do not have access to them.

Manufacturers are not required to use child-resistant closures on stock bottles of medication that are not intended to reach the patient. However, if the packaging provided by the manufacturer is that which will be dispensed to the patient, eg, packages bearing antibiotic powders for reconstitution, safety tops must be used.

Federal Hazardous Substances Act

The Federal Hazardous Substances Act is the standard for the cautionary labeling of hazardous substances, including poisons. That Act provides that no state or political subdivision (municipality) may establish or continue to effect a cautionary labeling requirement that is applicable to hazardous substances or their packaging unless the cautionary labeling requirement is identical to that of the federal act, or unless the state labeling requirements provide a higher degree of protection than the federal requirements [15 U.S.C. §§1261(p) and §1262(b)]. However, not all state poison sale laws are pre-empted by federal law; only the labeling requirements are affected by the federal pre-emption. A number of state poison control laws contained provisions for the recording of the sale and inquiry into the purchaser's intended use and knowledge of the substance. These provisions may still be the legal standard, although the author does not know of a current court case illustrating the point. The practicing pharmacist should be aware of the general nature of the recording and warning proviso and should be knowledgeable of the exact requirement in the state in which he or she practices.

Federal Anti-Tampering Act

The Federal Anti-Tampering Act, passed by Congress as a result of a deliberate contamination of Tylenol capsules in 1982, makes it a federal offense to tamper with consumer products and gives regulatory authority to the Federal Bureau of Investigation, US Department of Agriculture, and FDA. The term

tamper, when used in a criminal statute, has the limited meaning of improper interference "as for the purpose of alteration and to make objectionable or unauthorized changes." Tampering involves changing a product from what it was intended to be by the manufacturer. There are 5 sections of the Act:

Tampering with a consumer product that affects interstate or foreign commerce with reckless disregard for the risk of death or bodily injury to another person;
Tainting a consumer product with the intent of injuring a business;
Communicating false information that a consumer product has been tainted;
Threatening to tamper with a consumer product; and
Conspiring to tamper.

By regulation, tamper-resistant packaging is required for certain OTC drug products, cosmetics, and medical devices (contact lens solutions and lubricants). Dentifrices, dermatologics, lozenges, and insulin are excluded. A tamper-resistant package is defined as "one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred." The regulations do not require the use of specific packaging technologies; any technology that achieves the required effect is acceptable. For tamper-resistant packaging to be fully effective, consumers need to examine the packaging carefully before consuming the contents, and they must be aware of the specific tamper-resistant features that have been used. FDA regulations require that the labeling of products with tamper-resistant packaging bear a statement alerting the consumer to the tamper-resistant feature. This labeling statement must be placed so it remains intact even if the tamper-resistant feature is breached or missing. If tampering is suspected, the closest FDA district office should be immediately notified.

The tamper-resistant packaging regulations for OTC drug products (21 CFR §211.132) are part of the CGMP's for finished drug products. For devices, the tamper-resistant packaging regulations are in 21 CFR §800.12, and those for cosmetics are in 21 CFR §700.25. A Compliance Policy Guide (7132a.17) that describes specific tamper-resistant packaging technologies is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

Electronic Signatures in Global and National Commerce Act (E-Sign)

In June 2000, President Bill Clinton signed the "E-Sign" Law (Public Law 106-229). Most of its provisions went into effect on October 1, 2000. While this law is not pharmacy specific, it may have great impact on the way pharmacy is practiced. The essence of the law is to spur the growth of electronic commerce by ensuring electronic contracts, signatures, and records will have the same legal status and effect as their ink and paper counterparts. Because E-Sign applies to all "transactions" (with few exceptions) in interstate commerce, it clearly encompasses the filling of prescriptions. This legislation has the potential to propel the electronic transmission of prescriptions. It is also important to note that the legislation is "technology neutral." It does not predetermine what technology to use or standards for such technology.

The legislation has 2 parts—one addressing primarily electronic signatures, and the other addressing electronic records. E-Sign states that electronic contracts, signatures, and records cannot be denied legal effect because the signature or record is in electronic form. E-Sign also declares that all other statutes, regulations, or rules of law requiring written signatures or written records are invalid or "pre-empted" in most circumstances. However, E-Sign does not require anyone (except governmental agencies) to accept an electronic signature or record. So, individuals still have a choice in determining whether to conduct business electronically.

ELECTRONIC SIGNATURES—By declaring that an electronic signature "may not be denied legal effect, validity, or enforceability solely because it is in electronic form," E-Sign effectively voids requirements that prescriptions be on paper or printed as a hard copy. In addition, E-Sign eliminates requirements that prescriptions be "hand-signed" or signed by the practitioner "in writing" or in the practitioner's "own handwriting." These types of handwriting requirements often are contained in state pharmacy practice acts and regulations but also appear in federal law through DEA requirements.

ELECTRONIC RECORDKEEPING—The recordkeeping portion of E-Sign states that any recordkeeping requirement related to transactions involving interstate commerce may be met by keeping electronic records—as long as the record accurately reflects the information to be retained and that it remains accessible to all who have a right to see the information. This portion of E-Sign is in direct conflict with many or most state pharmacy regulations. To avoid the provisions of E-Sign, a federal agency that attempts to require written signatures or records must show there is a "substantial justification" for making an exception.

THE COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

Current laws and regulations pertaining to controlled substances are online at www.deadiversion.usdoj.gov. The Federal *Comprehensive Drug Abuse Prevention and Control Act* became effective on May 1, 1971. Title II of that Act is known as the *Controlled Substances Act* (CSA) and it regulates the manufacture, distribution and dispensing of controlled substances. This law supersedes most previous narcotic and drug-abuse control laws, and places the enforcement of this Act with the Drug Enforcement Administration (DEA), which is part of the US Department of Justice. The DEA has promulgated extensive regulations to implement the Act, and these regulations appear in 21 CFR §§1300–end.

The statute provides a *closed* system for virtually every person who legitimately handles controlled substances other than the ultimate user. Over 500,000 individuals and institutions, such as hospitals, pharmacies, researchers, drug manufacturers and physicians are included in the class of persons subject to direct regulation through registration with the DEA. In addition to replacing or amending the numerous Federal laws relating to the control of drugs, the CSA is intended to aid in reducing the widespread diversion of these substances from legitimate channels.

When enacting the CSA Congress no longer relied upon the tax clause of the US Constitution, as had been done in the past. The authority for Congress to enact this legislation was derived from the interstate commerce clause of the Constitution. The power to regulate the health, safety and welfare of the American people has been left primarily within the jurisdiction of the individual states through the *police powers* that were reserved to the states via the Tenth Amendment of the US Constitution. However, Congress determined that the Federal control of intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic, and it thereby felt compelled to enter into the regulation of subject matter that previously had been left to the states. It must be remembered that if a provision of state or local law is inconsistent or conflicts with a provision of the CSA, the state or local law must yield to the Federal provision. However, if the state or local law augments or strengthens the Federal act, the more stringent state provision must be followed. To provide uniformity with the Federal Government, the majority of the states have adopted a *Uniform Controlled Substances Act.*

IMPORTANT DEFINITIONS

The following selected definitions are derived from the CSA or from the DEA regulations. These definitions must be read carefully for their language will affect greatly the use of the words within the Act. The following definitions are those that bear most heavily upon pharmacy practice:

Administer refers to the direct application of a controlled substance to the body of a patient or research subject.

Dispenser means an individual practitioner, an institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

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

Institutional practitioner means a hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the US or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Narcotic drug means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis: (a) opium, coca leaves and opiates; (b) a compound, manufacture, salt, derivative or preparation of opium, coca leaves or opiates; (c) a substance that is chemically identical with any of the substances referred to in a or b.

Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association or other legal entity.

Pharmacist means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (eg, pharmacist-intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

Prescription means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user (eg, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recording systems in such a manner that they can be separated from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined or in some other manner visually identifiable apart from other items appearing on the records.

SCHEDULES

The drugs that come under the jurisdiction of the CSA have been categorized according to their potential for abuse and are divided into five schedules. Procedures for controlling a substance under the CSA are set forth in Section 201 of the Act. Scheduling requests may be initiated by the DHHS, by the DEA or by petition of a manufacturer, medical society, pharmaceutical association, public interest group or an individual citizen.

Once the DEA receives a request to control a drug or remove a substance entirely from the schedules, the agency must request that the DHHS conduct a scientific and medical evaluation. The Secretary of the DHHS then consults with the FDA and the other affected agencies regarding recommendations whether the drug or other substance should be controlled or removed from control. The medical and scientific evaluations are binding on the DEA with respect to scientific and medical matters and, if the DHHS recommends that a drug not be controlled, the DEA may not control the substance.

After the DEA receives the DHHS report, it then will proceed to make a final decision. If it has determined to control the drug, a proposal will be published in the *Federal Register* setting forth the proposed schedule and inviting all interested parties to file comments. At this point the affected parties may request a hearing before an administrative law judge. If no hearing is requested, the DEA will evaluate all the comments received and publish a final order in the *Federal Register*.

In reaching a final decision, the DEA is required by the Act to consider a number of factors with respect to each drug proposed to be controlled or removed from the schedules. These include potential for abuse; pharmacological effects; risk to public health; the history, scope, duration and significance of the abuse and the potential for psychic or physiological dependence.

The drugs that come under the jurisdiction of the CSA are divided into five schedules based upon their potential for abuse as follows:

SCHEDULE I—These drugs have a high potential for abuse and no accepted medical use in the US. The three broad categories of substances found in this schedule are the opiates, opium derivatives and hallucinogens. Some examples are heroin, marihuana, LSD, peyote, mescaline, psilocybin, tetrahydrocannabinols (THC) and dihydromorphine and others.

Properly registered persons may use Schedule I substances for research purposes. The FDA has approved the marketing of the THC product, dronabinol (Marinol), and the synthetic cannabinoid, nabilone (Cesamet), for the treatment of the nausea and vomiting associated with cancer chemotherapy. Both agents have been placed in Schedule II. All other tetrahydrocannabinols and marihuana remain in Schedule I.

SCHEDULE II—These drugs also have a high potential for abuse, but do have a currently accepted medical use in treatment in the US. It has been determined that the abuse of a drug, or other substances included in this schedule, may lead to severe psychological or physical dependence. The broad categories of Schedule II drugs include opiates and opium derivatives, derivatives of coca leaves and certain CNS stimulants and depressants. Some examples of Schedule II controlled narcotic substances are opium, morphine, codeine, hydromorphone (Dilaudid), methadone (Dolophine), pantopon, meperidine (Demerol), cocaine, oxycodone (Percodan—in combination with aspirin), anileridine (Leritine) and oxymorphone (Numorphan). Also in Schedule II are amphetamine (Benzedrine, Dexedrine) and methamphetamine (Desoxyn), phenmetrazine (Preludin), methylphenidate (Ritalin), amobarbital, pentobarbital, secobarbital, etorphine hydrochloride, diphenoxylate and phencyclidine.

The quantity of the substance in a drug product often determines under which schedule it will be controlled. For example, amphetamines and codeine generally are included in Schedule II. However, certain products containing smaller quantities, most often in combination with a noncontrolled substance, are controlled in Schedules III and V.

SCHEDULE III—These drugs have accepted medical use in the US, but they have a lower potential for abuse than Schedule I and II drugs. Schedule III drugs include compounds containing limited quantities of certain narcotic drugs, and nonnarcotic drugs such as derivatives of barbituric acid except those that are listed in another schedule, glutethimide, methyprylon (Noludar), nalorphine, benzphetamine, chlorphentermine, clortermine, phendimetrazine and paregoric. Any suppository dosage form containing amobarbital, secobarbital or pentobarbital is in this schedule.

SCHEDULE IV—These drugs have a low potential for abuse relative to those in Schedule III. Abuse of Schedule IV drugs or substances may lead to limited physical dependence or psychological dependence as compared to those included in Schedule III. Schedule IV drugs are generally the long-acting barbiturates, certain hypnotics and the minor tranquilizers. For all practical purposes there are no regulatory differences between Schedule III and IV. Some of the more common drugs found in Schedule IV are barbital, phenobarbital, methylphenobarbital, chloral betaine, chloral hydrate, ethchlorvynol (Placidyl), ethinamate (Valmid), meprobamate (Equanil, Miltown), paraldehyde, methohexital, fenfluramine, diethylpropion, phentermine, chlordiazepoxide (Librium), diazepam (Valium), oxazepam (Serax), clorazepate (Tranxene), flurazepam (Dalmane), clonazepam (Clonopin), prazepam (Verstran), lo-

razepam (Ativan), mebutamate, propoxyphene (Darvon) and pentazocine (Talwin-NX).

SCHEDULE V—These drugs have the lowest abuse potential of the controlled substances and consist of preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarrheal purposes. As a general rule, Schedule V items are OTC preparations that might be sold without a prescription. There are notable exceptions, and the pharmacist should always check the label to see if the FDA has determined the item to be a prescription-only item. For example, Lomotil is a Schedule V item, but it is prescription-only.

Manufacturers of nonnarcotic substances that may be sold OTC under the terms of the FD&C Act may apply to the DEA to have their product excluded from any schedule. Phenobarbital is the most common substance found in those products that are excluded from the scheduling process. One of the prime factors considered in determining whether to exclude a product would be the amount of the controlled substance involved. Once a product is excluded under Section 201 (g)(1) of the CSA it is no longer subject to DEA control. However, the pharmacist always should consult state and local laws to determine if any of the federally excluded products have been given more restrictive controls.

Schedule V Retail Distribution Restrictions

Controlled substances listed in Schedule V, which are not prescription only drugs, may be dispensed without a prescription by a pharmacist to a purchaser at retail, provided the following conditions are met:

1. Such dispensing is made only by a pharmacist (which, by definition, also includes a pharmacy intern unless prohibited by state law). However, after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction or delivery may be completed by a nonpharmacist.
2. Not more than 240 mL (8 oz) or 48 solid dosage units of any substance containing opium, or more than 120 mL (4 oz) or 24 solid dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given 48-hr period without a prescription.
3. The purchaser at retail is at least 18 years of age.
4. The pharmacist requires every retail purchaser of a controlled substance, who is not known to him, to furnish suitable identification (including proof of age where appropriate).
5. A bound record book is maintained that contains the name and address of the purchaser, name and quantity of controlled substance purchased, date of each sale and initials of the selling pharmacist. This record book shall be maintained for a period of 2 years from the date of the last transaction entered in the record book, and it must be made available for inspection and copying by officers of the US, authorized by the Attorney General.
6. Other federal, state or local law does not require a prescription.

The pharmacist must be cautioned that in some states certain, or all, Schedule V substances have been placed on prescription-only status. In these states the more restrictive state law would apply and prohibit the OTC sale of Schedule V items.

Symbols and Labeling

Each commercial container of controlled substances will have on its label a symbol designating to which schedule it belongs. The symbol for Schedule I through V controlled substances will be as follows:

I or C-I
II or C-II
III or C-III
IV or C-IV
V or C-V.

The symbols will be at least twice as large as the largest letter printed on the label. There are exceptions to these labeling requirements. In those cases where the commercial container is too small to accommodate the label, only the box and the package insert must contain the *C* symbol.

As a general rule, these symbols are not required on prescription containers dispensed by a pharmacist to a patient in the course of his professional practice, although laws of some states may require such symbols on prescriptions dispensed to extended-care facilities.

Registration

Every "person" who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance must obtain a registration unless exempted. Registrations vary in length from 1 to 3 years. Most pharmacy registrations will be issued for a three year period. A unique DEA number is assigned to those who must register under the law including manufacturers, distributors, wholesalers and practitioners such as physicians, dentists, veterinarians, scientists, pharmacies, podiatrists and hospitals. There are, however, seven general categories of persons who are exempt from registration under the statute or the regulations, including civil defense officials, law enforcement officials, certain government employees, practitioners affiliated with registered institutions and agents or employees of registrants. It is this latter exemption that permits individual pharmacists not to register with the DEA since such pharmacists serve as agents of the registered pharmacies.

In other words, pharmacies must register with the DEA to dispense controlled substances but pharmacists do not. The one exception is for a pharmacist who owns a pharmacy as a sole proprietor; in such a case, the pharmacist would be required to register. The certificate of registration must be maintained at the registered location and kept available for official inspections. If an individual owns and operates more than one pharmacy, each place of business must be registered separately.

Applications for reregistration will be mailed by the DEA to each registered person approximately 60 days before the expiration date of the registration. If a registered pharmacy does not receive such forms within 45 days prior to the expiration date of the registration, it must give notice of such fact and request the reregistration forms.

New Registrations

Pharmacies that seek to become registered for the first time must request a registration application from the DEA. No pharmacy may engage in any activity for which registration is required until its application for registration has been granted and a certificate issued to it by the DEA. However, a pharmacy may not dispense controlled substances if it has not been issued a valid state license, even though the DEA already may have registered the pharmacy and authorized it to obtain controlled substances. See *Wedgewood Village Pharmacy v. Ashcroft*, 2003 US Dist Lexis 22401 (Dec 15, 2003).

Modifications such as change of address, location or name by existing registrants may be made without going through the new registration process. To make such a modification, the registrant should submit a letter to the DEA requesting it. No fee is required. A registrant also may apply to modify his registration to authorize the handling of additional schedules of controlled substances, but may not modify his registration to transfer it to another party.

Termination

The DEA has the authority under the CSA to suspend or revoke a registration where the registrant has falsified his ap-

plication, or has been convicted of a felony under the federal or state CSA or has had his state license or registration suspended and no longer is authorized by state law to dispense controlled substances. Except in emergency situations, registrants are assured of a hearing and due process of law prior to suspension or revocation of registration. In addition, the registration of any person terminates if and when such a person dies, ceases legal existence or discontinues business or professional practice.

Distribution

As a general rule a separate DEA registration is required for each activity a registrant wishes to engage in such as manufacturing, distributing, dispensing or conducting research. However, a pharmacy registered to dispense a controlled substance may distribute (without being registered as a distributor) a quantity of controlled substances to a physician, another pharmacy, hospital or nursing home for the purpose of general dispensing by that practitioner provided the following conditions are met:

1. The pharmacy or practitioner to which the controlled substance is being distributed is registered under the Act to dispense that controlled substance.
2. The distribution is recorded as being distributed by the pharmacy and the pharmacist, or practitioner, records the substance being received. The pharmacy distributing a controlled substance must record the name of the substance, the dosage form, the quantity and the name, address and DEA registration number of the pharmacy or practitioner to whom it is distributed as well as the date of distribution.
3. If the substance is listed in Schedule I or II, the transfer must be made on official DEA order form 222.
4. The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered. If at any time it does exceed 5% the pharmacy is required to register as a distributor as well as being registered as a pharmacy.

As an incident to this distribution, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20% of the complete solution, compound or mixture.

The regulations also permit a person lawfully in possession of controlled substances to return them to the supplier without registering as a distributor. Registrants would have to use official DEA order forms for the return of Schedule I and II substances to a supplier.

Records and Reports

Every pharmacy handling controlled substances must keep complete and accurate records of all receiving and dispensing transactions that must be maintained for a period of at least 2 years. Many states require that the records be kept for as long as 5 years from the date of the last dispensation.

All inventories and records of controlled substances in Schedule II must be maintained separately from all other records of the registrant. All inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary professional and business records of the pharmacy.

All records pertaining to controlled substances must be made available for inspection and copying by duly authorized DEA officials and state authorized agents.

When a registrant first engages in business, and every 2 years thereafter, a complete and accurate inventory of all stocks of controlled substances on hand must be completed and kept by the registrant for a period of 2 years. Pharmacies are not required to submit a copy of the inventory to the DEA; however, many states require a copy of the inventory be sent to the regulatory agency.

Continuing Records

Every pharmacy must maintain, on a current basis, a complete and accurate record of each controlled substance received. Copy 3 of executed DEA order form 222 retained by the pharmacy, which have been completed as described under the section entitled *Order Forms*, will constitute a pharmacy's receiving records for Schedule II controlled substances. Invoices for Schedule III, IV, and V controlled substances will be considered as complete receiving records if the actual date of receipt is recorded clearly on the invoices by the pharmacist or other responsible individual.

Filing Prescriptions

Under federal law, prescription orders for controlled substances must be filed in one of the following three ways:

1. A pharmacy can maintain three separate files—a file for Schedule II drugs dispensed, a file for Schedules III, IV, and V drugs dispensed and a file for prescription orders for all other drugs dispensed.
2. A pharmacy can maintain two files—a file for all Schedule II drugs dispensed, and another file for all other drugs dispensed, including those in Schedules III, IV, and V. If this method is used, the prescription orders in the file for Schedules III, IV, and V must be stamped with the letter *C* in red ink, not less than 1-inch high, in the lower-right corner. This distinctive marking makes the records *readily retrievable* for inspection.
3. A pharmacy can maintain two files—one file for all controlled drugs in all schedules and a second file for all prescription orders for noncontrolled drugs dispensed. If this method is used, the prescription orders for drugs in Schedules III, IV, and V in the controlled drug prescription file must be stamped with the red letter *C* not less than 1-inch high in the lower-right corner, as previously mentioned. This latter requirement is waived for pharmacies using electronic record keeping methods. State requirements vary widely but usually do not permit as many options for maintaining prescription records as permitted under federal law. State laws may impose additional considerations.

Inventory

The CSA requires each registrant to make a complete and accurate record of all stocks of controlled substances on hand every 2 years. The DEA no longer specifies a date on which the inventory must be performed. Many states do, however, specify a date or provide for a window of time when the inventory must occur. The actual taking of the inventory should not vary more than 4 days from the biennial inventory date. The inventory record must:

1. List the name, address, and DEA registration number of the registrant.
2. Indicate the date and time the inventory is taken, ie, opening or closing of business.
3. Be signed by the person or persons responsible for taking the inventory.
4. Be maintained at the location appearing on the registration certificate for at least 2 years.
5. Keep records of Schedule II drugs separate from all other controlled substances.

When taking the inventory of Schedule II controlled substances, an exact count or measure must be made. When taking the inventory of Schedules III, IV, and V controlled substances, an estimated count may be made unless the container holds more than 1000 dosage units, in which case an exact count must be made if the container has been opened.

NEWLY CONTROLLED SUBSTANCES—Occasionally a drug that has not been controlled previously will be placed in one of the drug schedules or a controlled substance will be moved into a higher or lower schedule. In either case the drug must be inventoried as of the effective date of transfer, and this inventory should be added to the biennial inventory. Note that many states require pharmacies to perform an audit of CS drugs annually.

Order Forms

The order form system developed by the DEA is a completely closed system of drug distribution. The DEA permits only authorized persons to obtain or distribute *Schedule I* or *II* controlled substances and only pursuant to official DEA order form 222. The regulations set forth those instances where official order forms are not required to transfer *Schedule I* or *II* controlled substances, eg, transfer to a patient pursuant to a written prescription, administration to a patient by a registered practitioner, procurement by civil defense officials or delivery by a common carrier to a warehouse.

A pharmacy desiring official order forms may requisition the appropriate ones from the DEA. Such forms are numbered serially and issued with the name, address and registration number of the pharmacy, the authorized activity and authorized schedules with respect to that pharmacy. Each triplicate form is contained in a book of seven. Up to six books may be ordered at one time unless the pharmacy can show that it needs to exceed this limit. There is no charge for these forms.

The pharmacist must prepare and execute the order form in triplicate using a typewriter, pen or indelible pencil. One must enter the name and address of the supplier from whom the controlled substances are being ordered. Only one supplier may be listed on any one form. There are ten lines in the *item* section of each form. Each of the ten lines must contain a different drug or *item*. The number of lines completed must be totaled at the bottom. This is the total number of lines or items and not the total number of commercial containers ordered. The order form must be completed properly and have no material alterations or erasures or a distributor will be obligated to refuse the form, and may elect to do so in other cases as well, if the order form is not completed correctly.

The purchaser must sign his name and date the order form on the day he places the order. If his name is different from the authorized registrant, ie, if the pharmacist has been given a power of attorney to complete order forms, he also must include the name of the authorized registrant in the signature space. When the form is completed, the purchaser separates the three copies in the following manner: Copies 1 and 2 must be kept intact with the carbon in between them. These are sent in with the registrant's order to his supplier. Copy 3 is retained by the purchaser separately from other records. When the registrant receives the items he must record, on the retained Copy 3, the number of packages and the date such packages were received. A space is provided for this.

Power of Attorney

Any registered pharmacy may authorize one or more individuals, whether or not they are at the registered location of the pharmacy, to obtain and execute order forms on its behalf by executing a power of attorney for each such individual. This must be signed by the same person who signed the most recent application for registration or reregistration and must contain the signature of the individual being authorized to obtain and execute order forms. The power of attorney is not submitted to the DEA but must be retained by the pharmacy with the executed forms. It must be available for inspection together with the order form records. A power of attorney may be revoked at any time by filing a notice of revocation, signed by the individual who signed the most recent application for registration or reregistration and by filing it with the power of attorney being revoked. Many states have restrictions on who may sign order forms under a power of attorney. For example only a licensed health-care worker such as a pharmacist may be permitted to sign the forms under such restrictions.

Lost or Theft

When unfilled order forms are lost, the pharmacy must execute a new form 222 in triplicate. The pharmacy also must execute form 106 containing the serial number and date of the lost form, stating that the drugs in it were never received, and attach a copy of that statement to Copy 3 of the lost form. A copy of that statement also should be attached to Copies 1 and 2 of the newly executed order form.

Whenever any used or unused order forms are stolen or lost, upon discovery, the pharmacy must report this immediately to the Drug Enforcement Administration on form 106, stating the serial numbers of each form lost or stolen. If an entire book or books of order forms are lost or stolen, and the pharmacist is unable to state the serial numbers, he shall report, in lieu of the serial numbers, the date or approximate date of issuance. Lost or stolen order forms also should be reported to the state board of pharmacy or other state controlled substance agency.

Prescriptions

WHO MAY ISSUE—To issue a prescription an individual practitioner must be both (1) authorized to prescribe controlled substances by the jurisdiction, usually a state, where licensed to practice and (2) either registered or exempted from registration by the DEA.

PURPOSE OF ISSUE—A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment, or in legitimate and authorized research, is not a prescription within the meaning and intent of Section 309 of the CSA. The person knowingly dispensing such a purported prescription, as well as the person issuing it, will be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription by which a practitioner attempts to resupply an office stock or maintain drug-dependent individuals is not a valid prescription and, therefore, is void.

EXECUTION OF PRESCRIPTIONS—All prescriptions for controlled substances must be dated as of, and signed on, the day when issued and bear the full name and address of the patient and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as a check or legal document, eg, J. H. Smith or John H Smith. Where an oral order is not permitted, prescriptions must be executed using a typewriter, ink or an indelible pencil and must be signed manually by the practitioner. The prescription may be prepared by a secretary or agent for the signature of a practitioner, but the prescriber is responsible in case the prescription does not conform, in all essential respects, to the law and regulations.

Prescription orders that are written for controlled substances in Schedule II must be executed using a typewriter, ink or indelible pencil and must be signed by the practitioner issuing such prescription orders. In an emergency, Schedule II drugs may be dispensed upon an oral or facsimile (fax) authorization (see below). Prescription orders for controlled substances in Schedules III, IV, or V may be issued either orally or

in writing by a practitioner or his authorized agent. Federal law also permits facsimile transmission of Schedule III, IV, and V prescriptions.

EMERGENCY DISPENSING-SCHEDULE II—In the case of a bona fide emergency, as defined by the Secretary of Health and Human Services, a pharmacist may dispense a Schedule II controlled substance upon receiving oral or facsimile authorization of a prescriber provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2. The oral prescription order is reduced immediately to writing by the pharmacist and contain all information, except for the prescriber's signature.
3. If the prescriber is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a prescriber, by verifying his telephone number against that listed in the directory and other good-faith efforts to insure his identity.
4. Within 7 days after authorizing an emergency oral prescription order, the prescriber must cause a written prescription order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription order shall have written on its face *Authorization for Emergency Dispensing*. The written prescription order may be delivered in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist must attach this prescription order to the oral emergency prescription order that had been reduced to writing earlier. The pharmacist shall notify the nearest office of the DEA, if the prescriber fails to deliver a written prescription order to him. Failure of the pharmacist to do so shall void the authority conferred by the subsection to dispense without a written prescription order of a prescriber.

Definition of Emergency—For the purpose of authorizing an oral prescription order of a controlled substance listed in Schedule II of the *Controlled Substances Act,* the term *emergency situation* means those situations in which the prescriber determines that:

1. Immediate administration of the controlled substance is necessary for the proper treatment of the intended user.
2. No appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under Schedule II of the Act.
3. It is not reasonably possible for the prescriber to provide a written prescription order to be presented to the person dispensing the substance, prior to the dispensing.

TRANSMISSION OF PRESCRIPTION FACSIMILE–DEA regulations do permit facsimile transmission of prescriptions for medications in Schedules II-V directly from the prescriber to the pharmacy. However, this authorization is contingent upon such activity also be authorized under relevant state law.

Schedule II medications may be dispensed pursuant to faxed authorization only if the patient is [a] receiving home infusion treatment, [b] in a long-term care facility, or [c] a hospice patient. Detailed regulations regarding this are located at 21 CFR §1306.

With Schedule III and IV medications the transmitted facsimile may serve as authority for dispensing the controlled substance.

REFILLS AND RENEWALS—No prescription for a Schedule II controlled substance may be refilled; however, in certain limited circumstances, federal law allows the partial filling of Schedule II prescriptions. (See below) Prescriptions for Schedule III or IV controlled substances may be refilled if so authorized. These prescriptions may not be filled or refilled more than 6 months after the date issued or be refilled more than five times after the date issued. After five refills or after 6 months, the practitioner may renew the prescription. A renewal of any such prescription must be recorded on a new prescription blank and a new prescription number assigned. Oral prescriptions must be committed to writing by the pharmacist who receives the oral order.

Prescriptions for a Schedule V controlled substance may be refilled only as authorized by the prescribing practitioner on the prescription. If no such authorization is given, the prescription may not be refilled. However, if the item may be sold over the counter legally, the burden of determining the propriety of the sale will be upon the pharmacist.

Recording Refills—A pharmacist, after refilling a prescription for any controlled substance in Schedules III, IV, or V, must enter on the back of that prescription his initials, the date the prescription was refilled and the amount of drug dispensed. If the pharmacist merely initials and dates the back of the prescription, he shall be deemed to have dispensed a refill for the full face amount of the prescription.

Computerization—A pharmacy is permitted to use a data processing system as an alternative method for the storage and retrieval of prescription refill information for controlled substances in Schedules III and IV.

The computerized system must provide immediate retrieval, (via CRT display or hard-copy printout) of original prescription information for those prescriptions that currently are authorized for refilling. The information that readily must be retrievable must include, but is not limited to, data such as the original prescription number, date of issuance of the prescription by the practitioner, full name and address of the patient, practitioner's name and DEA registration number, name, strength, dosage form, quantity of the controlled substance prescribed, quantity dispensed if different from the quantity prescribed and the total number of refills authorized by the prescriber.

In addition, the system must provide immediate retrieval of the current refill history for Schedule III or IV controlled substance prescriptions that have been authorized for refills during the past 6 months and backup documentation to show that the refill information is correct. The backup documentation must be stored in a separate file at the pharmacy and maintained for a 2-year period from the dispensing date.

TRANSMITTAL OF ORAL AUTHORIZATION—A practitioner's nurse, or other member of the staff, cannot authorize the renewal of a prescription for a controlled substance that has been refilled five times or is 6-months old. The authority for prescribing controlled substances is vested only with the practitioner, and cannot be delegated to anyone else. However, nurses or staff members receiving calls from pharmacies regarding renewals may act as the practitioners agent and transmit the practitioners order. In other words, once the practitioner authorizes the order, an agent may communicate that order to the pharmacy.

PRACTITIONERS OFFICE STOCK—A pharmacist may not dispense a controlled substance on the order of a prescription that is issued by a practitioner and is intended for the office use of the practitioner. Distribution must be made on invoice and/or order form, if required.

LABEL REQUIREMENTS—The pharmacist filling a prescription for controlled substances listed in Schedules II, III, IV or V must affix to the package a label showing the pharmacy name and address, serial number and date of initial filling, name of the patient, name of the practitioner issuing the prescription, directions for use and cautionary statements, if any. This labeling requirement does not apply to institutionalized patients.

The label of any drug listed as a controlled substance in Schedules II, III, or IV of the CSA must, when dispensed to a patient, contain the following warning:

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

PARTIAL FILLING-*SCHEDULE II*—The partial filling of a *Schedule II* controlled substance prescription is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. The pharmacist may supply a portion of the quantity called for provided a notation of the quantity supplied is made on the face of the written

prescription (or written record of the emergency oral prescription). The remaining portion may be filled within 72 hr of the first dispensing; however, if the remaining portion is not, or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber. No further quantity may be supplied beyond the 72 hours except on a new prescription. However, the partial dispensing of a prescription for Schedule II controlled substances beyond the 72-hour limitation is permissible for patients in long-term care facilities.

A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is *terminally ill* or an *LTCF patient*. A prescription that is partially filled and does not contain the notation *terminally ill* or *LTCF patient* shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

PARTIAL FILLING-*SCHEDULE III* AND *IV*—Partial filling of prescriptions for controlled substances in Schedules III and IV is permitted if the pharmacist filling or refilling the prescription sets forth the quantity dispensed and his initials on the back of the prescription. In addition, the partial fillings may not exceed the total amount authorized in the prescription and the dispensing of all refills must be within the 6-month limit.

TRANSFERS—Prescriptions for Schedules III, IV, and V drugs may be transferred between pharmacies for refill purposes. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between differently owned pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

Write the word *VOID* on the face of the invalidated prescription.

Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

Record the date of the transfer and the name of the pharmacist transferring the information.

The pharmacist receiving the transferred prescription information is required to reduce to writing the following:

Write the word *transfer* on the face of the transferred prescription.

Provide all information required to be on a prescription pursuant to 21 CFR §1306.05 and include:

- Date of issuance of original prescription;
- Original number of refills authorized on original prescription;
- Date of original dispensing;
- Number of valid refills remaining and date(s) and locations of previous refill(s)
- Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
- Name of pharmacist who transferred the prescription;
- Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.

The original and transferred prescription(s) must be maintained for a period of 2 years from the date of last refill.

Distribution on Discontinuance or Transfer

Any registrant desiring to discontinue business activities altogether, or with respect to controlled substances (without transferring such business activities to another person), must return, for cancellation, the registrant's certificate of registration and any unexecuted order forms in his possession to the location as instructed by the DEA Field Office.

Any controlled substances in possession of the registrant may be disposed of in accordance with instructions under the section on drug Disposal (below).

Any registrant desiring to discontinue business activities altogether, or with respect to controlled substances (by transferring such business activities to another person), must submit in person or by registered or certified mail, return receipt requested, to the nearest DEA office at least 14 days in advance of the date of the proposed transfer:

1. The name, address and registration number of the pharmacy discontinuing business.
2. The name, address and registration number of the person acquiring the pharmacy.
3. Whether the business activities will be continued at the location registered by the person discontinuing business or moved to another location (if the latter, the address of the new location should be listed).
4. The date on which the transfer of controlled substances will occur.

On the day of transfer a complete inventory of all controlled substances being transferred must be taken in accordance with 21 CFR §§1304.11–1304.19. This inventory serves as the final inventory of the registrant transferor and the initial inventory for the registrant transferee. A copy of the inventory must be included in the records of each person. It is not necessary to file a copy with the DEA unless requested by the Regional Director. Transfers of any Schedule II substances require the use of order form 222.

On the day of transfer all records required to be kept by the registrant transferor, with reference to the controlled substances being transferred, are to be transferred to the registrant transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

Miscellaneous Requirements

SECURITY—Pharmacies must keep Schedules II, III, IV, and V controlled substances in a locked cabinet or dispersed throughout the noncontrolled stock in such a manner as to deter theft. A combination of these two methods is permissible. For example, many pharmacies lock Schedule II drugs in a drawer or cabinet while dispersing Schedule III, IV, and V drugs alphabetically throughout the nonscheduled drug inventory.

DISPOSAL—A pharmacy wishing to dispose of any excess or undesired stock of controlled substances must contact its nearest DEA Office and request the necessary form (DEA-41). A cover letter from the pharmacy must be attached to the report

stating that the controlled substances are not desired and the pharmacy wishes to dispose of them.

Upon the receipt of the letter from the pharmacy, one of four courses of action will be chosen by the DEA; this will be stated in letter form, attached to the original copy of the DEA-41 form and returned to the pharmacy.

The four courses of action are:

1. The drugs may be destroyed by two responsible parties employed or acting on behalf of the registrant. This course of action will be used when there are factors that preclude an on-the-site destruction witnessed by DEA personnel, such as the firms history of compliance and the abuse potential of the drugs involved.
2. The excess or undesired stocks of controlled substances should be forwarded to the appropriate state agency for destruction. In lieu of actual surrender to the state agency, destructions witnessed by state personnel are acceptable.
3. The substances should be held until DEA personnel arrive at a mutually convenient time to witness their destruction. DEA personnel will date and sign the reports or forms after witnessing the destruction.
4. The substances should be forwarded to the DEA Field Office that serves the area in which the registrant is located. Upon receipt of the substances, the DEA Field Office will verify the actual substance submitted. If errors are found, a corrected form must be prepared and the registrant duly notified. The original form will be returned to the registrant.

DRUG THEFT—Any pharmacy involved in loss of controlled substances must notify the nearest DEA office of the theft or significant loss upon discovery. The pharmacy must make a report regarding the loss or theft by completing DEA-106 form. Such reports shall contain the following information: name and address of firm, DEA registration number, date of theft, local police department notified, type of theft, listing of symbols or cost code used by the pharmacy in marking containers and listing of the controlled substances missing. Four copies of this report should be made. The pharmacy should keep the original copy for its records and forward two copies to the nearest DEA office. Most states require a copy be sent to the Board of Pharmacy as well. Local ordinances may require notification be provided to the appropriate police authority.

Mailing

Title 39 of the Code of Federal Regulations contains the US Postal Service Regulations regarding nonmailable matter and special mailing rules for various articles and substances. Controlled substances may be mailed to a patient's home if they are sent in a reasonable quantity intended for personal use. Controlled substances may also be transmitted in the mail between persons registered with the DEA or between persons who are exempted from registration such as military, law enforcement or civil defense personnel in the performance of their official duties.

Parcels containing controlled substances must be prepared and packaged for mailing in accordance with the regulations set forth in 39 CFR §124. Regular mail may be used for these parcels.

DEA Inspections

The CSA specifically requires an administrative search warrant for most nonconsentual DEA inspections. Therefore, for an agent of the DEA to enter any DEA-registered premise, the agent must state the purpose for the inspection and present appropriate identification. In addition, the agent must either obtain an informed consent from the registrant, secure an administrative inspection warrant or fit into one of the special exceptions set forth in the statute. The Act recognizes certain exigent circumstances in which an inspection warrant is not required such as the initial registration inspection, inspection of mobile vehicles, emergency situations or dangerous health situations.

TORT LAW

Tort law is that subdivision of the civil law that deals with relationships between individuals created by law rather than by the parties themselves. A tort is a private injury or wrong arising from a breach of a duty created by law. It may involve harm to a person, as well as damage to property, caused negligently or intentionally.

Negligent torts are those that arise because the tort-feasor (the person doing the act) breached a duty or level of care expected of him. Intentional torts are those that the actor does purposefully or with an intention of achieving the desired result.

NEGLIGENCE

Negligence has been defined as the omission to do something that a reasonable person, guided by those ordinary considerations that ordinarily regulate human affairs, would do, or the doing of something that a reasonable and prudent individual would not do. As is obvious from this statement, one can be negligent either by doing or failing to do something. A more direct description is that negligence occurs when a person under a duty to another to use due care breaches that duty, resulting in the other party suffering damages as a direct result of that breach. Using this statement as a point of departure, each element of negligence shall be considered in order.

In the normal situation, the existence of a legal duty will be created by the activities of other persons. The jury will be charged with determining what the fictional reasonable and prudent person mentioned above would have done under the circumstances. To do this, the jurors receive testimony from a number of people to determine what they would have done. The jury then decides what the reasonable and prudent person would have done, and that creates the existence of a legal duty. In the ordinary circumstance, the duty will be created by the actions of laymen. Yet, when pharmacists are acting within the scope of their professional calling, their performance will be evaluated in light of what professional peers would have done. Generally, pharmacists will be held liable for negligence only if they departed from the practice of other reputable practitioners of pharmacy. For the general practitioner of pharmacy, the reference standard to be used is other general practitioners of pharmacy. While there may be individuals within the profession with greater knowledge or skill in a particular area, eg, the detection of drug interactions, the general practitioner of pharmacy will be required to discharge only that amount of skill exhibited by peers, not the experts.

Nonetheless, this does not mean that the members of a profession can lag unduly in adopting new methods or procedures. A number of courts have ruled that while in the usual case the law will recognize the standard of care established by the members of the trade, industry or profession, the entire group may

have lagged in adopting an innovation. In such cases the courts will not be bound by the standards used by the profession, but rather the court will establish the standard of care to be exercised under the circumstance.

The concept of duty is not fixed but constantly evolving and changing. An example of this is the doctrine of the pharmacists duty to consult with patients about proper drug use. Through a number of cases decided during the past 40 years, various courts have ruled that the pharmacist does have the legal duty to instruct the patient about safe and proper use of medication. This duty is owed to the patient, and should a pharmacist fail to fulfill this responsibility, he may be held answerable in court.

A second requirement for the existence of negligence is damage. The party who is alleging negligence must prove that he suffered legally sufficient damages. Generally, these damages must be substantial, not slight, eg, a temporary skin rash would be insufficient.

The party bringing the suit next must prove that the damages were the direct result of the pharmacist's breach of a legal duty. This may be quite difficult. In some cases it is known that the patient suffered legally cognizable damages, but it cannot be established by a preponderance of the evidence that damages flowed directly from a breach of duty.

The plaintiff has the burden of establishing those first three elements. Once they have been shown in a legally sufficient manner, the pharmacist has a number of defenses that may be available to result in a verdict of not liable. One such defense may be contributory negligence. That is the rule that a person who has in some way contributed to his own injury will not be entitled to recover. In a majority of states the rule is one of comparative negligence. While contributory negligence is a total bar to recovery by the plaintiff, in states that follow the comparative negligence rule the jury engages in an allocation of responsibility and bases the amount of damages awarded on the parties' relative contributions to the injury.

Another defense that the pharmacist has is known as voluntary assumption of the risk. This is the doctrine that states that a patient who understands the risk inherent in a transaction or procedure, and who voluntarily gives his informed consent to assume the risk, cannot sue to recover for damages that occur from the defined risk. An unresolved issue is whether presenting a patient with a patient package insert or leaflet that outlines the potential hazards of a certain medication results in informed consent and, consequently, voluntary assumption of the risk. Generally the procedure required for informed consent is a lengthy discussion covering the alternatives and the relative incidence of the various risks. This point probably will be litigated in the future.

Another defense that may be available to the pharmacist is the statute of limitations. The legislature imposes a time limit on filing suits for negligence. Generally, the statute of limitations in this area is 2 years, meaning that the suit must be filed within 2 years of the time of reasonable discovery of the damage. Note, however, that a person may suffer some damage and not be able to discover it until some time long after the incident, as in the diethylstilbestrol cases that were litigated. In those cases, the injured parties, daughters of women who took the drug during pregnancy, developed precancerous lesions 15 to 20 years after the drug was consumed. The statute of limitations would begin to run at the time of reasonable discovery, not the time when the drug was dispensed.

The issue of liability of the pharmacist for negligence has been raised in conjunction with a number of developments and innovations in pharmacy practice in recent years. A consideration of the application of the above discussion to these developments is in order. Of necessity, a detailed discussion of these areas is impossible in this chapter. The professional literature contains a number of articles that address these issues in detail, and the interested reader may wish to refer to those.

Patient medication records (PMRs) have been adopted widely in community pharmacy practice. This is largely attributable to the requirements of federal legislation adopted during 1990 known as OBRA '90. This mandated that pharmacists maintain records of medication dispensed to Medicaid patients and offer to consult with those patients at the time of dispensing. Most states expanded this dictate to include all patients.

Some states have mandated by statute that PMR's be maintained. In such a case a special rule of negligence may apply. The doctrine of negligence *per se* is that where a statute mandates that a certain activity be performed to protect an identifiable group of people from an identifiable type of harm and one does not do it, that fact and the statute may be introduced into evidence at trial to establish the duty and breach of it. This facilitates the case of the plaintiff. Note that this rule of negligence per se is applicable only in the case where the activity is required by a statute. A regulation of a board of pharmacy, for example, would not suffice to establish the duty in and of itself. Nonetheless, such a regulation could be introduced into evidence to buttress the testimony of pharmacists on this point.

All states have now enacted drug product selection legislation that frees the pharmacist from the restrictions of the antisubstitution laws, enabling him to use his professional judgment in selecting products to be dispensed on certain prescriptions. Naturally, because these statutes give pharmacists greater responsibility, they increase their potential liability. However, so long as they discharge this responsibility in a prudent fashion, the potential for legal entanglements will be minimal. In some states the government has provided guidance for the pharmacist in the form of a positive formulary, designating those drugs for which interchange is permissible. The FDA also has published such a list. In the case of pharmacists who selects a product from the formulary for brand interchange, they then should have a fairly good defense based on a reliance on such governmental lists.

There has not been a successful law suit based on negligence in drug product selection. This even more is significant in light of the fact that pharmacists have been selecting extensively the brand of product to be dispensed for years pursuant to prescriptions written using generic terminology.

Pharmacists should not be concerned unduly with their potential liability exposure as they move into new areas of practice. So long as they are competent to assume the new responsibility and perform the task in a diligent fashion, their liability problems should continue to be minimal.

INTENTIONAL TORTS

The law distinguishes intentional acts from those that are negligent or careless in nature. Intentional wrongs to persons or property involve such torts as assault, battery, and false imprisonment. At the onset, it is important to distinguish between a tort and a crime. The same act may give rise, but not necessarily, to both a tort and a crime. The criminal violation will be prosecuted in the name of the state, but the same act also may result in a separate civil lawsuit between the individuals involved. Quite naturally, intentional torts require a showing of the element of intent, but it is not necessary to demonstrate harmful or hostile design.

ASSAULT—An intentional act, other than the mere speaking of words, which places another individual in apprehension of harmful or offensive contact is an assault. The danger must be of an immediate nature and the individual must be aware of the defendant's apparent intent. Bodily contact is not necessary to establish a claim for relief and, thus, damages for an assault alone are likely to be nominal.

BATTERY—A battery is defined as an intentional act that, directly or indirectly, is the cause of harmful or offensive contact with another person. Assault and battery are separate torts but very often will appear together. A person may be liable for battery even though he intended only to play a practical joke or intended to confer a benefit on the other party. In

patient-care settings it is possible for a cause of action based upon battery to arise during unauthorized surgical operations.

A number of defenses exist for the torts of assault and battery. An individual who consents to physical contact may not claim a battery successfully. Consent to physical contact may be expressed or implied in nature. Consent to surgical procedures also will negate an action based upon assault and battery, but the consent obtained from the patient should be an informed consent, ie, the patient must have a sufficient understanding of that to which he is consenting. The use of investigational drugs also will require informed consent.

DEFAMATION—Defamation is a false communication that injures the good name or reputation of another. Defamatory statements that are communicated in a permanent form such as the written word, pictures, statues, etc, are called libel. Communications that are more transient in nature such as the spoken word or a gesture are termed slander.

A defamatory statement, either libel or slander, must be communicated to a third person, ie, one other than the person defamed. The statement will be deemed defamatory if it harms the reputation of another or exposes an individual to scorn, ridicule or contempt.

Because of its historical background, special rules have been developed regarding the showing of actual damages in a case of defamation. Almost any action based upon libel will be able to proceed regardless of whether actual monetary damages have been suffered by the plaintiff. Most courts have held that special harm or actual dollar loss must be shown in cases of slander unless the slander fits into established exceptions.

As is true with the other tort situations, several defenses exist to actions for libel and slander. Truth is always a defense to actions based upon defamation of character. The burden is on the defendant, in a defamation action, to prove that the statement was true.

Certain individuals are said to be privileged to defame, or free from liability for slander or libel. An absolute privilege exists for defamatory remarks made during the course of judicial, legislative or executive proceedings. Many states have enacted statutes that provide immunity from civil lawsuits for pharmacists and other health-care professionals who file charges or present evidence against another member of their profession regarding alleged incompetence or gross misconduct. The immunity often is extended to claims filed with a board of pharmacy or with the regularly constituted review committee of a pharmaceutical society or hospital. In addition, most states also will provide immunity for those individuals, including pharmacists, who are required to report suspected cases of child abuse.

Pharmacists may subject themselves to litigation for careless remarks made about patients or other health-care professionals in the community. Oral statements that accuse another of improper conduct of a business or unprofessionalism are slanderous per se, and subject the maker to liability without the necessity of showing actual damages. A pharmacist's untrue imputation of certain loathsome diseases also could result in litigation based upon slander *per se*.

RIGHT TO PRIVACY—A relatively new tort is invasion of another's privacy. The oral or written dissemination of private information about an individual, even if true, may give rise to an action based on invasion of privacy. Information contained in patient medication records or prescriptions is confidential in nature and should be released only with the consent of the patient or pursuant to a warrant, subpoena or other statutory authority. The invasion must be objectionable and not too trifling. Truth is not a defense to this type of action nor is the absence of malice.

The right to privacy often conflicts with the state's authority to exercise its power to protect the public health, safety and welfare, known as the "police power." An example of this right was the subject of a lawsuit. Certain individuals in the state of New York filed a lawsuit against that state for the inclusion of prescription information in a computerized data bank. The plaintiffs alleged that the inclusion of the names of patients, who receive Schedule II prescription drugs, in a centralized computer file violated their rights to privacy. The case eventually was decided by the US Supreme Court, which ruled that the New York statute did not impair any privacy interest. The court found that the requirement was a reasonable exercise of the state's police powers. This decision led to the implementation of triplicate prescription requirements for Schedule II prescriptions now in place in a number of states.

Liability based upon the tortious invasion of privacy should not be confused with the constitutional right of privacy that protects an individual from unconstitutional intrusions by government. The constitutional right of privacy increasingly is being used by courts as the basis for allowing health-care decisions to be made by patients.

Recent statutory law adopted by the federal congress and implemented through regulations promulgated by various federal agencies codifies the common law rights of privacy and confidentiality with regards to medical records. The Health Insurance Portability and Accountability Act (HIPAA) was signed into law on August 21, 1996. It took the federal agencies charged with enforcement of the statutes several years to adopt regulations that explain the rights and duties of those affected by the law. The final rule can be found at www.hhs.gov/ocr/hipaa/finalreg.html. Questions and answers from OCR can be found at www.hhs.gov/ocr/hipaa/privacy.html.

Most of the regulations took effect in April 2003. The regulations and statutes include significant new protections for individuals who have preexisting medical conditions or might suffer discrimination in health coverage based on a factor that relates to the individual's health. This part of HIPAA, Title I (Health Care Access, Portability, and Renewability) amends the Employee Retirement Income Security Act of 1974 (ERISA). Portions of the Internal Revenue Code and the Public Health Service Act are also affected. The new rules place requirements on employer-sponsored group health plans, insurance companies, and health maintenance organizations (HMOs). In addition, these HIPAA provisions require that certain employers and individuals must guarantee the renewability and availability of health coverage and protect many workers who lose health coverage by providing better access to individual health insurance coverage.

Title II (Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform) is intended to reduce the costs and administrative burdens of health care by replacing the many non-standard formats currently used nationally, with a single set of electronic standards that would be used throughout the health care industry.

Title II, Subtitle F (Administrative Simplification) presents implications for all health providers. The goals of these HIPAA regulations are to improve the efficiency and effectiveness of health care, to improve the Medicaid and Medicare programs, to control fraud and abuse with regard to health plans, and to simplify administrative aspects of health care. According to the federal Department of Health and Human Services that oversees this part of the regulations, the rules set forth standards for each of the following areas:

- Electronic Data Interchange (EDI) for Claims/Transaction Administration. The standards relate to claims data forms and attachments; plan enrollment and disenrollment; premium payments; claims status; referral certification and authorization. The law mandates the use of national standards for electronic exchange of health care data—to help reduce the volume of paperwork and facilitate efficient processing of health care claims.
- National Unique Identifiers. The standards will facilitate the creation and adoption of the use of a national identification system for health care providers, payers (or plans), and employers. Each provider will be assigned its own unique identifier to be used for all transactions.
- Standardized Code Sets. These standards specify the medical and administrative code sets for diagnoses, procedures, pharmaceuticals and other health care data Standardized codes will streamline the processing of health care claims/transactions.

- Security. These standards establish measures that ensure the security of health care information maintained by health care providers, health plans, hospitals, health insurers, and health care clearinghouses.
- Electronic Signatures. The standards specify procedures for electronic transmission and authentication of signatures.
- Transfer of Information among Health Plans. Set standards for transferring across health plans the data elements needed for coordination of benefits and processing of claims.
- Privacy. The law stipulates the standards for privacy of individually identifiable medical and health information.

It is the privacy rights that will likely have the most impact on the practice of pharmacy. While pharmacists have always respected the confidentiality duties imbedded in the profession's Code of Ethics, HIPAA sets forth specific regulatory mandates about what kind of information may or must be disclosed and the entities to whom the information may or must be disclosed. In most instances pharmacies will have to obtain prior consent, or at least make a good faith effort, from patients before releasing any "protected health information" (PHI) for "treatment, payment and health care operations" (TPO). Providers are also required to give notice to patients about their privacy rights within the institution or location where the information is stored.

The HIPAA law is complicated and extensive. Pharmacists and pharmacy interns as well as all technicians and others who may have access to PHI data should be well versed in the mandates of the law. Breaches of duties mandated by these regulations carry significant and severe sanctions that could result in heavy fines and, in some circumstances, prison time. Prevention of even innocent or accidental disclosures requires all providers to invest time in learning about HIPAA rules and regulations.

COMMERCIAL LAW

The pharmacist should understand the general principles of the law of contracts to realize the responsibility he undertakes when entering a business obligation or an employment relationship. The law of advertising has a direct bearing on the day-to-day activities of pharmacists, both as professionals and as consumers. Questions concerning ownership of prescriptions and application of the federal antitrust laws to the pharmacist's relationships with third-party prescription program administrators may be encountered frequently by pharmacists.

It is impossible in a general treatise of this kind to describe in detail the legal subjects on which the pharmacist should keep posted. All that can be attempted is a general outline.

Because the US is composed of 50 individual jurisdictions, the law may vary from state to state. Nonetheless, it is possible to provide an overview of the law applicable to pharmacists in the operation of their practices. To a certain extent the laws applicable to commercial activities have been rendered uniform in most of the states through enactment of the Uniform Commercial Code (UCC); it was drafted in the early part of the last century by a group of noted legal scholars to bring some order out of the patchwork quilt of states laws applicable to business affairs. Enacted nearly intact in almost all states, the UCC has done a great deal to facilitate the flow of commerce among the states.

CONTRACT LAW

A contract may be defined as a promise or set of promises for the breach of which the law provides a remedy, or the performance of which the law, in some way, recognizes as a duty. Yet, the law requires much more for a contract to result than a mere exchange of promises. Perhaps a more complete definition of a contract is an agreement between legally competent individuals based on genuine assent of the parties and supported by consideration, made for a lawful purpose and in the form required by law, if any. This definition provides a framework for discussion of these elements of a contract.

The agreement between the parties, which forms a basis for the contract, is composed of both an offer and an acceptance. For an offer to be legally sufficient the party making it must have the intention of entering into an agreement with the other party. For example, an offer made in jest would not indicate the required contractual intent. Moreover, an invitation to make an offer or an offer to negotiate is not a legally cognizable offer for it, too, lacks contractual intent. Advertisements are not an offer of sale but, rather, an indication of willingness to consider an offer made by the potential purchaser. The offer must be communicated to the other party prior to acceptance for an agreement to result.

An additional requirement for an offer is that it be definite. This means that the offer must be detailed sufficiently to provide a basis for the agreement. Courts will not add an essential element to an offer, agreement or contract. At the time of acceptance the offer must still be viable. An offer may be withdrawn prior to acceptance, in the absence of an option having been granted. An option is a binding promise to keep an offer open for a stated period of time. If an option exists, the person making the offer may not withdraw it until the option period has expired. An offer also may be terminated by rejection or by lapse of a period of time stated in the offer.

Acceptance is assent by the recipient of the offer to the terms of the offer. No particular form of acceptance is required, eg, in writing, unless specified in the offer. However, the acceptance must be absolute and unconditional. Any variation of the terms or conditions in the acceptance will result in rejection of the offer.

The parties entering into a contract must be competent legally to do so. This means that each party must have contractual capacity. Minors generally lack contractual capacity and contracts they enter into are subject to their avoidance. The other party may not be able to enforce the contract against a minor because the contract can be voided by the minor due to his lack of contractual capacity. However, parents may be liable under contract theory for necessaries provided to their minor dependents. Necessaries are those things relating to the health, education or comfort of the minor. Prescription drugs probably would fall within this category and a pharmacist providing them to a minor would, in all likelihood, be able to collect the reasonable value of the medication from the parents.

Insane persons also may be under a contractual incapacity. If a person is so mentally deranged as not to know that a contract is being made or does not understand the consequences of what he is doing, the contract may be voided on recovering sanity. The same is true of a person who is so intoxicated as to be unaware that he is making a contract.

The requirement of genuineness of assent relates to mistake, misrepresentation, concealment, fraud or exercise of undue influence or duress over one of the parties. Each of these activities has a different effect on the enforceability of the contract, and a full discussion of each is beyond the scope of this

discussion. Nonetheless, the pharmacist should be aware that each bears a possibility for interference with the enforceability of the contract.

Consideration is essential for a contract to be enforceable. It may be defined as an act or forbearance, or the promise of either, which is offered by one party to an agreement and accepted by the other as an inducement to the others' act or promise. When you have given consideration you have agreed to do something that you were not bound to do or you have agreed to refrain from doing that which you have the right to do.

Consideration must be provided by both parties to the contract. If only one is providing consideration, no contract results. It is a mere gift and not legally enforceable.

Ordinarily, courts will not inquire into the adequacy of the consideration exchanged by the parties. The fact that the amount of consideration may appear to be small in the eyes of one person does not necessarily mean that the amount is inadequate or inappropriate. Hence, if some consideration is provided, the contract will be enforceable. One sometimes hears of employment contracts for a dollar-a-year person, as in the case of a wealthy individual working for the government or a charity. Such an employment contract will be enforceable even though the value of a person's services will be much greater than the amount of compensation provided.

For a contract to be enforceable it must be made for a lawful purpose, and this must be achieved in a lawful manner. If this were not so, the courts might be placed in the uncomfortable situation of compelling one party to a contract to commit a crime to have the contract performed. An example of this doctrine is the rule that contracts of an unlicensed operator cannot be enforced. Hence, one who practices pharmacy without being licensed to do so, is likely to be charged with the crime of violating the state pharmacy practice act, and also will be unable to enforce the contracts he made while practicing pharmacy, ie, he will be unable to sue to collect for his services.

Contracts for the sale of prohibited articles also are unenforceable. The sale of a prescription drug without valid authorization would fall in this category. Contracts that unreasonably restrain trade also are unlawful and, consequently, unenforceable. When a pharmacist sells a pharmacy it is customary for the purchaser to request that the contract contain a noncompetition clause that bans the seller from owning a pharmacy within certain geographic and time limits. The purpose is to prevent the seller from selling and immediately opening up a pharmacy, attracting all his prior patients. If such a clause is drafted to include too large a geographic area, or for too long a time, it will be unenforceable due to its restraint on trade. However, note that only contracts that unreasonably restrain trade are unlawful. Consequently, if the noncompetition clause is drafted carefully it will be enforceable. Such provisions increasingly are being seen in employment contracts for pharmacists as well.

Most contracts are not required to be in writing to be enforceable. Obviously, though, it is much easier to prove the existence of and enforce one that is written. Each state has a Statute of Frauds that dictates which types of contracts must be in writing to be enforceable. Generally, contracts for creation of an interest in land, which run for more than 1 year, must be in writing. Those that involve employment for more than 1 year and those that are for sale of goods of a value of $500 or more also must be in writing. Each state may have additional categories, and the minimum limits just mentioned may vary from state to state.

When a contract is breached, the nonbreaching party has the right to bring legal action against the breaching party to recover that sum of money that will place him in the same position as he would have been had the contract been performed. There are a number of types of damages that may be assessed against the breaching party. Nominal damages are awarded when the injured party did not suffer an actual loss. They usually are of minimal magnitude. Compensatory damages are those that are designed to compensate the injured party for his loss. Liquidated damages also may be encountered; these are those for which provision was made in the contract itself by the contracting parties when they entered into the agreement. Liquidated-damage clauses generally will be enforced if the amount specified is not excessive and if the contract is of such a nature that it would be difficult to determine the actual amount of damages.

The UCC addresses a special category of contracts known as sales. A sale may be defined as a transaction wherein a seller transfers title for personal property to a buyer for a price (consideration).

Of particular interest to pharmacists is the law applicable to warranties in sales transactions. A warranty is an assurance or guarantee, by a seller, that the goods sold are, or will be, as represented. Warranties may be divided into two general categories: express and implied.

Express warranties are those based on an affirmation of fact or promise relating to the goods, whereas an implied warranty is one that exists by virtue of law, not because of an express statement by the seller. Express warranties may be made about almost any attribute of the goods, but the warranties implied by law are more limited in scope. One such implied warranty is the implied warranty of merchantability. It is seen only with sellers who usually deal in goods of that type and means that the goods provided must be fit for the ordinary purposes for which such goods are used.

The implied warranty of fitness for a particular purpose is present when the seller knows the use to which the goods will be put and has reason to know that the buyer is relying on the sellers' skill and judgment to select suitable goods for the purpose. These implied warranties automatically are present in a transaction without any action on the part of the seller to place them there. They can be removed from the sale but require a specific type of action.

Goods sold *as is* are sold with no implied warranties. To remove the implied warranty of merchantability those specific words must be used, but the disclaimer can be made orally. Removal of the implied warranty of fitness for a particular purpose can be done only by written words, but no special language is required. However, the statement that the warranty is absent must be conspicuous. Naturally, express warranties can be kept out of a transaction merely by not making an express statement about the goods.

PRESCRIPTION OWNERSHIP

A question arises from time to time regarding ownership of the prescription. When it is issued by the prescriber, the patient gains ownership of the document. When it is transferred to the pharmacist for purposes of dispensing the medication, ownership then passes to the pharmacist, pursuant to the contract between the pharmacist and the patient. However, the patient retains certain rights with regard to the document.

While the document itself is the property of the pharmacist and must be retained by law for recordkeeping purposes, the patient has the legal right to refills that the law and the prescriber have authorized. Moreover, the patient may have a right to obtain a copy of the prescription, except in those cases where the giving of a copy is prohibited or limited. For example, in some states copies provided to patients must be marked with a statement indicating that the prescription copy is provided for informational use only and cannot serve as the basis for dispensing medication.

In some situations, such as with prescriptions that are suspected to be forgeries or those that bear the potential for a harmful drug interaction, the pharmacist may wish to deface or retain the document even though the medication will not be dispensed. Such action does, however, present the risk that the prescription might be legitimate or that the drug interaction would not result. In such a case a suit for damages that resulted from his action may result because he does not own the document. Should the pharmacist receive a prescription that he

does not intend to follow, the problem should be handled through communication with either the patient or the prescriber, not by defacing the document that he does not own.

Because the pharmacist owns the prescription records reflecting medication that he has dispensed, they are assets of the pharmacy that may be transferred on the cessation of the practice. Prescription records should be maintained for a minimum of 5 years, the statute of limitations of the FD&C Act.

ANTITRUST AND PRESCRIPTION INSURANCE PLANS

Third-party prescription drug insurance programs have burgeoned in the US in recent years, and a substantial portion of Americans now have insurance coverage for their medication expenditures. This brief discussion shall center on the legal problems associated with private third-party prescription plans, not those administered by governmental agencies.

In the typical third-party plan, the pharmacy owner receives an offer to participate in the insurance plan and a contract to be signed. This usually provides for reimbursement of the pharmacist's cost in acquiring the drug product dispensed and the addition of a dispensing fee of fixed magnitude. Other provisions may relate to what products are compensable, eg, many plans will not pay for nonprescription medication, or limit quantities that may be dispensed. Provisions also are seen dealing with claims submission, services the pharmacist is required to provide and access to the pharmacists financial records for purposes of program accountability. Often, the offer to participate in such plans is distributed to many pharmacies in an area for the insurer to offer the subscriber maximum flexibility in selecting a pharmacist with whom to deal or to offer enrollees a variety of options for service.

When such offers to participate are disseminated widely, the possibility of the offers being discussed collectively arises. This may run afoul of the Sherman Antitrust Act of 1890, which provides that

> Every contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States . . . is declared to be illegal.

Thus, collective action by pharmacists to withhold entering into contracts with the insurer because the professional fee is too low or because other provisions of the contract are objectionable may violate this federal statute. Individual penalties may be assessed under this statute. Applicability of this statute to pharmacy was affirmed in the 1962 case of *US v. Northern California Pharmaceutical Association.* In that case the activity that brought federal sanctions was publication of a recommended fee schedule in an attempt to encourage the adoption of uniform pricing.

With prescription drug insurance plans, the activity that may violate the statute is collective action by pharmacists (combination . . . or conspiracy) to withhold their participation (restrain trade) in the insurance plan until the contract is worded in terms acceptable to them as a group. While such action is legally permissible if done by an individual acting alone, collective action toward the same end would be unlawful.

In addition to the criminal penalties mentioned above, the patients who are injured by such unlawful activity may bring a civil suit to recover damages. Of importance is the fact that in an antitrust claim, the award is for treble damages, ie, the amount of damages is calculated and then multiplied by three to yield the amount the party engaging in the unlawful activity must pay.

ADVERTISING

The regulation of the advertising and promotion of drugs on an interstate commerce basis is a shared commitment of numerous federal agencies, including the Postal Service, FCC, FTC and FDA. The latter two bear the brunt of the responsibility. The FTC is involved actively in the regulation of OTC drug advertising while the FDA exercises its jurisdiction primarily over matters involving the labeling and advertising of prescription drugs. There is, however, considerable overlap between the two agencies because of statutory definitions and by mutual agreement.

States can also regulate drug advertising. However, state limitations imposed primarily by budget give these controls much less effect in comparison to federal activities. The pharmacist, therefore, will be bound primarily by federal restrictions in the area of advertising.

FEDERAL TRADE COMMISSION—The FTC derives its authority over advertising in general and drug advertising in particular from the Federal Trade Commission Act. Section 5 of that statute provides

> "Unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce are hereby declared unlawful."

In addition, Section 12 makes it unlawful to disseminate a false advertisement for the purpose of inducing, or that is likely to induce, the purchase of food, drugs, devices or cosmetics. The Wheeler-Lea Amendment to the Act defines *false advertising* as follows:

> "The term 'false advertisement' means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) representations made or suggested by statement, word, design, device, sound or any combination thereof, and also the extent to which the advertisement fails to reveal facts, material in the light of such representations or material with respect to consequences, which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual."

Based on the above provision, the FTC has authority to move against false advertisements for OTC drug products and also advertisements that operate in an unfair or deceptive way. The Commission can use its powers by either promulgating a Trade Regulation Rule or by issuing a complaint against an advertiser when there is reason to believe that the law has been violated.

In most cases in which a complaint is issued by the FTC, the advertiser is willing to enter into an agreement to cease and desist from the use of the acts and practices being investigated. Such an agreement is for settlement purposes only, and it does not constitute an admission by the advertiser that the law has been violated. The FTC has been successful in obtaining consent agreements from a number of corporations, including those practicing pharmacy, which require all items advertised to be available for sale readily at or below the advertised price. Displays of advertised items must be marked conspicuously by a sign or other means disclosing that the item is *as advertised* or *on sale*. In addition, many of the consent orders provide that if the advertised item is unavailable, the consumer may either be given a rain-check or be allowed to purchase a similar product of equal or better quality at or below the advertised price. Phrases such as *regular price* or *manufacturers suggested list price* and words of similar import should not be used unless they can be documented. Whenever a *free*, *2-for-1*, *half price sale*, *1¢ sale* or similar type of offer is made, all of its terms and conditions to the consumer should be made clear at the outset.

If the parties are unable to agree to a consent order, an FTC complaint will result in a trial before an administrative law judge who will determine if a violation has occurred and, if so, the appropriate remedies. This decision may be appealed by either party to the full Commission sitting as an appellate body. Thereafter, review can be pursued to a US Court of Appeals and possibly to the US Supreme Court. A case involving a well-known mouthwash followed just such a procedure. An administrative law judge ruled that the advertisements for the mouthwash had made claims that were false, misleading and deceptive. Under the administrative ruling, the manufacturer was ordered to stop making such claims and also to institute corrective advertising to inform consumers that the product would not help prevent colds or sore throats or lessen their

severity. This ruling was upheld by the full Commission and by a federal appeals court, and the US Supreme Court rejected the manufacturer's petition for further review.

In another action, a 1975 FTC complaint alleging false and misleading advertising included a pharmacy as a defendant even though the ads were prepared by the manufacturer's advertising agency. The administrative law judge held that although the retailer did not know whether the ad claims were true or false, it was not relieved of responsibility simply because the ad copy and content were prepared by others. The full FTC bench ruled that the Act does not exempt the seller of a product from investigating the truthfulness of claims set forth over the retailers own name. The lack of knowledge of the falsity of the ad was found not to be a defense.

FOOD AND DRUG ADMINISTRATION—Prior to 1962 the FTC was vested with sole authority for regulating the advertising of drugs. The Kefauver-Harris Amendments of 1962 to the FD&C Act gave the FDA control over prescription drug advertising. Thus, the FDA regulates the labeling of prescription drugs and their advertising as well. All advertisements and other descriptive printed matter issued by the manufacturer must include a statement of the established name, quantitative formula and other information such as side effects, contraindications and effectiveness.

The FDA's authority over the regulation of prescription drug advertising extends to advertising directed to professionals and also to that presented to the lay public. Up until 1997, the FDA required manufacturers to include a *brief summary* of important information health-care professionals and patients need about use of prescription drugs in any advertising. This rule effectively banned any television or radio advertising. In late 1997 the FDA changed its policy and began permitting direct to consumer advertising of prescription drugs on broadcast media as long as the manufacturer includes a *major statement* that discloses significant risks associated with the drugs use. The new approach presumes the advertising is truthful and not misleading. Under the proposed guidelines broadcast advertising will have to include:

Providing a toll-free telephone number for consumers to access detailed product information in a timely fashion—either by mail, fax or phone.

Referring to direct-to-consumer print ads that contain a brief summary of the product labeling. Reference to brochures containing similar information would also be acceptable if the brochures were distributed in a variety of publicly available sites such as doctors' offices, libraries and stores.

Providing an Internet web page (URL) address with full access to the approved product labeling.

Containing a statement that pharmacists, and/or physicians and/or veterinarians (in the case of animal drugs) may provide additional information about the product.

At the time of this revision, the proposed guidelines were not adopted. By internal policy decision, the FDA permits broadcast advertising of prescription drugs as long as the content conforms to the proposed guidelines. Print advertising still must comply with the *brief summary* requirement.

STATE REGULATION—For some time, many states had pharmacy act provisions or pharmacy board regulations that prohibited or severely restricted prescription drug advertising. Numerous state court decisions had been handed down regarding the permissibility of such prohibitions, but their dictate was anything but clear. To obtain an ultimate decision on this controversy, a group of consumers filed suit against the Virginia State Board of Pharmacy alleging a First Amendment right to receive prescription price information. The case of Virginia State Board of Pharmacy v Virginia Citizens Consumer Council, Inc. eventually reached the US Supreme Court. The court, basing its decision on the First Amendment, held that even speech that primarily is commercial in nature is protected. The consumer should have the freedom to obtain the price information necessary to make a choice regarding prescription drugs. The FTC previously had proposed a Trade Regulation Rule that would preempt and override all state statutes and regulations that prohibited prescription drug advertising, but with the advent of the Virginia case the FTC did not feel it was necessary to move further in this area.

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CHAPTER 112

Re-Engineering Pharmacy Practice

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Caring practitioners are of crucial importance to all health professions. Most individuals attracted to a career as a health professional desire and expect to provide patient care. These attitudes remain despite the tremendous changes that are occurring in health care. In fact, the one constant in health care in the last century has been change. This change has led to a re-engineering of the health care system, fueled by the explosion of technological advances and the movement toward patient-focused health care. The nature of pharmacy practice also must change to a focus on pharmaceutical care in response to the advancements in the health care environment. For the pharmacist to be recognized as a health professional, pharmaceutical care and the direct patient contact it requires must be fully implemented. There must be a focus of the caring pharmacist's abilities and responsibilities on achieving optimal therapeutic outcomes to improve a patient's quality of life.[1,2]

Re-engineering pharmacy practice to provide pharmaceutical care assumes that a pharmacy core value is caring for the patient; advancing the good of every patient in a caring, compassionate, and confidential manner.[3] Caring assumes that the pharmacist has an emotional commitment to the well-being of the patient who needs and deserves the pharmacist's compassion and attention.[3]

This adaptation to pharmaceutical care requires a major shift in the essential skills, education, and mindset of pharmacists. The pharmacy professionals who have been successful in this endeavor have successfully changed the way they work and think about the use of drugs in the patients they serve. They have developed interpersonal skills, collaborated with other health professionals, and implemented programs that provide care to individual patients. However, while the provision of pharmaceutical care is the goal, it has not yet been achieved in the majority of practices. Thus, practice re-engineering for pharmaceutical care is necessary. To make suggestions for where re-engineering should take pharmacy practice in the future, it is important to look back at where pharmacy has been and how it has evolved to its present position.

THE EVOLUTION OF PHARMACY PRACTICE

Over the last 150 years, the profession of pharmacy has advanced from a practice focused on manufacturing and compounding, to distribution of drug product, to clinical practice with an eventual role as providers of pharmaceutical care.[4] In considering these changes, it appears that the profession has truly changed completely from one focused on a drug product to one focused on the patient. The only common thread that ties today's pharmacists with those who practiced at the turn of the last century seems to be drug therapy itself. Each of these steps in the evolution of pharmacy practice requires different skill sets of the practitioner and even a different type of personality for the individual to find a personal fit with the tasks involved. The various levels of pharmacy services provided have also held a different perceived value to the patient and other decision-makers involved in the provision of health care.

STAGES OF EVOLUTION OF PHARMACY PRACTICE (1860 TO 2000s)

In the late 1800s, the pharmacist was serving the social role of apothecary by manufacturing drug products; preparing elixirs and powders for individual patients. Pharmacists learned these skills through apprenticeships. Patients came to see the pharmacist whose primary role was to provide pure, unadulterated medication while meeting a secondary role of providing advice as to how the specific remedy was to be used. Society valued the pharmacist's ability to prepare the drug and advise those in need of their product as well as the care provided by the pharmacist.

As the industrial age took hold in the United States, companies whose sole purpose was bulk and mass production of drug productions grew and propagated. The development of these commercial products left community pharmacy practice to focus on compounding preparations that were not commercially available. By providing these compounding services to patients along with advice on how to use the compounds to care for illness, the pharmacist working in the apothecary continued to provide a valued service to society.

Though World War I took place thousands of miles away in Europe, this conflict played an important role in shaping the course of pharmaceutical education in the United States. The War Department refused to commission pharmacists as officers. This decision pushed the profession to formalize their education process by requiring a four-year bachelor's degree for entry to the profession. When World War II began, pharmacists felt they were in a better position to achieve commission as officers in the new conflict. However, the War Emergency Department Advisory Committee decided pharmacists entering military service would not be commissioned while nurses would be granted rank as officers.[5] Unfortunately, this decision along with opinion surveys indicated that society considered the pharmacy profession of little value.

During the post-war period, a review of the profession by the American Council on Education's Pharmaceutical Survey

indicated that pharmaceutical education was quite conservative and obsolescent, providing knowledge in current skills rather than future needs or professional skills. Tension developed in the various practice areas of pharmacy when the survey encouraged the profession to adopt a 6-year doctor of pharmacy degree as a standard across the country. Only California colleges/schools followed the recommendation, while the rest of the nation settled for a 5-year degree that fell short of the suggested requirements for teaching skills needed for future professional expansion. Thus, compromise set the stage for future debates over the educational requirements needed for pharmacists.

At the same time of change, the discipline of hospital pharmacy developed as a service to manage the drug product inventory for use in the inpatient setting. Hospital growth was spurred by the passage of the Hill-Burton Act, and the result was increased expansion and new construction of hospitals in underserved areas. This growth and expansion attitude in the hospital industry was reflected in pharmacy practice as the pharmacist's role expanded beyond the distribution of medication. Hospital pharmacists became involved in a variety of tasks including nursing education regarding the administration of drugs, and participation in Pharmacy and Therapeutics Committees that selected drug products for use in the institution. Through these activities, hospital pharmacists preserved some of their educational focus in the scientific use of medications acquired in pharmacy school. However, consistent with their community practice colleagues, the emphasis of practice remained on a drug product.

In 1951, the Durham-Humphrey Amendment to the 1938 Food, Drug and Cosmetic Act required that drugs which cannot be safely used without medical supervision be dispensed only by prescription of a licensed practitioner. Until this amendment, there was no requirement that any drug be labeled for sale by prescription only. The amendment defined prescription drugs as those unsafe for self-medication and should, therefore, be used only under a doctor's supervision. With this legislation, the pharmacist's role in the provision of care was dramatically limited by removing any latitude the pharmacist may have had in selecting (a) drug(s) for the individual patient. The pharmacist became only the dispenser of the drugs ordered by the physician. Even the 1952 American Pharmaceutical Association's (APhA) Code of Ethics prohibited the pharmacist from discussing in detail the nature of the drug dispensed and its therapeutic effect. With this changing attitude and legislation, the pharmacists in the community setting lost their social purpose and became merely suppliers of drug orders and not the providers of the service of care. Without the ability to help the patient select drug therapy and discuss medication use, those successful in the profession called upon skills of managing a business and shifted away from a focus on scientific skills previously mentored in their pharmacy school training or apprenticeship.

In the 1960s, as laws changed, community pharmacists again began counseling their patients on the use of drug products. In 1969, APhA revised its Code of Ethics, eliminating the old restrictions on patient counseling. Pharmacists were encouraged to provide the necessary information to assure the patient's health and safety. Some pharmacies branched into other areas of practice such as durable medical equipment that required the pharmacist to educate patients in the use of these items for self-care. During this time, drugs available for over-the-counter or nonprescription use expanded, and community pharmacists found a niche educating patients on the proper use of nonprescription drugs. However, as pharmacists focused their skills on the business of running the pharmacy, the education needed for scientific assessment of new medication and counseling skills was limited in most pharmacy school curricula. For pharmacists who had been in practice for some time, the therapeutic skills that were present upon graduation had declined over time due to lack of use. Thus, the move to counseling in the community setting was limited by the pharmacist's skill set and also by the work environment which varied from employment as an owner or employee of an independent or a chain community pharmacy. Due to the limited move to providing education on medication use to the patients, pharmacists at this time continued to have a weak social value in the provision of health care.

Unfortunately, this lack of perceived social value of pharmacy services occurred at a critical time in the development of health care benefits in the United States. In 1965, amendments to the Social Security Act created Medicare and Medicaid to provide health benefits to Americans 65 years of age or older, low-income children lacking parental support, their caretaker relatives, the blind, and individuals with disabilities. Hospital pharmacists benefited from the enactment of the legislation that required the pharmacy department to be directed by a pharmacist to receive reimbursement. However, Part B of Medicare, the elective portion of this federal insurance that covers outpatient treatment such as physician office visits, did not include coverage for outpatient prescription medications. Besides leaving prescription coverage out of this Federal insurance program, pharmacists were not included as providers of health care services while nurses, physical therapists, occupational therapists, and allied health care professionals were considered providers eligible to be reimbursed for services rendered. This exclusion of the pharmacist was simply a mirror of the societal value placed on pharmacy services in the early 1960s. It was not until the late 1980s and early 1990s that procedures were developed for documentation and billing of outpatient counseling and patient monitoring by pharmacists. Using these procedures, some community pharmacists were paid for services by private insurance companies when the pharmacy could justify the value of its services to company officials. However, due to lack of support within the Medicare program for coverage, general support of payment for these services has been severely limited. Outside of the hospital setting, expansion of counseling and medication monitoring and management services has occurred very slowly in the last quarter of the 20th century.

During this same period, pharmacists practicing in hospitals were expanding the application of their scientific knowledge of drug therapy by providing clinical services. These clinical services provided physicians with information about pharmacokinetics and the nature of drug action to improve the prescriber's ability to effectively select and utilize appropriate drug therapy. Thus, pharmacists in hospitals were better able to use and expand their knowledge of drug therapy gained during their education. However, while these new services moved the pharmacist to the bedside, their focus continued to be on the drug therapy rather than on the patient being treated. In providing these new services, these pharmacists began to have a social value to other the health care providers in the institutional setting. This value allowed hospital pharmacy managers to find support in their organization to develop or adopt training programs to aid staff pharmacists in the understanding, adoption, and provision of these new clinical services. The addition of Medicare and Medicaid coverage for hospital care in the 1960s caused hospitals to experience immense growth that fueled expansion and the emergence of technology. During this period, the development of hospital-based clinical pharmacy services was encouraged and well received. Fortunately, clinical pharmacy practice became established and proved its value to hospital administration before the controls on health care spending were implemented with prospective payment system in the mid 1980s. Pharmacists had shown that they could decrease the length of stay for the hospitalized patient through clinical services, a critical factor in controlling costs. However, with continuing trends at the end of the century to cut hospital costs, clinical pharmacy services are often considered as areas for potential cuts in funding, especially where the value of the service is not truly embraced by the administration.

Pharmacy at the beginning of the 21st century continues to finds itself in transition as the profession moves from a focus on

the drug product to the actual use of the agents by patients to control and eliminate disease. Discussions in the 1980s looking at the future of pharmacy in the next century called for the shift in the profession's focus and thus curricular change in the education of pharmacy practitioners. Hepler and Strand presented these concerns in the early 1990s and called for a movement to the pharmaceutical care model as a commitment to true growth and change in the pharmacy profession.[6] They defined pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life." These outcomes include the cure of disease, reduction or elimination of symptoms, arresting or slowing a disease process, and preventing a disease or symptom. The major functions the pharmacist performs in this care model include identifying any drug-related problems, and resolving or preventing these problems. As previously stated, Hepler and Strand called for pharmacists to accept responsibility for care, not merely perform functions that provide care. Thus, a serious change in mindset is required for pharmacists to work within this new professional model. They are no longer just providing a service; they are responsible for the outcome of the medication use process. Hepler and Strand go so far as to indicate that a pharmacist who does not accept this responsibility is not performing a professional role, and thus has not achieved professional maturation. For the pharmacists already involved the clinical practice, acceptance of pharmaceutical care primarily requires a shift in attitude. For those still practicing in the dispensing mode, a significant change in knowledge and skills will be necessary to move to pharmaceutical care.

Higby and Hepler describe an evolutionary process that has occurred in pharmacy where the adoption of the pharmaceutical care model takes place as opportunities arise.[5,7] Because these isolated opportunities happen sporadically, there is no true expansion to the new practice model. Before the opportunity to provide such care arises, the pharmacist must become skilled in the techniques to provide such care. Depending on the nature of their original educational experience, the mid-career pharmacist may need additional education or additional practice using skills that were acquired in school, but have become weak due to lack of exercise. Further, the individual pharmacists may embrace the notion of pharmaceutical care, but their work environment and assignment may not support or nurture the pharmaceutical care model. These pharmacists need the support of their employers, be that a hospital or a retail pharmacy organization, to "re-engineer" their practice. It is important that these employers come to understand the value in the provision of pharmaceutical care as this practice provides a safer medication use system that optimizes the investment in drug therapy.

Re-engineering practice requires a problem-solving approach to identify and define the barriers that are impeding incorporation of pharmaceutical care into practice. Once the barriers are identified, strategies can be developed to overcome them. In some instances, careful identification of problems raises the level of awareness and sets in motion the processes needed for resolution. In other cases, the problems are so deeply rooted that resolution is very difficult.

CURRENT BARRIERS TO THE PROVISION OF PHARMACEUTICAL CARE

Numerous barriers frustrate the provision of pharmaceutical care to patients by pharmacists. Practice-related issues such as lack of time, insufficient knowledge and confidence, conflicting job functions, poorly designed workflow, physical layout problems, and lack of institutional or corporate support are commonly stated as important barriers to the provision of pharmaceutical care. However, education-related issues in pharmacist training and development also contribute to the lack of incorporation of pharmaceutical care into the practice setting. These education-related issues are at the root of this problem.

Education-Related Barriers

The professional socialization of pharmacy students and pharmacists is influenced by two conflicting roles.[2] One role is that of pharmacy operations/business person while the other is health care professional. In its attempts to re-engineer pharmacy practice to the provision of pharmaceutical care, pharmaceutical education has often come into direct conflict with the operations side of pharmacy practice. This conflict has led to what Manasse et al termed "inconsistent socialization" to describe the incompatibility between the operations/business and professional forces of socialization.[8]

While professional socialization involves learning the knowledge and skills needed to practice as a pharmacist, it also involves the important acquisition of appropriate behaviors, attitudes, and values. Socialization of a future pharmacist begins when the individual selects pharmacy as a career. However, the extent of professional socialization develops rapidly once the individual is accepted to pharmacy school. During their years in school, pharmacy students are exposed to numerous influences on the role of the pharmacist through interactions with other influential people including basic and applied science faculty, practice and clinical faculty, pharmacists, patients, family members and friends, fellow students, and allied health care professionals. The absence of uniformity or agreement among these influences causes the student to develop conflicting behaviors, beliefs, and values regarding their practice role.

Longitudinal studies on the socialization of pharmacy students have identified this inconsistent socialization.[9–13] The clashes of socialization forces lead to differences between student's and recent graduate's expectations about their role in providing pharmaceutical care and others' expectations of their role.[9] This incomplete socialization of the neophyte pharmacist is thought to carry over and the majority of pharmacists in active practice have not been adequately prepared to take on the pharmaceutical care role.[14,15] While efforts to improve the development of caring attributes in pharmacy students have been incorporated into the accreditation standards for pharmacy schools and of active pharmacists through certificate and nontraditional doctor of pharmacy programs, pharmaceutical education has a long way to go to socialize professionally students and pharmacists as providers of pharmaceutical care. The longitudinal studies also found that pharmacy students have a reduced sense of calling to the profession in their last year of pharmacy school compared to prior years. The students develop "disillusionment" or "realistic disenchantment" with their professional role *versus* their operations/business role as they progress through the curriculum.[10,16,17] Students enter school with a level of idealism or are given this idealism early in their training, only to have it diminish over time. It has been argued that students are presented the patient-focused pharmaceutical care perspective of professional practice by pharmacy educators, only to have this perspective largely unsupported as they gain experience in the real world and enter a practice where pharmacy operations and the business role are the main emphasis. When students and pharmacists are unclear about what is expected of them, their perceived role can be easily swayed by the opinions of powerful others (eg, employers, patients, physicians). This role conflict results in dissatisfaction with practice for pharmacists whose expectations of practice were to serve as health professionals and provide pharmaceutical care. Over time, these pharmacy practitioners become socialized into the pharmacy operations role. Many are unable to assume the professional role of pharmaceutical care provider even though they participate in pharmaceutical care credentialing programs and are provided opportunities by their employer to implement patient-focused programs at their practice. Therefore, if pharmaceutical care is going to be fully implemented in practice, it is important for pharmaceutical education, pharmacy associations, and corporate and institutional pharmacy to work together and develop a common vision for the professional role of the pharmacist; a role that is

complimentary to, not in conflict with, the business/operations side of the pharmacy.

Physicians are professionally socialized to provide medical care to individual patients and view it as their primary role even though they also manage their office operations and are under increasing stress to treat more and more patients. Nurses often have a heavy load of patients plus documentation and other operations-related functions but still view provision of nursing care for the individual patient as their primary role.[18–20] Medical and nursing students are attracted to their chosen profession because there is an expectation that the practitioners will have an emotional caring for the individual patient.[21–23] Because this role is supported consistently by their power figures throughout training and entry into practice, a physician or nurse that is socialized to provide patient care is usually produced. If the profession of pharmacy is able to come together and create a climate where its practitioners are viewed by the public and allied health care professionals as a providers of care to individual patients, schools will attract individuals with that expectation and their training and entry into practice will better prepare them for this role.[24,25]

Practice-Related Barriers

Before discussing barriers in practice that prevent the pharmacist from providing care to individual patients, the process of pharmaceutical care must be reviewed in more detail. The process to provide pharmaceutical care to the patient requires several steps. The first step is to identify and define the patient's disease- and drug-related problems. For instance, a problem might be identified that a child with asthma is overusing his albuterol inhaler. Defining the problem would require investigation of the factors leading to the overuse. Perhaps the presence of three asthma triggers were defined: the child received a cat for Christmas, his parents started smoking in the house again, and the family is short of money so his Serevent prescription was not refilled.

The next step in the pharmaceutical care process would be to review the patient's medication regimen and available information on medical treatment, peak flow meter results, laboratory values, etc. The information gathered from all of these activities would then be used by the pharmacist as a basis for an assessment of the patient's pharmaceutical care needs. For the child with asthma, the assessment would include the increased number of daily asthma problems, noncompliance with his/her Serevent® inhaler, and lack of parent understanding of asthma triggers and medication use. Based on the assessment, the pharmacist would develop and implement a care plan to help the patient and his caregivers (parents). The plan should be recorded and include desired outcomes of the care to be provided including education for the child and parents concerning all asthma medications and their role in preventing/controlling exacerbations, help with prioritizing medication purchase and possibly, information on programs that could assist with lowering medication cost. The plan also would include education on asthma triggers, especially cat dander and second hand smoke. In implementing this plan, the pharmacist is establishing a covenant to provide care to the child and his parents. This is the emotional caring referred to above. The pharmacist should document the care provided and provide a report to the primary care provider of patient needs identified and pharmacist actions taken to help the patient. Using this approach will allow the pharmacist to be viewed by allied health care professionals as a care provider. In addition, the pharmacist will be viewed as a caring individual by the patient and caregiver that will hopefully motivate and empower him/her to take an active role in asthma self-management. The last step in the process is to monitor the patient to determine if the desired outcomes are being met. The first important monitoring function is to determine if the patient is receiving therapeutic benefit. Because the pharmacist is justifiably concerned with untoward effects (eg, adverse drug effects, drug interactions) and other drug-related problems (eg, over/under use, noncompliance), (s)he may not gather sufficient information to determine the degree of therapeutic benefit the patient is receiving from his drug therapy. This can lead to conflict because the primary care provider is usually most concerned with therapeutic benefit. The pharmacist must take this issue into careful consideration in recommendations for changes in care. For example, if in the eyes of the physician, the child with asthma has benefited from Serevent, the physician would likely not be inclined to accept any recommendation to replace it in the regimen. If the pharmacist felt a change in therapy was needed, recommending Advair, a combination product containing Serevent and an inhaled steroid, might be the best way to impact the patient's care. Thus, monitoring requires the pharmacist to view the total patient.

It is also essential that the pharmacist be conscientious in following up on all matters concerning the patient. If the patient has questions or concerns that the pharmacist is unable to satisfy when meeting with the patient, the pharmacist should get back to the patient with the answers or educational information as soon as feasible. Whenever possible, it also is important that the pharmacist personally follow up with the primary care provider on concerns or recommendations rather than just suggesting to the patient to talk to the provider. One reason is because if the patient is not complying with the provider's previous advice, (s)he may be reluctant to admit it to the provider. A second reason is that it is difficult to predict how the patient will convey the pharmacist's concern or recommendation to the provider. Some patients may even tell the provider, "The pharmacist said your treatment is wrong." Another reason is that the patient may simply not understand the information in a way to communicate it properly to the physician. It is difficult to reach many providers and compliance with HIPAA privacy regulations may complicate the process further. However, if the information is imperative to the patient's treatment plan, the pharmacist should gain the patient's permission by explaining the importance of informing the provider.

The pharmaceutical care process outlined above requires a great time commitment by the pharmacist and considerable interpersonal and communication skills are required. Diplomacy is a must, and significant skills as an educator are required. Thus, pharmaceutical care provision requires a knowledgeable, highly skilled practitioner who has a passion for taking care of patients.

Numerous practice-related barriers stand in the way of the pharmacist's ability to provide individualized patient care to optimize the patient's therapeutic outcomes to the prescribed drug therapy. Table 112-1 shows the barriers to providing pharmaceutical care among a group of Indiana community pharmacists participating in a one-year pharmaceutical care certificate program.[26] The pharmacists' perceptions at the beginning of the program (baseline) are typical of most pharmacists. Their perceptions after one year of training will be discussed later. Time to provide care is the major barrier for pharmacists. Lack of time is based on the pharmacist's involvement in processing a high volume of prescriptions/drug orders. Poor workflow design and staffing shortages often contribute to this problem. Studies have shown that pharmacists spend the majority of their time processing and dispensing prescriptions.[27–29] A Midwestern study found that staff pharmacists in high-volume community pharmacies interacted with patients at a rate of once every 3 to 4 minutes.[30]

Most pharmacists are busy and pharmacies are staffed based on drug order/prescription processing needs. No standardized staffing formula has been developed for pharmacy workload allocation. The State of North Carolina has set limits of 150 prescriptions and 12 work hours per pharmacist, but each pharmacy will have unique staffing needs and this formula may or may not be applicable to specific pharmacies depending on other activities required of the pharmacist and staffing of technicians and other personnel.[31] In many settings,

Table 112-1. Perceived Barriers to Providing Pharmaceutical Care—Pharmacists' Responses at Baseline and 1-year Follow-up

BARRIER	BASELINE (%)	1 YEAR (%)
High-volume store	83	32
Poor workflow	23	23
Patients do not want pharmaceutical care	23	27
Lack of data/documentation systems	20	50
Pharmacist has too many interruptions	17	41
Pharmacist needs more education on pharmaceutical care	14	14
Lack of support from management	11	9
Physical layout of the pharmacy	11	32
Lack of sufficient clinical reference resources	9	9
Lack of patient continuity	6	6
Third party will not reimburse for care services	3	5
Management responsibilities take too much time	3	9
Pharmacist colleagues do not believe in care services	3	9

improved workflow, increased use of automated dispensing systems and technicians have allowed the same number of pharmacists to dispense more prescriptions. This improved prescription processing has not contributed to increased opportunities for pharmacists to provide pharmaceutical care because that is not their purpose. The measures have not even freed up time for most pharmacists to counsel patients on new and/or refill prescriptions despite OBRA '90. In the Midwestern study, low rates of personal interaction with patients also occurred with hospital pharmacists. These practitioners tended to focus on medication dispensing, telephone interactions with providers, and population-based drug use management.[30] If pharmaceutical care is going to become a priority, system development for pharmaceutical care services and outcomes must be given the same attention that prescription-processing operations currently receive.

The pharmaceutical care process described above dictates that pharmacists work with other health professionals, identify and solve problems, and communicate orally and in writing. Many neophyte and experienced pharmacists are not adequately prepared to perform these new roles. For some, it is lack of knowledge and skills. For others, it is lack of confidence in their ability. Others prefer to be involved in more passive activities. A study of Ohio pharmacists divided pharmaceutical care practice into four dimensions: Drug Information Source, Information Gathering, Patient Counseling, and Drug Monitoring.[15] The first two dimensions were operationalized by the researchers as "passive" activities of pharmaceutical care meaning they can be completed without much direct patient contact, follow-up activities or anticipation of problems that might be encountered. Pharmacists wait for questions to arise then answer the question or process the prescription drug order. The last two dimensions were operationalized by the Ohio investigators as "active" functions because they dictate proactive involvement by the pharmacist with the patient and other health care providers. They also require the pharmacist to anticipate potential problems that might be encountered. Both of the active functions demand relationship building, problem solving and implementing strategies for optimizing drug outcomes.

The results of the study found that pharmacists were engaged in mostly passive activities suggesting that current pharmaceutical care activities involve being an information resource and maintaining medication records. Even hospital clinical pharmacists tend to be more involved with drug information centers, pharmacokinetic monitoring programs, drug management programs, and adverse drug and medication error analysis reporting where direct patient contact is limited. Even many of the pharmacists who participate on rounding teams serve as information resources rather than providers of direct patient care. Further, in some schools of pharmacy, clinical faculty that have been professionally socialized to serve as passive resource models create clerkship rotations for students who also function as information sources to their rounding teams. These information resource pharmacists work very hard and perform valuable services; they just are not involved in providing individualized pharmaceutical care to patients. Only a small percentage of students have the vision and confidence to seek opportunities to be involved in direct patient care. A desperate need exists for preceptors to serve as direct patient care pharmacist role models. The best examples of pharmacists who have transitioned to the active dimensions of care are the disease management pharmacists involved in collaborative care such as diabetes self-management programs, anticoagulation clinics, and asthma, hypertension or dyslipidemia management programs. These pharmacists also serve as excellent role model preceptors for advanced clerkship students. Fortunately, this practitioner group is a growing percentage of practicing pharmacists.

Lack of demand by patients for these services is also cited as a significant barrier. The image portrayed by pharmacy is one of prescription processing and patients do not know to expect pharmaceutical care. In addition, patients often view their prescriptions as expensive and do not want to pay for additional care services. Another factor is that pharmacists are reluctant and shy away from asking patients to pay for care services and typically fail to train pharmacy staff to fulfill these functions. Also, marketing efforts have not been directed educating the public on the value of individualized pharmacist care. Finally, there is debate on the best approach for pharmacy to gain compensation.[32] Some feel that free services have value to the pharmacy and market them as free to gain a competitive edge. They contend that high patient loyalty and improved store traffic pays for the expenses through increased store revenue. For example, a patient with type-1 diabetes will purchase a large number of diabetes supplies each year in addition to their other store purchases. Another important consideration is that pharmacist participation in patient care programs increases job satisfaction and retention. Pharmacist job retention is important due to the high cost of training new employees.

Other pharmacists favor developing programs and marketing them to patients who are willing to pay for them as an out-of-pocket expense. There are groups of patients who value the pharmacist and are willing to pay, if asked. Making these patients aware that the service exists is of primary importance. However, many patients only want pharmacist care services when most of the cost is covered by insurance. While pharmacy organizations and pharmacists are working to obtain insurance coverage for its services, broad acceptance by the insurance companies may result in the same problems currently faced by pharmacy with prescription reimbursement; insurers who drastically discount the fees for pharmacist services.[32] The most effective approach is that the pharmacists develop relationships with insurers to provide specific services to their patients. The pharmacist provides specific documentation for the services provided and the insurer can track the patients' total medical costs to determine if the pharmacist services are cost effective. A major barrier to this approach is the tremendous effort required of the pharmacist to develop the relationship, service structure and payment mechanism. An alternative approach is for the pharmacist to develop a relationship with an employer to provide services to their employees. This can be a win-win for both the pharmacy and the employer. The pharmacist receives payment for services provided while the employer is viewed by the employee as interested in his health. The success of the service will be improved employee health, productivity and work attendance.

The barriers to this approach are the effort and patience required to put a disease management program into place and the complex issue of demonstrating improved patient outcomes. Development of outcome measures can be completed by partnering with a faculty member skilled in pharmacoeconomics research at a school/college of pharmacy.

Community and outpatient clinic pharmacists struggle with three additional barriers (ie, lack of an adequate patient database, lack of disease management resources, lack of a private patient consultation area). Most of these settings do not have a system that allows them access to patient medical records, treatment protocols, lab values, and diagnostic test results. Health Care Smart Cards containing pertinent patient medical information have been proposed for many years but the concept has never been operationalized for a variety of reasons. While the lack of medical information does put the pharmacist at a disadvantage, pharmacists also contribute to the problem. Even when pharmacists interact with patients and their providers to solve drug- and disease-related problems, these interactions are seldom documented. Documentation is limited to interactions involving the processing of the prescription. Building a patient pharmacy chart by keeping a record of patient and provider interactions, problem assessments and plans developed to solve problems, monitoring results and follow-up interactions with the patient would form a valuable patient database. Again, the emphasis is placed on pharmacy operations instead of pharmaceutical care provision.

Most pharmacists are at a distinct disadvantage with respect to having sufficient resources available for pharmaceutical care provisions. Most in-pharmacy references are limited to drug compendia such as the *Red Book, Physician's Desk Reference*, or *Facts and Comparison's*, and possibly a drug interactions text. Medical and therapeutics texts are seldom available. The Internet is a rich source of information that can satisfy nearly all informational needs, but the majority of pharmacies do not have a personal computer and/or an Internet connection dedicated to this use.

A huge problem for many community pharmacies and outpatient clinics is lack of a private patient consultation area. Newer pharmacy layouts provide plenty of semiprivate space for consultation with patients but the high ceilings, open counters and patients waiting all along the counter do not allow for complete privacy. Thus, patients are not inclined to discuss the private issues of their medical conditions when others can easily overhear. The new HIPAA privacy guidelines implemented on April 14, 2003, call for the pharmacist to make every attempt in this semiprivate environment to protect each patient's privacy. However, the semiprivate nature of the environment may discourage an open-relationship between many pharmacists and patients. In the past, private consultation rooms were included in some pharmacy designs, but these were largely abandoned. The rooms were not utilized because emphasis was on prescription processing, not on providing individualized care to patients. Perhaps it is time to revisit this design concept in the pharmaceutical care model.

The final barrier pertains to a variety of cultural, language, financial, and attitudinal factors that affect the ability of the pharmacist to interact with the patient. For certain ethnic groups, it is important to include the father in educational programs pertaining to treatment of a child's disease because the father has the final say on meal plans or even the acceptability of drug treatment. Populations of non-English speaking patients (eg, Hispanic, Vietnamese, Russian) may have difficulty accessing pharmaceutical care in many areas of the country. Many patients have difficulty identifying the resources needed to purchase medications, let alone paying for care, education, and monitoring. A variety of attitudinal problems result in patients not receiving pharmaceutical care. Many people do not like to take medication and will only do so when convinced it is absolutely necessary. Others simply do not understand the importance of taking medication or just take it while they feel ill, stopping as soon as they feel better. Noncompliance is a vast problem that has been well described.[33,34] Pharmacy has contributed to the problem through insufficient patient counseling and the failure to implement in-pharmacy programs to identify and correct patient noncompliance with medications.

If pharmacies and pharmacists want to commit to pharmaceutical care provision, systems must be designed to provide pharmacists the opportunity to provide care. In a study in which Indiana community pharmacists participated in a 12-month pharmaceutical care certificate program, pharmacist's perception of the importance of time due to excessive prescription volume as a barrier changed (Table 112-1).[26] At the beginning of the training, a vast majority of the pharmacists (83%) felt prescription volume was the major barrier to pharmaceutical care provision. After completing the year-long certificate program, major perceived barriers were lack of data and documentation systems, poor physical layout of the pharmacy, and excessive interruptions. The perception of prescription volume as a barrier fell to 32% of the participants. For pharmacy to be in a position to provide pharmaceutical care, all barriers must be addressed and strategies developed to overcome them.

STRATEGIES TO OVERCOME IDENTIFIED BARRIERS

It has been well documented that pharmaceutical care improves therapeutic benefit and patient outcomes, decreases negative untoward effects, and avoids the financial costs of negative therapeutic outcomes.[33–36] However, as previously discussed, the main pharmacist job function revolves around routine prescription processing *in lieu* of pharmaceutical care functions.

In describing pharmaceutical care, Strand asserted that essentials for its success included pharmacists with a passion for providing care, technicians and other pharmacy support staff trained to perform the tasks associated with prescription processing, and a change in mindset in which the pharmacist's role is perceived as providing care to patients.[37,38] A 2003 White Paper endorsed by 12 prominent national pharmacy organizations states that "implementation of pharmaceutical care requires a fundamental change in the way pharmacies operate. Pharmacists must relinquish routine product-handling functions to competent technicians and technology."[39] This paradigm shift will not be completed easily. Even pharmacists who want to be pharmaceutical care providers may have difficulty turning over prescription processing to others because pharmacists have been taught that this function is critical to safe medication use. Most caring pharmacists are "recovering dispensers" because dispensing is an integral part of their professional socialization process and training. To make the transition to being a pharmaceutical care practitioner, many pharmacists will need substantial training in a wide range of subject areas. Examples of the range of areas would include: working effectively with technicians and partner pharmacists, adult education techniques, disease state management, pharmacist-patient communication techniques, documentation of care, and marketing techniques for pharmaceutical care. Gaining these skills will require a multifaceted approach to educational opportunities. The pharmacists will need support, reassurance, mentors, role models, and networks of pharmacists who are working toward a common goal of pharmaceutical care. Thus, strategies must be devised to overcome the myriad of barriers needed to implement and evaluate the effectiveness of pharmaceutical care practice models. This approach is to get the pharmacists in practice "up to speed." The Schools/Colleges of Pharmacy must also continue to improve curricula to professionally socialize students to have an expectation and commitment to pharmaceutical care provision. Strategies to overcome practice barriers will be presented first followed by approaches to overcome pharmaceutical education barriers.

Strategies to Overcome Practice Barriers

The pharmacy must create, implement, and evaluate a plan for pharmaceutical care service provision. Planning is multifaceted and getting started with plan development is often the hardest part. Most pharmacies provide many services to patients but the services are random, provided only when a patient presents or when the pharmacist has time. To develop an organized program of care, the pharmacy must first organize its services by developing a plan. Key questions to answer during plan development include: what service is to be offered, what policies and procedures will be followed, who is going to staff it, how will other pharmacy operations be staffed, how will potential patients be identified, what computer hardware and software is needed, what information will need to be documented, what forms will be used, what other records will be needed, how will the program be evaluated, what will the program cost to operate, how will the program be financed, will there be a charge to the patient? Coming up with the answers to these questions and many others may appear to be a daunting task, but a team of enthusiastic pharmacists, pharmacy managers, and business people can accomplish the task. Patience and persistence will be required.

For all of the above reasons, it is often best to start with a pilot program on a small, controllable project to gain experience without making a huge time or financial commitment. If the pilot program proves successful, it can be expanded and refined. An example program on compliance improvement for new antihypertensive patients is described below.

Example Compliance Improvement/ Antihypertensive Callback Program

An extremely important service that could start out on a small scale and expand as experience in gained is a Compliance Improvement Program. Noncompliance with prescribed medications and the resulting hospitalizations and physician office visits were estimated in a 1995 study to cost between $75 and $150 million dollars per year in unnecessary expenditures.[33] These costs do not include lost work time and decreased productivity as a result of illness. Noncompliance continues to be a huge problem, and most pharmacies have no programs to identify and manage noncompliance in their patient population. Implementing a service that encourages a patient to take medications as prescribed is good for patient care and it is good for business. A pilot could be initiated in one particular area. For example, it is not uncommon for patients receiving a new antihypertensive agent to not have the prescription refilled because they do not understand the need or may experience a problem that causes them to discontinue the agent. A pharmacy-based pilot Antihypertensive Callback Program to contact the patient 3 weeks after the fill date for the new blood pressure lowering agent may help to identify and correct these problems and improve compliance. The purpose of this telephone call would be to ascertain if the patient is still taking the drug, find out if he has been checking his blood pressure regularly using the proper techniques, and to point out the importance of regular refills, monitoring, and physician visits. The first step in establishing the service would be to develop a list of antihypertensive agents and a procedure to identify patients with a diagnosis of hypertension, because many of these agents may be used to manage other conditions. The next step is to establish a protocol for informing patients about the purpose of the program and that the pharmacist will be in contact in three weeks. Forms would need to be developed to record the patient's contact information (phone and fax numbers, email address) and to document the pharmacist-patient interaction. It also must be decided which pharmacist(s) will do the calling and what times will be allocated to make the calls and complete the documentation. Some practice calls might be even necessary to help the pharmacist feel comfortable and to establish the information to be covered at each call. At this point, the program can be implemented. Because a patient record has been generated, the pharmacy can continue to follow these patients on a regular basis to provide support and solve problems. This service would be invaluable to helping antihypertensive patients comply with their medication and over the long term prevent complications of untreated hypertension. In addition, it would support the pharmacy's refill business and open the door for sales of blood pressure measurement kits or bring the patient into the pharmacy to use the BP kiosk, which may lead to additional purchases. It also would improve patient loyalty for the pharmacy. Surveys can be used to collect information on patient satisfaction. The compliance rates of patients that receive the service should be measured and recorded. It also would be important to collect data on the patients' blood pressure readings. Many blood pressure kiosks will maintain a record of a patient's blood pressure readings or the pharmacy may want to invest in a Dynapulse blood pressure kit, a BP cuff and software that allows measurements to be banked in a computer so that graphs can be generated for use by health care providers. Summation of the data collected can be used in marketing efforts to patients and health care providers and to support requests for payment from insurers or employees. Summation of data collected and debriefing of pharmacists and other care service staff is also important to program evaluation. The evaluation results are used to improve the service and make continuous changes.

Strategies to Overcome Practice Barriers (Continued)

The next step in the planning process is to determine what opportunities exist to provide care to patients in the pharmacy's service area. For example, if the pharmacy is considering the development of services to patients with diabetes, it would be important to determine the number of patients with diabetes presently served by the pharmacy, the estimated diabetes population in the pharmacy's service area, and other diabetes education programs offered to this population. It would also be important to generate a report from the pharmacy's prescription database to identify current patients with prescriptions for euglycemic agents and/or other diabetes-related products. Other necessary data would be important to collect. Many states have disease-related statistics on web sites that can be accessed to determine the estimated number of persons with diabetes in each county. For example, the Access Indiana government web site is a valuable resource.[40] The existence of other diabetes education programs would require evaluating programs offered through hospitals, regional diabetes centers, doctor's offices, and other pharmacies. Even though other programs are offered, it should be ascertained if there are unmet needs that a new diabetes care service can satisfy. For instance, many hospital-based programs have diabetes classes for newly diagnosed patients. However, once the patient is discharged, little follow-up care may be available. A diabetes self-management education program that offers the patient an opportunity for regular interaction with a caring pharmacist may satisfy this unmet need. It will be essential for the pharmacy to document the services provided. Data to be collected would include: blood glucose monitoring and glycosylated hemoglobin results, patient quality of life, patient satisfaction with the service, amount of time spent with the patient, and problems identified and solved. This data would be important in demonstrating the value of the service and marketing the service to key employers and insurance providers in an effort to gain payment and show cost-benefit. It is advisable for the pharmacy to partner with other pharmacies and faculty members with expertise in pharmacoeconomics from a nearby pharmacy school to design the study, collect data, and analyze it for positive outcomes of the pharmacists' contribution to pa-

tient care. The Asheville Project, a community pharmacy diabetes care program in Asheville, NC, is a partnership of pharmacists and faculty members. One of the benefits of this partnership is a group of publications in the *Journal of the American Pharmaceutical Association* that demonstrate the value of the community pharmacist in the provision of diabetes care.[41–44]

At the same time, the plan for a care service is being developed and refined, it is important to prepare a vision and mission statement for the pharmacy and the service. The pharmacy's vision is a guiding image of success, formed in terms of a contribution to society. It answers the question, "What will success look like?" For example, the vision for a pharmacy's diabetes self-management education program might be: "To partner with diabetes patients to show improved therapeutic outcomes and reduce long-term disease complications." The entire pharmacy staff must reach a consensus on this vision and work as a team to achieve it. It also is important to note that the vision has measurable components that can be used to demonstrate success.

The mission statement answers the question, "Why does our service exist?" All members of the pharmacy staff also must be in agreement on the mission. For example, the mission of a pharmacy's Diabetes Self-Management Training (DSMT) that has been implemented is: "To provide quality educational services to persons with diabetes in order to assist in improving their quality of life."[45] This mission should be prominently posted in the pharmacy for all to read. In addition, all patients who enroll in the service should be provided a copy of the mission and how the mission will be accomplished by the pharmacy. For example, to accomplish the DSMT mission stated above, the pharmacy informs its patients that it help them understand: (1) diabetes and its acute and long-term complications; (2) monitoring techniques and goal levels for blood glucose and hemoglobin A1c; (3) one's diabetes medications; (4) healthy eating concepts and your meal plan; (5) one's exercise plan and how it fits with daily activities.[45]

Another important part of the plan involves staffing and workflow. Retention of staff is a constant problem that causes considerable stress in most pharmacies. Just as it is important to develop a plan to staff the prescription processing activities and devise a workflow that uses the pharmacist's knowledge and skills effectively, pharmaceutical care activities must be properly staffed with an efficient flow of work. Many pharmacies try to fit the care service into the prescription processing workflow. In a low volume operation that may work, but medium and high-volume pharmacies put so many demands on the pharmacist to oversee the dispensing aspects, it is difficult for the pharmacist to comply with OBRA '90 patient counseling activities, let alone implement a care service. Therefore, a good staffing plan must be developed and managers and staff pharmacists on both the dispensing and service side must reach a consensus on the roles of all members of the pharmacy staff in this plan. The first step in the process is to determine the staff members who will be involved and estimate the amount of their time that will be spent on the project. As with any new project, much of the developmental work may require some of the pharmacist's personal time to create the service. This is not too much to ask of a career-oriented professional and would be expected of any salaried employee. However, once the service has been approved and implemented, the pharmacist must be freed from other work activities to staff the service. In the beginning, it will likely be possible to schedule overlap with partners to free the care pharmacist to provide the service. However, as the service grows, specific pharmacist care hours must be scheduled. All members of the pharmacy staff must buy into this concept and understand that each staff member has an important role in keeping both distributive and care areas of the pharmacy functioning smoothly. In addition, everyone who works in the pharmacy, store, clinic, or hospital (checkout clerks, receptionists, anyone who will come into contact with patients seeking service or health professionals seeking consultation) must be aware of the care service and be able to refer inquiries correctly. In case the pharmacist is not on duty at the time, a calendar should be in the pharmacy showing the pharmacist's schedule and available appointment times.

Another important part of the planning process is to calculate the cost of the service. The pharmacist's time will be a large part of the cost, thus calculating the time involved will be important. There are many ways to calculate this cost based on the method used to pay the pharmacist (eg, hourly or salaried). As an example, assume the pharmacist spends 5.0 hours per week on a new care service and the pharmacist's salary/fringe is $100,000 based on 2080 work-hours per year. Thus, the rate for the pharmacist (100,000/2080) is $48 per hour and the pharmacist cost is $240 for 5.0 hours. In the same fashion, the cost of other staff involved in the service also must be calculated. Other expenses must be estimated such as computer hardware/software, Internet service providers, office and copying charges, costs for designing brochures and/or program materials, equipment and supplies, demonstration devices (many of these can be donated by the manufacturer), and telephone tolls. It is important to estimate as many of the expenses as possible. This gives the pharmacy a handle on how many dollars the service must earn to break-even. Once the break-even point is determined, the desired profit can be added to determine the total revenue projection for the service. This projection can be divided by the number of patients expected to utilize the service allowing one to calculate a per visit patient fee. If the patient were self-pay, this amount would be the fee charged. It also is the usual and customary charge that would be submitted to an insurance carrier. Finally, if the pharmacy is expecting to pay for all or part of the service by increased volume, the pharmacy must have a special key function or store card that allows a patient's spending to be tracked.

The fee setting approach described above is preferable to the one used by many pharmacies to determine care service fees. Many pharmacies charge a fee based on $1.50 to $2.50 per minute. Unless, the pharmacy has calculated its expenses and desired profit, how is it to know if $1.50 to $2.50 per minute is appropriate?

The planning process should determine if special permits (eg, a CLIA waiver) are required? The CLIA waiver applies to laboratory tests excluded from regulatory oversight by the FDA. It must be obtained if these tests will be performed in the pharmacy. Common CLIA waived tests include including blood glucose, hemoglobin A1c, and cholesterol tests measured by approved monitors. The purpose of obtaining the waiver is to assure that the pharmacy's policies and procedures include safe handling and disposal of biohazardous testing materials.

The planning process should also include evaluation of pharmacy staff abilities and identification of the training required to provide the planned service. Training should include all preparation required to perform the service. If the pharmacy were implementing a lipid monitoring and consultation service, training would certainly include use of the cholesterol monitor, knowledge and skills on dyslipidema, and its management. However, training might also correct other weaknesses such as interpersonal skills, marketing, and documentation techniques. Technicians and other pharmacy personnel must understand and be trained in job functions that will allow the pharmacist the freedom to provide care. In some situations, the pharmacy may hire another health professional (eg, a nurse or dietician) to provide monitoring functions thus freeing the pharmacist time to provide drug therapy management services. A pharmacist and nurse can, for example, form an effective team in providing care to patients.

Proper training for pharmacists is a must to improve knowledge, skills, and confidence. As mentioned above, pharmacists should take a careful inventory of their strengths and weaknesses then search for (a) training program(s) that will bring them up to the necessary level. Training is available through academic course work, continuing education pro-

grams, and certificate programs. Academic course work is directed at a specific topic area. For example, a class in Spanish for Health Professionals, Professional Leadership and Supervision, Marketing of Professional Services, or Outcomes Assessment may satisfy a specific pharmacist need for a developing a care service. A course in pathophysiology, pharmacology, or therapeutics would be useful to update the knowledge of a pharmacist who has been out of school for a while.

Continuing education programs are usually limited in scope. The purpose of most CE programs is to update knowledge in a particular area via lectures at live seminars or teleconferences or readings for online or home study programs. To implement a care service, development of skills in addition to knowledge is also required. For skill development to occur, the CE program must be interactive (usually in a workshop format) and provide an opportunity for the participant to practice and problem-solve.

Many certificate programs are marketed to help practitioners develop the knowledge and skills needed to provide a care service. In deciding on which certificate program to select, the pharmacist must look at the topics covered and at the method of delivery. Most certificate programs are designed to be interactive combining lectures and home study to improve knowledge and skills. However, many certificate programs fail to provide a mechanism that allows the pharmacist to apply the knowledge and skills to his/her practice setting. This application of the knowledge and skills to the actual practice setting is crucial to implementing a care service. Thus, certificate programs that include assignments to be completed on actual patients or within the practice setting enable the pharmacist to adapt the information presented to a real situation.

Once sufficient planning has occurred, the next step is to implement the program and continuously evaluate it. Program planning is actually a circular process that consists of identifying a need → creating a mission → designing a program to carry out the mission → implementing the program → and evaluating the results. The experience gained in program delivery and evaluation is used to refine/expand the need → adjust the mission → redesign the program → implement the revised program→ and evaluate the new offering. This circular process is repeated each time the program is offered. It is important to understand that evaluation of a service is not the end of the program. The results of the evaluation process are used for continuous quality improvement and program expansion.

It is important to note that the program does not have to be planned to perfection or have every detail complete before it is implemented. Many programs have never been implemented because the pharmacist felt the need to complete one more task, certificate program, or pharmacy staff hire before beginning the program. Planning is crucial, but it is also important to start, gaining experience along the way, then make refinements based on that experience. Setting a start date and sticking to it may avoid this pitfall.

Strategies to Overcome Educational Barriers

The American Association of Colleges of Pharmacy (AACP) and American Council on Pharmaceutical Education (ACPE) have worked closely with member Schools/Colleges of Pharmacy over the past several years to focus curricula on the pharmaceutical care provision. Accreditation standards require each school to be able to document its progress in implementing a curriculum that addresses the professional socialization of the students and allows them to integrate the knowledge, skills, and attitudes from all of the disciplines that contribute to preparation of a pharmaceutical care practitioner.[46,47] While there is still much work to do in this regard, much progress has been made. The conversion to the Doctor of Pharmacy as the first professional degree was a major step in the process. In addition, schools have incorporated a patient-centered, ability-based outcome approach that provides consistent assessment and feedback for each student in his/her learning and application of basic and applied sciences, pharmacy practice principles, pharmaceutical care provision, and professional development. A program of continuous quality assessment and improvement must be in place and demonstrated to ACPE as each school's accreditation is reviewed every six years.[46] Advanced clerkship rotations must be rigorous, and core objectives for inpatient and ambulatory care rotations must be met.[46] Introductory practice experiences (IPEs) are now a curricular requirement by ACPE.[46] IPEs are experiential coursework that fall early in the professional curriculum (ie, the 1st and 2nd professional year).[9] A major purpose of the IPE is for the school/college to develop educational outcomes that establish what the students can perform, not just what they know.[9] The educational experiences needed to achieve these outcomes can be designed to socialize the student with a caring attitude, internalize the components of pharmaceutical care, and develop a passion for lifelong learning. As new practitioners are trained in these programs, enter practice, and become preceptors, the expectation is that they will have the leadership and interpersonal skills to re-engineer practice to pharmaceutical care provision and be able to instill this process in the students they precept.

TOTAL PHARMACY CARE: A MODEL FOR THE FUTURE

The strategies discussed previously have proved useful to many pharmacies as they move from traditional distribution to pharmaceutical care provision. It is a difficult and time-consuming undertaking. For complete practice re-engineering to occur, a model is needed that can focus a pharmacy and its staff on all aspects of the job at hand. In the late 1990s, Holland and Nimmo studied the nature and extent of the shift in pharmacy practice to the pharmaceutical care model.[4] They discovered continuing reports of widespread failure to persuade pharmacists to become involved in clinical pharmacy and pharmaceutical care roles despite efforts by management to motivate this change through application of traditional managerial theory regarding motivation in the workplace. Holland and Nimmo found that while many managers urged the move to the new model of care, individual pharmacists did not have an understanding of how the pharmaceutical care work in their own practice environment. Thus, in an attempt to communicate effectively the needed transition to pharmaceutical care to those working at the forefront of patient care, Holland and Nimmo proposed a descriptive model of practice they referred to as Total Pharmacy Care (TPC).[4] This model was intended to help pharmacists understand how they fit into the larger scheme while accommodating individual differences in health care delivery systems and individual practice sites, and account for ongoing need for change as we move to the pharmaceutical care model.

TPC describes the state of pharmacy practice in the late 1990s as a combination of five distinct practice models: drug information, self-care, clinical pharmacy, pharmaceutical care, and distribution. All components of TPC operate concurrently to provide a comprehensive range of services to maximize the outcome of drug therapy defined as the provision of pharmaceutical care.

In the Drug Information practice model, the pharmacist provides general advice to health care consumers by, for example, participating in the design and provision of wellness campaigns. These pharmacists participate in the formulary decision-making process and evaluate and monitor the use of medication once it is accepted to the formulary. In the Drug Information model, the pharmacist is involved in educating

physicians and allied health care professionals, as well as the patient, regarding selection and safe use of medication.

In the Self-Care practice model, the pharmacist provides general advice to the consumer on health care matters. These pharmacists assess individual patient needs, recommend effective and safe drug therapies, and provide the patients with referrals when the treatment is outside the pharmacist's scope of practice.

Pharmacists working in the clinical practice model contribute to the physician's therapeutic management of the patient by providing the physician with drug information, pharmacokinetic calculations and interpretations, taking patient drug histories, or by designing, monitoring, and evaluating the patient's specific drug treatment.

The Pharmaceutical Care practice model allows the pharmacist to take the responsibility as part of the patient care team for modifying, designing, recommending, monitoring, or evaluating pharmacotherapy, and most importantly, to ensure the desired outcomes of the selected drug therapy.

The Distributive practice model includes the roles traditionally assigned to the pharmacist to ensure the integrity of the prescription through proper handling of records and dispensing of the drug product. While one would expect that this role would have lessened with the move to pharmaceutical care and the introduction of automated dispensing systems at the end of the 20th century, distribution and its associated technical tasks are still a major role of the most pharmacists in practice today.

The TPC model acknowledges the numerous ways that pharmacists provide the various components of practice needed to assure safe medication use. It also allows for the varying amount of time individual pharmacists spend in different practice models and how that will change as the need and opportunity arises. The model assumes that, if the concept of pharmaceutical care is widely adopted by the profession, individual pharmacists will influence their environment to allow the provision of this type of care. Thus, the proportion of pharmacists who practice pharmaceutical care will ultimately increase.

TPC does not suggest that pharmaceutical care will be the only accepted practice model; it requires all five models to meet a population's need. Even Hepler in discussing issues raised by the pharmaceutical care model acknowledged the need for a pharmacy services that fall outside the definition of pharmaceutical care.[48] TPC says it is the sum of all models that will maximize pharmacy's contribution to the nation's health and well-being. However, the hope is that all pharmacists will adopt the idea that pharmacists are at least partially responsible for the outcome of drug therapy regardless of the five models in which the pharmacist is practicing.

Pharmacists can use the TPC model to identify current practice characteristics. Once these characteristics are identified, they can use it to plan what they need to accomplish in their environment to provide TPC. They also can use it to determine how the proportions of pharmacists working in the various practice models would change if pharmacy were contributing maximally to positive patient care outcomes. Thus, TPC can be used as a long-range planning tool for individual pharmacists and pharmacy managers.

TPC indicates that the number of pharmacists engaged in the distributive model will decrease, although the nature of the pharmacists' involvement is likely to change dramatically as automation takes over the process. As health care moves to more managed care, the drug information practice model will likely increase, especially as the focus of care moves to drug selection for the population, instead of the individual. As the patient mix shifts to ambulatory care and as patients view themselves as the primary managers of care, especially with the shift of drugs in major therapeutic care areas switching to over-the-counter status, the portion of pharmacists involved in the self-care practice model will increase. As patients begin to value pharmaceutical care, demand for the assistance of pharmacist will increase.

TOTAL PHARMACY CARE: VARYING KNOWLEDGE, SKILLS, AND ATTITUDES

The tasks required in each of the five practice models each require a different set of skills and abilities to function successfully. Thus, each has differing needs of professional competency. Professional competence is defined as the degree to which the individual can use the knowledge, skills, and judgment associated with the profession to perform effectively in the domain of possible encounters defining the scope of professional practice.[49] Nimmo and Holland furthered their discussion of the TPC model with a description of the pharmacist's professional competency equation that was intended to provide a framework for the review of the prerequisites for success in each of the five practice models.[50] Their professional competence equation has three components: skills, professional socialization, and judgment.

Skills include consideration of psychomotor skills and the intellectual problem-solving skills. This would include conducting an effective literature search and drawing the appropriate conclusions for pharmacists practicing in the drug information model. For those working in self-care, the ability to determine the diagnosis for a stage of a common cold and recommending the correct OTC medications is a required competence. Problem-solving skills depend on the possession of content-matter knowledge, a procedural knowledge, and appropriate thinking strategy for working toward a solution.[51] Different methods of communication are required when talking with patients, discussing care with teams, or influencing prescriber drug choice because these involve intellectual problem-solving skills.

Professional socialization is defined as the attitudes and values associated with pharmacists' expectation of themselves as a professional. The attitudes and values instilled in pharmacists during early education and skill development in the classroom and through experiential training form a mindset as to whom they are as professionals. This mindset establishes what the person considers as appropriate job responsibilities for a pharmacist, to whom they considers themselves responsible, their social purpose, their relationship with other health care providers, their responsibility to the profession, and the nature of their relationship with patients. Professional socialization differs in each of the five components in the Total Pharmacy Care Model.

The remaining component of professional competency is judgment. A professional does not just perform routine tasks, but applies a critical decision-making process to his/her work. Judgment results from continuous practice of the required psychomotor and problem solving skills that reflect the nature of one's attitudes and values (ie, professional socialization). Over time, the pharmacist develops a wealth of experience that allows him/her to deal with situations by going beyond just applying rules or protocols, but to exercise creativity and intellectual problem solving to the situation. Judgment has also been referred to as tacit knowledge. Judgment is developed in a specific practice model by giving the pharmacist an opportunity to perform activities required while at the same time providing constructive feedback. Pharmacists with high standards of professional socialization will reflect on their daily practice and constantly judge the quality of their work while continuing to seek additional knowledge and skills to improve their performance.

DIFFERENTIATING THE PRACTICE MODELS

As we review the tasks performed in each of the five practice models considered in the TPC model, it becomes clear the variation in professional competence required for those successful in each model. There is one skill that is consistent in all five models, that being communication. However, the type and in-

tensity of communication vary. As pharmacists move from the distributive model to the pharmaceutical care model, the communication skills become more important and more extensively involved in the success of the pharmacists.

The Drug Information model requires pharmacists to be skilled in literature evaluation and able to apply analytical skills to influence medication policy decisions. These pharmacists must be effective presenting information to groups and should function well in committees. Pharmacists working in this model enjoy searching the compendia of drug and disease knowledge for answers and do not require a high degree of social interaction. Their primary role is on the analysis and provision of drug information to groups, be that for patients as health promotion information or as drug monographs for health care professionals.

The pharmacist practicing in the Self-Care model must possess skills required to perform health screening and make basic diagnosis to aid in the selection of nonprescription drug use or for referral for more complete care. Besides disease and care knowledge, these pharmacists must have well-developed communication skills to allow them to communicate effectively with patients about their condition. These pharmacists enjoy solving technical problems and enjoy a high level of social interaction.

The Clinical Pharmacy model requires the pharmacist to have highly developed technical problem-solving skills as they assess chronic and acute diseases and monitor drug therapy. Communication in this model is concentrated between the pharmacists and the physician as well as other members of the health care team. While some of these pharmacists may be involved in taking medication histories, communication skills required for these pharmacist-patient interactions are minimal. These pharmacists enjoy technical problem-solving, but generally do not require a high level of social interaction.

The Pharmaceutical Care model is similar to the Clinical Pharmacy practice model in that it requires the technical skills to design, implement and monitor drug therapy. However, it differs in required communication skills because the Pharmaceutical Care model now adds the requirement high level of communication with the patient in addition to the health care team. The pharmacist becomes the patient advocate in this model, communicating the patient's concerns, condition, and problems to allied health care professionals. This model requires the highest level of commitment to the patient as the pharmacist takes on an ethical responsibility to the patient for the outcome of drug therapy.

The Distributive model focuses on the technical knowledge of drugs and their storage, preparation, and delivery. Pharmacists successful in this model enjoy the daily routine, solving technical problems, and working alone. Requirements for communication skills focus on conveying their knowledge of drug therapy to patients and providing information on the administration of medication to other health care providers.

FACILITATING PRACTICE CHANGE, THE HOLLAND-NIMMO PRACTICE CHANGE MODEL

To assure the pharmacy profession's shift to the more patient care focused models of Pharmaceutical Care and Self-Care, individual pharmacists must be encouraged to embrace the concept of changing their practice and make the commitment to acquire the professional competency (ie, the knowledge, skills, and professional judgment) to function effectively in their new chosen model. The direct facilitator of the change is most frequently the employer, whether an institutional or community pharmacy manager, acting in the leadership role to ensure that the vision for change is realized.

In the late 1990s, Holland and Nimmo found that although well-developed educational programming exists to allow pharmacists to acquire the skills needed to make changes in their daily practice, few actually implemented these changes.[52] An intensive examination of the process needed for changes resulted in the Holland-Nimmo practice change model. The model is an analytic tool that can be used regardless of the practice change desired. The model proposes that there are three components that must be satisfied simultaneously before the change is likely to be implemented, regardless of the nature of a change in practice desired. If any of the components is missing or not provided simultaneously, the likelihood of successful change is limited. The three required components are a favorable practice environment, appropriate learning resources, and viable motivational strategies.

Pharmacists are unlikely to follow through on a personal commitment to change their practice unless they work in an environment where they can use the new practice model. While they may wish to practice pharmaceutical care and find personal time to acquire the new skills they may need, they are unlikely to make the effort if they will not be able to apply their new skills and commitment to care in their daily practice. If the desire to change and the work environment are conducive, the pharmacist must have access to resources that will allow him/her to acquire any new knowledge and skills required to function in the new practice model. If the environment is conducive and the learning resources are available, the pharmacist must be motivated to take the necessary steps to make the changes needed to implement the new practice model.

The first element required for practice change is a practice environment that allows the pharmacist to function in the new practice model as a routine part of his/her work. Creating a new environment may require an acceptance of the new role for pharmacists at the higher administrative levels in the organization in which the pharmacist is employed. It may require pharmacy management to demonstrate cost-savings or at least show that the new practice model will be cost neutral to win corporate administrations support for the change. With this support, necessary financial resources will be available to provide the workspace redesign, personnel, and equipment required to redesign the work environment to facilitate the new practice model. Additionally, there must be support for the new services among the other health care providers in the patient care area. As previously stated, in the Clinical Pharmacy and the Pharmaceutical Care models, the pharmacist becomes a member of the health care team. Acceptance of the pharmacist's new or expanding role by the other members of the patient care team, including the patient, is prerequisite to success of the new model.

Once these are in place, pharmacy management can set out to make the specific changes within their own departments to facilitate change. These will include a re-working of the specific jobs in the department to allow the pharmacists time to undertake their new professional responsibilities. This may include training technicians to take on additional responsibilities to free pharmacist time. It may also require additional technology such as automated dispensing machines or computer support to streamline traditional dispensing processes to free the pharmacists for time with patient care. These changes should culminate with a new position description written to reflect the new duties and responsibilities for the pharmacist taking on patient care roles.

Learning resources will be necessary to allow the pharmacists to acquire the new knowledge and skills required with the new practice model. The quest for knowledge should begin by systematically comparing the skills required in the new job description with the pharmacist's current set of skills, knowledge, and attitudes. Once the determination of the needed skills is complete, educational programs to fill these gaps must be accessible and affordable for the pharmacist. Employers can help facilitate this process by providing educational programs at the workplace or providing financial support to allow the pharmacist to attend programs on their own time. In addition, employers may consider allowing pharmacists to undertake the educa-

tional programs during work hours to further encourage the acquisition of these new skills. Finally, employers can encourage or sponsor membership and active involvement in state and national pharmacy associations.

The motivation to make the change must be present in the individual pharmacist. Pharmacists will vary in their motivation to change in that some will embrace the new practice model and actively seek any necessary means to facilitate change. Others will sit back and watch the situation and contemplate the effects of the change before deciding to make the change themselves. Still other pharmacists will never adopt the new practice model. These differences point to the important concept that motivation is very complex and involve one's personality, values, and attitudes. Managers wishing to influence their staff must account for the mindset of each practitioner and apply a systematic motivational process that will maximize the possibility of a decision to change.

The two major factors influencing a pharmacist's receptiveness to change are personality and professional socialization.[53] Personality is defined long before the pharmacist enters the profession. It may be difficult for pharmacists whose personalities do not match the practice models make the changes needed to be successful. However, professional socialization while it begins to take shape during pharmacy school continues to be shaped and molded throughout the professional's career.

Personality is the characteristic ways in which an individual thinks, feels, and behaves while reacting to the environment. Its makeup includes a person's major traits, motivations, self-concept, and emotional behaviors. The sources of these components are multifaceted and include hereditary and constitutional tendencies, training, and identification with parents and cultural environment, along with person's experiences and major relationships in early life. Personality in an adult is usually considered to be stable, and change only occurs if there is some alteration in fundamental perceptual, ideational, or responsive tendencies. People tend to choose a vocation they consider to be consistent with their personality traits. Gross dissatisfaction in the workplace, ineffective coping behavior on the job, and job changing is common when the personality and the work situation do not match with personality type. It is important to consider the personality of an individual pharmacist when changing practice models.

The studies suggest personality types among pharmacists characterized by a strong sense of responsibility, conscientiousness, practicality, logic, and, in about one in five, fear of personal communication. This personality profile represents a match between type and the profession of pharmacy when it was an occupation that mostly required technical problem solving with limited interaction with patients and allied health care professionals. Thus, it was considered that these practitioners chose pharmacy because they preferred well-planned, routine work found commonly in the traditional dispensing model of practice. Communication apprehension, described as avoidance of verbal interaction with others due to anxiety, occurs in 20% of pharmacists. This is consistent with the general population.[54]

When these prevalent personality types found in current practitioners are compared to the types required in the newer practice models, one finds potential for major mismatch of personality when a move to a new practice model is attempted. Pharmacists with personalities lacking the traits of independent decision-making, original thinking, patience and understanding, and sociability will have difficulty functioning in the pharmaceutical care model where these characteristics are required. The one in five with communication apprehension is unlikely to find comfort in a practice role requiring additional communication with physicians or patients. However, the common traits of logic and practicality can serve pharmacists well in all practice models when they take on complex problem-solving and analysis. Their conscientiousness can help to assure that all-important information, be it drug information for professionals or patient information, is considered in complex decision making processes. Those who find comfort in communicating with others may be able to make the transition to practices in the Drug Information model or the Clinical Pharmacy model as their communication requirements focus on interaction with like individuals (ie, allied health care providers). Those communicators who do have an extroverted nature will find comfort working in the Self-Care and Pharmaceutical Care models once they acquire the skills and knowledge to handle the complex problem-solving required. Thus, it is important for the pharmacist to understand his/her role personality type. Completion of the Myers-Briggs Personality Test may be worthwhile exercise to help these pharmacists gain a better understanding of their personality. It is not uncommon for personality testing to be sponsored by employers at retreats and other job-related functions to help employees determine their personality types and work within some team-building exercises to learn how individuals of different types can work together to accomplish the company's objectives. For an individual who has never had personality testing available, the test can be taken online (a fee is involved) at www.cpp.com.

With this understanding, the individual can best determine the areas of practice where he/she will best function and, thus, find satisfaction and comfort. If the individual wishes to function in a practice model unsuited for his/her personality type, corrective measures do exist to the individual overcome certain personality deficiencies. For instance, assume that an introverted practitioner is interested in becoming a Drug Information specialist, but has a fear of speaking to groups. Participating in Toastmasters or another public speaking organization may be sufficient to help overcome this fear.

For practicing pharmacists to make a change in their practice model they must re-formulate their practice values and attitudes - or be "resocialized." While personality characteristics are relatively set in early life, professional socialization continues to develop throughout the course of one's career. Traditional management methods to facilitate work changes have failed because their focus is on the performance of a "job" rather than an actual change in the way a professional accepts the values and attitudes required by the new practice model. Thus, there is an opportunity here to employ new methods to facilitate the changes needed in attitudes and values–or in professional socialization–to be successful in the new practice model.

Nimmo and Holland proposed a systematic process to assist managers to motivate their staffs to be "resocialized" into the new pharmacy practice models.[53] The process adapted accepted educational and psychological theories including Krathwohl's taxonomy of learning,[55] Roger's diffusion of innovation,[56] and instructional psychology.[57] The use of the learning theory encourages the managers to facilitate actively the change in values and attitudes and does not use passive or nonassertive methods to accomplish the change which needs to progress rapidly throughout the profession.

Krathwohl's taxonomy suggests that affective learning has a five-level hierarchy of stages that include Receiving, Responding, Valuing, Organization, and ultimately Characterization by a value or value complex. To relate this model to the changes in pharmacy practice, the pharmacist working in the distributive model begins to change by *receiving* information about the practice of pharmaceutical care. If the change progresses, these practitioners will actively *respond* to the information they received about the new model and then will *value* pharmaceutical care as an appropriate model for their practice. As they value the new model they will *reorganize* their practice to incorporate these new values. Ultimately, the new values will be so strongly embraced that they will *characterize* the pharmacist's overall approach to the profession.

As a prerequisite to engaging in the motivational strategy, managers should consider the existing characteristics of their staff. The development of new attitudes and values is most effective in the presence of an understanding of each practi-

tioner's personality and previous professional socialization. In some cases, personality and the strength of previous professional socialization may not allow the pharmacist to make the change to a new practice model despite use of the very best motivational strategy.

To begin the change process, the manager should determine the current professional orientation of staff members to understand which attitudes and values require nurturing and any variance between the current and desired situations. With this background, an effective motivational strategy can be customized for individual staff members by apply the following process to "resocialize" the pharmacists to provide care under the new model.

LEVEL 1.0: RECEIVING

To begin the process of professional resocialization, the pharmacist must "receive" the information about the new practice model. The three stages in this step are awareness, willingness to receive, and controlled or selected attention. Here the practitioner moves from an awareness of the new practice model, to becoming interested in learning the new model, and finally to actually actively seeking or paying attention to information the new model.

FACILITATING LEVEL 1.0 RECEIVING

Before change can be considered, knowledge of the new practice model must be available to understand what change might be considered. Due to variations in the original professional socialization of pharmacists, some practitioners look routinely for information about new practice opportunities. Others who consider pharmacy a job, not a profession, tend not to seek additional knowledge. Thus, at this step of the change process the manager should focus on providing information about the new practice model to those who would not be looking for it.

Practitioners bring their personalities and professional socialization that form their mindset with which the new practice model will be considered. The mindset may facilitate or hinder willingness to recognize AND consider the implications of the new model. Those trained in school when the focus was on technical problem-solving and limited patient interaction may find the new Pharmaceutical Care practice model incongruous with in their mindset. To deal with this situation, the educational technique using an interactive lecture to provide information including a clear concept of the new model and allow discussion of critical information guided with carefully framed questions can help provide understanding. Guided discussions can also help to reach this desired effect. The facilitator of the discussion or lecture should be an opinion leader among the pharmacists, and not necessarily the supervisor. Included in the presentations should be demonstrations of the bridge between the current practice model and the proposed one, as well as examples of success with the transformation. The discussion should be conducted to include all participants because only through dialogue can the discussion leader be sure that the participants have secured an understanding of the information. These lectures or discussion should occur in an environment conducive to learning because the acceptance of this information is critical to begin the change process needed for the profession. An off-site meeting (eg, retreat, away from distractions is a good way to generate enthusiasm for a new model.

Once the pharmacists have shown awareness and willingness to receive the information, management should be sure to provide opportunities for them to do so. Providing printed material, access, and time to connect to the Internet for information searches facilitates learning for those who have now moved to the controlled or selected attention stage. The pharmacists should be encouraged to observe and encouraged to converse with pharmacists who are already practicing in the new model, whether it is locally or through visits to other institutions or educational meetings. In addition, membership in and attending meetings of professional associations is an excellent method to network with practitioners involved in changing practice. Understanding of the new model is improved through these opportunities to network and learn. Management should encourage and provide the opportunity for these discussions to take place. By participating in the discussions, management can determine if the pharmacists are ready for the next step. However, management must walk a fine line between dominating the discussions in an attempt to force the pharmacists to accept its point of view, and leading the discussions to help the pharmacists arrive and the desired point of view.

LEVEL 2.0: RESPONDING

As pharmacists pass through the responding phase, they advance from complying with a request that they learn more about the new model of practice to deriving personal pleasure and psychic reward from the learning. In this step the pharmacist has a limited commitment to the new practice model because it is value is not yet realized. However, interest in the possibility of expanding practice is enough to stimulate learning. When the pharmacist becomes willing to consider the new model as a possible method of accepted practice the development of motivation to change has begun.

FACILITATING LEVEL 2.0 RESPONDING

In this step, the practitioner determines if he/she can fit into the new practice model and most importantly does he/she consider this an option for his/her practice. The pharmacist will consider what (s)he has to gain by adopting the new model and if (s)he will fit in the new type of practice. Nimmo and Holland suggest that a trial of the new practice behavior at this stage can speed up the formation of attitudes and values needed to facilitate the new practice model. Witnessing the new practice model in action provides the pharmacist with a personal sense of the new practice model and is critical to a change in attitudes and values. However, pharmacists are socialized to require accuracy in their work. If introduced to a practice situation in which (s)he feels incompetent, the pharmacist will likely reject rather than accept the new practice model. Coaching to recognize personal competence is a must.

LEVEL 3.0: VALUING

The practitioner comes into this level with a belief in the values of the new practice model that becomes a mindset. Over time a mindset develops that reflects a complete transformation to the required new values and attitudes. The pharmacist now has a preference for the new model and wishes to become more involved in the new practice. Once a preference is established, there is a true commitment to the new concept where formation of the new attitudes and values associated with the new practice model is complete and the pharmacist is truly ready to make the change in practice.

FACILITATING LEVEL 3.0 VALUING

At this level, pharmacists are engaged in an internal process of evaluation. They enter this level with a full understanding of the proposed form of practice and have tested it against their capacity to perform it and their interest in doing it. Now they begin an internal analysis comparing their old paradigm

against the new one and resolve any remaining uncertainty of the value and fit of the new model. Because personal evaluation and decision is the activity here, it is difficult for the pharmacy manager to be involved in this step–except to provide support and encouragement to the pharmacist undertaking this evaluation.

LEVEL 4.0: ORGANIZATION

Once there is a commitment to the change, the pharmacist must reorganize professional and personal priorities to allow a change in practice to occur. First, the pharmacists must grasp the value by understanding how the new practice model relates to all other methods of practice and why it is the preferred model for practice. Once the understanding takes place, the pharmacist commits to organizing priorities–whether there be educational or work process needs–to allow for the change to a new practice model to truly occur.

FACILITATING LEVEL 4.0: ORGANIZATION

While the manager's role in facilitating the reorganization of the practitioner's value system remains limited as the pharmacist determines his/her own priorities, it can be useful to facilitate conversations with peers who are involved actively in the new practice. This can help the pharmacist understand the fit of his/her own values and attitudes into the new model and begin to understand the organization needed to allow his/her practice to convert to the new model. This interaction can be helpful for those who are having difficulty determining how to handle the change when conflicts exist with personal priorities.

It is while organizing these priorities that pharmacists will determine what new skills or knowledge they will need to acquire to become competent providers in the new model. The manager can be most helpful by providing the learning resources needed and providing financial assistance and work time or release from work to allow for training and studying. By providing these educational opportunities, management can remove an important barrier that many times has prevented pharmacists from moving forward to the advanced practice models of clinical pharmacy and pharmaceutical care.

LEVEL 5.0: CHARACTERIZATION BY A VALUE OR VALUE COMPLEX

At this level resocialization is complete. Here the positive values and attitudes about the new practice model go beyond being just being adopted, they become the definition of the person as a professional. This occurs as the pharmacist internalizes the new practice to the point that the attitudes and values are considered part of the mindset without thinking. Beyond becoming part of the mindset, the new practice model characterizes the personal values of the individual where the new practice behavior has come to characterize the individual.

FACILITATING LEVEL 5.0

As a person internalizes values and moves to characterization, management has little role in this step. The best way to facilitate the progression to this highest level of learning is to facilitate the steps along the way, allowing the individual to progress to this point of characterization.

FACILITATING MOTIVATION

Reflecting on Krathwohl's Taxonomy of Affected Learning can help managers find areas where they can encourage the changes in attitudes and values pharmacists must make to become effective practitioners in the new practice models. Success in motivating pharmacists to develop new values as a part of their professional socialization will help advance the profession as providers of pharmaceutical care to all patients in the 21st century.

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CHAPTER 113

Pharmacoeconomics

William F McGhan

Practitioners and managers face a multitude of economic challenges as the ability to discover new therapies seems boundless while patients' resources to purchase these cures remains limited. How does one decide which are the best medicines to use within restricted budgets? The continuing impact of cost-containment is causing administrators and policymakers in all health fields to examine closely the costs and benefits of both proposed and existing programs. It is increasingly evident that private employers and public agencies are demanding that health programs be evaluated in terms of clinical and social outcomes related to costs incurred.

Cost-benefit analysis and other pharmacoeconomic tools are ways to analyze the value of the service to the public. These methods supplement the traditional marketplace value as measured by the prices that the patient or patron is willing to pay. As third parties continue to pay for a higher percentage of prescriptions dispensed, pharmacy managers are very cognizant that pharmacy services require continual cost-justification to survive and thrive in the future.[1–3]

Pharmacy entrepreneurs have established numerous innovative roles for pharmacists, such as home intravenous therapy, drug-level monitoring, parenteral nutrition management, hospice care, and self-care counseling, among others. The use of valid economic evaluation methods (eg, cost-benefit and cost-effectiveness analysis) to measure the value and impact of new services can increase acceptance of such programs by the medical profession, third-party payers, and consumers.[4–6]

There is increasing competition among health professionals for the limited dollars and resources available. Within institutions and communities, pharmacists will have to compete increasingly with nursing, medical, and other groups for adequate reimbursement and payment.[7,8] Therefore, pharmacy must document the cost-benefits of distinct pharmacy services and develop priorities for those services to compete successfully in the ever-changing health care landscapes.

The purpose of this chapter is to present the fundamental concepts of pharmacoeconomics and to suggest how these concepts can be applied in justifying, evaluating, and improving pharmacy programs and services.

As a general background, it is important to appreciate the types of evaluations that are involved when examining costs and consequences in health interventions. To facilitate an understanding of terminology used in this chapter, the reader is referred to the glossary of terms in Table 113-1. In addition, Table 113-2 provides a framework from Drummond et al[9] emphasizing that full economic evaluations involve the comparison of at least two interventions and an examination of all costs and consequences.

ANALYTICAL PERSPECTIVES

Point of view is a vital consideration in pharmacoeconomics. If a pharmacy service is providing a positive benefit to cost in terms of value to society as a whole, the service may not be valued in the same way by separate segments of society. For example, a drug therapy that reduces the number of admissions or patient-days in an acute care institution is positive from society's point of view but not necessarily from that of the institution's administrator who depends upon a high number of patient admissions to meet expenses. One must determine whose interests are being served when identifying outcome criteria for evaluation. When considering pharmacoeconomic perspectives, one must always consider who pays the costs and who receives the benefits. For example, a proposal to start a new pharmacy service that is funded by a hospital administrator would usually want to demonstrate that based on the projected number of inpatients, the revenues to the hospital would outweigh the pharmacy service costs. However, a pharmacy proposal to be funded by an outside employer group, such as an automobile manufacturer, would probably want to attempt to decrease hospital admissions and that could decrease the normal revenue for the hospital. A favorable economic analysis that showed savings in hospital expenditure from the employer perspective would probably not be viewed positively from the hospital perspective. More broadly, what is viewed as saving money for society may be viewed differently by third-party payers, administrators, health providers, governmental agencies, or even the individual patient. It is generally agreed among health economists that the societal perspective should always be discussed in an evaluative report, even though the focus of the report might deal with other segments such as hospitals or insurance agencies.

OVERVIEW OF ECONOMIC METHODS

This section will acquaint the reader with some of the methodological issues regarding two common pharmacoeconomic analyses including cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA). Table 113-3 provides a basic comparison of these methods along with cost of illness, cost-minimization, and cost-utility analysis. One can differentiate between the various approaches according to the units used to measure the inputs and outcomes, as shown in the table. In classic operations research (inputs versus outputs), the inputs would be measured in "pharmacy hours" and the output "production" units would be "number of prescriptions dispensed" or "number of patients monitored." In general, the outputs in CEA are related to vari-

Table 113-1. Glossary

Contingent valuation: a method for evaluation of benefit or value to individuals of therapy that uses survey methods to establish willingness-to-pay.
Cost-benefit analysis (CBA): a type of analysis that measures costs and benefits in pecuniary units and computes a net monetary gain/loss or a cost-benefit ratio.
Cost-effectiveness analysis (CEA): a type of analysis that compares interventions or programs having a common health outcome (eg, reduction of blood pressure; life-years saved) in a situation where, for a given level of resources, the decision maker wishes to maximize the health benefits conferred to the population of concern. This type of analysis can be used to assess cost-effectiveness efficiency.
Cost-utility analysis (CUA): a type of analysis that measures benefits in utility-weighted life-years (QALYs) and which computes a cost per utility-measure ratio for comparison between programs.
Decision analysis: an explicit quantitative approach for prescribing decisions under conditions of uncertainty.
Decision tree: a framework for representing alternatives for use in decision analysis.
Direct costs: those that are wholly attributable to the service in question, for example, the services of professional and paraprofessional personnel, equipment, and materials.
Discount rate: rate of discount used to convert future costs and benefits into equivalent present values; typically 2% to 6% per annum.
Equity: fairness in the allocation of resources or treatments among different individuals or groups.
Indirect costs: (1) indirect costs are societal, economic, and productivity losses due to morbidity and early mortality; also (2) indirect cost is sometimes used to refer to overhead costs that are based on costs that are shared by many services concurrently, for example maintenance, electricity, and administration.
Net benefit: total benefit (in monetary units) minus total cost (in monetary units); a basic decision criterion in cost-benefit analysis.
Opportunity cost: the opportunity cost of a commodity is the value of the best alternative use to which those resources could have been put; the value of the productive opportunities foregone by the decision to use them in producing that commodity.
Pharmacoeconomics: the study of how individuals and societies choose to allocate scarce pharmaceutical and health resources among competing alternative uses and to distribute the products and services among members of the society.
Quality of life (QOL): physical, social, and emotional aspects of a patient's well being that are relevant and important to the individual.
Quality-adjusted life year (QALY): a common measure of health improvement used in cost-utility analysis; combines mortality and quality of life gains (outcome of a treatment measured as the number of years of life saved, adjusted for quality).
Sensitivity analysis: a process through which the robustness of an economic model is assessed by examining the changes in results of the analysis when key variables are varied over a specified range.
Utility: a measure of value of an outcome that reflects attitudes toward risk.
Willingness-to-pay: the maximum amount of money that an individual is prepared to give up to ensure that a proposed health care measure is undertaken.

ous outcome measures, such as lives saved, life-years added, disability-days prevented, and so on. CBA is differentiated from CEA because CBA uses monetary values, dollars to measure the output of the respective program. Further discussion and examples of these techniques have been presented elsewhere.[1–3,10–18] It is hoped that the evaluation mechanisms delineated here may be helpful in managing pharmaceutical services toward improved societal value and generate greater acceptance by health care providers, administrators, and the public.

COST-BENEFIT ANALYSIS

The use of CBA is not a new concept in evaluating health programs. CBA is a basic tool that can be utilized to improve the decision-making process in the allocation of funds to health and other programs.[10,19–28] While the overall concept of CBA is simple, many of the methodological considerations require a certain degree of technical expertise, that will be introduced below, to apply CBA appropriately.

CBA evolved from the need to ascertain estimates of the costs and benefits of public investment projects. Expenditures for health care should produce net social benefits for the public. CBA techniques can be applied to make such resource allocation decisions in the health care field. Economists have indicated that medical care is an investment good and consumption good. When considered as an investment good, medical care is an investment in human capital.[29] As Pigou has pointed out, "the most important investment of all is the investment in health, intelligence, and character of the people."[30] In economic terms, the present value of a person's lifetime productivity is generally considered the appropriate measure of the benefit from investment in human capital.[31,32]

A major function in any pharmacy planning process is the formulation of alternative ways to achieve desired objectives and then choosing between those alternatives. Many times, decisions are made on the basis of intuition and personal judgment. By requiring one to state precise definitions and objectives (eg, to identify criteria for judging results, to quantify the results of each alternative, to provide formal exposition of alternatives and examination of the effects of assumptions and uncertainties), cost-benefit analysis provides a more solid basis for decision-making.

Table 113-2. Types of Pharmacoeconomics Evaluations

		ARE BOTH COSTS AND CONSEQUENCES OF THE ALTERNATIVES EXAMINED?		
		NO		YES
		Examines only Consequences	Examines only Costs	Examines both
IS THERE A COMPARISON OF TWO OR MORE ALTERNATIVES	NO	Outcome Description	Cost Description	Cost-Outcome Description
	YES	Efficacy Description	Cost Analysis	Full Economic Evaluation CBA, CEA, CUA, (etc.)

Adapted from Drummond MF, O'Bien BJ, Stoddart GL, et al. Methods for the Economic Evaluation of Health Care Programs. Oxford: Oxford University Press, 1997.

Table 113-3. Comparison of Pharmacoeconomic Methods and Calculations

METHOD	ABBR.	BASIC FORMULA	DISCOUNTING MATH	INPUT	OUTPUT	RESULTS EXPRESSED	GOAL Determine:	Advantage / Disadvantage	EXAMPLE
COST OF ILLNESS	COI	(DC+IC)	$\sum^{n}_{t=1}[C_t/(1+r)^t]$	$	$	Total cost of illness.	Total cost of illness.	Does not look at TXs separately.	Cost of migraine in U.S.
COST MINIMIZATION ANALYSIS	CMA	C_1-C_2 Or [Preferred Formula] $(DC_1+IC_1)-(DC_2+IC_2)$	$\sum^{n}_{t=1}[C_t/(1+r)^t]$	$	Assumed Equal	Net cost savings.	Lowest cost TX.	Assume both TXs have same effectiveness.	Assume two antibiotics have same effects for killing bugs but differ on RN & IV cost.
COST EFFECT-IVENESS ANALYSIS	CEA	$(C_1-C_2) / (E_1 - E_2)$ or [Preferred Formula] $(DC_1+IC_1)-(DC_2+IC_2) / (E_1 - E_2)$	$\sum^{n}_{t=1}[C_t/(1+r)^t]/ \sum^{n}_{t=1}[E_t/(1+r)^t]$	$	Health Effect	Incremental cost against change in unit of outcome.	TX attaining effect for lower cost.	Compare TXs that have same type of effect units.	Compare two HTN Rxs for life yrs.
COST BENEFIT ANALYSIS or NET BENEFIT	CBA	$(B_1-B_2) / (DC_1+IC_1)-(DC_2-IC_2)$ or [Preferred Formula] NET BENEFIT = (B_1-B_2) - $(DC_1+IC_1)-(DC_2+IC_2)$	$\sum^{n}_{t=1}[B_t/(1+r)^t]/ \sum^{n}_{t=1}[C_t/(1+r)^t]$ or $\sum^{n}_{t=1}[(B_t-C_t)/(1+r)^t]$	$	Dollars	Net benefit or ratio of incremental benefits to incremental costs.	TX giving best net benefit or higher B/C ratio (or Return on Investment).	TXs can have diff effects, but must put into dollars.	Compare two cholesterol Rxs and convert life yrs to wages.
COST UTILITY ANALYSIS	CUA	$(C_1-C_2) / (U_1-U_2)$ or [Preferred Formula] $(DC_1+IC_1)-(DC_2+IC_2) / (U_1 - U_2)$	$\sum^{n}_{t=1}[C_t/(1+r)^t]/ \sum^{n}_{t=1}[U_t/(1+r)^t]$	$	Patient Preference preference.	Incremental cost against change in unit of outcome adjusted by patient	TX attaining effect (adjusted for patient preference) for lower cost.	Preferences are difficult to measure.	Compare two cancer Rxs & use QOL adjusted life years gained.

Although it may not be easy to conduct a full economic evaluation, an important advantage of cost-benefit analysis is that it forces those responsible to quantify input (costs) and outputs (benefits) as thoroughly as possible rather than rest content with vague qualitative judgments or personal hunches.[30,31]

Cost-benefit analysis consists of identifying all the societal benefits that will accrue from a health program of interest and converting them into equivalent dollars in the year in which they will occur. This stream of benefit dollars is then discounted to its equivalent present value at the selected interest rate. On the other side of the equation, all costs of the program are identified and allocated to a specific year in the future and, again, the costs are discounted to their present value at usually the same interest rate. Then, other things being equal, the program with the largest present value of benefits minus costs is the "best" in terms of its economic value.

Ideally, all benefits and costs caused by the program should be included. This presents considerable difficulty, especially on the benefits side of the equation because many of the benefits are either difficult to measure, difficult to convert to dollars, or both. For example, benefits such as improved patient comfort, improved patient satisfaction with the health care system, improved working conditions for the physician, among others are difficult to measure and extremely difficult to convert into dollars.[33–38]

Another problem in cost-benefit analysis is how one determines the proper interest rate for discounting future benefits and costs. Prest and Turvey recommend that the selection of an interest rate be based on similar projects, followed by sensitivity analysis of the problem to determine the effect of a range of discount rates as the final solution. The problem of selecting an appropriate discount rate and other methodological considerations will be discussed in further detail later in the chapter.

MEASURING BENEFITS AND COSTS

The economic benefits of a health program are defined as the reduction in costs realized because of the implementation of that program. The conventional classification of these benefits and costs are threefold: direct, indirect, and intangible. There is sometimes disagreement on where to include a cost or benefit value in various economic equations, especially those dealing with CBA ratios where all benefits are on top of the equation as the numerator and all input costs are on the bottom as the denominator. For example, if a new drug allows you to use that one drug instead of two different drugs for patients, should the savings of not having to use the second drug be considered a minus value in the input costs of the numerator or should it be a positive figure on the benefit side of the ratio equation in the denominator? To resolve this ratio dilemma, it has become more popular to calculate net benefits (B−C) in place of the traditional CBA ratio (B/C).

DIRECT COSTS

Direct costs include those costs incurred prior to diagnosis and hospitalization, during hospitalization, during convalescent care, and during continued medical surveillance. Rice suggested that these costs include "expenditures for prevention, detection, treatment, rehabilitation, research, training, and capital investments in medical facilities as well as professional services, drugs, medical supplies, and nonpersonal health services." Direct benefits are defined as "that portion of averted costs currently borne that are associated with spending for health services; they represent potential savings in the use of health resources."[39,40] In other words, direct benefits are estimations of savings on direct costs. These terms are often subdivided into direct medical costs as described above and then direct nonmedical costs that include patient telephone expenses, taxi and parking fares, etc.

INDIRECT COSTS

Rice[39,40] provided a systematic method of measuring indirect costs. Her estimates include wage and productivity losses resulting from illness, disability, and death based on age and sex for major causal categories of morbidity and mortality. Indirect benefits represent the potential savings on indirect costs. Despite extensive treatment in the literature, indirect benefits can be difficult to quantify. They are the result of the avoidance of earnings and productivity losses that would have been borne without the health program in question.

INTANGIBLE COSTS

Intangible costs of ill health are difficult, if not impossible, to measure. These costs may be described as the "psychic" costs of disease such as those incurred from pain, suffering, and grief.[41,42] The measurement of such intangible benefits poses a most challenging task. Mishan[43] emphasizes that attempts should be made to account for these valuable "spillover" effects, if at all possible.

DISCOUNT RATES

All benefits and costs that occur at different times must be adjusted to reflect comparable values. This is accomplished by converting dollar amounts into present values through the use of an interest rate referred to as the discount rate. Although most economists agree that discounting is essential, there is much discussion as to the appropriate rate for any given situation. The consequences of choosing a high or a low discount rate are clear: a low discount rate favors projects with benefits accruing in the distant future, while a high rate favors projects with costs in the distant future.[44–47] One commonly used rate is the current yield rate on long-term government bonds. This seems practical because it represents a riskless long-term alternative use of funds by a tax-free institution and, therefore, appears valid for use by hospitals in evaluating long-term investment proposals. Theoretical support can be found in the literature for practically any figure between the pure time-reference (riskless) rate, as low as 4%, and the corporate return on capital, approximately 20%.[48–50]

Cost-benefit methodology is based upon certain assumptions. It is important to have these assumptions clearly in mind before proceeding. The basic assumptions of CBA are as follows:

1. It is possible to separate one service from another service in a sensible way.
2. There is a possibility of choice between the interventions.
3. It is possible to estimate the outcomes associated with each service.
4. It is possible to value these outcomes.
5. It is possible to estimate the cost of providing each service.
6. These costs and benefits can be weighed against each other.
7. The goal should be to provide only those services/treatments in which the benefits outweigh the costs.

Using these assumptions, there are several mathematical methods for developing the classic benefit to cost ratio. All have the same objective, but they differ in the way in which they handle the data mathematically.[51,52] The most common method is the following calculation:

$$\text{Cost Benefit Ratio} = \frac{\sum^{n}_{t=1}[B_t/(1+r)^t]}{\sum^{n}_{t=1}[C_t/(1+r)^t]}$$

where B_t = total benefits for time period t, C_t = total costs for time period t, r = discount rate, and n = number of time periods. The decision criterion is as follows:

If B/C > 1, then benefits exceed costs and program is socially valuable.

If B/C = 1, then benefits equal costs.

If B/C < 1, then benefits are less than costs; therefore, program is not socially beneficial.

Table 113-4. Sample Comparison Using Three Different Cost-Benefit Equations

	COSTS STARTUP t(0)	BENEFITS END OF FIRST YEAR t(1)	1 COST BENEFIT RATIO (B/C)	2 NET PRESENT VALUE (B−C)	3 INTERNAL RATE OF RETURN (B−C)/C
Program A	$10,000	$15,000	1.5:1	$5,000	50%
Program B	$100,000	$180,000	1.8:1	$80,000	80%

A major problem with any economic analysis is in choosing "r," the discount rate that was discussed earlier.

The more popular equation used in cost-benefit analysis relates to the logical concept of net benefit and net present value (NPV) represented in the equation below.

$$\text{Benefit-Costs} = \text{NPV} = \sum {}^{n}{}_{t=1}[(B_t - C_t)/(1+r)^t]$$

The results of these equations can be misleading, depending on the potential differences in the magnitude of dollars and time involved when comparing the costs and benefits of competing programs. In Table 113-3, there is comparative information about the formulae and factors for pharmacoeconomic calculations. In Table 113-4 simplified versions of three different cost-benefit approaches have been presented to illustrate how the decision factors may vary. The third approach presented in the table includes calculation of a "rate of return" on the investment, which is a rearrangement of the above equations to allow calculation of the "rate of return" from an initial program investment over a potential stream of benefits over time. From these various calculation options, one must select which formula is most appropriate in their institution or setting and perhaps the calculated answers from all three CBA equations should be presented in the report. Many economists recommend the net present value (NPV) approach because of the problems with comparing ratios.

In the example provided in Table 113-4, Program A might represent a proposal for a medium-size computer in the pharmacy while Program B might represent a large computer system with multiple decentralized terminals. Although Program B has a higher cost-benefit ratio and rate of return, it is an expensive system and the pharmacy may not be able to commit such a substantial amount of funds. Numerous other examples could be considered here which change the results from the various formulas and make it more difficult to select between programs.

It should be emphasized that, for the numbers presented in this example, the calculations have been greatly simplified. The calculations and comparisons become more complex as benefits are accrued at different increments of time and as costs and benefits are properly discounted with the more complete formulas presented earlier.

If a new project involves start-up costs, such as a laminar flow hood for a home IV service, calculations from the above formulas can be considered. If there are extra benefits accrued by an efficient distribution system, the amount of money that must be saved as benefits each year becomes similar to paying off a start-up loan (SL) over time (t) with interest rate (r) and with extra yearly benefits (Bx). Therefore:

$$Bx = SL[r/1 - (1+r)^{-t}]$$

COST-EFFECTIVENESS ANALYSIS (CEA)

Requirements for Cost-Effectiveness Analysis[53–55] are that:

1. The optimal alternative (not necessarily the least costly) for accomplishing an objective should be possible;
2. At least two alternative interventions should be possible;
3. It need not be cost-reduction analysis but rather an optimizing process; and
4. The outcomes of the alternatives can be quantified using a common unit of measurement.

In CEA, costs are calculated in dollars but alternative ways are then compared for achieving a specific set of results such as blood pressure or life expectancy changes. The objective is not just how to use funds most wisely; CEA also includes the constraint that similar output measurements must be obtained in order to properly compare interventions. Thus, CEA is applied to health matters in situations where the program's inputs can be readily measured in dollars, but the program's outputs are more appropriately stated in terms of the health improvement created (eg, life-years extended). Weinstein and Stason provided an explanation of the use of CEA for the practicing physician as well as for the physician-administrator.[10]

Basic mathematical examples of various economic analyses are presented for cost benefit (Table 113-5), cost-effectiveness (Table 113-6), cost-utility (Table 113-7), and cost-minimization (Table 113-8).[59]

QUALITY OF LIFE OUTCOMES AND PATIENT PREFERENCES

Equally significant and equally misunderstood in pharmacoeconomics and patient outcomes management is the issue of quality of life.[56,57] Although it is recognized that there are physical, mental, and social impairments associated with disease, there is not strong consensus on how to accurately measure these factors. Consequently, the concept of satisfaction with care is often overlooked in cost-effectiveness studies and even the approval process of the Food and Drug Administration (FDA). However, pharmacoeconomics and outcomes research considers quality of life an important predictor in creating a full model of survival and improvement. Quality of life (QOL) is related to clinical outcomes as much as drugs, practitioners, settings, and types of disease. The question is how to select and utilize the most appropriate instruments (sample titles listed in Table 113-9) for measuring quality of life and satisfaction with care in a meaningful way.

Another important aspect of quality of life research is the number of healthy years within life extension. In an average life span of 73 or 74 years, people may have about 11 or 12 dysfunctional years. Therefore, whenever one examines the pharmacoeconomic impact of pharmaceuticals, one should adjust for the

Table 113-5. Cost-Benefit Analysis Example

	COST OF THERAPIES	
	DRUG A	DRUG B
Costs		
Acquisition Cost	300	400
Administration	50	0
Monitoring	50	0
Adverse Effects	100	0
Subtotal	500	400
Benefits		
Days at Work ($)	1000	1000
Extra Mos of Life ($)	2000	3000
Subtotal ($)	3000	4000
Benefit to Cost Ratio:	3000/500 = 6:1	4000/400 =10:1

Table 113-6. Cost-Effectiveness Analysis Example

	COST OF THERAPIES ($)	
	DRUG A	DRUG B
Costs		
Acquisition Cost	300	400
Administration	50	0
Monitoring	50	0
Adverse Effects	100	0
Subtotal	500	400
Outputs		
Extra Years of Life	1.5	1.6
Cost-Effectiveness Ratio:	500/1.5 =$333[a]	400/1.6 =$250[a]

[a] Per extra year of life.

Table 113-8. Cost Minimization Analysis Example

	COST OF THERAPIES ($)	
	DRUG A	DRUG B
Costs		
Acquisition Cost	250	350
Administration	75	0
Monitoring	75	25
Adverse Effects	100	25
Subtotal	500	400
Outcomes		
Antibiotic Effectiveness	90%	90%
Result = Cost of Drug A > Cost of Drug B		

Note: In cost minimization, both interventions (drugs) are considered to be equally effective; and in this example, the cost minimization question is answered by stating that Drug B is $100 less than Drug A.

quality of life of any extra years to reflect whether this increase leads to full, healthy years or includes some dysfunctional adjustments as well. Likewise, if adjustments are not made for comorbidities, the resulting health profile may be skewed. For example, untreated hypertension may escape a quality-of-life measurement because it does not overtly affect daily life. But a myocardial infarction, for example, would definitely lessen quality of life. The FDA has been leery of drugs that make patients feel better while life expectancy is reduced. Nevertheless, one must be able to present to patients the different probabilities between perfect health and death, the compromises associated with different treatments, and then administer care accordingly. To present these probabilities, though, one must monitor what happens to patients during clinical treatments over time and collect data on their utilities. This means that one should ask patients how they feel about their therapy options, which therapies they prefer, and how their quantity and quality of life are affected. Pharmaceutical companies have sponsored work that examines probabilities, utilities, and cost-effectiveness and then charts the results over time.

QALY (quality adjusted life year) has become a major term in pharmacoeconomics. It is a measure of health improvement used in cost utility analysis (CUA). It combines mortality and QOL gains and considers the outcome of a treatment measured as the number of years of life saved, adjusted for quality. See Table 113-7 for a cost-utility example that illustrates the basic calculations on how the number of life years is adjusted for quality.

DECISION ANALYSIS

Weinstein and Fineberg define decision analysis as ". . . a systematic approach to decision making under conditions of uncertainty." Decision analysis is an approach that is: explicit, quantitative, and prescriptive.[5]

It is explicit in that it forces the decision maker to separate the logical structure into its component parts so they can be analyzed individually then recombined systematically to suggest a decision. It is quantitative in that the decision maker is compelled to be precise about values placed on outcomes. Finally, it is prescriptive in that it aids in deciding what a person should do under a given set of circumstances. The basic steps in decision analysis include identifying and bounding the decision problem; structuring the decision problem over time; characterizing the information needed to fill in the structure; and then choosing the preferred course of action.

Table 113-7. Cost-Utility Analysis Example

	COST OF THERAPIES ($)	
	DRUG A	DRUG B
Costs		
Acquisition Cost	300	400
Administration'	50	0
Monitoring	50	0
Adverse Effects	100	0
Subtotal	500	400
Utilities		
Extra Years of Life	1.5	1.6
Quality of Life	.33	.25
QALYs[a]	0.50	0.40
Cost to Utility Ratio:	500/0.5 = $1000[b]	400/0.4 = $1000[b]

[a] QALYs = Quality Adjusted Life Years.
[b] Per extra quality adjusted life year.

Table113-9. Outcomes and Quality of Life Measurement Approaches

I. Basic Outcomes List
   A. Death
   B. Disease
   C. Disability
   D. Discomfort
   E. Dissatisfaction
II. Major Quality of Life Domains
   A. Physical status and functional abilities
   B. Psychological status and well-being
   C. Social interactions
   D. Economic status and factors
III. Expanded Outcomes List
   A. Clinical End Points
      1. Symptoms & Signs
      2. Laboratory Values
      3. Death
   B. Functional Parameters
      1. Physical (activities)
      2. Mental (depression)
      3. Social (fiends)
      4. Role (work)
   C. General Well Being
      1. Pain
      2. Energy/Fatigue
      3. Health perceptions
      4. Opportunity (future)
      5. Life satisfaction
   D. Satisfaction with Care
      1. Access
      2. Convenience
      3. Financial Coverage
      4. Quality
      5. General
III. Sample of Instruments for Outcomes Measurement
   A. Generic Instruments—SIP, Nottingham, QWB, SF-36, EQ-5D
   B. Specific Instruments—Pain, Arthritis, Epilepsy, Cancer, COPD, GI

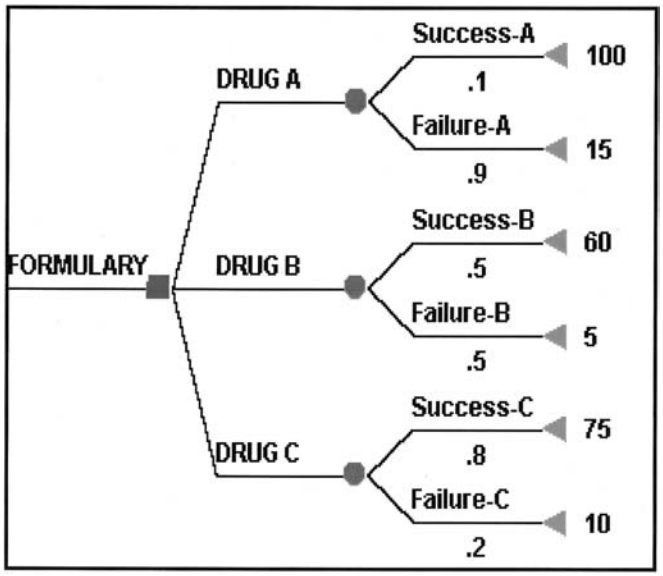

Figure 113-1. Decision tree. Note: this decision tree is constructed from the same numbers in Table 113-10. For example, the numbers listed on the far right of this tree are utility values which could represent quality of life scores or cost. The calculations in basic trees are performed the same

Decision trees, as illustrated in Figure 113-1 may be considered by the reader to be the most familiar image for decision analyses. It is important to remind ourselves that the mathematics along a horizontal "branch" in decision trees can be converted to rows in a spreadsheet (Table 113-10).[61] Even more importantly we must realize that there are other, theory related, alternative mechanism (in addition to the traditional decision trees) that are being utilized and published in the health care evaluations.[58,59]

In this example, quality of life and cost data may be incorporated into the utility score (U). Utility scores can be ascertained from previous research, expert panels, practitioners, and/or from patients themselves. If desirable and possible, the utility score could in fact be replaced with "net benefits" in dollars (benefits minus costs) of one therapy over another. As the table shows, one is seeking the therapy that generates the highest expected utility. If the outcome of the study is focused on cost, then one is usually seeking the intervention with the lowest expected value. Using decision-analysis concepts, researchers can construct decision tree models of what actually happens to the patient from diagnosis to cure. As a result of utilizing such analytical approaches, one can more clearly see not only costs, but also the probability of entering one health state over another. For example, with the visual decision tree in Figure 113-1, one should be able to more clearly understand the pharmacoeconomic implications of the health states related to success or failure with different therapies.

Another alternative decision-making approach is Multi-attribute Utility Theory (MAUT). MAUT is a procedure for identifying, characterizing, and comparing the variables that may affect a decision. Each criteria in a MAUT decision is usually given a different weight, often provided from an expert panel, and the total scores for each intervention option are mathematically calculated. MAUT has been used to analyze managerial and policy decisions and it is used in health care publications for providers and patients.[60] MAUT methods are useful when conducting cost-consequence analysis where multiple outcomes are included in the analysis.

From computer modeling, one can develop treatment protocols. Each branch of a decision tree designates specific treatments for patients at specific health states. In a simplified form, a decision tree can double as an educational tool for presenting available therapy options and probable consequences to the patient.[61,62]

Wennberg has been exploring ways to involve patients in a shared decision-making process.[62] One of his projects involved a computer interactive program on prostrate surgery education. The program explains to patients the probability of success, what degree of pain that might be encountered at each step, and what the procedure actually entails. After viewing this program with visual graphic depictions of the surgery, many of the patients changed their decisions about wanting surgery over watchful waiting. This reduction in a major procedure resulted from a greater focus on quality of life and patient satisfaction. With further evaluation and perhaps modification of the computer program, it should also produce more cost-effective care. Wennberg's work is an application of outcomes research which helped to weigh costs, utilities, and quality of life for the patient.

DEVELOPING A FORMULARY LIST–RANKING PRIORITIES

Table 113-11 illustrates how cost ratios can be used to rank alternative therapies as one might do for a drug formulary. The numbers in the second column of the table lists the total quality-adjusted life years (QALYs) for all of one's patient population benefiting from the treatment options in each row. The numbers in the third column lists the total cost of treatment for all of one's targeted patient population for each treatment option in each row. For the next step in the selection process, rank the therapy options by their cost-effectiveness ratios. Options have already been ranked appropriately in this table. For the final selection step, add each therapy option into one's formulary, moving down each row until your allocated budget is exhausted. In other words, if you have only $420,000, you would be able to fund therapies A, B, and C. These options have the best cost-utility for one's population given one's available budget. Cost effectiveness and cost utility ratios are sometimes presented in similar fashion and are called League Tables. Tengs et al[63] have published an extensive list of interventions (Table 113-12) and Neumann and

Table 113-10. Example of Expected Utility Calculations Often Seen in Decision Tree Analysis

	OUTCOME	UTILITY (U)	PROBABILITY (P)	EXPECTED UTILITY (U × P)	TOTAL EXPECTED UTILITY	TOTAL EXPECTED RANK
DRUG A	Success	100	0.1	10		—
	Fail	15	0.9	13.5	23.5	Third
DRUG B	Success	60	0.5	30		
	Fail	5	0.5	2.5	32.5	Second
DRUG C	Success	75	0.8	60		
	Fail	10	0.2	2	62	First

Note: The drug with the highest expected utility is the preferred therapy (ie, Drug C).

Table 113-11. Health Economic Selections With Fixed Budget

THERAPY OR PROGRAM	QALYS[a]	COST[b] ($THOUSAND)	C/U RATIO ($THOUSAND)
A	50	100	2
B	50	200	4
C	20	120	6
D	25	200	8
E	10	120	12
F	5	80	16
G	10	180	18
H	10	220	22
I	15	450	30

[a] Total Quality Adjusted Life Years (QALYs) for all of patient population benefitting.
[b] Total cost of treatment for all of targeted patient population.
Selection procedure: first, rank therapies by cost-effectiveness ratios, then add therapy options until budget is exhausted.

colleagues[64] maintain a website with a substantial list of cost utility ratios based on health economic studies.

These listings must be used with caution, because there are a number of criticisms of rankings with cost outcome ratios, often called league tables, including[9]:

- Different reports use different methods
- What were the comparators (eg, which drugs, which surgeries)?
- Difficult to be flexible about future comparators
- Orphan and rare disease consideration
- Randomized trials versus epidemiology
- Regional and international differences in resource use
- Regional and international differences in cost
- Confidence intervals of findings
- Difficult to test statistical significance between treatments but can consider financial impact

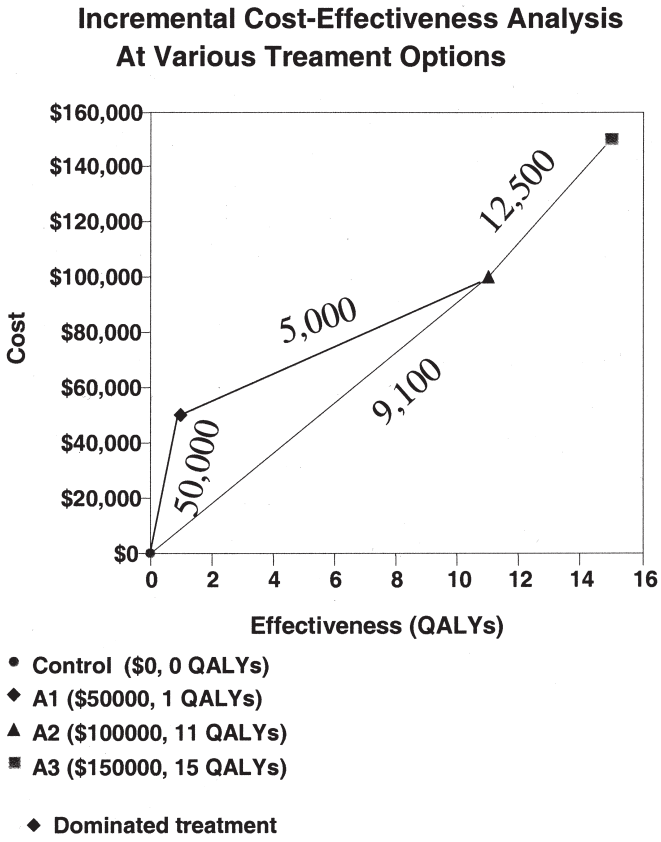

Figure 113-2. Incremental analysis and slopes.

INCREMENTAL ANALYSIS

Whether one is dealing with cost analyses or decision analysis, it is important to properly compare one treatment to another, and one should understand the concepts in incremental analysis. Incremental analysis does not mean that one is adding a second therapy to the patient's regimen, but it is a technique for comparing one therapy to another. The basic incremental formulas are as follows:

$$\text{CEA: } (\text{Cost}_1 - \text{Cost}_2) / (\text{Effectiveness}_1 - \text{Effectiveness}_2) \text{ or}$$

$$\text{CUA: } (\text{Cost}_1 - \text{Cost}_2) / (\text{Utility}_1 - \text{Utility}_2) \text{ or}$$

As illustrated in Figure 113-2 and explained by Drummond et al, suppose one is interested in program treatment A2 which could be a new vaccination program or a new drug proposed for formulary adoption and reimbursement. Compared to placebo or doing nothing, A2 costs an additional $100,000 and provides 11 extra QALYs in the population, with an incremental cost-effectiveness ratio of $9,100 per QALY. This might be the figure included in a league table for comparison to other interventions or formulary drugs. The cost per QALY ratio between two points is given by the slope of the line. But suppose current practice is to have program A1. This costs $50,000 but generated only 1 QALY. If one compares A2 with A1, a more acceptable incremental cost-effectiveness ratio of $5000 per QALY is obtained. But A1 is a "dominated" program and should not be considered in the relevant set of alternative therapies. This illustrates that the incremental analysis of A2 over A1 could be misleading.

An interesting way of presenting this information is illustrated in Figure 113-3. By thinking of this information in quadrants, one can more easily visualize the relationship between therapies. Drugs that are cheaper and more effective would fall in the "accept" or "dominant" sector, while drugs that are more expensive and less effective would be "dominated" (ie, overshadowed, discouraged from use) by better treatments that are more cost-effective. The slopes of the lines represent the incremental cost ratios and, in general, therapies between $20,000

Table 113-12. Comparison of Interventions—Cost per Life Year Gained

INTERVENTION CATEGORY	NUMBER OF STUDIES	MEDIAN COST PER LIFE-YEAR ($)
Child Immunization	6	<0
Drug & EtOH Tx	4	<0
Beta-Blocker post MI	4	2,000
Tuberculosis Tx	2	9,000
Smoking Advice	15	6,000
Hypertension Tx	6	15,000
HIV/AIDS Tx	6	23,000
Hormone Replacement	13	42,000
Renal Dia. &/or Transplant	22	44,500
Heart Transplant	2	54,000
Radon Control	7	141,000
Cholesterol Tx	19	154,000
Vinyl Chloride Control	2	1,614,000
School Bus Safety	8	1,757,000
Asbestos Control	41	1,865,000
Benzene Control	27	14,153,000
Radiation Control	28	27,386,000

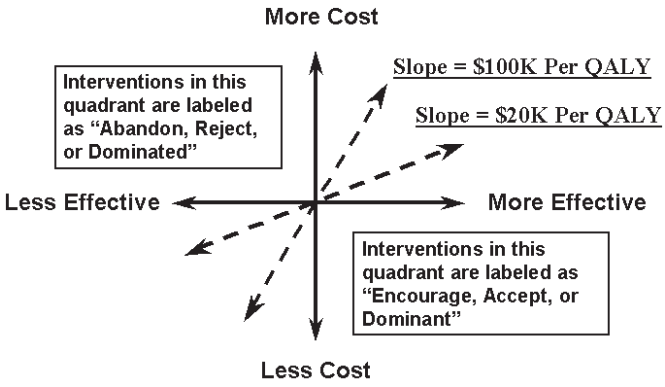

Figure 113-3. Pharmacoeconomic ratios and quadrants.

to $100,000 per life year saved (or per QALY) are often considered acceptable in public policy reports.

A classic manuscript involving incremental analysis deals with the comparison of tissue plasminogen activator (TPA) to streptokinase.[65] In this study, the important question did not involve looking at the CEA ratio of each drug individually; but instead, it analyzed the incremental differences of the new drug TPA over the standard therapy at the time. The analysis demonstrated that TPA, when compared to streptokinase, had an incremental cost per life year saved of about $40,000 which was considered a socially acceptable value.[65]

PHARMACOECONOMIC CONSULT FORM

Figure 113-4 provides a basic consult form that suggests a framework for pharmacoeconomic assessments. If a decision needs to be made between alternative treatments, this form could help structure the calculations and considerations related to pharmacoeconomics. This consult worksheet is a template for evaluating therapy options for a drug formulary, framing a formal pharmacoeconomic study, or the worksheet could be used for a basic pharmacoeconomic calculation sheet to be discussed with a physician or patient and then placed in a patient's record. At an individual patient level, it might be difficult to have the time with each patient to consider complicated discounting calculations.

CHECKLIST AND SCORING FORM FOR A PHARMACOECONOMIC STUDY

In Table 113-13 the reader is provided with an evaluation checklist that includes a weighting system for evaluating an article or a research proposal. This form could be utilized for an external review or self-assessment of a research proposal. It could also be utilized to compare several articles to determine which articles are more rigorous than others. This comparison might be useful in formulary decisions when comparing several articles on alternative treatments.

DISCUSSION

A key impact that the profession of pharmacy needs to give more attention to is the idea that the greatest benefit we can generate for society as a whole is to target and take more responsibility toward decreasing mortality, not just decreasing morbidity. Giving extra years of life to a patient population can be converted to dollars for society, which greatly enhances the benefit-to-cost ratio of a program. Substantially more research remains to be performed on the potential impact of pharmacists and their services on mortality rate. Computer technology and the Internet are tremendous resources for learning and applying these evaluation techniques, and then continually documenting outcomes for practitioners and patients.[66] It is expected that reimbursement plans will include more incentives for documented decreases in patient morbidity and mortality.

Pharmacy practitioners and managers must consider cost-benefit and cost-effectiveness based on the outcomes of the services that pharmacy delivers and the impact that pharmacy services can provide. There are a number of ways that the profession of pharmacy can produce positive outcomes on hospital services. For example, pharmaceutical services can:

- Decrease morbidity in patient populations
- Increase the percentage of patients in therapeutic control
- Reduce the overall costs of the treatment by utilizing more efficient modes of therapy
- Reduce the number of physician visits
- Reduce the rate of hospitalization attributable to or affected by the improper use of drugs
- Contribute to better use of health manpower by utilizing computers and technicians
- Decrease the incidence and intensity of iatrogenic disease, such as adverse drug reactions

Other examples of the types of pharmacy services and their potential benefits and effects include patient consultation, which improves patient compliance, reduces medication errors, reduces misuse of medication, and provides efficient use of all personnel. A unit dose distribution program can improve patient therapy while reducing drug waste and, perhaps, nursing personnel costs.

By monitoring drug therapy in acute care situations, pharmacy can provide early detection of therapy failure or adverse reaction. Admixture programs provide better intravenous therapy and possibly more efficient use of personnel. Under patient and therapy responsibilities, drug prescribing by pharmacists might be added, which can be highly cost-effective. What is being performed in defined patient care situations is substituting a pharmacist's salary for that of a physician, which may be two or even three times greater. Pharmacists can be very beneficial in the areas of patient discharge interviews and in recording patient histories. Under personnel substitutions, one can look at ways that pharmacists can increase physician productivity and, by using computers and technicians, how the pharmacy salary budget can be best allocated.

In this chapter, a general explanation of pharmacoeconomics has been provided with the intent of helping the reader in cost-justification efforts and providing cost-effective outcomes. There are encouraging reports in the literature that demonstrate that pharmacists can have cost-beneficial effects in a numerous areas. Still, it must be realized that even though this research is positive, there is a need to continue to develop programs that maximize the benefit-to-cost ratio to society and to institutions. Even though a pharmacy endeavor can demonstrate a positive ratio of benefit to cost, society or the institutions will ultimately invest their resources in programs that have the higher benefit-to-cost or the best cost-utility ratio. Similarly, the health system must be convinced that these beneficial pharmacy services are worth utilizing with modification or even deletion of other less effective programs if necessary. Pharmacy managers must fully understand these evaluation tools if their programs are to thrive in the future.[67]

PHARMACOECONOMICS CONSULT:
BASIC CALCULATION SHEET

I. ID NUMBER:
II. TREATMENT OBJECTIVES:
III. PERSPECTIVE: ☐ Society ☐ Patient ☐ Payer ☐ Provider ☐ Hospital ☐ Other
IV. TYPE OF ANALYSIS:[a] ☐ COI ☐ CMA ☐ CBA ☐ CEA ☐ CUA ☐ Other
V. TREATMENT OPTIONS:

	Treatment A	Treatment B	
Names of Treatment:			
Disease/Symptom:			
Major Outcome Measure:			

VI. COST FACTORS

	Treatment A	Treatment B	Incremental
A. DIRECT COSTS: (HEALTH CARE RESOURCES)			
Practitioner			
Clinic/Hospital			
Acquisition			
Administration			
Monitoring			
Managing			
ADRs			
_____			
_____			
B. DIRECT COSTS: (NON-HEALTH CARE RESOURCES)			
Transport			
Telephone			
_____			
_____			

	Treatment A	Treatment B	Incremental
C. INDIRECT COSTS			
Morbidity Costs (time lost from work in dollars)			
Mortality Costs (time lost from work in dollars)			
D. INTANGIBLE COSTS (difficult to put in dollars)			
Discomfort/Pain			
Emotional			
QOL Quality of Life Index (as percentage of full health)			
TOTAL COST			

VII. MEASUREMENT CONSIDERATIONS
of effectiveness, benefit, or utility.

Unit of measurement

COI	(direct and indirect costs of illness)
CMA	(input costs only, outcomes assumed equivalent)
CBA & NB	(input = $, outcomes all in dollars)
CEA	(input = $, outcomes in natural units, mmHg, etc.)
CUA	(input = $, outcomes in utiles, QALYs)
Other	

VIII. CALCULATED RESULTS:
(Ratios are results of Outcomes divided by Inputs.)

		Treatment A	Treatment B	Incremental
COI	(direct & indirect costs of illness)			
CMA:	(total direct & indirect costs)			
CBA:	(benefit over cost ratio)			
[NB:	(benefit minus cost)]			
CEA:	(cost over effectiveness over ratio)			
CUA:	(cost over utility ratio)			
Other:				

[a] See calculation formula table for definitions.
From McGhan WF, Smith MD. *Pharmacy Business* 1993; (Spring):6.

Figure 113-4. Pharmacoeconomic consult template.

Table 113-13. Evaluation Criteria for Assessing a Pharmacoeconomic Study

EVALUATION CRITERIA	RELATIVE CRITERIA WEIGHT/IMPORTANCE (SCALE 0 'NOT APPLICABLE' TO 10 'VERY IMPORTANT')	ITEM QUALITY SCORE (SCALE 1 'NOT AT ALL SATISFACTORY' TO 10 'TOTALLY SATISFACTORY')
1. APPROPRIATE QUESTION? Was a well-defined question posed in answerable form? Did the study examine both costs and effects of the service(s) or program(s)? Did the study involve a comparison of alternatives? Was a viewpoint for the analysis stated and was the study placed in any particular decision-making content?		
2. PROPER ALTERNATIVES? Was a comprehensive description of the competing alternatives given? Were any important alternatives omitted? Was (Should) a do-nothing alternative (be) considered?		
3. EFFECTIVENESS DETERMINED? Was there evidence that the program's effectiveness had been established? Has this been done through a randomized, controlled clinical trial? If not, how strong was the evidence of effectiveness?		
4. ALL COSTS AND CONSEQUENCES? Were all the important and relevant costs and consequences for each alternative identified? Was the range wide enough for the research question at hand? Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending upon the particular analysis.) Were capital costs, as well as operating costs, included?		
5. ACCURATE MEASUREMENT? Were costs and consequences measured accurately in appropriate physical units? (eg, hours of nursing time, number of physician visits, lost workdays, gained life-years) Were any of the identified terms omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis? Were there any special circumstances (eg, joint use of resources) that made measurement difficult?		
6. PROPER VALUES ASSIGNED? Were costs and consequences valued credibly? Were the sources of all values clearly identified? Were market values employed for changes involving resources gained or depleted? Where market values were absent (eg, volunteer labor) or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values? Was the valuation of consequences appropriate for the question posed? (ie, has the appropriate type or types of analysis—cost-effectiveness, cost-benefit, cost-utility–been selected?)		
7. DISCOUNTING & TIME ADJUSTMENTS? Were costs and consequences adjusted for differential timing? Were costs and consequences that occur in the future "discounted" to their present value? Was any justification given for the discount rate used?		
8. INCREMENTAL ANALYSIS? Was an incremental analysis of costs and consequences of alternatives performed? Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits, or utilities generated?		
9. SENSITIVITY ANALYSIS? Was a sensitivity analysis performed? Was justification provided for the ranges of values (for key study parameters) employed in the sensitivity analysis? Were study results sensitive to changes in the values (within the assumed range)?		
10. ALL ISSUES DISCUSSED? Did the presentation and discussion of study results include all issues of concern to users? Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (eg, cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion? Were the results compared with those of others who have investigated the same question?		
Did the study discuss the generalizability of the results to other settings and patient/client groups?		
Did the study allude to, or take account of, other important factors in the choice or decision under consideration (eg, distribution of costs and consequences or relevant ethical issues)		
TOTAL WEIGHTED SCORE FOR A STUDY IS CALCULATED BY MULTIPLYING EACH OF THE TEN IMPORTANCE WEIGHTS BY ITS CORRESPONDING QUALITY SCORE		

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CHAPTER 114

Community Pharmacy Economics and Management

The economic effect of the health-care industry on our society is difficult to evaluate. However, recognizing that health care currently represents over 13% of National Gross Domestic Product (GDP) should give some indication of its effect. It is accepted that advances made by the industry during the past few decades have reduced morbidity and mortality rates that, in turn, have increased productivity and added to the gross domestic product. At the same time, the cost of health care is rising at a faster rate than is the consumer price index (CPI) for all items, and this cost continues to represent an increasingly larger share of the GDP.

ECONOMICS OF HEALTH CARE

According to the US Health Care Financing Administration, Americans spent $969 billion on personal health care in 1997. Projections based on historical trends indicate that personal health-care expenditures may exceed $1.8 trillion by the year 2007. However, the actual level of future expenditures will be determined by the outcome of current efforts to reform the US health-care system. The increase in expenditures for personal health care is the result of a number of factors, including

Population increases and aging of the population.
Inflation (general and medical).
Increased use of facilities and services.
Increased governmental involvement in health care.
Increased quality of care from new technologies, equipment, and drugs.

Further analysis of national health expenditures reveals that a significant portion of personal health costs are paid with public funds. In 1997, governmental outlays represented more than 46% of all health-care expenditures. Medicare payments accounted for a major portion of governmental health-care expenditures. However, state Medicaid programs and other social welfare programs also contributed to the public expenditures for health care.

The magnitude of health-care expenditures in the US and the growing governmental involvement as a third-party payer of health-care costs are evidence of society's commitment to providing the best care possible for all citizens. Those involved in the delivery of health care share society's commitment and, therefore, must be concerned with the economics of the delivery system.

The pharmaceutical segment of the health-care industry entails a significant expenditure. In 1997 more than $108 billion was spent at the retail level for drugs and other medical nondurables in the United States. The 1997 expenditure for prescription drugs represented 7.2% of the nation's personal health bill.

In view of the level of expenditures for drugs and pharmaceutical services and given the trend of health-care costs, it is apparent that those involved in the delivery of pharmaceutical services must be aware of their responsibility to provide high-quality services in the most economical way. Although some look on third-party payment as a mechanism for solving the high cost of health care, including the drug-cost segment, it should be understood that third-party payment does not reduce the cost. It simply spreads it over a larger population.

Actually, third-party payment may increase the total cost of health care as additional administrative costs and increased use of services are inherent in these programs. It follows that third-party payers, whether governmental or private, have an obligation to their constituents to ensure the delivery of quality services at reasonable prices. In this regard, health professionals find their services under scrutiny by a sophisticated group of agencies representing a large portion of the general public.

In recent years, concern over increasing personal health-care expenditures has led to the development of various alternative delivery systems for prepaid health care. These systems, sometimes referred to as managed-care programs, include Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs) and Administrative Service Organizations (ASOs) sponsored by providers of health care.

The objectives of all of the managed-care programs are to provide quality health services while attempting to reduce the rate of increase of health-care expenditures. The cost-containment objective of managed-care programs has generated increased competition among providers, as only the most cost-effective providers are eligible to participate in some programs.

With the development of managed-care programs, those who provide pharmacy services must consider economic and professional factors as they make decisions about participation in the programs. Pharmacy owners and managers face the challenge of maintaining the economic practicality of their pharmacies as participants in managed-care programs.

Participation in such programs often increases administrative expenses for the pharmacy while providing reimbursement that may not be adequate to cover the costs of providing quality pharmacy services. In response to the move to managed-care programs, several pharmacy organizations have formed Pharmacy Services Administrative Organizations (PSAOs) that are attempting to provide an alternative system that balances the public need for cost-effective services with the professional and economic needs of those who provide pharmacy services.

In the past, the cost of health care was given little attention by the providers of health services. It was assumed that the primary obligation of the provider was to ensure the physical well-being of the patient, without regard to cost. It is now

apparent that it does little good to develop a level of health care that is unsurpassed in the world if a sizable segment of the population cannot afford to pay for it.

The obligation of health professionals to consider the economic dimensions of health care is now recognized. For example, pharmacy practice laws in all states have been amended to allow pharmacists to practice drug-product selection. These amendments allow the pharmacist, under specified conditions, to choose drug products with due regard for both the physical and the economic well-being of the patient. The drug-product selection amendments are tangible evidence of societal concern with the cost of health care. The concern of health professionals with the cost of health care now reinforces the efforts of consumer groups, government, and others involved in financing health care, to the end of providing the best care for all, regardless of economic status.

According to the Health Insurance Council, comprehensive health-service planning and delivery should be based on the following guidelines.

Health services cost money, and good health service costs a good deal of money. Agencies that spend money on behalf of others have a responsibility to get their money's worth for their beneficiaries.

Financing methods for health service should encourage efficient organization and management of the professional personnel and institutions.

Financing methods should distribute the burden of medical care costs in the way that best assures proper care of the entire population.

Health personnel and institutions must be reimbursed in amounts and by methods that permit them to maintain standards and achieve efficiency.

Although these guidelines are intended for the total health-care system, they may be applied to any segment of the system. The guidelines include concepts that are applicable to pharmacy practice. The guidelines suggest that health insurers promote efficient organization and management of personnel and facilities. It follows that pharmacists should promote efficient organization and management. Using carefully developed organizational plans and modern management techniques, pharmacists in community practice can contribute to the efforts being made to contain health-care costs.

THE COMMUNITY PHARMACY

The majority of consumer expenditures for prescription drugs, proprietary medicines and health appliances are channeled through the over 51,000 community pharmacies in the United States. Although heterogeneous in some respects, as in type of ownership and type of goods and services offered, community pharmacies generally are recognized by the public as the most accessible source of drugs and of information about drugs.

Community pharmacy, as used here, is defined broadly to include all of those establishments that are privately owned and whose function, in varying degrees, is to serve society's need for both drug products and pharmaceutical services. It is difficult to characterize or describe the typical pharmacy because of the great variance among them. They range from the corporately owned chain pharmacy, to the pharmacy department in a supermarket, to the independently owned pharmaceutical center that provides prescription service plus a relatively few lines of health-related products.

According to the operating data submitted to the National Community Pharmacist Association Searle Digest (NCPA; Alexandria, VA) by community pharmacy owners, the average independent community pharmacy generated sales of $1,649,052 in 1997. These data represent a summary of individual pharmacy operating figures that were supplied voluntarily by pharmacy managers and owners.

Note that the editors of the NCPA-Searle Digest make no attempt to structure the sample that comprises the data input and, therefore, their citations are subject to the statistical limitations inherent in the collection of unstructured voluntary data. It appears, however, that the figures serve to describe fairly accurately the financial profile of the independent community pharmacy.

The data from the 1996 NCPA-Searle Digest indicate that approximately 75% of the revenues of the pharmacies reporting are derived from prescription medications and services. The average prescription charge in 1991, as reported in the NCPA-Searle Digest, was $30.53, compared with an average charge reported 6 years earlier of $22.44. Note that the average prescription charge is not an accurate measure of the price changes for prescription medications. Over a period of years, the types of drugs dispensed have changed with the introduction of new products that usually provide improved drug therapy at a higher cost. In addition, there has been an increase in the number of maintenance drugs prescribed with a corresponding increase in the average number of dosage units per prescription order. Therefore, the average prescription charge in 1997 was for a different mix of prescription products, in larger quantities, than was represented by the average charge in 1991.

CHAIN PHARMACIES—The foregoing discussion dealt mainly with the independent pharmacies that represent approximately 43% of the community pharmacies in the United States. Chain pharmacies also are an important factor in the delivery of pharmaceutical services and products to the public.

There is no consensus on the definition for a chain pharmacy, as there appears to be a question as to what criteria are appropriate for classifying a group of centrally owned pharmacies as chain pharmacies. To some, the matter of central ownership, alone, is sufficient to classify the individual units as chain pharmacies. Another approach is to classify individual units that are owned centrally as chain pharmacies only when there also is centralized organization and management.

The number of centrally owned units also has been used as a method of defining chain pharmacies. However, this criterion does not provide a satisfactory answer to the question, as many multiple-unit pharmacies are owned centrally and yet each unit functions independently from the central ownership. In mode of operation these pharmacies are more similar to individually owned community pharmacies. On the other hand, as the number of units under a central ownership increases, at some point there must be some coordination of policies and activities that results in more central management.

Although it is not possible to establish an exact number of units as the point at which all units assume the characteristics of a true chain pharmacy operation, it appears that there is some relation between the number of units owned and the definition of a pharmacy chain. The US Department of Commerce defines a pharmacy chain as those units with prescription departments that are centrally owned by individuals or organizations who own 11 or more units.

The typical chain pharmacy operates from a broader base in the variety of goods offered for sale than does the independent pharmacy. The kinds of goods offered for sale in chain pharmacies are almost limitless and include durable consumer goods in addition to health-related products.

In this regard it may be somewhat misleading to compare sales in the chain pharmacy with sales in the independent community pharmacy. However, when trends over the past few years are studied, it is apparent that the chain pharmacies have improved their relative position in such areas as revenues from prescription medications and over-the-counter (OTC) drugs.

Establishment of a Community Pharmacy

The pharmacist considering the establishment of a new pharmacy should subject the basic decision to an objective analysis that should include a consideration of community needs—does the community really need another facility for pharmaceutical services? This question may have both a quantitative and a qualitative dimension. Perhaps a given community has a suffi-

cient number of pharmacies and yet none of them is providing the full scope of needed services. If a community need is identified, the analysis should continue in terms of evaluating the various alternatives that are available for satisfying it. Perhaps an existing pharmacy could be purchased and made to provide more-extensive pharmaceutical services or there may be an opportunity to join with another pharmacist in the ownership of an existing pharmacy and establish a group practice. Such alternatives provide the opportunity for improving services to the community while promoting the most efficient use of professional personnel and facilities.

If the analysis indicates that a new pharmacy should be established, the pharmacist must consider a number of questions, some of them simultaneously, eg

What is the appropriate legal organization for the enterprise?
What specific location should be chosen?
How may the necessary capital be obtained?

Although each of the foregoing questions is related to the others and cannot be isolated in a practical situation, each will be treated by itself for purposes of this discussion.

ORGANIZATION

The pharmacist may choose from three widely recognized forms of legal organization for the community pharmacy enterprise. Traditionally, the majority of these have been organized as individual or sole proprietorships, with little governmental control applied to the organizational structure.

In recent years, because of the increase in the joint ownership of pharmacies by two or more individuals, the partnership and corporate forms of organization have become more significant. The partnership, as a form of business organization, enjoys relative independence from governmental control. The corporation, as a creation of the state government, is subject to rather strict governmental regulation. Each form presents advantages that must be weighed against the disadvantages and limitations that become apparent when compared with the alternative forms of organization.

UNINCORPORATED SOLE PROPRIETORSHIPS— The business enterprise owned and managed by an unincorporated sole proprietor is not considered in law a separate legal entity; rather, the owner and the enterprise are considered one. It follows that the risk inherent in establishing a business enterprise in this way has implications for the nonbusiness assets of the proprietor.

The unincorporated sole proprietor has unlimited personal liability. Personal assets are available to satisfy business obligations, and business assets may be used to satisfy personal debts. In return for assuming unlimited liability, the sole proprietor enjoys the freedom to conduct the enterprise in any lawful manner he or she deems appropriate.

Except for the required licenses, the sole proprietor may begin or quit operations without legal formality or governmental permission. Some states do require that a statement of ownership be filed with a designated office when the owner's name is not indicated in the name of the enterprise. The sole proprietor receives all profits from the enterprise.

The size or scope of the operation is not necessarily a determining factor in the decision to organize as a sole proprietorship, as opposed to one of the other forms of organization. However, because of the risks involved and the fact that few persons possess all of the abilities and capacities necessary for carrying on a large complex enterprise, the sole proprietorship most often is associated with smaller, less complex operations.

Historically, the majority of community pharmacists are independent by nature and have chosen this rather informal form of organization. The typical community pharmacy being geographically local and only moderately complex in scope of operation generally succeeds under the unincorporated sole-ownership system.

PARTNERSHIPS—When the resources of one individual are not sufficient to provide a proper base for establishing a pharmacy or when the individual does not wish to assume the entire risk associated with the entrepreneurial function, joint ownership may be considered. Partnership arrangements and incorporation are mechanisms that may be used to broaden the financial or talent base for an enterprise and also may serve to spread the risk. The partnership may be described as an association of two or more individuals based on an expressed or implied contract. They combine their resources as co-owners of an enterprise for their mutual profit. This provides a way for the individuals to do jointly what they could not do separately.

As to liability, a partnership may be described as an association of sole proprietors, because at law the partnership is not considered separate from those who compose it. As with the sole proprietorship, each partner is liable for all debts of the partnership, even to the extent of personal assets. Within the scope of partnership activities, each general partner is considered an agent of the other general partners and, as such, each has the right to bind or commit the partnership in business affairs. Because of the mutual-agency concept and the unlimited liability inherent in partnership associations, it is especially important that the full implications of such an arrangement be understood before adopting this form.

Although it is a contractual arrangement, there are few legal restrictions or regulations applied to the partnership association. No expressed governmental consent is required for establishing or dissolving a partnership, and the contract may be written or simply based on a handshake, as long as the elements of a valid contract are present. This is not to imply that the partnership should be consummated on the basis of an informal verbal agreement. The contractual relation between partners should be verified by a written agreement drafted with the assistance of a lawyer.

The close personal relationship among partners tends to foster a disregard for formalized written documents relating to the operation of the partnership. In the interest of producing a smoothly functioning organization and helping to prevent disagreements among the partners, it is most important that a written partnership agreement be prepared at the outset.

Such matters as the investment, duties, responsibilities, and division of profits and losses of each partner should be considered and incorporated into the partnership agreement. The agreement not only provides a reference for solving future misunderstanding but also serves to compel the partners, at the inception of the agreement, to consider matters that might otherwise remain hidden until a specific problem arises.

The partnership as a form of business organization provides a mechanism for joint ownership of an enterprise that is relatively free of governmental regulation and that embodies the same flexibility of operation enjoyed by the sole proprietorship. As the partnership is not considered a legal entity, it is not required to pay income taxes on profits; rather, the individual partners are assigned their share of profits and pay income taxes on them as individuals.

When compared with the corporate form of joint ownership, the partnership usually presents an advantage to the co-owners with regard to income tax liability. The partnership has been a popular form of organization for the co-ownership of community pharmacies.

CORPORATIONS—Co-ownership also may be effected through a more formal organization known as the corporation, which is a separate legal entity, created by the expressed authority of the state. A properly constituted corporation offers the stockholders the advantage of limited liability for business debts.

In contrast to the sole proprietorship and the partnership, the incorporated business enterprise is considered a separate entity from the persons who own it. Consequently, in the absence of a statute to the contrary, corporate stockholders are liable only to the extent of their contributions to the capital of

the enterprise. As a general rule, creditors of the corporation cannot proceed against the individual stock holders for debts of the corporation.

As a legal entity created by the state, the corporation enjoys continuity of life subject only to the limitation(s) included in its charter. The death or incapacity of a stockholder or the transfer of ownership in no way affects the corporate existence.

The corporation provides a way for individuals to invest in a business venture without placing their personal assets in jeopardy. It also provides a convenient, highly organized mechanism for accumulating a large amount of capital from several individuals to establish a business enterprise.

In terms of initial organization, the formation of a corporation is more complex and formal than other types of ownership. Each state has a required procedure to be followed in the creation of a corporation, and once franchised, it is subject to regulation and control by the state.

By definition, the corporation only has those powers and can do those things that are authorized by the state, in contrast to the partnership, which may do any lawful thing agreed to by the partners. The corporation may be dissolved only by or with the expressed consent of the state.

The status of the corporate enterprise as a legal entity makes it subject to local, state, and federal income taxes on its earnings. When the earnings after corporate income taxes are distributed as dividends, the individual stockholders are required to pay personal income taxes on them. As a result, the owners of corporations are said to be subject to double taxation, a factor that in many cases has deterred sole proprietorships and partnerships from adopting the corporate form of organization. However, under special conditions the owners of a corporation may avoid double taxation of profits by requesting designation as a Subchapter S corporation under provisions of the US Internal Revenue Code. If Subchapter S status is granted, profits are not subject to corporate income taxes but are passed through to stockholders and taxed as part of their personal income.

In the field of community pharmacy, the majority of chain organizations are corporations. The corporate form provides the protection of limited liability, which is especially important for larger multiunit operations. In addition, a fair number of the larger nonchain pharmacies are also incorporated, although it should be noted that neither size nor scope of operation is necessarily the only determinant in the decision to incorporate.

In establishing a new pharmacy, the prospective owner(s) must decide at the outset which form of organization to follow. The factors of liability, flexibility of operations, governmental regulation, continuity of life, and income taxes should be considered in relation to the scope of the operation and the personal circumstances of the organizers. It is especially important to seek legal counsel in arriving at a decision.

SITE SELECTION

Much has been written on the criteria that should be employed in choosing a specific community as the site for a new pharmacy. Such factors as population in the trading area, distribution of income among the population, type of industry, and the competitive climate have been cited as being important.

Sometimes a pharmacy is established in a community because the pharmacist-owner is determined to own a pharmacy in a specific community because of personal factors such as family ties, climate, or other appeals of the community. In such cases the decision often is made without regard to the key issue of whether the community needs another facility for pharmaceutical services.

If a need is identified in a given town or city, the selection of a specific site requires careful consideration. The degree of success of a community pharmacy may depend on the choice of the location most suitable among those available. In some cases, the choice of a specific site is extremely limited; the pharmacist must choose from what is available rather than that which is most desirable.

The majority of consumers choose the pharmacy they will patronize on the basis of convenience and accessibility, so long as the pharmacy offers adequate service and fair prices. Therefore, the primary emphasis in site selection should be on obtaining a location that is central to the population to be served. The modern pharmacy must provide easy access and adequate parking. The growth of shopping centers may be cited as evidence of the importance of these factors.

As a general rule, shopping centers are located centrally in relation to the neighborhood, community or region they serve. They provide easy access and adequate free parking.

Interestingly, as a general rule, community pharmacies are more successful in neighborhood and community shopping centers than in the larger regional centers. This tends to substantiate the impression that consumers wish to obtain pharmacy services near home.

Although a site in a neighborhood or community shopping center may be considered a choice location for a new pharmacy, as a practical matter, few independent community pharmacists are able to obtain such locations. Because of the nature of the system used to finance new shopping centers, preference is given by the developers of the centers to large well-established chain pharmacies. However, it appears that there are other suitable locations for a traditional pharmacy that emphasized professional services rather than the sale of non-health-related merchandise.

The island type of location, where the pharmacy sits by itself on a main traffic artery into a suburb and surrounded by adequate parking facilities, has proved to be attractive to consumers. A location within a large medical clinic also may prove to be valuable, although, because of the tendency of patients to obtain prescription service near home, the clinic location may not be so important as some believe.

The selection of a site solely because it is available readily or inexpensively, should be avoided. Usually, a bargain location in terms of rent proves to be a liability rather than an asset in the long run.

The selection of the proper site for a new pharmacy is important especially as it is a decision that the pharmacist may have to live with for 5, 10, or more years, depending on the terms of the lease, if the pharmacy is operated in a rented facility. Whenever possible, advice should be obtained from others regarding site selection. Some wholesale drug firms provide counsel in this regard, or a business consulting firm may be engaged to assist in making an objective evaluation of alternatives.

CAPITAL

Planning and assembling the capital requirements for a new pharmacy are predicated on careful evaluation of projected sales volume, breadth and depth of inventory requirements, and estimated operating expenses. The amount of capital required for the operation of a successful pharmacy is a function of its productivity.

Although certain of the assets required represent a fixed core necessary for any pharmacy, regardless of sales volume, beyond these, the amount of assets required largely depends on the scope of operation and the volume anticipated. As illustrated in Table 114-1, as sales volume increases, investment in inventory, fixtures, and other assets also increases.

Other factors also have an effect on capital requirements. For example, the policy of the owner toward offering credit may require more or less working capital. The mix of sales volume also may affect capital requirements.

The problem of determining capital requirements for a new pharmacy is difficult. Most of the underlying factors are based on conjecture and forecasts regarding the future, for which there is no reliable basis at the outset. However, some

Table 114-1. Balance Sheets for NCPA-Searle Digest Pharmacies under 5 Years Old: 1996 (Averages per Pharmacy)[a]

	SALES UNDER $750,000	SALES $750,000 TO $1,500,000
Assets		
Current assets		
Cash	$ 14,473	$ 35,379
Accounts receivable	15,353	40,097
Inventory	68,113	132,223
Total current assets	$ 97,939	$ 207,699
Fixed assets		
Fixtures and equipment and leasehold improvements (net after reserve for depreciation)	11,019	18,438
Other assets		
Prepaid expenses, deposits, etc.	4,823	8,210
Total assets[b]	$114,781	$ 234,347
Liabilities		
Current and accrued liabilities		
Accounts payable	$ 19,344	$ 47,063
Notes payable (within 1 yr)	9,830	20,573
Accrued expenses and other liabilities	7,173	8,343
Total current and accrued liabilities	$ 36,347	$ 75,979
Long-term liabilities		
Notes payable (later than 1 yr)	40,513	77,181
Total liabilities	$ 76,860	$ 153,160
Net Worth	37,921	81,187
Total liabilities and net worth[b]	$114,781	$ 234,347
Net working capital	$ 61,592	$ 131,720
Sales	$500,014	$1,113,921
Purchases	$363,613	$ 816,748
New profit (before taxes)	$ 10,308	$ 47,101

[a] Source: The NCPA-Searle Digest for 1997.
[b] Excludes land, building, investments and goodwill plus corresponding liabilities.

judgment must be made as to what assets are required for a specific venture, so that the pharmacist may explore the feasibility of assembling a definite amount of capital.

When making the forecasts and estimates needed to establish the basis from which to estimate capital requirements, a sense of conservatism should prevail. The projected sales volume should be estimated at minimum level and operating expenses, at maximum level. It is usually easier to add new capital if sales exceed expectation than it is to recall committed capital if sales are less than anticipated. When operating expenses are estimated on the high side and planned for accordingly with adequate capital, a margin of safety is provided. If expenses are estimated at a level lower than is actually realized, financial difficulty may be encountered.

The method of estimating the capital requirements for a new pharmacy can be described by example. Assume that a conservative estimate indicates that a new pharmacy can produce $750,000 in sales volume during the first year of operation. The question becomes, What kinds of capital will be necessary to support the estimated volume and in what amounts? The answer is as follows: cash, inventory, fixtures, and equipment. The assumption made here is that the owner will not own the building or land used for the pharmacy. The amount of capital required in each category is related, in varying degrees, to the anticipated sales volume and may be estimated as follows.

CASH—Sufficient cash is needed to pay preopening expenses, operating expenses for a stated period, and some excess for emergency use. Preopening expenses include license fees, legal fees, utility deposits, and advertising. These expenses, with the possible exception of advertising, are fixed relatively for any new pharmacy and are not related to sales volume. They are determined easily and usually total $2000 to $3000. The higher figure will be assumed here.

It is considered good practice to start a new business venture with sufficient cash to pay the first 2 to 3 months of operating expenses, on the theory that the first months of operation may be extremely slow. For a new pharmacy, the amount required may be determined by relating estimated monthly sales volume to operating expense statistics, available from such sources as the NCPA-Searle Digest. Only cash expense items are used in the calculation. Such noncash expenses as depreciation and bad debt losses are not considered.

For a pharmacy in the volume category of this example, the NCPA-Searle Digest indicates that approximately 25% of sales go to cover cash operating expenses, including a salary for the pharmacy owner. Applying this percentage to 3-month sales of a pharmacy with annual sales of $750,000 gives a figure of $46,875 needed to pay operating expenses for a 3-month period. The total amount of cash required for preopening expenses and early operating expenses equals $49,875. In addition, cash is needed to provide the other kinds of capital described below.

INVENTORY—The amount of inventory necessary to support a $750,000 sales volume may be determined by referring to data that give averages for cost of goods sold and annual stock-turnover rates. Again referring to the NCPA-Searle Digest, the cost of goods sold for a pharmacy with sales of $750,000 is approximately 73%, or $547,000. The average annual stock-turnover rate is given as 4.7 for a pharmacy with this sales volume and is determined by division of the cost of goods sold by the average inventory at cost. Knowing the cost of goods sold and the stock-turnover rate, it is possible to estimate the average inventory; in this case it is approximately $116,400.

FIXTURES AND EQUIPMENT—The fixtures and equipment necessary for a new pharmacy also are related to estimated volume. Larger volume means more inventory, which, in turn, requires more fixtures and equipment to facilitate storage and display. The size of the building to be furnished and the quality of fixtures chosen also affects the total expended. On occasion, savings may be realized by purchasing good, used fixtures and equipment, usually available at a fraction of the cost of new ones. A reasonable expenditure for these items for a pharmacy properly equipped to generate annual sales of $750,000 would be approximately $30,000.

TOTAL INVESTMENT AND SOURCES OF CAPITAL —The total investment required for a new pharmacy with estimated sales per year of $750,000 would be approximately $196,275, broken down as

Cash (for preopening and operating expenses)	$ 49,875
Inventory	116,400
Fixtures and equipment	30,000
Total investment	$ 196,275

The total represents the cash value of the assets required to establish the new pharmacy in this example. However, the amount of actual cash needed will be somewhat less than the total amount stated. In most cases, the owner can assemble the required assets by using a combination of equity capital, borrowed capital, and credit.

Equity capital consists of the investment of the owner or owners, and it comes from personal savings or from other sources that require no security and no commitment as to date of repayment. Relatives may be a source of equity capital, either on a co-ownership basis or simply by providing unse-

cured, undated loans. It is thought that at least one-half to two-thirds of the total requirement should be equity capital, although many successful pharmacies have been established with lower amounts. The amount of equity capital provided influences the availability of borrowed capital and the level of credit that may be obtained by the owner.

Commercial lending institutions, such as banks and savings and loan associations, usually require a substantial equity interest in a new business venture before they consider lending the funds necessary to supplement the owner's contribution. Generally, commercial lending institutions should not be depended on for a significant portion of initial capital needs. Such institutions are limited in the amount of risk they are willing to assume, especially for new ventures.

Trade sources, such as suppliers of fixtures and wholesale drug firms, present the best opportunity for obtaining nonequity capital for the new pharmacy. It is common for wholesalers to supply the opening inventory requirements for a new pharmacy on the basis of approximately 50% of the total cost as a down payment, with the balance to be paid over an extended period that varies with the individual circumstances. Usually, if the time exceeds 90 to 180 days, the supplier attaches an interest charge to the unpaid balance.

The amount of cash required for inventory may be further reduced by cutting back the level of inventory at the outset and then building it up to the required level as operations continue and sales volume increase. Two cautions should be considered in obtaining any significant amount of capital through the use of trade credit:

The interest factor should be studied; depending on the rate and the method of calculation, interest charges can be surprisingly high.

The use of credit simply postpones the underlying obligation to some future date or dates. Repayment of credit obligations should be considered in terms of the practical feasibility of meeting the obligations when they are due.

Fixtures and equipment may be obtained by relatively long-term financing through suppliers, or in some cases through finance companies by a mechanism similar to the one used to finance a personal automobile. Underlying this form of financing is a chattel mortgage that places title to the fixtures and equipment in the hands of the lender as security.

The interest charges from this type of financing may be especially significant, often reaching an effective rate of 15% or more annually. Usually a down payment of one-quarter to one-third of the value of the fixtures is required, with the balance to be paid in installments over as many as 5 years. The scheduled installment payments should be included in long-range financial budgeting and planning.

After the potential sources of capital have been evaluated carefully, it may be necessary to make compromises or adjustments regarding the amounts estimated originally. In some cases the owner will reduce his withdrawals or salary during early operations to reduce the amount of cash needed for operating expenses. Inventories also may be reduced at the outset. In fact, it is considered good practice to hold approximately 20% of the amount budgeted for inventory in abeyance until the needs of the particular community are identified.

The amount required for fixtures and equipment may be reduced by purchasing some used fixtures and equipment. It also is possible to lease fixtures and equipment, although this may increase the cost of fixtures and equipment over the long term. However, such arrangements also reduce initial capital requirements. By these means and through the judicious use of borrowed funds and credit, a new pharmacy may be established with less cash than is indicated by the figure for the total investment.

MANAGEMENT

In general terms, the management function may be described as all those activities involved in the organization and direction of the elements of an economically productive enterprise. Money, material, equipment, and people must be brought together in the proper relations to one another to achieve the objectives and goals that management has identified. Management practices predicated on predetermined goals and objectives provide for more efficient operation and provide a basis for measuring the effectiveness of management activities.

The management activities of the pharmacist too often consist of handling day-to-day problems and crises. Much of the activity labeled management in the typical community pharmacy is actually routine administrative work that can and should be delegated to nonmanagement personnel. Perhaps this point is best illustrated by the axiom "management's job is not to do, but to get others to do."

The traditional approach to community pharmacy management consisting of the ad hoc handling of problems as they arise is inconsistent with the nature or responsibilities of modern practice. The total of all activities in a pharmacy is becoming increasingly complex, because of increased volume of operations and outside pressures for more efficient delivery of pharmaceutical services and products.

All health workers are being called on to develop a social conscience and assume more responsibility for the economic effect of their activities. Although technological changes may relieve some of the pressure on health-care costs, better management and administrative techniques also can contribute significantly to solving the problem.

The effect of more effective management also may be reflected in improved professional services to the public. For example, a management decision to assign certain record-keeping functions in the prescription department to nonprofessional personnel allows a more economical use of professional staff. At the same time, it provides the pharmacist with more time for consultation with the patient.

The Role of Management

OBJECTIVES AND GOALS—The first role of management for any business enterprise should be to establish the objectives and goals for the organization. Concurrently, management must provide the policies that serve as the framework for accomplishing the stated objectives. For example, one objective might be an atmosphere of patient orientation, the elements of which would need to be identified. Proper record-keeping procedures, facilities for consultations, and patient-oriented personnel would be prerequisite for carrying out this objective.

Working with predetermined objectives provides the manager with a basis for establishing policy and assists in decision making. As in the example cited, the objective has implications in the area of personnel policies and practices. Recruitment and selection techniques geared toward obtaining professional and supporting staff who can function effectively in a patient-oriented environment would have to be developed by the manager.

The kinds of objectives to be established by management might be divided into two categories:

1. A set of rather basic, almost philosophical objectives need to be developed; for example, will the pharmacy stress low prices rather than full service?
2. Objectives concerned with more specific operational matters are needed, as meeting a projected sales volume level during a given year.

In either case, it is management's responsibility to provide a sense of direction by setting forth both basic and specific objectives as guidelines for current and future activities.

Objectives lie in the future and, therefore, are subject to adjustments dictated by forces outside the control of management. Management personnel should keep abreast of those technological, economic, and social changes that relate to stated organizational objectives. In this regard the role of management in establishing objectives and goals must include a mechanism for continuing re-evaluation and updating of objectives.

MATERIAL AND HUMAN RESOURCES—The organization of these resources to pursue the objectives of the enterprise represents the second management function. The kinds and amounts of resources required are largely dictated by the nature of the objectives. The ability to obtain capital, generally considered an entrepreneurial rather than a managerial function, also may influence this management responsibility.

For the typical independent community pharmacy, it is neither possible nor practical to divorce acquisition of capital from its application and management. In most cases, the same person is charged with both functions. Assuming that the required inventories, equipment, and people can be assembled, it remains for management to provide the organizational structure and the coordination necessary to mold these resources into an efficiently functioning community pharmacy.

PLANNING AND CONTROLLING OPERATIONS—Although a major share of the manager's time must be devoted to controlling day-to-day operations, it is important to maintain a balance between the present and the future. Control of current operations far too often becomes the sole function of many managers, who devote little or no time to planning for future operations.

The lack of planning often compounds the problems associated with day-to-day operations, resulting in a situation in which the controlling function requires all of the management effort. For example, many managers spend a disproportionate amount of time ordering merchandise and maintaining inventory when, through a properly planned inventory-control program, this routine activity could be delegated to others.

The brief and simplistic description of management functions given here tends to understate their complexity and significance. Management may be considered an art rather than a science. There are few established laws or formulas for solving the problems inherent in conducting an economically productive enterprise. It especially is difficult to make the numerous and varied decisions required in exercising the management functions. Although there have been attempts to quantify these decisions through the use of mathematics and mathematical models, in the last analysis the human element still dominates the decision-making process.

As management decisions are made and implemented by human beings to affect human beings, it is apparent that those who manage need to consider and study the behavioral and social sciences so they may function effectively. For the community pharmacist who performs the dual role of health professional and manager, such a background especially is appropriate.

Essentially, management is an exercise in group dynamics. The manager must be able to organize, direct, and control a group of individuals toward the stated objectives of the organization. The manager who is unable to obtain the cooperation of his subordinates or who fails to delegate the responsibility for routine operational matters to others is not functioning effectively.

In the community pharmacy the human dimension of management especially is crucial. The nature of the typical community pharmacy is such that the manager constantly is in close personal contact with his employees, suppliers, and patrons.

In such an environment it is difficult to make consistently objective decisions. Further, the dual role of the pharmacist-manager tends to create situations involving conflicts between sound management decisions and professional responsibilities. For example, as a manager, the pharmacist establishes policies regarding the extension of credit to patrons. Yet when a patron with a poor credit rating has an immediate need for prescription medication, the established policies may be waived or adjusted to satisfy the professional obligation of the pharmacist to the patron.

These rather unique characteristics and the need for the pharmacist-manager to be more flexible than those performing the management function in other types of organizations should not be construed to minimize the importance of effective management in the community pharmacy. In the current socioeconomic climate, with increasing costs of operation and pressures to reduce the costs of health care, the management function takes on greater, rather than lesser, significance.

The functions of management provide a somewhat theoretical basis for understanding the overall role of management in the continuing operation of an economically viable enterprise. For practical purposes, however, it may be more valuable to examine the role of management as it relates to the various resources and activities that go to compose the business entity.

In the community pharmacy the following items require effective management: money, inventory, facilities, personnel, credit, and risk. Establishing objectives, organization, planning, and control apply to each of these items, as well as to the pharmacy as a unit. At this level the objectives are more specific, and the organization, planning, and control more definitive.

Consideration of the management of the specific elements that in total represent the community pharmacy does not imply that each element is managed in isolation. There are many interrelations among the various elements, and a decision regarding one element often has an effect on one or more of the others. For example, the decision to expand the inventory may have implications to the management of money, facilities, personnel, and risk.

Money

To a large extent, the success of a community pharmacy depends on the ability to obtain money from various sources in sufficient quantity to acquire and support the resources necessary for operation. Once the money is obtained it becomes management's function to employ it in the most appropriate way to achieve the objectives of the pharmacy.

In its simplest and most pragmatic form, the objective of money management is to maximize the rate of return on investment. Such an objective may appear inconsistent with the responsibilities of professionals engaged in providing health services, yet in the long run the economical use of money is beneficial to society.

In theory, money is in limited supply and demand usually exceeds supply. In the competition for the limited supply, only the most efficient users of money can obtain it. Applying this concept to community pharmacy practice would suggest that only those owners who can manage money effectively, in all its forms, succeed. In a sense, the foregoing concept simply is a statement of the basis of our economic system in which efficiency is rewarded and inefficiency is not.

In the broad sense, money management applies not only to cash but to all those materials and services that are used in the operation of a pharmacy and are purchased with money. Given a limited amount, the manager must make judgments and decisions about the use of the money in terms of the stated objectives.

In this regard conflicts may develop between basic objectives. For example, the objective of maximizing return on investment may conflict with the objective of offering full services, as in the case in which a decision must be made regarding the purchase of a delivery vehicle. The money invested for this purpose represents an inefficient use of money for many pharmacies and thus is contrary to the objective of maximizing return on investment. Yet, for the goal of providing full services to the patrons of the pharmacy to be met, such an investment may be necessary.

The effectiveness of money management may be measured to some extent by the progress made toward meeting noneconomic objectives. For the most part, however, the most meaningful measure of effectiveness is in economic terms,

specifically, by the return on investment, which for a pharmacy may be expressed in two ways:

Return on Total Assets—The rate of return on total assets is determined by dividing the total of all assets employed in the pharmacy into the net profit. No distinction is made between owner's equity and borrowed capital in this calculation. This ratio describes the productivity of the total asset investment.

Return on Owner's Equity—The rate of return realized on the owner's investment in the pharmacy is determined by division of the difference between total assets and total liabilities (owner's equity) into the net profit. This ratio describes how well the funds provided by the owners are being used.

The manager may calculate these rates and compare them with national data to obtain some idea of the effectiveness of the money management policies. Rates below the national averages, such as those reported in the NCPA-Searle Digest, may indicate too much investment for the level of operation or the inefficient management of the pharmacy.

In either event, by using the return on investment concept and analyzing the operation of the pharmacy, the manager can identify a problem requiring attention and can take appropriate steps to correct it.

The management of money in terms of both the total commitment of capital and the application of the owner's equity represents only one dimension of the management function in this area. In a narrower sense, money management also is concerned with day-to-day inflow and outflow of cash from operations. The maintenance of balanced cash flow requires the application of the management functions of planning and control.

Budgeting is necessary to assure that sufficient cash is available to meet such obligations as accounts payable, wages, and taxes. To a large extent, cash needs can be anticipated by an analysis of past experiences combined with projections of future operations.

The inflow of cash may be estimated in the same way. Matching cash revenues with cash expenditures is of more than academic significance: both excessive and deficient cash balances may prove to be uneconomical. When more cash is maintained than is necessary for normal operations, the excess represents earning power that is not being used.

For the pharmacy that consistently maintains a balance of several thousand dollars in its checking account, it may be possible to transfer some of the cash to a savings account or to convert the cash into high-quality marketable securities. In this way, the excess cash earns interest or otherwise appreciates and yet still is available easily for emergency use. A deficient cash position presents some obvious problems, including the possible impairment of the firm's credit rating that may have long-term implications.

One problem associated with an unfavorable cash position is inability to pay bills on time. In many cases this results in a loss of cash discounts. It is a common practice for suppliers to allow a 1% or 2% discount for the payment of invoices within a given time. The usual terms allow the discount to be taken if the amount is paid within 10 days of a specified date; otherwise, the full amount is due in 30 days. The buyer is offered what appears to be a small discount for paying the bill 20 days early. In terms of interest rates, however, the 2% cash discount for paying 20 days early represents an annual interest rate of approximately 36%.

For the typical pharmacy, cash discounts can amount to thousands of dollars each year. Too often, managers do not recognize the significance of taking advantage of all cash discounts, and consequently they do not devote sufficient thought to alternative courses of action when faced with an unfavorable cash position. It may be possible to borrow money on a short-term basis at a low annual interest to take advantage of a 2% cash discount representing an effective annual interest rate of approximately 36%.

To some extent, the manager can control the cash flow in the pharmacy. Although certain obligations such as payrolls and taxes are fixed as to time of payment, the manager may be able to influence other aspects of cash flow. Good management of credit and collection procedures, for example, can increase inflow. Proper scheduling of purchases of inventory can effect a degree of control over the timing of the outflow for such purposes.

The manager makes the decisions regarding acquisition of new fixtures and equipment that requires outflows of cash either in a lump sum or in installments. Depending on future prospects for cash inflow, the manager can decide whether to proceed with such acquisitions.

In actual practice, inflow for a given period should be estimated, and known fixed obligations for the same period should be deducted. If a balance remains, this represents discretionary cash available for expenditure. If a negative figure results, it is management's responsibility to attempt to increase inflow or decrease outflow to achieve a balance.

During periods of temporary cash deficiencies, management may be required to obtain additional funds through borrowing. Knowledge of the sources of funds and the cost of such funds is a prerequisite for effective money management.

Inventory

The merchandise inventory represents the largest single asset on the balance sheet for the typical community pharmacy. More than 50% of all assets, excluding real estate holdings, were reported as merchandise inventory for NCPA-Searle Digest pharmacies in 1996. The extent of this investment plus the fact that the inventory requirements for a given pharmacy are in a constant state of flux forces a need for continuing management attention to this area of operation.

It has been stated that the community pharmacist is the buying agent in the community for health-related products. He or she must provide the right products, in the right quantities, at the right time, and at the right prices to serve the needs of patrons.

Because of varying consumer preferences and geographical differences in prescribing habits of physicians, the management of inventory becomes a highly individualized function in each community pharmacy. Given a limited amount of capital and the responsibility to use the capital economically, the manager must develop systems and policies that ensure a continuous flow of needed goods while avoiding the problems of excessive inventory levels.

Although the objective of effective inventory management is stated simply here, in practice it represents one of the most challenging responsibilities of management. In the community pharmacy the management of inventory is complicated by a major portion of the inventory consisting of prescription (legend) drugs. This makes the problem of inventory control in the pharmacy unique in comparison with control in other enterprises that distribute products at the retail level.

The demand for prescription drugs is generated by physicians and other health practitioners rather than by the ultimate consumer. When dealing directly with the consumer, it is easier to manage inventory. Excessive inventory levels can be reduced by special sales and markdowns. These techniques cannot be used to effect reduction in overstock of prescription drugs.

On the other hand, the successful pharmacy depends on maintaining a breadth and depth of prescription drug inventory that is adequate to handle all prescription orders received. Usually, the need for a prescription drug is immediate. The patient cannot wait until it is ordered or is delivered in a few days. The dilemma of the manager in this situation is apparent—that of providing a continuous supply of products that are characterized by an unpredictable and uncontrollable demand.

The management of other segments of the inventory such as OTC drugs, cosmetics, and sundry items, although not subject to the limitations inherent in the prescription drug segment,

presents no less a problem to the manager. Changing consumer preferences and pressures by suppliers to buy greater quantities and assortments of OTC drugs and nondrug items increase the need for careful attention to this area of management.

Three basic decisions are required for the effective management of inventory. They are as follows: the specific items to be included in the inventory, the quantity of each item required, and the best source of supply.

The specific items included in the inventory should be chosen according to the needs of the community. Although there is a core of items common to every pharmacy, a significant portion of the inventory is dictated by local demand. In this regard the manager must be objective in the selection of goods and ignore those personal preferences that might influence purchasing decisions. For the newly established pharmacy it is important that a portion of the capital budgeted for the initial inventory is held in reserve until the preferences of the local community are identified. As operations continue, the manager is constantly faced with decisions on additions to the original selection.

Some managers adopt the policy of stocking all new items immediately, as long as the items are related to current merchandise assortments. Other managers adopt the wait-and-see policy, stocking new items only when a local demand is established. Both approaches have advantages and drawbacks.

The wait-and-see manager runs the risk of losing considerable sales volume and, perhaps more importantly, develops a reputation for not having in stock what the patrons desire. On the other hand, the manager who indiscriminately adds all new items to the inventory runs the risk of an overcommitment of capital to inventory, with its serious economic implications. Striking a balance between these two extremes presents a challenge to the manager.

Perhaps as important as the specific items to be included in the inventory is the quantity of each item carried in stock. Assuming that a given item should be stocked, the manager must decide what quantity is necessary. At this point, several decisions must be made, based on a consideration of sources of supply, extent of demand, and such financial factors as quantity discounts and buying terms.

In most instances the manager may choose from alternative sources of supply. Some manufacturers of prescription drugs and many producers of the other goods distributed through pharmacies sell directly to the pharmacy. The pharmacist also may obtain inventory needs from indirect sources, such as wholesale drug companies.

Direct sources offer the advantage of lower prices, whereas indirect sources offer the advantage of faster delivery. Generally, direct purchasing requires a larger commitment to inventory investment because of minimum order requirements established by the manufacturer and increased delivery time.

Indirect sellers, such as wholesale drug firms, usually do not establish a minimum order level and emphasize rapid and frequent delivery service. The quantity of a given item carried in the pharmacy's stock, therefore, is influenced, to some degree, by the source of supply.

Quantity-purchase discounts play an important role in decisions regarding inventory levels. Generally, the purchase of larger numbers or sizes of the items stocked in the pharmacy effects a lower cost per item or unit. Such cost savings can be beneficial to both the owner of the pharmacy and to the public being served. However, note that cost savings on the purchase of goods in larger quantities can be offset by additional expenses that accrue from excessive inventory levels.

The costs associated with maintaining a merchandise inventory include implicit and explicit interest, obsolescence, deterioration, storage, property taxes, and insurance. Generally, these costs increase in direct proportion to the level of inventory.

The capital invested in inventory represents money that could be used in other ways to earn a return. To the extent that such an investment is necessary to generate sales and to earn a profit, it may be said that the investment is economically sound. However, when the investment in inventory exceeds what is actually required for the level of operation realized, the excess represents an uneconomical use of capital.

For example, assume that a pharmacy has $90,000 invested in inventory. The safest alternative use of this capital might be to buy time-savings certificates at an effective annual rate of 5%. At this rate, the $90,000 would earn $4,500 per year and it can be said that this inventory investment has an implicit interest cost of $4,500. To the extent that the inventory produces net profit in excess of $4,500 the capital represented is being used economically.

Assume further that it can be shown that the $90,000 inventory could be reduced to $80,000 without adversely affecting sales or net profit. In terms of the safest alternative use of funds, the excess inventory of $10,000 is costing $500 per year in interest that could be earned and added to net profit.

An explicit interest cost also may result from excess inventory levels if the capital tied up in inventory is needed to pay other operational expenses. To support current activities, the pharmacy owner may be forced to borrow money at current interest rates. To the extent that the need to borrow is caused by excessive inventory investment, the cost of borrowing should be considered a cost of the excess inventory.

The possibility of obsolescence and deterioration are risks associated with the maintenance of an inventory, and although such risks may result in some unavoidable losses, they are minimized at optimum inventory levels. When the costs of storage, insurance, and taxes are added to the interest factors and to the risk of obsolescence and deterioration, the cost of each dollar invested in inventory can be significant. An awareness of the costs associated with inventory investment proves useful to the manager as he or she makes decisions regarding the types and quantities of goods to be included in the merchandise inventory.

The effectiveness of inventory management traditionally has been measured by the stock-turnover rate (the annual rate of turnover for the inventory). The rate is calculated with the following formula:

$$\text{cost of goods sold for the year/average inventory at cost} = \text{stock-turnover rate}$$

This rate denotes the number of times, on the average, that the inventory has been sold and replaced during a given year. It represents the turnover of dollars invested in inventory but tells nothing of the turnover of specific items or units that go to make up the inventory. As presented here, the rate relates to the entire inventory of the pharmacy. However, the same concept may be applied to departments if appropriate data are available.

The stock-turnover rate may be calculated for a specific pharmacy and then compared with national averages such as those reported in the NCPA-Searle Digest. The average rate reported by the NCPA-Searle Digest pharmacies for 1996 was 6.6. It generally is assumed that a rate of approximately 5 to 6 times per year is indicative of adequate management of inventory. Rates considerably below this level may indicate an overinvestment in inventory.

Note that pharmacies with rather low sales volumes typically have stock-turnover rates much lower than the average. For these pharmacies, increased sales represent the only real opportunity for improving their position in this area.

The typical community pharmacy with a sales volume near the national average should show an annual stock-turnover rate of at least 5 times/year. If it falls significantly below the average, the management of inventory should be reexamined.

The rate may be improved in two ways. Attempts can be made to increase sales while keeping the inventory level constant. Generating more sales with the same inventory increases the rate. In the event it is not possible to increase sales, the alternative is to reduce the inventory level. With constant sales, this produces a faster rate of turnover.

A combination of the two alternatives, increasing sales while reducing inventory, can have a profound effect on the stock-turnover rate. As a practical matter, the manager may best be able to work toward a reduction of the inventory level as an immediate means of improving the rate. Certain items in the inventory may be returned to suppliers for refunds or credit. Items that cannot be returned may be sold at reduced prices. Most important, buying practices should be reviewed with the objective of reducing purchases until a more favorable rate is achieved.

If a stock-turnover rate of 5 is adequate, a rate of 7 or 8 might appear to be excellent. In some cases this is a valid assumption. However, unless the inventory is managed carefully, high rates may cause problems that are as serious as those resulting from low rates. An extremely high rate may be achieved by ultraconservative buying policies.

Conservative buying betters the rate for capital invested in inventory, but the improvement may prove to be uneconomical in the long run. When undue emphasis is placed on maintaining a high stock-turnover rate, quantity discounts may be lost, resulting in an increase in cost of goods sold. Usually, a pharmacy can afford to do at least some quantity buying, thus realizing the benefits accruing from quantity discounts.

Frequently, buying in small quantities increases the time and effort involved in the buying process. More orders must be submitted and checked in, and more accounting time is required for processing several small orders as compared with a few large ones.

Finally, and perhaps most important, the manager who attempts to control the inventory level too closely runs the risk of frequently being out of items. The disadvantages of this include a reduced sales volume and accompanying gross margin. Further, a reputation for being out of stock may result in a loss of patrons to other pharmacies where their needs are met more consistently.

Through good management, however, it is possible to realize an annual stock-turnover rate higher than the accepted norm without creating the problems described here, and many successful pharmacies do this. However, unusually high rates reduce the likelihood of meeting the objective of having on hand the right goods at the right time, in the right quantity, and at the right price.

In the final analysis, the key to effective management of merchandise is stock control on a day-to-day basis. The manager is responsible for designing policies, procedures, and systems for controlling and maintaining the proper selection and level of goods carried in stock. Proper training of employees in the importance of stock control and proper use of established control systems are the responsibilities of management.

There are several formal systems that may be employed to assist in inventory control. Many pharmacies, for example, maintain and control stock by using computer-based reorder systems. Other firms use the perpetual inventory method of stock control.

The pharmacy manager also can effect reasonable control over inventory by implementing a well-organized visual stock-control system. By predetermining the number of units of each item to be carried in stock, based on estimated sales and adequate turnover, the manager can establish minimum and maximum stock levels for each item. The indicated levels for each item are recorded in an inventory-control book or on the shelf where the item is stored. It becomes a simple task for an employee to check the stock on a regularly scheduled basis and to note those items that should be reordered.

There is nothing profound about such a system, but it does formalize an important function and provides a mechanism for the maintenance of inventory levels. Such a system also forces the manager to think in terms of the minimum and maximum stock levels for each item. This in itself effects a degree of control over the total inventory.

Often, overcommitment of capital to inventory is not apparent until the end of an accounting period, when a physical inventory is made. In many cases the inventory level creeps upward without a corresponding increase in sales.

When little attention is given to a comparison of the inflow of goods against the outflow, it is easy to accumulate excessive inventory. One mechanism that may be used to combat this problem is the buying budget. In its simplest form the buying budget provides a means of dollar control of inventory on the basis of matching purchases with sales. In a pharmacy, each dollar of sales generally represents approximately $0.70 in inventory at cost prices. Assuming a balanced inventory level at the outset, approximately $700 would be needed to restore the inventory level after $1000 worth of goods had been sold at retail.

The buying budget concept is most effective when used to plan purchases in the near future. The manager determines a budget by estimating sales for a future period, as for the next month, then calculating the amount of new inventory that is necessary to support the anticipated sales. The resulting figure becomes the buying budget for the period involved.

As purchases of inventory items are made during the period, they are subtracted from the budgeted amount. The balance is termed the open-to-buy allowance for the remainder of the period. Although the budgeted figure represents neither an absolute minimum nor maximum, it does provide a guide for management control of the dollars invested in inventory.

The real advantage of the buying budget lies in the fact that continuing management attention is directed toward an important operating problem.

Facilities

On the average, approximately 15% of the capital required for a typical community pharmacy is invested in fixtures, equipment, and leasehold improvements. Charges for housing the pharmacy are second only to wages among the costs of operation. Expressed as a percentage of annual net sales, rent represents approximately 2.0%.

Overall, the cost of facilities necessary to operate a pharmacy represents a significant portion of total costs. Management of these costs is difficult, especially because they are based on long-term commitments from which there is little opportunity for retreat. Rent, for example, most often is agreed on in advance for a 5- to 10-year period. The lease that establishes the level of rent to be paid is a legal contract that, once agreed to, is enforceable for its term. Fixtures and equipment, once purchased, represent costs that only can be recovered by longtime use.

Management's main role in the effective and economical use of facilities lies in a careful consideration of the original commitment to these assets. In a sense, facilities must be managed in advance.

RENTAL AGREEMENTS—As is the case in most areas of management, decisions regarding the types and amounts of facilities depend in large measure on projections and forecasts of future operations. Basic decisions on the size of the building and quantities of fixtures and equipment are related intimately to anticipated sales volume. The nature of the pharmacy also plays a role in these decisions. An exclusively prescription pharmacy usually requires less space than does a pharmacy that emphasizes general merchandise.

In negotiating the rental agreement the manager must have some notion of anticipated sales and the relation of rent to sales. Although such information may be useful as a guideline for negotiating with potential landlords, generally, landlords refuse to be bound by statistics.

In many cases rental figures for two or more pharmacies are difficult to compare because the services provided by landlords may vary. A pharmacy located in a medical clinic may pay rent considerably in excess of the average figure for a pharmacy doing a similar volume in another location. However, it may be that the rent includes janitorial services, centralized heating, air conditioning, or other services normally not provided.

When negotiating a rental agreement or renewing a lease, the manager may be able to get a stabilization of the rental charge as a percentage of sales by obtaining a percentage lease arrangement. This provides that the landlord receives rent based on a percentage of net sales. Such an arrangement is attractive, especially for a new pharmacy for which there is doubt about the level of sales volume that may be realized.

Landlords increasingly are receptive to percentage lease arrangements. In most cases, however, they insist on a guaranteed minimum rent, with a percentage to be added after a specified sales volume has been realized. If the guaranteed minimum rent is set at a modest figure, this may prove to be advantageous for the pharmacy.

It would be inaccurate to infer that the manager has significant command of the alternatives and terms of the rental agreement. Most often, the landlord dictates the terms of the lease. Management's main role is to avoid gross errors in judgment, resulting in long-term overcommitments for space and rent.

FIXTURES AND EQUIPMENT—The original commitment for fixtures and equipment should be made only after careful analysis of requirements and after searching the market for the most economical and suitable fixtures and equipment. The manager has options regarding quantity, quality, and sources of supply for these facilities. It is good practice to secure bids from several sources before making the final decision on the purchase of fixtures and equipment. Further, many suppliers provide counsel and advice.

Once acquired, the problem of proper arrangement of fixtures and equipment requires additional management decisions. For example, should the prescription laboratory be located in the front or the rear of the pharmacy? When located in the front, it is visible from the street and tends to emphasize prescription service to passersby; when located in the rear, it provides a private atmosphere, free from congestion and activity.

Numerous other decisions regarding layout must be made. Thus, the manager is well-advised to make use of the services of experts in store design before making these decisions.

Studies have demonstrated that the arrangement of fixtures and proper departmentalization of goods can help increase sales volume, promote employee efficiency, and make the pharmacy more pleasant and convenient for patrons. With modern fixtures designed for flexibility, the manager can experiment with various arrangements and layouts until the most efficient combination is achieved. Proper management of facilities can play a significant role in efficient and profitable operation.

Personnel

One of the most important aspects of developing an efficiently operating community pharmacy is a well-conceived program of personnel management. The uniquely personal nature of the atmosphere in the typical community pharmacy dictates that the proper selection, training, and maintenance of employees be given top priority as management functions.

Each employee represents the pharmacy in daily interaction with patrons, physicians, and suppliers. Their ability to reflect and to carry out the objectives of the pharmacy may mean the difference between financial success and failure.

In view of the obvious benefits of sound personnel management, it is surprising to observe that many managers look on good personnel administration as an area for which they have neither the inclination nor the time. Deficiencies in this area arise in part from the numerous and diverse responsibilities assumed by most pharmacy managers. Yet, time and attention devoted to personnel management would, in the long run, free more time for other management functions. The properly selected and well-trained employee can assume many duties that otherwise may be the responsibility of the manager.

The nature of retail employment also contributes to the complexity of personnel management in the pharmacy. In general, retail concerns experience significant variations in the demand for employees. Seasonal variations in sales require adjustments in staff needs. Further, retail activity often is concentrated during certain days of the week and certain hours of the day. Under such conditions, it is difficult to manage payroll costs without the extensive use of part-time help.

Because of the extensive use of part-time employees, many of the people employed by retail firms are young people without previous work experience. Often they have little understanding of the economic value of the services they are expected to render. Personnel of this type present special problems in training and orientation, not only to a specific job but also to the general obligation of an employee to an employer.

Attracting competent employees is made more difficult by the need to cater to the desires of the public regarding store hours. Modern consumers expect to shop 7 days a week and into the late evening hours. The retail employee, therefore, is expected to work during hours and on days when others in society are free to shop and play.

Other problems associated with obtaining good employees are inherent in the nature of retailing. Retail employees are meeting the public continually, so they must be of at least average intelligence, present a good appearance, and have an acceptable personality. Also, wages paid to retail employees ordinarily are well below those paid in other industries.

SELECTION—Although the nature of retail employment is unique in many respects, the basic principles of personnel management may be applied in the development of a program for selecting, training, and maintaining employees for the retail field and specifically for the community pharmacy. Proper selection techniques must be developed to ensure that employees are compatible with the job to be done and with the objectives of the pharmacy.

A high turnover rate in a pharmacy often makes the attitude of management toward selecting employees rather casual. Managers rationalize that the employee will not be staying long, therefore, why worry about selectivity?

Further, the manager frequently is faced with the problem of replacing employees on relatively short notice. In such emergencies selectivity often is ignored.

Improper selection of employees has the effect of perpetuating and intensifying the turnover problem, and the employee who is not suited to his job can be detrimental to the operation of the pharmacy. Two general rules should be incorporated into the personnel policies regarding selection.

1. Minimum standards for qualifications of employees should not be allowed to fall below the minimum standards for service established for the pharmacy. To "underhire" for a given position can serve only to undermine the reputation of the pharmacy.
2. "Overhiring" should be avoided; obviously superior people should not be hired for inferior jobs. Such personnel rapidly become discontented and may have an adverse effect on staff morale and efficiency.

Proper selection of personnel for a specific job is predicated on an understanding of the duties and responsibilities involved and on knowledge of the individual characteristics required for efficient performance. The manager should develop a job description and a job specification for each position in the pharmacy.

The job description is a brief summary of the scope of the job, its relation to other jobs, and such details as working hours and pay scales. It also serves to prevent misunderstandings about the nature or duties of a particular job. The job specification sets forth the characteristics and competencies necessary in the individual who fills the position.

With these materials, the manager is in a position to evaluate objectively the candidates who apply for the position. Selection also requires a knowledge of the sources of potential employees. For some jobs, promotion from within the pharmacy staff may be appropriate. In most cases external sources must be used, such as employment agencies, placement offices of schools, and universities or classified newspaper advertising.

A growing source of part-time employees are the co-op work-study programs of many high schools. An availability file

should be established in the pharmacy—a record of qualified people who applied for jobs when no openings existed.

The manager should develop an application form to assist in the selection process. Although the application form serves basically to provide information about the applicant, it can serve other purposes as well; for example,

It provides a means for observing the applicant's ability to follow simple written instructions.

It serves as a guide in the employment interview. If no openings currently are available, it can go into the availability file.

It serves a practical purpose as a part of the employee's permanent record and as a source of information for social security and withholding tax reports.

A properly designed application form can serve as an effective screening device for prospective employees. The information supplied on the application form often indicates that the applicant does not meet the job specifications and, thus, should not be considered further. If the information suggests that the applicant is a good prospect, the selection procedure should continue with an interview.

Often the employment interview is the sole selection procedure used by pharmacy managers, and this is not advisable. At the least, the references provided by the applicant should be checked thoroughly to substantiate the impressions generated by the interview. The interview, however, is a key step in most selections. It should be conducted in an unhurried manner, in privacy and in a relatively informal atmosphere. Much can be learned about the prospective employee through a properly conducted interview.

The manager also might consider developing some simple tests to be used in the selection process. Testing is used as a selection technique by many larger firms and can be most useful. In the pharmacy, simple arithmetic tests can be used in selecting personnel for sales or clerking positions that may require that the person be able to handle the simple problems involved in making change and computing sales taxes.

Note that all employment policies and procedures must be consistent with applicable federal and state laws governing equal employment opportunity. In general such laws prohibit discrimination in selection and hiring practices.

ORIENTATION AND TRAINING—Proper selection needs to be followed by adequate orientation and training of the employee. These can serve to increase productivity and to reduce employee turnover. The orientation process should include a give-and-take discussion with the employee on the following questions:

What are the basic philosophies of the pharmacy (toward patrons, other health professionals, and employees)?

What are the hours the employee is expected to work (evenings, weekends, and holidays)?

How long is the lunch hour?

How is overtime handled?

What is the policy regarding coffee breaks?

What are the regulations about smoking?

What are the rules regarding punctuality?

Are uniforms required? If so, who buys them and who pays for laundering?

What are the safety and security regulations?

May this employee answer the telephone? If so what information is he or she authorized to give?

Can the telephone be used for personal calls?

What is the vacation policy?

What is the policy regarding leave (sick or personal business)?

What are the opportunities and procedures for advancement?

What are the policies on employee purchases and discounts?

These questions are by no means all-inclusive on those matters that might be of concern to both the employer and the employee, but the use of such a list provides a basis for posing additional specific questions. Although some of the questions may appear to be trivial, these are the kinds of matters that often cause problems between employers and employees.

In an extreme case disagreements over such matters may lead to termination of employment. In other cases, employee resentment may be reflected in attitudes toward and dealings with patrons of the pharmacy, and this could be the most serious consequence of such disagreement. If these matters are discussed in advance, misunderstandings may be minimized, to the mutual benefit of both parties.

After a general orientation to the pharmacy the employee needs specific training in the duties and responsibilities of the job. Too often the new pharmacy employee is trained by the sink-or-swim method. The employee is simply put to work and is expected to pick up knowledge on the job. Obviously, such a method of training is inefficient and in the long run costly, although it does offer the advantage of requiring little or no management time or effort.

Although the typical community pharmacy has neither the staff nor the facilities for sophisticated training programs, there are effective, simple, training methods that can be used. The sponsor system of training is the most appropriate for a pharmacy. A new employee is assigned to a capable experienced employee who explains and demonstrates the job in question. The conference method also may be used, by itself or to supplement the sponsor system. Here, the new employee meets privately with the pharmacy manager or a designated employee to discuss the techniques of the job. In either case the management responsibility lies in organizing and structuring the training so that all aspects of the employee's duties are considered.

COMPENSATION—Retaining good employees is one of the most difficult problems faced by the community pharmacy manager. There are many elements in the employment environment that may help in keeping employees, but most important is the compensation plan. Adequate compensation is necessary, not only to retain employees but also to encourage them to work toward the overall goals and objectives of the pharmacy. The basic elements of a sound plan are

Adequacy—The amount of compensation should be commensurate with the responsibilities of the job. Adequacy also may be viewed in a legal sense in terms of state and federal minimum wage laws.

Simplicity—Plans that are uncomplicated are understood easily by the employee and have the further advantage of being easy to administer.

Progressiveness—A plan should recognize and reward initiative, productivity, and increasing value of the employee to the pharmacy. It should provide incentive for doing a better job. Periodic review of performance and salary should be provided for in the plan.

Patron Protection—The plan should not encourage acts that are detrimental to the best interests of the patrons of the pharmacy. For example, it is inappropriate to offer extra commissions for promoting the sale of OTC drugs. If commissions are paid on these drugs, the employee may be tempted to place personal economic gain ahead of the real needs of the patron.

Traditionally, the compensation plan for pharmacy employees has consisted of an hourly or weekly salary plus the legally required social security contribution by the employer for each employee. Modern personnel management calls for a broader compensation plan to compete effectively for the limited number of good employees.

Increasingly, even small pharmacies are offering plans that include not only salary but such fringe benefits as health insurance, life insurance, paid vacation, and sick days plus supplemental retirement benefits. When such benefits are provided, the employer should calculate their value in terms of preincome tax dollars, thus demonstrating to the employee their real economic value.

Credit

The need for credit is apparent especially when health products and services are involved. The need for drugs and pharmaceutical services often is immediate and independent of the cash position of the patient. Further, a charge account statement provides the patient with a mechanism for keeping track of expenditures for drugs for insurance and income tax purposes.

Credit management in the community pharmacy, on occasion, presents a conflict between sound business practice and professional responsibility. Sound business practice may indi-

cate that credit should not be given to a particular patron, whereas professional responsibility may dictate that credit must be given. It is not possible to develop inflexible credit policies that solves such problems. However, it is possible to develop policies and procedures that are effective in a majority of such situations. There are two general areas that require attention in credit management.

POLICIES AND PROCEDURES—Included here are the matters of eligibility, limits on credit, credit terms, maintaining accurate records and identification of credit patrons. Deciding which patrons are eligible for credit is the most troublesome problem for the pharmacy manager.

It is difficult to make a decision without knowing the credit history of the patron. Data on past credit experiences must be obtained and should be checked. The patron can be asked to supply the necessary information and usually will do so.

However, verification presents a serious practical problem. Some managers attempt to verify the information personally by contacting each credit reference. Such a procedure is time consuming, and the information received is often incomplete.

A better approach appears to lie in the use of professional credit bureaus. Most localities are now served by such bureaus that, for a fee, investigates prospective credit customers and supplies a report on their ratings. With this information the manager can make better decisions and minimize the problems associated with granting credit.

COLLECTION—The best policies can be thwarted by careless collection procedures. The terms of credit granted should be made clear to the grantee at the outset. If the terms are not met, appropriate and prompt action should be taken.

The manager is responsible for establishing the guidelines and procedures necessary to ensure prompt payment of credit accounts. Collection policies that result in prompt payment offer a number of advantages.

Prompt payment means rapid turnover of capital invested in accounts receivable, and this permits a given level of operations to be supported with less capital. Operating expenses are lower when accounts are paid on time as delinquent accounts cost money in terms of employee time and supplies required for follow-ups.

Finally, there is a definite relation between the length of time accounts are outstanding and bad debt losses; usually, the longer an account is outstanding, the less likely it is to be collected.

Although guidelines and procedures should be established for collecting past-due accounts, rarely is the same procedure appropriate for all such accounts. New accounts, for example, should be handled firmly to impress the patron with the importance of prompt payment. Casual handling or lack of follow-up of delinquent new accounts sets a precedent that may be hard to overcome.

For established accounts, more individualized treatment is indicated. Some patrons fail to pay promptly simply out of negligence. Usually a simple reminder stimulates payment. Others may be willing to pay their debts but for reasons beyond their control are unable to do so. The manager may be able to work out a budget plan for those to help solve their problems.

A small group of patrons may fall into the category of those who simply do not wish to pay. Outside collection agencies or legal action may be the only alternative for this group. In any event, policies and procedures for collection should be included as part of the credit management function.

Credit also may be provided to patrons by means of various credit card systems operated by banks. The credit card system involves the establishment of a line of credit for an individual with a participating bank or group of banks. The individual is issued a credit card that is honored by participating businesses for goods or services. The participating business then forwards the receipts for sales of goods or services to the bank and receives immediate payment, less a service charge based on the amount of the sale.

The advantages of this system lie in the fact that bad-debt losses are reduced almost to zero, and the cost of billing is assumed by the bank. Even though the amount realized from the sales transaction is reduced by the amount of the service charge, some pharmacy owners view the bank credit card system as the answer to problems associated with credit transactions. In fact, many pharmacies use such systems as their only credit program.

As a practical matter, however, many people who require drugs and pharmaceutical services cannot qualify, and some people refuse to participate in the credit card system. As a result, some pharmacies use such systems simply as a supplement to their own charge-account system. In addition, increasing numbers of pharmacies are accepting nationally recognized credit cards.

Most, if not all, community pharmacies today also extend credit for prescription drugs and pharmacy services to private and government third-party programs. In 1997 it was estimated that 71% of all outpatient prescriptions were paid for, either in full or in part, by third-party programs. As a result, a significant portion of the accounts receivable for the typical community pharmacy represents payments due from third-party payers. Generally, credit extended to third-party payers involves minimal risk of bad-debt losses if services are provided to patients who are eligible for benefits, program requirements are met, and accurate claims are submitted. However, the payment cycle from the submission of a claim to receipt of reimbursement varies greatly among third-party payers. Some process claims within 15 to 20 days, whereas others may take a month or more. To minimize delays in reimbursement, the pharmacy manager must implement systems that assure the prompt submission of accurately prepared claims to all third parties.

Fortunately, increasing numbers of third-party payers are using electronic systems that provide for on-line processing and adjudication of claims for pharmacy services. The electronic transmission of claims directly from the pharmacy to the third-party payer provides for instant verification of patient eligibility, confirms whether the service provided is a payable benefit and confirms the amount to be paid to the pharmacy provider. Electronic submission of claims also may shorten the payment cycle and reduce the average collection period for accounts receivable from third-party payers.

To measure the effectiveness of management control over credit sales, it is useful to calculate the average collection period of customers' accounts receivable. Average daily credit sales are divided into the total of accounts receivable at the end of a period, giving the average collection period for accounts receivable. In theory, this figure should be approximately 40 days if all accounts are paid on time. Figures in excess of 60 days indicate deficiencies in credit policies and credit management, and call for prompt action.

Risk

As a commercial enterprise, a community pharmacy presents numerous risks in terms of economic gain or loss. Some risks inherent in the operation are speculative in nature. For example, will operations produce a profit or a loss? With this type of risk there is an uncertainty that may work either to the detriment or to the benefit of the pharmacy owner. Such risks can be managed only indirectly by careful attention to the management of all of the elements comprising the pharmacy. Even then there is no guarantee of success.

Other risks associated with the operation of a pharmacy may be termed pure risks. These involve uncertainty and chance of loss but do not provide a gain directly if the loss is not realized. Tangible destructible property is subject to pure risk; its destruction always is possible but not certain.

For example, there is a risk that the merchandise inventory owned by the pharmacy may be destroyed by fire. If a fire occurs a loss surely will be suffered, but if it does not occur no direct increase in value or profit is realized. Pure risk may be controlled or protected against by appropriate direct management action.

TYPES—The first function of management related to controlling pure risk is to identify and analyze the several perils to

which business assets are subject. Some perils are common to all pharmacies; others are unique to specific situations. It is important, therefore, that the analysis of risk be individualized. There are four common categories of perils to be considered.

Actual Loss of Property—All tangible property is subject to being lost. For the pharmacy, most such losses are due to dishonesty such as shoplifting, burglary, robbery, or embezzlement.

Damage or Destruction of Property—Most tangible property is exposed to possible destruction or damage by fire, the elements, civil commotion, and various other causes.

Civil Liability—Every pharmacy is subject to various risks associated with dealing with the public and with employing people. Negligence or breach of responsibility, alleged or proven, can cause financial losses. Injuries to individuals in the pharmacy, malpractice by pharmacists, and product liability are examples of these perils.

Contractual Liability—Legal liability beyond that imposed by the law may be assumed in a contractual relationship between a pharmacist and other persons. The lease signed by the pharmacist to obtain the building for the pharmacy is an example of contractual liability.

RISK MANAGEMENT—Each peril identified by the pharmacy manager must be further analyzed to determine the probability of occurrence of an actual loss as follows: the loss must be quantified in terms of its effect on the total assets of the pharmacy and the ability to handle the loss; the manager must decide which of the alternative methods or combination of methods should be utilized to protect against each peril or loss. The three commonly recognized ways to handle risks are

Self-Insurance—This may be used to protect against small losses with a low probability of occurrence. A reserve is established and, in the event such losses occur, they are paid for out of the reserve that is created by systematically setting aside money for this purpose. A major danger is that a large loss may occur before a sufficient reserve has been established. Except for large, multiunit pharmacies, self-insurance is not practical for community pharmacies.

Assumption of Risk—When the probability of loss is low and the loss is of small magnitude, it may be economically advantageous for the owner to assume the risk. For example, when the cost of insuring plate glass against perils other than fire and the elements is compared with the probability of loss from these perils, most owners decide to assume the risk. Assumption of risk differs from self-insurance in that no reserve is established. Obviously, this method of risk management must be used carefully.

Insurance through Others—The majority of pure risks associated with community pharmacy practice are of sufficient magnitude to dictate the placement of risks with other parties such as insurance companies. They offer service to the insured and provide indemnity in the event a loss is suffered. Such firms provide the technical knowledge and the legal experience required for settling losses quickly and efficiently. Often the services of insurance companies are as important as the indemnification they provide, as is the case in liability suits.

Too often the management of risk is considered adequate when proper provision has been made to insure indemnification in the event of a loss. A complete risk-management program should include a consideration of loss prevention as well as protection. An attempt to prevent losses can be beneficial in many ways.

Insurance companies are beginning to recognize clients with good records and to reward them by reductions in premiums. A direct cash savings thus is effected by reduction of prevention of losses. More important, most tangible losses result in other losses that cannot be handled by insurance. For example, when an error is made in dispensing prescription medication and a malpractice suit is brought, the tangible dollar cost of such a suit may be paid by the insurance company.

The intangible loss caused by damage to the reputation of the pharmacy cannot be alleviated by cash payment. Prevention of such occurrences is the best way to avoid all of the losses involved. Loss prevention, both philosophically and practically, should be an integral part of risk-management programs.

The services of an insurance counselor may prove valuable to the manager of a pharmacy in developing a risk-management program. The complexities involved in evaluating risks and in understanding the various types of insurance policies and terminology call for expert advice. The insurance counselor generally is the best source of unbiased information.

The insurance counselor usually does not order policies. The counselor's function is to evaluate the risks of a specific individual or firm and to make recommendations regarding the best way to deal with them. The fee for these services is paid by the insured rather than the insurer. Expenditures of money for this service may prove to be extremely economical in the long run.

INSURANCE—Among the types of coverage required for the community pharmacy are

Fire insurance
Malpractice insurance
General public liability insurance
Products liability insurance
Employer's liability or worker's compensation
Crime insurance
Business interruption insurance

These specific coverages may be acquired separately or several of them may be included in a package policy, similar to the well-known homeowner's policy. Package policies have the advantage of offering broader coverage at the same or even at a lower cost than do the individual policies purchased separately. Such policies should be evaluated carefully; the multiple coverage involved may leave gaps in protection that are not apparent until a loss occurs. It often is difficult to know exactly what is covered, and to what extent, under package, all-risks policies.

Perhaps the most important coverage for the tangible assets of the pharmacy is fire insurance. Although most pharmacies are protected to some degree, often the amount of the fire insurance falls below the actual value of the property.

This is particularly important because most fire insurance policies contain a co-insurance clause. This clause requires that insurance equal to a specified percentage of the value of the property be carried at all times. A common requirement is 80% of the value.

Under co-insurance if, at the time of a loss, the amount of insurance carried is below the required amount, the insured must bear part of the loss. For example, if the insurable value of the property owned by a pharmacist is $50,000 and the fire insurance policy has an 80% co-insurance clause, the pharmacist must carry $40,000 worth of insurance on the property. If only $30,000 is carried and a $10,000 loss is suffered, the insurer is required to pay only $7,500. The pharmacist must assume the balance of the loss because only 75% of the required amount of insurance was maintained.

The standard fire insurance policy should be supplemented by an extended coverage endorsement. For a small additional fee this endorsement has the effect of extending protection to cover damage by windstorm, hail, explosion, riot, smoke, and from land vehicles and aircraft. Note that usually neither the standard fire insurance policy nor the extended coverage endorsement covers losses of documents, accounts receivable, prescription files, or currency.

Several types of liability insurance are becoming increasingly important in modern practice. Pharmacy owners may be required to answer a suit arising out of the negligence or alleged negligence of them or of their employees. In addition, the pharmacy is a public facility where there are innumerable opportunities for injury to patrons.

Product liability may arise out of claims of patrons that have suffered injuries from products purchased in the pharmacy. Although the pharmacist may be able to fall back on the manufacturer under the concept of implied warranty, such claims must be answered by the pharmacist. Insurance can

provide the financial and legal resources necessary to answer suits of this type.

The owner must obtain coverage of sufficient scope and amounts adequate to protect against liability claims. Without insurance coverage, an unfavorable judgment from one such claim may be sufficient to bankrupt the owner.

Insurance coverage against criminal acts also should be obtained. In addition, the manager is in an excellent position to use loss prevention as a means of minimizing these risks. Minimizing the amount of cash carried on the premises, installation of burglar alarm systems, and carefully observed security measures can greatly reduce losses in this area.

The dishonesty of employees can be controlled best by adequate systems and policies regarding handling of cash and other assets. Shoplifting losses can be reduced by proper surveillance and proper training of employees. As a rule, insurance is not available to cover these losses.

When a pharmacy suffers losses because of fire or other causes that interrupt operations, the actual loss goes beyond the property that is damaged or destroyed. Profits are lost while the pharmacy is closed. Certain business expenses continue, even during interrupted operations. Key employees may be forced to seek other employment. Such losses may be covered by business interruption insurance. This is designed to indemnify the owner for lost profits, continuing expenses, and salaries of key employees during a reasonable period of interrupted operations.

Life insurance also may have a role in a comprehensive risk-management program for a community pharmacy. If a pharmacist is the sole owner of a pharmacy, insurance on his life can provide funds to take care of the debts of the pharmacy in the event of the owner's death. If the pharmacist is the co-owner of the pharmacy as a partner, arrangements should be made for life insurance on each partner with the other partner(s) named as beneficiaries. The amount of such insurance should be sufficient to pay for each partner's equity in the enterprise.

In the event of the death of a partner, the surviving partner(s) can use the proceeds from the insurance to buy a deceased partner's interest in the pharmacy from the heirs. Such an arrangement reduces the possibility that the enterprise would be dissolved to settle the estate of a deceased partner. The premium payments made for partnership life insurance policies are regarded as a business expense.

There are various other risks that may be covered effectively by insurance. Some of these are peculiar to individual circumstances and must be analyzed and managed in terms of the specific pharmacy. Effective management of all the insurable risks associated with modern community pharmacy practice must be combined with effective management of the uninsurable speculative risks inherent in entrepreneurial activity.

Records

For various reasons—some legal, some financial, and some professional—the maintenance of records in the pharmacy is becoming increasingly important. The types of records required may be classified as

Records required by law regarding the acquisition and disposition of drugs.
Records regarding patient utilization of drugs.
Records regarding the past and the present financial status of the pharmacy.

Management's role in this function is to identify the specific records required, develop systems for keeping them, and delegate the responsibility for day-to-day record keeping to capable personnel.

LEGAL RECORDS—According to federal and state law, the pharmacy owner or manager is charged with maintaining accurate up-to-date records on specific classes of drugs and poisons. Under the provisions of the *Federal Controlled Substances Act of 1970*, the pharmacist is charged with maintaining accurate records related to the acquisition and disposition of certain drugs that are deemed to be subject to possible misuse or abuse. Several states have enacted legislation that requires accurate records on the distribution of poisons and other hazardous substances.

The legal implications of record keeping, as it relates to these drugs, are serious. Improperly maintained or incomplete records can bring legal action and penalties.

PATIENT RECORDS—In recent years many pharmacists have broadened their record-keeping activities to include patient drug histories. Although the form of patient record varies, the basic idea is to establish a record (usually on a family-unit basis) that allows the pharmacist to monitor the drug usage of each member of the family. It increasingly is apparent that, because of the kinds and amounts of drugs being taken by the average patient, there is need for a drug history for each individual.

To reduce the problems associated with drug interactions and individual idiosyncrasies to drugs, the pharmacist has a professional obligation to maintain records of this type. In addition, these records also may serve economic purposes, as sources of information for insurance claims and for income tax deductions of the patient.

FINANCIAL RECORDS—Properly collected and organized accounting data serve various important uses and are of value to the pharmacy owner in the following ways:

Providing the basic tools for efficient management and measuring its effect.
Making sound decisions regarding future cash needs, inventory requirements, personnel matters, and expansion of facilities.
Evaluating past operations, controlling current operations, and providing information for planning and forecasting.
Analyzing revenues and expenses.
Measuring return on investment.
Providing the required information to potential grantors of credit and loans as well as to federal, state, and local governmental agencies regarding income and business taxes.
Helping to ensure a profitable operation.

Generally, the manager no longer acts as bookkeeper in the community pharmacy. Considering the complexities of contemporary business and the importance of good financial records, the pharmacist is well advised to employ experts to assist in the development and the maintenance of his or her accounting system. The experts can help to develop an individualized system that meets the accepted criteria for good financial records: objectivity, conservatism, consistency, and comparability.

Financial records should reflect, insofar as is possible, an objective evaluation of the transactions and data on which they are based. Personal opinion and judgment should not be allowed to prevail over an objective analysis of financial data. For example, the cost of fixtures in the pharmacy should be reported in the financial statement on the basis of acquisition cost as evidenced by a bill of sale or an invoice.

The value of these fixtures should not be increased on the statements simply because management feels they are worth more than the original cost because of increasing price levels. Convincing objective evidence of the dollar amounts reported on the financial statement is a prerequisite to maintaining the integrity of such statements.

The general optimism of many owners and managers may be in conflict with the principle of conservatism as it relates to financial records. A moderately conservative approach should be employed in reporting financial data; otherwise, the data may tend to overstate earnings and assets and to understate liabilities. The consequences of overstated earnings include the possibility of excess income tax liability in a given year.

If a choice must be made between understatement or overstatement of income or assets, the principle of conservatism would dictate understatement. This does not imply that earnings or assets should be understated deliberately. However, when estimates or opinions must be used in making decisions regarding financial records, a conservative attitude should prevail. For example, many managers are reluctant to

admit that a certain percentage of accounts receivable will prove to be uncollectable.

They are inclined to report accounts receivable in the financial records without a realistic reduction for bad debts. To do this without adjustment based on recognition of the likelihood of some not being collected is to violate the principle of conservatism.

Although there is no hard and fast rule for accounting for financial transactions, it is important that a given enterprise be consistent in its accounting system. This also is linked closely to the final criterion for good financial records: comparability.

There are various methods of recording and reporting financial transactions, and decisions must be made regarding the best method. Once chosen, it should be applied consistently throughout the life of the enterprise so that financial records will be comparable from period to period. For example, there are several ways to allocate depreciation charges to expense. If the policy on depreciation is changed from one period to the next, the net income may be altered significantly. Such a change would have an effect on the comparability of the financial statements for the two periods.

Attention to consistency and comparability should not necessarily rule out all changes in accounting methods. When valid reasons dictate a change in method, it should be made. However, the nature of the change should be indicated clearly on future financial statements.

Comparability of financial records also is important in the broader sense to compare records between firms in the same field. It is advantageous to be able to compare the financial statements for the pharmacy with similar statements such as those reported in the NCPA-Searle Digest and other references. Such comparisons are facilitated if relatively standard accounting systems are used. The manager could instruct his or her accountant to classify expenses according to the NCPA-Searle Digest system. He or she then would be able to analyze the expenses of their pharmacies in relation to national trends and averages.

The day-by-day financial transactions are summarized in the statements prepared at the end of the accounting period. Among the statements most important to those concerned with the financial progress of the pharmacy are the balance sheet and the income statement. Assuming that the underlying data have been treated objectively and conservatively, the balance sheet should represent fairly accurately the financial position of the pharmacy at the end of a given period. It reflects the basic accounting equation:

$$\text{assets} = \text{liabilities} + \text{owner's equity}$$

Assets are the items of value owned by the enterprise, listed at cost prices less any allowances for depreciation or doubtful accounts. The liabilities and owner's equity represent the claims against the assets.

The balance sheet is of interest to the owners in terms of the total value of their investment and the value of specific assets that make up the total investment. Managers especially are interested in such items as total merchandise inventory and accounts receivable.

Future management decisions regarding inventory control and credit policies may be influenced by the information included on the balance sheet. Those who are asked to grant credit to the pharmacy will be interested in the current liabilities and the owner's equity, as reported on the balance sheet. A formal detailed balance sheet should be prepared at least once a year. One commonly used format for reporting balance-sheet information for community pharmacies is illustrated in Table 94-1.

The income statement details the effects of revenue and expense transactions during a given accounting period. Unlike the balance sheet, which describes the financial position of an enterprise on a given date, the income statement summarizes only those transactions directly related to income production for a specific period, usually a year. For most purposes the income statement is used in concert with the balance sheet, each supplementing the other.

The owners of the pharmacy are interested not only in total investment but also in the net profit, which represents return on investment. The manager cannot accurately judge the appropriateness of the level of merchandise inventory reported in the balance sheet without knowing the sales revenue generated by the inventory as reported in the income statement.

The information included in the income statement can be used by the manager to plan for future operations and as a means for controlling current operations. When the information is compared against past years and national averages, trends are observed and problem areas may be identified. The manager then can make decisions and take actions intended to improve the profit-making potential of the pharmacy.

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CHAPTER 115

Product Recalls and Withdrawals

Michael R McConnell, RPh

Occasionally, pharmaceutical manufacturers must recall or withdraw products from wholesalers, pharmacies, and/or patients. There are approximately 200 pharmaceutical recalls every year. The reasons for recalls and withdrawals range from life-threatening situations (eg, a product that is supposed to be sterile but is instead contaminated with bacteria) to situations where there is no health hazard or risk, but simply, the product does not measure up to the quality control standards that the pharmaceutical community wishes to present to the public (eg, a label that appears upside-down on its container).

The purpose of this chapter is to offer guidelines and background information for practicing pharmacists to handle efficiently and in a professional manner recalls and withdrawals. It is impossible to anticipate every possible situation, and it is unwise to have a "cookie cutter" solution for every recall or withdrawal.[1] It is hoped that pharmacists will take these guidelines and then enhance or modify them to fit their particular practice. This chapter is divided into several sections: (1) Recall Procedures; (2) Action When a Recall Happens; and (3) Background Information, Future Directions, and Implications of Recalls.

RECALL PROCEDURES

Documenting Recall Procedures

The lack of documentation for quality systems seems to be a typical condition for many American companies. In the 20th century, America seems to have been successful without having to write everything down, without keeping extensive records, without issuing many standard operating procedures. Now, everyone is faced with the challenge of documenting what it is that we do. The watchwords for the future seem to be: "*If you do it, write it. If you write it, do it!*"[2]

The purpose of any written procedure is to provide a documented plan for what to do in a certain situation. Pharmacists may well find that it is better to create procedures (eg, Policies and Procedures) prior to a crisis situation, when a "cooler" head and more time allows for better quality consideration. The middle of a life-threatening recall is not the time to try and think of everything to do. Established written procedures better ensure that policies are carried out consistently and with the same level of quality from event to event. In large institutions, there may be dozens of pharmacy personnel, and written procedures are essential if the pharmacy department is to function as a cohesive unit. Written procedures are also valuable in a one-pharmacist facility. Even in the case of a sole-practitioner community pharmacist working most of the hours the pharmacy is open, recalls may not happen with enough regularity for the pharmacist to remember exactly what to do from one recall to another. Never mind that Murphy's Law says that the "worst recalls will happen when the sole-practitioner pharmacist is on a rare vacation and a relief pharmacist is on duty." In a situation such as this, written procedures can help to ensure the smooth delivery of high quality patient services, and lessen the risk of legal liability.

In developing the procedures' documentation, the pharmacist may want to *create forms* or templates to guide pharmacy personnel through the recall procedures. A form is simply a printed or typed document with blank spaces for insertion of required information. Creating a form does not have to involve deluxe design skills. In the interest of getting a procedure form created in a timely manner, a simple handwritten layout may be the most efficient way to get it accomplished in today's environment.

Elements Of A Recall Procedure

There may be many elements of a recall procedure. A simple list includes the following three major elements:

1. Communication
2. Product handling
3. Recordkeeping

A pharmacist may discover that for a particular pharmacy institution, facility, or type of pharmacy practice, there needs to be additional elements. There is probably no one right answer.

COMMUNICATION

After becoming aware of a product recall or withdrawal, one of the first things a pharmacist will probably need to do is to communicate the recall to someone else. It may be helpful to think in terms of:

who to contact (who needs to know about this recall event? ie, other pharmacists, physicians, patients, etc.);
what to communicate (what facts, options, advice, etc., need to be communicated?);
when to send out communication (how quickly does the communication need to take place?);
how to communicate (what are the appropriate methods to send communication quickly, accurately, etc.?).

Regarding to ***whom*** a communication should be forwarded, the pharmacist may wish to make a list of those who could be affected by a recall. Here, the idea is not that all those who might possibly be affected by any recall need to be notified about every aspect of every recall. As will be discussed later (ie, in the background discussion on recalls), recalls vary in importance, and there may be situations where it is perfectly reasonable **not** to communicate a recall to a wide audience. A sample

checklist of *Who to Contact* is shown in Figure 115-1. In preparing the *Who to Contact* list, the pharmacist may want to list actual specific facilities in the area for which he/she feels a responsibility to notify about recalls. For example, even if a recall is being carried out only to the pharmacy level (more about *levels* later), the pharmacist may want to notify some physicians'offices, nursing homes, and other similarly interested parties.

Regarding ***what*** should be communicated, the pharmacist may wish to think in terms of the following:

1. Identifying the **product**
2. Stating the **reason** for recall
3. The **action** to be taken by the person being contacted

Also, when considering what should be communicated, one should think about the audience. For example, to communicate the product identity *within a pharmacy* the pharmacist should include the product name, strength, manufacturer, package size, NDC, and lot number. To communicate product identity *to a patient*, things such as package size, NDC, and lot number may have little meaning and may be confusing. Likewise, when communicating the reason for a recall to a patient, it may be factual to say that a product "contains *Pseudomonas aeruginosa*," but it may have more meaning for the patient if the pharmacist said that the product is "contaminated with bacteria." Care must be taken when communicating the original reason for the product recall, especially when communicating to patients.

Although it can be said that everyone (eg, other pharmacists, physicians, patients) has a right to know the reason for the recall, pharmacists should keep in mind the ramifications that a recall communication may have for patients. For example, will the wording used when stating the reason for a recall possibly cause a patient to stop taking a life-saving medication and, thus, be subject to a possibly greater harm than if the recalled product was continued? A patient who discontinues an anticonvulsant or an antiarrhythmic drug may place himself/herself in a greater danger than by continuing to take a recalled medication that may only be slightly subpotent at the end of its expiration date. This leads to the next consideration.

What course of *action* should be communicated? In general, if a recall is being communicated officially to the patient level, then it is usually, but not always, serious enough that the patient will probably be instructed to stop taking the product. Sometimes a patient will be instructed to continue his/her medication but to see his/her physician as soon as possible. The original recall communication from the pharmaceutical manufacturer or the Food and Drug Administration (FDA) will probably have presented actions to communicate to patients. In any case, the impact of a recalled product on any individual patient's health and exactly what action an individual patient should take is a matter best addressed by the patient's physician.

Pharmacists play a very important role in one aspect of what action to take after a recall, and that regards the availability of alternative therapy. In preparing for consultations with physicians and patients regarding possible alternative therapy, the pharmacist may want to consider such questions as follows:

- Is the same product available in a different strength? For example, taking two 5 mg tablets instead of the recalled 10 mg tablet?
- Is the same product available in an alternative dosage form (eg, oral liquid, subcutaneous injection)?
- Is the same chemical entity available from a different manufacturer? If so, are there any important differences in the formulation (eg, different color dyes, different preservatives)?
- If no alternative identical chemical entity is available, then what products are in the same therapeutic class as the recalled product and, therefore, might be viable options for alternative patient therapy?

The pharmacist who is prepared with answers to these questions can be instrumental in helping a physician work through the implications of whether or not a patient should discontinue a recalled product.

More mundane, but still important, considerations involve product disposition and reimbursement. Regarding disposition, should the product be returned to the pharmacy, sent directly to the manufacturer, disposed of down the drain, or handled with some other action? If it should be returned to the manufacturer, should it be sent by secured carrier (which may be important for legal liability reasons)? If product tampering is suspected, then the patient may be asked to hold the product pending imminent retrieval by an agent of the FDA or the Federal Bureau of Investigation (FBI). A patient may be tempted to just dispose of a product "down the drain" and forego reimbursement. But, if the product is potentially hazardous, then disposing down the drain may have environmental ramifications. This is usually a consideration only when large quantities of product are involved (eg, in a pharmacy or wholesaler), but environmental regulations may state that *any* quantities of certain substances (eg, chemotoxic agents or heavy metals) are forbidden to be dumped into a sanitary sewer.

Regarding reimbursement, questions may include the following:

- How much will the patient be reimbursed for the actual product (eg, full price paid vs full price minus any amount used, or minus any co-pay or deductible)?.
- Will reimbursement be given for follow-up physician visits, and if so, what kind of receipts or documentation will the patient need to secure?

The matter of *when* to communicate a recall can be naively answered with "as soon as possible." But, one must recognize the effect that the decision of *when* to communicate has on *how* a communication is then made. For example, if the recall communication should be made as soon as possible, does that imply that sending a letter by first class mail is unacceptable and that everyone should be contacted by telephone or by facsimile (fax)? And, what is a practical time frame for a pharmacy to contact hundreds of patients, even if it is an urgent matter? Within hours? The same day? Within a few days?

The target date or time for completing recall communications to patients, physicians, or other pharmacists should be commensurate with the degree of health hazard of the recall. For example, in the case of a minor product mislabeling that does not pose a serious health risk and the recall is to be carried out only to other pharmacies that may have purchased the product from the pharmacy, then it may be perfectly reasonable to set a notification goal of a few days. In the case of a sterile product that is contaminated with bacteria where the recall is being carried out to the patient level, it may be more prudent to set a goal of notifying all patients within a 24-hour time period.

The methods that a pharmacist chooses for *how* to communicate recalls should follow directly from the above considerations of the *whos*, *whats*, and *whens* of communication. Again, using the present examples, if communication of a recall with no health hazard needs to be completed within a few days, then sending a first class mail letter may be the most appropriate method. If a recall communication involves potential health risks, using the telephone or faxing to communicate more quickly and have some degree of confirmation that the recall notice was received, may be the more appropriate method. The pharmacy's written procedures for how to communicate may include considerable details, such as whether or not the pharmacist should leave a message on a patient's answering machine, and if a message is to be left on an answering machine, whether or not the message mentions details about a recalled product, or just a message for a particular person to call the pharmacy. HIPAA regulations regarding patient confidentiality would be a consideration in these instances.

PRODUCT HANDLING

Establishing written procedures for how product is to be handled should address such items as:

1. Identifying the recalled product
2. Locating the product in the pharmacy
3. Quarantining and returning the product

Identifying the recalled product is accomplished most reliably if its NDC number is used. Reliance on identifying factors such as name, manufacturer, etc. can be confusing in the modern pharmaceutical marketplace considering repackaging, contract manufacturing, and group purchasing and labeling. The other identifier necessary in most pharmaceutical recalls is the product lot number. The lot number identifies which manufactured batch of the product is affected by any particular recall. Some recalls affect all lots manufactured, but most are limited to certain lots.

In locating the recalled product within the pharmacy or facility, it is vital that pharmacists establish a checklist of all locations where a recalled product might possibly reside (Fig. 115-3). In addition to the obvious answer of looking for a recalled product on the main shelves, the pharmacist should consider other locations, such as, the fast mover section, refrigerator, special section categories (eg, otics, ophthalmics, dermatologicals), returns box, and prescriptions in will-call, just to identify a few. In the case of hospital or institutional pharmacies, it is important that written procedures clearly delineate the locations where the pharmacy is responsible for managing the inventory. These will vary from institution to institution, but may include such locations as satellite pharmacies, clinic pharmacies, nursing stations, automated dispensing units (eg, Pyxis machines), emergency rooms, and operating rooms. It may be that the pharmacy department is *not* responsible for all pharmaceuticals in all locations throughout the facility, and that is all the more reason why the locations for which the pharmacy department *is* responsible should be clearly identified in the written procedures.

Once all of the affected recalled product has been identified and located, it must be collected and labeled as *recalled*. While immediate removal of the recalled product from the facility may be desirable, as a practical matter it is often the case that the return instructions from the manufacturer have not been finalized. It may take several days before return shipping instructions and the attendant materials such as inventory forms and shipping labels, arrive in the pharmacy. In the meantime, it is vital that all the recalled product be clearly labeled in some manner as not for use and quarantined. A procedure for this may include such means as using bright orange tape to secure the recalled bottles (boxes, etc.) and then marking the tape with words such as "*RECALLED - DO NOT USE*" or "*QUARANTINE*." This procedure is very important. It cannot be assumed that just because the recalled product has been removed from shelves, there is no danger of dispensing it to patients. Unfortunately, the FDA has many anecdotal reports of recalled merchandise that was removed from pharmacy shelves and placed in a "safe" location only to have another pharmacist pick up the recalled product and dispense it later.[3]

A pharmacy's written procedure for product return should include where the product is to be forwarded and how it should be packaged and shipped. For most pharmacies, it will probably be that the product will be returned to a location as described in the pharmaceutical manufacturer's recall letter. This may be a manufacturer's warehouse, distribution center, or an approved third-party reverse distribution handler. Or, the manufacturer may instruct that the product be returned through the wholesaler where the product was initially purchased. The importance of established written procedures comes into play when the case arises that a pharmacy will choose *not* to return product according to the manufacturers instructions. An example of this situation occurs with many community chain pharmacies who are required by their corporate headquarters to return recalled product to, perhaps, a chain warehouse where all recalled product will be consolidated and handled as one big return. Deviating from the manufacturer's recommendation can be reasonable and acceptable, however, it is important for the pharmacist to be able to reference the pharmacy's own standard operating procedures as justification.

When packaging the product for return shipping, good packaging practices should be followed, such as allowing for sufficient cushion packing so that liquids do not break in shipment. The choice of a return shipping method should be carefully considered. The manufacturer may provide pre-paid shipping labels that dictate that a certain carrier be used. If no carrier is chosen by the manufacturer, pharmacists may wish to choose a carrier that can provide proof of pickup and proof of delivery. This can be very important in situations where the product may be hazardous or where product has a high monetary value.

Special Note—There may be some instances where the product should not be sent by common carrier or the US Postal Service at all. One example occurs when product tampering is suspected. If it is possible that a prosecution could result, then the government may want to establish an *unbroken chain* of custody of the product. Another example occurs in those situations of major adverse health consequences whereby the causative agent (eg, bacterial contamination, wrong product in bottle) has not been definitively established and immediate investigation is warranted. If the product has been returned through a ground or air carrier, it may be days before it is received by the FDA or the manufacturer. Instead, the pharmacist should hold the product for pickup. The FDA will gladly send its own agents, or local law enforcement agents, to the pharmacy to pick up the product when the situation is warranted.[4]

RECORDKEEPING

The reasons that a pharmacist would want to document the actions in a recall range from the simple determination of fact (eg, which product was affected, whether patients were notified) to lessening of legal liability (ie, good records may show a pattern of a pharmacist's diligent concern for patient health). Documenting a pharmacist's actions during a recall can be greatly facilitated by forms and checklists. Examples of forms that may be appropriate are demonstrated in Figures 115-1, 115-2, and 115-3. In addition to using forms to establish documentation of a pharmacist's own actions, copies of documents created by others should also be kept (eg, the original recall letter from the manufacturer, a copy of the pre-paid shipping label,). A simple pocket file folder can be labeled with the name of the particular recall and then all documents, forms, letters, responses, etc., can be kept in one place.

Action When a Recall Happens

Once a recall event has begun, the pharmacist should proceed in a step-by-step manner. A good outline that the pharmacist may wish to customize might include:

1. Receiving the initial notification
2. Listing further action steps
3. Carrying out further notification
4. Responding to the initial notification
5. Product handling
6. Reimbursement

INITIAL NOTIFICATION

By definition, the first thing that will occur in any particular recall is that the pharmacist will learn about that recall for the first time. This may be by one of several methods. Most common is a notice from a pharmaceutical manufacturer, a wholesaler, or a community chain headquarters. This can be by letter, facsimile, or automated telephone voice message. However, other methods include reading a report in pharmacy journals, on an Internet webpage, learning about it from a pharmacist at another pharmacy, a mass media news report, or (frustratingly) hearing about it from a patient. In any case, the pharmacist should make a note of the date and time that the notice was received. If the notice was not received in writing, then the pharmacist should consolidate in writing the pertinent facts known at that time and date that piece of paper (it has now become the first document of that recall).

Recalled Product Name _____ Today's Date _____

Manufacturer _____

NDC # ___ ___ ___ ___ ___ - ___ ___ ___ ___ - ___ ___

Contacted for this Recall ?

Yes (date & initial)	No	INTERNAL PHARMACY PERSONNEL	NOTES
☐ _____	☐	Director of Pharmacy	
☐ _____	☐	Staff Pharmacists	
☐ _____	☐	Pharmacy Interns / Technicians	
☐ _____	☐	Front-end Clerks / Window Clerks / Receptionist	
☐ _____	☐	Materials Management / Inventory Clerks	
☐ _____	☐	Other _____	

Yes (date & initial)	No	EXTERNAL PHARMACY PERSONNEL
☐ _____	☐	Other Pharmacy of Same Ownership
☐ _____	☐	Other Pharmacist to whom product sold or loaned
☐ _____	☐	Other _____

Yes (date & initial)	No	HEALTHCARE PROFESSIONALS
☐ _____	☐	Local Physicians
☐ _____	☐	Nurses / Physician's Assistants
☐ _____	☐	Other _____

Yes (date & initial)	No	PATIENTS
☐ _____	☐	Patients Identified having Rx filled within _____ months
☐ _____	☐	All Patients / Customers
☐ _____	☐	Other _____

Yes (date & initial)	No	
☐ _____	☐	_____
☐ _____	☐	_____

Personnel Name _____ Title _____ Date _____

Personnel Name _____ Title _____ Date _____

Figure 115-1. Recall or Withdrawal WHO to CONTACT LIST.

	Date	Product	In Stock ?	Notify Patients?	Date Returned	RPh/Tech notes
1.	1/11/2005	amoxicillin 250mg caps 100s Acme Pharma NDC 99999-888-77 4 lots (see folder)	Yes 2 btls of lot# THX1188	No	1/13/2005	MJ Smith, RPh
2.	1/26/2005	meperidine inj 50mG/mL 20mL Wonderful Labs NDC 11111-2222-33 lot# BR549	No	N/A	N/A	MJ Smith, RPh
3.	2/6/2005	furosemide tabs 20mg 1000s November Pharmaceuticals NDC 98765-4321-00 4 lots (see folder)	Yes 1 full btl + 1/4 btl	Yes see folder for list	2/10/2005	K Ashby, Tech
4.	3/7/2005	infant glycerine suppos 24s August Products Co. NDC 12345-6789-10 6 lots (see folder)	No	N/A	N/A	MJ Smith, RPh
5.						
6.						
7.						
8.						
9.						

Figure 115-2. An example of a pharmacy recall log for calendar year 2005.

Recalled Product Name _____ Today's Date _____

Manufacturer _____

NDC # ___ ___ ___ ___ ___ - ___ ___ ___ ___ - ___ ___

Check & Initial	Location	Number of units found
_____	Main Shelves (Alphabetical)	_____
_____	Fast Mover Section	_____
_____	Refrigerator	_____
_____	Specialty Section (Otics, topicals)	_____
_____	Returns Box	_____
_____	Will Call Prescriptions	_____
_____	Satellite Stations	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Personnel Name _____ Title _____ Date _____

Personnel Name _____ Title _____ Date _____

Figure 115-3. Recall or withdrawal PRODUCT LOCATOR CHECKLIST.

ACTION STEPS

The next step the pharmacist should perform is to make a list of action steps dictated by that particular recall. If there are no written recall procedures for the pharmacist's particular facility, it is recommended that the pharmacist should first simply write down all the action steps that he/she can think of. The list may include items discussed in the paragraphs above, as well as instructions from the recall notice received from the manufacturer, wholesaler, or headquarters.

Then, the pharmacist should prioritize the actions' steps according to their urgency. For example, carrying out further notification to other pharmacists (and possibly patients) is more urgent than packaging the recalled product for return shipment.

FURTHER NOTIFICATION

Carrying out further notification, sometimes called a sub-recall, may be an important part of a particular recall. In the case where patient notification is required, the pharmacist will have to identify any patients who may have received the recalled product and then communicate the recall instructions to them. The timeliness of communicating to the patient could be a matter of life and death in the worst case, or could simply spare confusion and anxiety in the least case.

RESPONSE TO NOTIFICATION

An important aspect of the recall process is responding back to the manufacturer, wholesaler, or whomever initiated the recall notification. The pharmacist should promptly respond that the notice was received and that the pharmacist is carrying out the actions instructed in the recall communication. This response can be fulfilled by different methods. In the case of a letter sent by US mail, usually there is a postage-paid business reply card. Some manufacturers have a toll-free fax number, and the recall response can be transmitted by fax. If the notification was forwarded by automated telephone

voice messaging, then the pharmacist should listen to the entire message and press the appropriate button on the telephone keypad to respond.

Pharmacists must respond to the recall notification to indicate how many packages of the recalled product they have in stock. Also, pharmacists must respond ***even if they do not have any of the recalled product, and even if they do not carry the recalled product in stock***. This is a requirement of the Code of Federal Regulations.[5]

PRODUCT HANDLING

As described in the procedures section on product handling, the recalled product must be identified, located, quarantined, and returned.

REIMBURSEMENT

The pharmacist will want to monitor when reimbursement is received from the manufacturer. Although product reimbursement is not an urgent health-related issue, many patients may be understandably anxious about how much and when they will be reimbursed. Pharmacists should attempt to ascertain what the manufacturer's reimbursement policy will be, and, failing that, at least, reassure the patient that some form of reasonable compensation could be expected from most major manufacturers.

Long-Term Record Keeping

As stated in previous sections, the importance of long-term record keeping cannot be overemphasized. If, unfortunately, litigation ensues because of a recall, it probably will not happen in the weeks or months immediately following the recall. It will probably happen a year or more later. The pharmacist will be well served to have copies of all internal recall documents (eg, lists of contacts, when contacts were made), as well as copies of all documents created by others (eg, original recall letter from manufacturer, copy of business reply card returned to manufacturer).

BACKGROUND INFORMATION, FUTURE DIRECTION, AND IMPLICATIONS OF RECALLS

Importance of Lot Numbers

The overwhelming majority of pharmaceutical products are not manufactured in a continuous manner like automobiles rolling off an assembly line. Rather, pharmaceuticals are manufactured in batches (ie, synonymously "lots") like how one's mother might make chocolate chip cookies. Each lot manufactured is coded with a specific Lot Number so that if there is any need (eg, as in a product recall), then that particular lot can be traced back to discover such things as which raw materials were used, what equipment was used, and which personnel were on duty during the manufacture of that lot. The configuration of the lot number (eg, combination of letters and/or numbers) is at the discretion of each individual manufacturer. However, regulations require that the lot number be printed on each package. Recalls can affect one lot, multiple lots, or all lots that have ever been manufactured. The pharmacist can help the recall process by paying close attention to which lots are affected by a particular recall. Occasionally, to spare time and resources, some pharmacists have simply returned all product in stock even though only certain lots were affected in that recall. Besides being generally wasteful, this can create an unnecessary product shortage.

Classes of Recalls and Withdrawals

The difference between a recall and a withdrawal is that the word *recall* applies if the product in question could potentially violate the FD&C (Food, Drug and Cosmetic) Act. A recall is defined as "a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (eg, seizure)."[6] A withdrawal is defined as "a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, eg, normal stock rotation practices, routine equipment adjustments, and repairs, etc."[6] It is not clear what is meant by "a minor violation that would not be subject to legal action" because the term "minor violation" is not defined in the Food, Drug and Cosmetic Act.[7]

One example of a withdrawal that would not violate the Act would be in that instance when a manufacturer changed the formulation from, for example, a green tablet to a blue tablet and desired to pull all of the old green tablets to avoid confusion in the marketplace. Another example would occur after the introduction of an approved new drug. A manufacturer may experience an unacceptable number of adverse drug reactions and decide to withdraw the product from the market.

Another recent (and unfortunate) example is the situation involving product tampering (including product counterfeiting). For reasons that may seem counterintuitive, situations involving product tampering or counterfeiting are usually classified as *withdrawals*, not recalls. This involves legal definitions regarding whether the manufacturer may be responsible for violations of the FD&C Act. If no manufacturing responsibility exists, then the definition of recall does not apply and the action is termed a withdrawal (Note: the legal intricacies associated with this example are beyond the scope of this chapter).

For legal liability reasons, a manufacturer may prefer to characterize a particular event as a *withdrawal* rather than a *recall*. This has occurred a few times in recent years when manufacturers have quickly taken the initiative to send out notifications (without conferring with the FDA) and describe the event as a withdrawal, when it really should have been termed a recall. This prompted the FDA to issue statements warning manufacturers to confer with the FDA on whether an event should be a recall or a withdrawal, or risk having to send out a corrective notice.[8,9] In any case, the following statement may be one of the most important of this chapter:

> **Whether a removal event is termed a *recall* or a *withdrawal*, the pharmacist should follow basically the same procedures.**

Officially, recalls are listed by the FDA in the FDA Enforcement Report. It is published weekly and can be viewed free on the Internet at http://www.fda.gov or a written version can be subscribed to at a cost of approximately $100 per year. The Enforcement Report is the official listing of FDA actions. However, it only includes *violative* actions, that is, it only lists recalls (seizures, etc.), not withdrawals. Also, any particular recall may not appear in the Enforcement Report for many weeks or even months after a recall was issued. The FDA is moving toward an Internet-based posting system for recall notices. It is anticipated that with this new system, recall notices might be posted within 1 to 2 days from the time a manufacturer first notifies the FDA of a problem.[13]

Strictly speaking, all recalls of drug products are *voluntary*. Through what might be described as a "loophole" in the law, the FDA has no authority under the Federal Food, Drug, and Cosmetic Act to order a recall without the aid of a court.[10] The FDA (more specifically, the Secretary of Health and Human Services) does have the authority to order a recall of medical devices, infant milk formulas, and some biologicals, but pharmaceutical product recalls are voluntary.

If a pharmaceutical manufacturer refuses to recall a product, then the only immediate enforcement tool the FDA has is to initiate a *seizure*. Seizures are slow, costly, and generally inefficient. However, there are some pharmaceutical seizures every year. Outside of the legal realm, the FDA has one very potent tool for inducing the manufacturer to conduct the recall, and that is the power of the press release. If the manufacturer is "dragging its heels" about doing a recall, essentially, the FDA will inform the manufacturer that the FDA has no choice but to issue a general press release naming the company, the product, and describing the potential for health hazard, etc. As a practical matter, the threat (whether explicit or implicit) of a press release usually prompts the manufacturer to initiate a *voluntary* recall.

Recall communications from manufacturers to pharmacists very often state that the recall is *voluntary* for the manufacturer, but pharmacists should NOT make the mistake of concluding that the recall is in any way voluntary for the pharmacist. Pharmacists should carry out all recall procedures with all due diligence.

The overwhelming number of things that can go wrong during the manufacture of a product, regardless how unintentional or minor, will usually result in the product being "misbranded" or "adulterated" under the Food Drug and Cosmetic Act, and thus subject to a "recall." Recalls are classified as follows:

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II is a situation in which the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.[11]

Of the approximately 200 drug recalls per year, about 45% are Class III; about 50% are Class II, and less than 5% are Class I.[12]

Usually, a health hazard evaluation committee within the FDA determines the Class of a recall. The committee is composed of physicians and other appropriate scientific personnel who may consult with private practice physicians, the Centers for Disease Control and Prevention, and the manufacturer's medical department. The Committee then makes a recommendation for that particular recall. Although the FDA will try to expedite this process, it can still take several days. This is the reason why some recall notifications have been sent to pharmacists directly without a Class of recall listed.

In an effort to streamline the process, the FDA has taken an initiative to have recall officers in local FDA offices make classification decisions. Whether this initiative will result in all future recall communications containing a classification remains to be seen. In any case, the lack of an official recall classification should in no way inhibit the pharmacist from implementing the recall process. The pharmacist's individual recall policies and procedures should be carried out forthwith. The possibility of a lack of official classification does, however, imply that *pharmacists should NOT write recall procedures that are dependent on knowing the Class of recall.* For example, having a procedure that instructs to notify patients in the case of a Class I recall but not in the case of a Class II recall, would be an inappropriate recall procedure because the class of recall may not be known for days or weeks after an initial recall announcement is made. Whether or not to notify patients about a recall should be based on the degree of health hazard, not on the official classification. The initial recall announcement from the manufacturer almost always has instructions for "if-and-when" to notify patients. However, if those instructions are absent or unclear, then the pharmacist should take whatever appropriate action that good judgment dictates (ie, as he/she performs many times a day).

Level of Recall and Distribution Channels

When a recall is announced by a manufacturer, there should be a statement about at what *level* the recall is being carried out. In its simplest form, the levels of pharmaceutical distribution system in the US can be charted thus:

Pharmaceutical Manufacturer > Drug Wholesaler > Pharmacy > Patient.

Additional distributors of pharmaceutical products, such as repackagers and nursing homes, complicate the distribution channel and do not always fit neatly into the definition of what is a wholesaler or pharmacy, but the above is a reasonable model. The initial recall notice issued by the manufacturer should state the level of the recall, but unfortunately, this is not always the case.

Some pharmacists make the erroneous assumption that the Class of recall correlates perfectly with the level of distribution (ie, that Class I = patient level, Class II = pharmacy level, and Class III = wholesaler level). This is NOT true. Many Class III recalls are carried out to the pharmacy level, some Class II recalls have been carried out to the patient level, and a few Class I recalls did not involve notifying patients because the product was caught before it was fully distributed.

Sometimes, wholesalers contribute to the confusion about recall level by sending pharmacies copies of recall letters that were sent to the wholesaler and were meant by the manufacturer to be a "wholesaler-only" recall. It might be said that the wholesaler is simply erring "on the side of caution" by sending the recall notice to the pharmacy. But if that is taken to its logical conclusion by all wholesalers then there would be a *de facto* elimination of the wholesaler-only recall and there would be two levels of recall: wholesaler/pharmacy and patient. There is some sentiment within the FDA that this should actually be the case (ie, if a product is worth recalling from the wholesaler, then it is worth recalling from the pharmacy). At this time there is no final word on the situation and pharmacists will just have to use their best judgment. Pharmacists must determine the *level* of the recall independently of the *class* of the recall and then take appropriate action.

Reasons for Recalls

The approximately 200 pharmaceutical recalls issued every year happen for a variety of reasons. Table 115-1 shows some major reasons and a rough approximation of what percentage of all pharmaceutical recalls these represent.[12]

Table 115-1. Reasons for, Descriptions of, and Approximate Incidence of Pharmaceutical Recalls

REASON	DESCRIPTION	% ALL DRUG RECALLS[a]
Potency	Failure to maintain potency at certain time points during the "in date" period.	20 %
Labeling/ packaging mixups	Incorrect strength on label; wrong product in bottle; etc.	25 %
Misc. product problems	Discoloration; leaking bottles; particulate matter; etc.	5 %
Dissolution	Failure to dissolve at certain time points during the "in-date" period.	5 %
Manufacturing discrepancies	Deviations from official manufacturing procedures	5 %
Contamination	Contamination with bacteria or general lack of sterility	45 %

[a] Approximate percentages based on data from 2002.

Future Directions and Implications

Some potential legal developments may affect pharmacists directly in coming years. Legislation (ie, state, federal) changes constantly, and pharmacists must keep abreast of new regulations. One possible legislative initiative may require pharmacists to notify patients in the case of certain recalls. While this chapter has stated that proper patient notification should be good normal practice for the pharmacist, currently there is no specific law or regulation that states that pharmacists must notify patients of a drug recall. Pending federal legislation may codify that item. This situation may be analogous to the patient counseling situation. Conscientious pharmacists tried to do patient counseling in a conscientious manner as part of overall professional responsibility, but legislation then required counseling, and rules and regulations spelled out specifics of how it should be performed (eg, some pharmacists would claim there are too many specifics while others would claim there are not enough specifics). If new legislation passes requiring that pharmacists notify patients of a recall, it is unclear whether that legislation will really make any difference in the conscientious pharmacist's day-to-day practice.

One outgrowth of recalls that may affect pharmacists' future practice is the topic of tracking dispensed drugs by lot number. For each manufactured lot of a pharmaceutical product, the manufacturer is required to track exactly where each bottle of that lot has been shipped. The overwhelming majority of wholesalers and pharmacies do not track by lot number where product has gone. Tracking by lot number is an enormous data management burden for manufacturers. However, it does have the benefit that when a product needs to be recalled and the product defect can be traced to specific lots only, then the manufacturer has to recall only those lots and not all of the product in the marketplace. With modern computerized shipping and billing records, wholesalers can determine if a particular product has been sold to a particular pharmacy. Because a wholesaler does not track by lot number, for each recall it must notify every pharmacy that purchased the product even though the pharmacy may have only purchased unaffected product. But, at least the pharmacy can check inventory, return only the affected product, and keep any unaffected product in stock to serve patients.

In the case where the pharmacist has dispensed the product, unless it was dispensed in the original container, currently, there is no way to determine whether the patient is holding product from a recalled lot or from an unaffected lot. Thus, patient level recalls involve removing *all* product from *all* patients. Theoretically, if pharmacists tracked dispensed product by lot number, then they could notify and recall product only from those patients with affected product, and patients with unaffected product would not necessarily even have to know that a recall took place. There are other problems with whether or not this scenario would work. Some overall *pros* and *cons* are apparent. A significant *con* is the detailed record keeping that would be required. Improved computer software might make it possible. The *pros* are that with detailed lot number records, a pharmacist might receive a recall notice and quickly be able to determine that he/she never stocked the product nor dispensed the recalled lot. Their recall obligations would be quickly concluded.

SUMMARY

Important steps for a pharmacist to take to handle recalls effectively are as follows:

1. Establish **procedures.** This should be performed before a recall occurs. If one is not sure how to start, one should just think of whatever one can, and write it down. Keep it simple and brief. As experience is gained and better methods are found, these can be incorporated into the procedure. Whatever can be performed before an actual recall hits, the "smoother" the recall will go.
2. **Document** what is performed. This may save a life. Legally, it may demonstrate and prove that the pharmacist acted with due diligence.
3. Use good **judgment**. Laws are not always clear; Definitions are not always exact. Instructions can be confusing. In the end, do what is best for the patient.

Thankfully, most recalls do not involve life-threatening situations. Occasionally, they will. The pharmacist is on the front line and plays a most important, crucial role in protecting the patient from potentially unsafe products.

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CHAPTER 116

Marketing Pharmaceutical Care Services

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> "Marketing is the business function that identifies customer needs and wants, determines which target markets the organization can serve best, and designs appropriate products, services, and programs to serve these markets. However, marketing is much more than just an isolated business function—it is a philosophy that guides the entire organization."[1]

Marketing is a proven approach for stimulating consumers to purchase new services. As pharmacists work to expand their role by providing new services, marketing can be used to create demand for these services. In recent years, practitioners have worked hard to re-engineer their practices to incorporate a philosophy of pharmaceutical care into their practices. This re-engineering has resulted in pharmacies presenting a *new look* to their patients by incorporating patient consultation areas, workflow improvements, and the increased use of pharmacy technicians within the practice. In addition, pharmacists are performing new activities in their practices as new services are offered to their patients. To reach their full potential, pharmacists can market their services.

An understanding of patient needs and wants is essential for developing and implementing a successful plan for marketing pharmacy services. The need for most of our patients is to have good health. If their health deteriorates, a need exists to return to a healthy state. Patients have many options for products, services, and providers to help them achieve this healthy state, including pharmacists and pharmacy-care services. Patients choose the resources that they believe best fit their needs. To be successful, a pharmacy can incorporate a marketing management process as a basic component of their operation.

MARKETING MANAGEMENT PROCESS

A marketing management process should include three primary steps: (1) evaluating a market, (2) planning marketing strategies and tactics, and (3) implementing and controlling marketing effort. A market can be viewed as containing buyers and sellers that react to each other and to other influences acting in the market. In this case, the actors in a market for pharmacy services usually include service providers, patients, payers, and employers. They interact in a local setting under the influence of a mix of external factors such as the socioeconomic conditions and the level of medical technology present in the community.

Evaluating a market entails consideration of both a macroenvironment and a microenvironment. A macroenvironment refers to forces that affect the parties in a market, and encompasses five sectors: economic, competitive, technological, social, and regulatory. Economic considerations can affect the likelihood that patients will be able to pay for a pharmacy service. For example, the closing of a large local employer can greatly limit the demand for services, perhaps by eliminating health insurance coverage.

Competitive factors such as consolidation of ownership can be important. For instance, the presence of a large chain usually affects pricing levels and could affect supply of pharmacists. Technology can support new services. For example, some pharmacists are incorporating personal digital assistants (PDAs) into their service provision. Social factors should be considered, such as the percentage of elderly without family support in the community. Regulatory issues can include state or federal regulations. For example, many states allow collaborative practice agreements between pharmacists and physicians.

In addition to identifying important influences in the macroenvironment, the microenvironment should be evaluated. This means that important stakeholders should be identified and appraised. Such an assessment can result in identification of parties that will facilitate, hinder, or not affect the pharmacy's marketing efforts. Types of parties to evaluate include patient groups, competitors, suppliers, and payers. One way to assess a pharmacy's microenvironment is to perform a SWOT analysis (Table 116-1) that can be used to assess the internal strengths and weaknesses of the pharmacy in context with the opportunities and threats that may exist in its external environment.[2,3]

Strengths can include the clinical expertise of pharmacists in certain disease-state management programs, the positive image of the pharmacy in the community, and the diversity of services offered by the practice. Weaknesses can include workflow issues, shortage of technician help, and lack of time to provide pharmaceutical care services. The opportunities of a practice may be with physician groups, collaborative practice strategies with certain physicians, and the needs of the community for innovative health-care services. When one identifies the threats to the practice, competitive programs should be distinguished, turf issues with other health-care providers need to be recognized, and lack of reimbursement for clinical services should be considered.

Through this analysis, pharmacists can determine what services or programs they offer or can offer in the future to gain a competitive or differential advantage in the marketplace. In addition, pharmacists within the practice need to identify their weaknesses and develop strategies that either minimize these factors or convert them into strengths.

After completing the SWOT Analysis, pharmacists can match the strengths of their pharmacy with the opportunities in the marketplace and minimize the threats (or competition) to a profitable practice. Examples of threats to the pharmacy can include a competitor with superior services, the lack of reimbursement for cognitive services, and increased costs to implementing and sustaining a clinical service.

Table 116-1. SWOT Analysis

S = Strengths of the practice (Internal environment)	W = Weaknesses of the practice (Internal environment)
O = Opportunities for the practice (External environment)	T = Threats to the practice (External environment)

A stakeholder analysis can be part of the SWOT analysis. A *stakeholder* is anyone who can affect the success of the practice. They include other health-care providers, community resources such as hospitals and clinics, community leaders, public agencies, employers, and third-party payers. Other potential stakeholders to the practice may include other pharmacists not employed by the pharmacy but who have created some type of alliance with the pharmacy. Stakeholders influence the practice by providing a support structure for new ideas, identifying key targets for marketing efforts, and providing a process that helps to improve the quality of the services provided by the pharmacy.

To better understand the external environment of their pharmacy, pharmacists may use marketing research techniques. This provides them with additional information about their marketplace and assists them in the development of strategies to increase sales, improve the practice, assess the competition, and determine the needs of patients. Market research can encompass several techniques that may include questionnaires, telephone surveys, focus groups, casual conversation, observation, and published data. This information should be collected and updated annually and the necessary adjustments made to the marketing plan.

The information gathered from this market research can be continually incorporated into the practice's SWOT analysis. The research provides new information regarding external opportunities and threats to the practice. Using this information, along with an internal inventory of the strengths and weaknesses of their pharmacy, provides an excellent starting point to develop a comprehensive marketing plan.

PLANNING OF MARKETING

The second phase of the marketing management process is to plan marketing strategies and tactics. A marketing plan should contain key elements that are essential for successful implementation. The marketing plan should be consistent with the mission of the practice and should incorporate analyses performed during the evaluation phase, especially the SWOT analysis. From the analyses, target markets may be identified, the marketing mix determined, and the marketing strategies developed. Included in the marketing plan should be a process to monitor the results of the plan. The key elements of a marketing plan include[4]

SWOT analysis (see Table 92-1)
Goals and objectives
Target markets
Marketing mix
Control processes

Goals and Objectives

After the SWOT analysis is written, a set of goal statements can be prepared. These statements lead to objectives that a pharmacy wants to accomplish. They should reflect the mission statement for the practice, which is the underlying philosophy of the pharmacy. Goal statements are general and provide direction for the practice to meet the mission of the pharmacy. Each goal statement has its own specific *objectives* that are the outcomes needed to meet the goals. The objectives that are developed for the practice should be clearly stated, realistic, and measurable. It is through the objectives that pharmacists can determine the success or failure of their marketing plan. Some common objectives that have been used by pharmacists include improved profitability, sales growth of a particular service or product, market share improvement, risk diversification, and practice innovation. A well-written marketing plan with clear, quantifiable goals and objectives can provide the pharmacist with the feedback mechanism to change and refine specific components of the plan. To achieve the goals and objectives, one must accomplish *specific tasks* in accordance with a *timeline* that provides a reasonable period for completion of each task. Table 116-2 provides examples of a mission statement, a goal statement, and objectives.

Once the goals and objectives are developed, time should be spent thinking about the persons (target markets) who can benefit from the services offered by the practice. The goal of a pharmacy's marketing activities is to stimulate exchanges with patients who are likely to benefit from services provided. A marketing approach focuses the marketing efforts on those groups in the market, known as target markets.

Target Markets

Target markets are those customers who behave in similar patterns and can benefit from the pharmacy care services offered by the practice.[5] It is important to identify key targets for the marketing efforts because it is neither efficient nor cost effective to market to the general public. Customers who are the targets of the marketing process should have needs and wants that the pharmacy services can meet. When initiating the market plan, it is beneficial to consider how customers behave. Research in this area shows that subgroups of consumers can be identified based on their adoption (ie, use of) new services.[6,7]

ADOPTION GROUPS—Five groups can be considered, based on their likelihood of trying new services. A list of these is as follows:

1. Innovators—less than 5% of customers.
2. Early adopters—10–15% of customers.
3. Early majority—30–35% of customers.
4. Late majority—30–35% of customers.
5. Late adopters—15–20% of customers.

Table 116-2. Mission, Goals Statements, and Objectives

Mission Statement of the practice	To enhance health status and provide innovative and high-quality pharmacy services by being sincere, compassionate, and focused on the individual needs of each patient.
Goal Statement	To market and promote the pharmacy services effectively to physicians and other health-care providers to increase the referrals to the practice.
Objectives	Within 3 months, identify key decision makers in each medical group. In the next 3 months, identify the key 100 primary-care physicians and develop a newsletter that provides information about the programs and pharmacy-care services offered by the practice. Identify 100% of the physicians (specialists and primary care) who care for a large percentage of diabetes and asthma patients. In the next 3 months, identify competing programs/services within the community. Within 1 month, develop promotional tools to use when marketing to physicians and other health-care providers.

Innovators represent the smallest percentage of customers, but they are the first to try a new service, if they believe it meets their needs. They are considered risk takers and venturesome. Early adopters, who often are opinion leaders in the community, need to hear the marketing message several times because they carefully evaluate new ideas and services. This group accepts a new service early in the marketing efforts.

The early majority, though not leaders, do adopt a new service earlier than the average consumer. Repeat marketing efforts need to stay focused on this group because they need to hear the marketing message several times before purchasing a new service. In addition, this group represents a large proportion of a market.

The late majority are consumers who question new products and services. However, they adopt a new service once the majority of consumers buy. This group is not likely to respond to early marketing efforts.

The last group is the late adopters who not only question a new innovation, but remain suspicious. This group buys only after the service has a well-proven record. Again, this group is not likely to be responsive to early marketing activities.

By understanding the characteristics of each of these groups, marketing plans can be created to focus on the appropriate group. For new pharmacy services, innovators and early adopters would be of most interest. Typically, consumers in these two groups are younger, have more education, and have higher income than other consumers.[6,7] Because they trust their own judgment, they are more willing to try new services and to respond to promotional strategies that attract them to such services.

Relationship Marketing

Relationship marketing is a strategy that pharmacists can use to improve their marketing efforts. The focus of this strategy is developing long-term and lasting relationships with like-minded customers who share a common desire or concern. In other words, pharmacists should focus their marketing efforts on those customers who are most likely to benefit from their services. Pharmacists who embrace the philosophy of relationship marketing realize that each patient encounter builds on the previous one. In this approach, pharmacists are more likely to identify the explicit health needs of their patients and provide a service that helps them achieve their therapeutic goals.

Marketing Mix

The term for the variables that are under the pharmacists' control is marketing mix. The variables are selected strategically to increase the likelihood of successful marketing. The elements of the marketing mix, also called the 4 P's of marketing include:[4,8–10]

1. Product
2. Price
3. Promotion.
4. Place

A fifth P, positioning, often is included as well.

The **product** refers to what is being marketed. With pharmaceutical care services, it is not a physical product that needs promoting but rather intangible services. Services have certain characteristics that differentiate them from products. These differences are referred to as the 4 I's in service marketing.[4,11]

1. Intangible
2. Inconsistent
3. Inseparable
4. Non-Inventoried

Because patients cannot physically see or touch a service (*intangible*), they must experience the services to receive the benefits. This experience and the quality of the interaction with the pharmacist provide the basis for patient satisfaction with the services. It may be useful to try to raise the tangibility of a service by adding a tangible component such as a paper report or some other materials.

Pharmacy services typically are delivered by individual pharmacists. This results in variability in delivery among different practitioners (*inconsistency*). The clinical competencies, knowledge base, communication skills, and personalities of the pharmacists are all key factors for provider performance in service delivery. Proper training of pharmacy personnel and use of a consistent service process can constrain problems with inconsistent service delivery.

Because pharmacy care services cannot be separated from the pharmacists who perform them (*inseparability*), quality programs need to be delivered by quality providers. Kotler[12] discussed the need for service providers to focus on the technical quality of the service (was the service successful?) and its functional quality (did the pharmacist demonstrate concern, empathy, and competence in providing the care?). In other words, providers that deliver *high-touch* as well as *high-tech* services are more likely to have satisfied customers. In addition, the development of protocols, policies and procedures, and standard educational materials helps to enhance pharmacists' performance with service delivery. Last, continuous quality-improvement activities should be implemented to keep the quality of the service at a high level.

The fourth characteristic of services is the concept of *inventory*. Unlike goods, services do not have a physical presence in the practice, and thus cannot be stored. Rather, to provide pharmacy-care services, a practitioner needs to be prepared to deliver services when purchased by the patient. There is a cost of inventory associated with the pharmacist who is working but who may not always be delivering pharmacy-care services. The challenge in this situation is to provide sufficient pharmacist coverage to provide services when needed but, at the same time, to minimize pharmacist overlap and costs. By understanding the patient flow in the pharmacy throughout the day, strategies can be developed to improve the efficiencies of the practice. The use of appointments for pharmacy services has become more common in pharmacies that have attained sufficient service volume.

Often, marketing a program or service involves making a major change in the perceptions of a patient of a pharmacy and the pharmacists who are employed there. For example, if patients view pharmacists as doing little more than dispensing, it is unlikely that they will want to participate in pharmacy-care activities. Increasing the expectations of patients can be accomplished by making changes, ranging from simply improving the workflow to becoming certified in a particular area of expertise. If a pharmacist wants to create the image of being knowledgeable about diabetes education, for example, he or she may want to become a Certified Diabetes Educator (CDE) or to enroll in a certificate program that focuses on that disease. Patients who perceive a service as new and different are more likely to see the benefit of those services. Another strategy to increase patient awareness of a service is to stock a variety of products related to the service (ie, a diabetes supply display). Helping patients select appropriate products can offer a unique opportunity to market the service of the pharmacy on a personal level. Pharmacists can also indirectly change patients' perceptions by partnering with physicians and other healthcare providers who may serve as a referral source for the practice. This helps to give the practice credibility and an improved public image.

FEATURES VERSUS BENEFITS OF A PHARMACY SERVICE

Changing perceptions and expectations of the practice are important, but not the sole activity that guarantees success for marketing a service. It is equally important to examine the

Table 116-3. Features and Benefits

FEATURES	BENEFITS
One-on-one patient education	Providing you with the information necessary to help you make better decisions about your own health care. Helping you take charge of your own health.
Medication review and assessment	Making sure your medications are working appropriately to improve your health. Reducing problems associated with medications, such as side effects and interactions with other medications.
Communication with other health-care providers	Keeping your physician informed about the education provided so he/she can better care for your health-care needs. Providing feedback about your medications to make sure you are receiving the benefits needed to keep you healthy.

needs of the persons identified as targets of the marketing efforts. Once these needs are recognized, the marketing message can focus on the features and benefits (Table 116-3) of the services that are specific for that group (target market or stakeholder).

The *features* of the service are the elements that describe what the service offers the patient. In contrast, the *benefits* of the service to the individual patient or the stakeholder help describe why that person should be interested in the service. Understanding these key principles in service marketing helps to develop effective marketing strategies and promotional materials. More important, it provides the pharmacist with a focus to discuss services to patients during one-on-one consultations.

Using features and benefits to market services may be helpful for patients, health-care providers, and third-party payers. However, the features and benefits for these other groups and payers may be different depending on their needs. For example, a medication review service feature may be used for discussing a disease management service with physicians as well as third-party payers, but the benefits are different. The benefit to physicians may be to relieve the time constraints they experience in their own practices. For example, it would be useful to discuss how the services can reduce the number of unnecessary calls from patients regarding their medications. Also, by providing this service, patient compliance and other issues related to the medications can be assessed by the pharmacist, with progress reports forwarded to the physician on a regular basis. This can complement the physician's educational efforts with the patient regarding proper medication use. In contrast, the benefit to the payer would focus on cost issues and how this service could potentially save them money by reducing the additional use of health-care resources (eg, hospitalizations and increased physician visits) due to inappropriate medication use.

Price considerations are difficult for most pharmacists because they have limited experience pricing pharmacy services. Nonetheless, setting an appropriate price that remains competitive yet profitable is important. Being aware of the pricing strategies of competing programs such as a diabetes center can provide information that helps to guide fees. If a competitive program does not exist or if an innovative program is developed, setting a fee structure then becomes more difficult. It is important to think about the resources and time (ie, costs) consumed by offering the service and set prices accordingly. By concentrating on the value of the service and creating the perception of expertise to the customer, fees can be set higher and adjusted only after the market has had time to respond. It is important to assess the prices for services continually to make sure the practice remains profitable and competitive.

Promotion, the third marketing principle is more than just advertising. Promotional strategies include publicity, public relations, direct mail, sales promotions, advertising, and personal selling (Table 116-4). To be cost effective, the strategies used should focus on customers who can benefit from the services offered. Using the features and benefits to describe the services to these customers helps in developing effective promotional material. The effectiveness of each strategy should be determined by measuring the outcomes associated with the promotional effort. This evaluation helps to determine which methods are worthwhile or ineffective and also provides the information needed to make adjustments in the overall plan.

The development of effective promotional materials requires much time and thought. When using *direct mail* as a strategy, developing a mailing list should be the first step in the process. Mailing lists can be created from the pharmacy computer record, a membership list from service groups and support groups, as well as from lists developed from special promotions when information is collected. There are certain guidelines that can be followed to create direct-mail pieces.[5] Keeping focused on the features and benefits for that particular target market helps organize the message.

Publicity is another form of promotion that should be considered in the marketing plan. Some of the strategies that are effective and inexpensive include newsletter articles, opinion editorials, and news and press releases. The same principles are important for these promotional materials: emphasize features and benefits, keep focused on the reader, and avoid complex medical terminology that may confuse the reader.

Providing presentations to support groups can be part of the promotional mix. The presentations should be well planned in advance. The pharmacist should know what points he/she wants to discuss with the group and how one will promote the services of the pharmacy. Avoid lecturing, and keep the presentation as much of a discussion as possible. By listening to the participants, information can be gathered about their needs and wants. The pharmacist should make sure to bring brochures, business cards, and other promotional materials that can be handed out to the group during the presentation. Attendees should be invited to visit the practice or call if they have any questions about the services or programs that the pharmacy offers.

Participating in special events or community-wide events can augment the overall marketing strategy. A goal when participating in events such as health fairs is to increase the good will of the pharmacy, to generate interest in the clinical programs developed, and to demonstrate the competence and skills of the pharmacists to potential patients. Creating special events such as health promotions and screenings, *brown bag* days, and open houses allow potential patients and local healthcare providers to learn about and experience the new services offered at the practice.

Other promotional strategies such as sales promotions and personal selling should be considered in the marketing plan. Sales promotions include any materials or efforts developed to assist the pharmacist in selling his/her clinical services, such as

Table 116-4. Promotional Strategies

PROMOTIONAL STRATEGY	TARGETS/STAKEHOLDERS	FREQUENCY
List the promotional strategies that will be used by the practice.	Identify the Target Markets and Stakeholders the promotional strategies are targeting.	How frequent will this promotional strategy be used, ie, quarterly, monthly, weekly, etc.

coupons or discounted service trials. Another promotional technique is personal selling, which occurs when someone describes the pharmacy service to a patient or stakeholder. During such a selling process, a pharmacist can use a series of questions to identify explicit needs of the patient. The explicit needs relate to the benefits that a patient might be able to achieve, in part, through receiving a pharmacy service. For example, a patient with asthma might be able to spend more time jogging or hiking after participating in an asthma management service at the pharmacy. Personal selling can help a patient recognize such an opportunity.

A skill that may help pharmacists in their personal selling efforts is learning to identify the needs of their patients. By identifying the needs, pharmacists can apply the personal selling process during their consultations with patients. This personal selling process is need(s) identification, a brief description of the clinical service or program that can satisfy the need(s), an explanation of its benefits and the cost to the patient. Because many pharmacists do not think of themselves as salespeople, training programs in personal selling techniques may provide additional skills to help them excel in this effort. One strategy that can be used by pharmacists to improve their abilities to uncover their patients' explicit needs is the SPIN model.[13] In this model pharmacists use four different types of probes to identify their patients' needs and wants: situating, problem, implication, and need-payoff questions.

Situation questions are used during the initial encounter with the patient. These types of probes are used to gather background information about the patient. The next types of probes in the SPIN model are the problem questions. These questions probe the patient for any dissatisfactions or concerns that they have with their health or medications. Problem questions help to uncover the patients' implicit needs, but at this point, the patient may not fully realize the impact their concerns have on their health or quality of life. Implication questions are used to help the patient become more aware of the true impact their health or medications concerns have on their daily lives. In answering these questions, patients may realize that their problem or dissatisfaction has significant implications and may require some action (eg, a pharmacy service) to resolve. Lastly, need-payoff questions help patients articulate their explicit needs about their health concerns or dissatisfactions. By answering these questions, patients begin to focus on possible solutions to their problems. Pharmacists can now discuss how a particular service they have can address the patients' problems. Table 116-5 provides examples of the four types of probes used for the SPIN model.

Table 116-5. Probing Questions Using the SPIN Model

SITUATION QUESTIONS:
What are your current complaints related to your health?
What medications are you taking?
What current medical conditions to you have?
How are you feeling?
PROBLEM QUESTIONS:
Have you experienced any drowsiness or other side effects with this medication that you are taking?
How have your blood pressures been since starting on your new blood pressure medication?
IMPLICATION QUESTIONS:
Has the drowsiness that you experienced with your new medication affect your daily activities?
What are your concerns about controlling your blood pressures?
NEED-PAYOFF QUESTIONS:
Would it be beneficial for you if a medication review service can identify alternative medications that may have less side effects such as drowsiness?
Did you know that keeping your blood pressures within goal range will substantially reduce your risk of developing long term complications?

Advertising, another promotional technique, includes the paid efforts of the practice to deliver the marketing message to a broader audience. Radio, television, and newspapers are effective media to market programs and services. The media selected depends on the message that the pharmacist wants to promote, the audience he/she wants to reach, and his/her budget. It is important to find out about the readership or viewership of the media and the costs of advertising because this information helps in deciding which promotional strategies fit within one's marketing plan and budget. It is possible that a local cable TV sponsorship can be cost-effective in reaching a particular target market.

The best promotion is providing quality care to the patient. Patients can be the greatest advocates of a pharmacy by sharing their experiences with their friends and other healthcare providers. If they discuss the services with their physicians and their satisfaction with those services, this could enhance the physician's image of the practice. Such an enhanced image could translate to an increased likelihood that the physician will refer patients to the pharmacy. It is important to assess the quality of the practice continually by receiving feedback from patients. This can be in the form of patient satisfaction surveys; the information collected from these surveys may be incorporated into new promotional materials. Table 116-4 can be used to generate a list of promotional strategies employed by a pharmacy.

Place refers to where and how the services are delivered. When providing services, it is important to make it available at the right place and at the right time. Convenience to the patient or customer needs to be assessed to assure success of the service. Within the pharmacy, an area that is considered private and professional helps in improving the perception of the patient. If possible, it may be necessary to deliver the service outside the pharmacy such as at a physician clinic or at the work site of the employer who contracts out for the services. The use of the telephone as an element of service delivery should be considered, especially with follow-up monitoring that may be associated with a service. If the practice has a delivery service, this service may be used to provide patient care and should be included in the marketing plan.

Positioning is the final element of marketing that needs to be considered. Positioning refers to creating a favorable image of the pharmacy in the minds of potential targets and stakeholders so they want and demand your services.[4] In a competitive environment, positioning helps to create a niche for the practice that addresses unmet needs of a group of patients. For example, some patients who have been newly diagnosed with diabetes prefer a one-on-one educational session with a health care provider instead of group sessions commonly seen in diabetes centers. A pharmacist can position his/her practice as one that provides individualized sessions to attract those patients to his/her practice. The messages contained in promotional materials are vital to establishing a favorable position in a market. Once a marketing plan is prepared, attention can be turned to implementing it and controlling the marketing activities.

IMPLEMENTING AND CONTROLLING MARKETING ACTIVITIES

Two components of implementing and controlling of marketing activities can be considered: rollout of the service and monitoring of activities. Pharmacy service rollout should be guided with an action plan that identifies the activities that need to be performed, when each activity will occur, and who will be responsible for getting it done. A starting place is to generate a task list for the service rollout. Tasks can address a variety of areas that are likely to require some change to accommodate a new pharmacy service. Such areas include: workflow and staffing, staff training, materials and systems for service

Table 116-6. Tasks and Timeline

TASK	PERSON RESPONSBILE	OBJECTIVES MET	DEADLINE TO COMPLETE TASK
List the tasks that need to be completed.	Identify who the person is responsible for specific tasks; this can be a pharmacist, technician, or clerk.	From the goal and objective statements listed, identify which one corresponds to each task.	Have a deadline for each task to be completed. Once completed have the person responsible for the task initial and date this form.

provision and documentation, pharmacy layout, and marketing materials (Table 116-6).

The workflow of a pharmacy service can be mapped out using a service blueprint.[14] A service blueprint is a map of service processes that depicts the steps that will occur during the service and details the roles of patients, service providers, and supporting services. By mapping the entire service process, a comprehensive view of the workflow can be assessed. Perhaps a new layout needs to be developed or new equipment needs to be purchased and then incorporated into the practice.

Another common need for service rollout is staff training. Some training may be needed to sharpen the clinical knowledge of the pharmacists. In addition, the actual service process should be learned by the pharmacists and other staff. Even if technicians do not provide a service, they will need to know its process to be able to coordinate activities with pharmacists who are providing services. Staff should be trained to fully utilize any documentation system that is used for new services.

Initially, not all marketing strategies, nor all promotional materials, provide the results anticipated. It is important to test, monitor, and refine strategies and tools continually and to minimize costly approaches to the marketing plan that are marginally effective. During evaluation of the effectiveness of new materials, it is also important to allow adequate time for testing. The marketing plan, timeline, and budget help to provide the boundaries or limits to the marketing process. Predefined outcome measures of the marketing plan provide the goals or the results of the marketing process. By referring to the written marketing plan, one can make an accurate assessment of marketing materials.

As the action plan is executed, the first day of service will draw nearer. A specific day should be set, on which the pharmacy is able to provide the new service. Some promotional efforts can create awareness for the service. The staff and facility should be ready to go, once the service goes live. A good approach is to spend special attention on the first few service patients to get an initial assessment of the service process. This will allow early identification of problems, which can be addressed before large problems develop.

To monitor the marketing activities, an information system should be utilized. Commonly, such a system needs to be developed as new pharmacy services are offered. The system should allow the evaluation of performance at achieving marketing objectives. Performance indicators should be identified, and processes for collecting and reporting this information can be established. Then, regular reports can be used to assess service quality and other marketing performance objectives.

A number of performance indicators can be monitored. These indicators should be established before implementation and processes are in place to collect the data. The outcomes may include:

Number of services or programs sold
Increase in pharmacy service revenue
Increase in referrals
Number of contracts with employers
Improved patient satisfaction surveys
Quality of the services

By assessing these outcome data from the marketing efforts, one can make decisions about future marketing efforts and the cost-effectiveness of certain strategies. For example, low patient satisfaction with a service can be used to guide improvements in the service delivery. Any performance shortfalls should lead to identification for the cause of the shortfall. All of the marketing mix should be considered. Once a potential cause is found, adjustments can be made in the marketing effort to address it.

Budgeting for the marketing plan will need to be addressed at this time as well. Several strategies can be used to determine the appropriate amount that should be spent for marketing and advertising.[15,16]

One common approach is to determine a fixed percentage of sales to set aside for advertising (*percentage of sales*). Although this method is easily applied, it has some inherent problems. Its major shortcoming is the implication that sales cause advertising. Instead, marketing and advertising should be seen as increasing sales.

A second method is to establish a marketing budget based on the competition or industry norms (*competitive parity*). This is not an optimal approach because the competition may be reaching a different target market or may not have appropriated sufficient funds for marketing. In addition, these figures may not be readily available.

The next approach is the *affordable method*. This strategy takes the marketing budget into consideration only after funds have been allocated to other important operations or projects to the pharmacy. The remaining funds then are applied to the marketing budget. This approach does not take into account the goals and objectives of the marketing plan and how to complete the tasks of the marketing plan effectively.

The last strategy, *objective and task approach*, is the most cost-effective method for determining a budget. This *bottom-up* method determines the goals and objectives of the marketing plan, the tasks that need to be completed, and the costs associated with each task. The marketing budget is created by determining what investment is needed to implement the marketing strategies developed during the planning process. Assessments of the effectiveness of each strategy allow adjustments to be made in the plan and budget.

Decisions about the amount spent on marketing should be evaluated routinely by looking at the return on investment. One should contact various sources to determine the most cost-effective methods of advertising. Certain promotional strategies may prove to be more effective than others, causing the need to reassess the investment in these strategies. Some pharmacies may invest a larger amount in the marketing budget earlier in the planning stages and hire a consultant. Once the plan is put into place and the consultant is no longer needed, the practice can decrease the budget to usual levels. Regardless of which strategies are used, developing and refining a budget is a dynamic process and helps guide decisions for the marketing plan.

Another key part of monitoring marketing effort is to seek feedback from patients. Receiving feedback from patients and stakeholders regarding promotional materials before market testing helps in the development of these marketing tools. One approach is to recruit a small group of patients and stakeholders to preview materials regularly. During the market testing, carefully evaluate patient and stakeholder response to the marketing strategies. It is during this time that feedback about the effectiveness of certain marketing materials and tools can be collected to help revise and refine these materials. For example, asking all new service customers how they found out about the

services can help identify effective promotions. Once this step is accomplished, implementation of the marketing plan follows.

Once decisions are finalized regarding each aspect of the marketing process, implementation of the plan is next. The goal is to follow the written action plan and timeline created during the planning process. Expect minor problems as new activities are undertaken. For example, territory battles may arise with other health-care providers and within one's own pharmacy. Delegating tasks and responsibilities to individuals within the practice distributes the workload associated with each task and can include all the staff. It is important that pharmacists remain supportive and realistic when assigning tasks to other employees in the practice, because each employee must feel that his or her contributions are equally important. Use of a monthly planner or calendar to assign responsibility to individuals to complete certain tasks can assist the pharmacist in the implementation process. Employees should date and initial each task as it is completed. Providing incentives for employees encourages their participation and creates a sense of ownership in the marketing process.

The different promotional strategies should be implemented at this time as well. Promotion and advertising dollars should be kept within the established budget. Because an increase in sales may not be immediate, cash-flow considerations should be part of the implementation plan. The practice may need to stagger activities to assure sufficient funds when needed. When the pharmacist is determining costs associated with certain tasks, economic considerations are important, as well as time constraints on the staff. Both are equally significant. The time and cost of the implementation phase can be substantial; pharmacists and staff need to remain committed to the marketing plan to help ensure its success. In addition, pharmacists should remain flexible and make adjustments to the plan if expected results are not realized.

CONCLUSIONS

To successfully implement pharmacy-care services, pharmacists can market their services. The three steps of the marketing process outlined in this chapter provide a basic framework that can be applied to any practice. Each step of the marketing process may be individualized to a particular practice site, demographic area, patient base, competitive environment, and financial constraint. Regardless of the pharmacy involved, however, the importance of adequate market research and planning should not be underestimated. A thorough analysis of one's environment is essential to identify key targets and stakeholders, recognize opportunities and threats to the practice's success, and ensure that marketing resources are used in the most cost-effective manner.

When implementing the marketing plan in an individual pharmacy, pharmacists should use goals, objectives, and individual tasks to give direction to the marketing process. Including all employees in this process, from clerks to pharmacist, helps to ensure consistency and commitment from all involved. During the implementation phase of the marketing plan, regularly scheduled meetings should be held to keep employees updated and informed on the marketing efforts. By careful consideration of the concepts described in this chapter and by involving all employees of the pharmacy in the process, pharmacists can achieve the optimal results from their marketing plan.

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CHAPTER 117

Documenting, Billing, and Reimbursement for Pharmaceutical Care Services

Michael T Rupp

THE ROLE OF DOCUMENTATION IN PHARMACEUTICAL CARE

The role of clinical documentation in pharmaceutical care is often underappreciated or misunderstood entirely. Documentation is viewed by some pharmacists as an activity that detracts from care by consuming time that could otherwise be spent with the patient. In fact, accurate and consistent documentation of clinical observations, decisions, and actions improves the quality of care delivered to patients in several important ways:

1. It imposes a logical structure on the clinician's thinking. Essentially, documentation requires the pharmacist to ask and answer the questions, "What did I do, and why did I do it?" Over the course of time, the same critical reasoning is incorporated into the process of planning and delivering care. This continuous critical self-assessment translates into a more logical, deliberate, and consistent approach to providing care.
2. It enhances the quality of care through improving the continuity of care. This effect is particularly pronounced in the community practice setting, where systems to ensure continuity of patient care are often not as fully developed as institutional practice settings. Properly integrated into a practice, written documentation provides a mechanism for assuring the consistent flow of patient information from encounter-to-encounter and from provider-to-provider. Like other health care providers, pharmacists often develop close relationships with their patients. As a result, some may erroneously conclude that documenting the services they perform is unnecessary because "they will remember." However, such a casual approach increases the risk that important patient information will be overlooked. When this happens, the quality of care inevitably suffers.
3. In addition to supporting patient care, clinical documentation also creates a permanent written record of observations made and actions taken for legal purposes. As Cohen has noted, "if it isn't documented, it wasn't done."[1] Perhaps more to the point is the admonition found on a nurses' station in a large hospital: "In God We Trust, All Others Must Document!"
4. Documentation of activities is useful in workload management to maximize the use of existing personnel and justify the need for additional positions.[2] Additionally, documentation of key professional activities, such as pharmacists' interventions to correct prescribing errors, can serve to establish the need for, and value of, the pharmacist in the channel of distribution for prescription medications.[3–6] Indeed, the importance of documenting pharmacist interventions has been recognized by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) who have included it as a key clinical quality indicator in a medication-use monitoring system.[7]
5. It may be performed for purposes of billing and getting paid for care provided to patients.[8] In November 1990, the Office of HHS Inspector General, Richard P Kusserow, released a report titled *The Clinical Role of the Community Pharmacist.*[9] The report concluded, "there is strong evidence that clinical pharmacy services add value to patient care," but that "in the community pharmacy setting, significant barriers exist that limit the range of clinical services generally provided." Among the most formidable of these barriers, the report concluded, is "a transaction-based reimbursement structure [which] links pharmacists' reimbursement to the sale of a product rather than provision of services."

Thus, the development of compensation strategies that recognize the value of professional services and equitably reward pharmacists who competently and consistently provide them, represents a clear and urgent priority for the profession. As a result, developing accurate and efficient documentation and billing systems represent a clinical, legal, and economic mandate for the pharmacy profession.

NARRATIVE DOCUMENTATION: THE SOAP SYSTEM

Many of the seminal advances in clinical documentation can be traced to the work of Dr Lawrence Weed, a physician and pioneer in creating systematic approaches to organizing the collection, storage, and use of clinical information.[10] Weed's intuitive problem-oriented medical record (POMR) represented a significant advance from the fragmented source-oriented record that had preceded it, in which notes were filed according to the source from which they had come, such as physician orders, nursing notes, laboratory reports, and so on.

As described by Weed, the POMR consisted of four essential components:

1. The defined data base
2. The complete problem list
3. The initial plan
4. The progress notes

Weed recommended that progress notes be further organized to reflect the four types of information that are commonly found in clinical documentation. This has come to be known as the SOAP approach to clinical documentation, SOAP representing an acronym for Subjective, Objective, Assessment, and Plan.

Subjective information includes a description of the problem and the associated symptoms in the patient's own words. These notes often contain verbatim quotes from the patient, "*I feel hot and achy, and I have a splitting headache,*" and/or those close to the patient such as a relative or friend, "*She has been complaining of fever and headache for a couple of days.*"

Portions of this chapter were excerpted with permission from: Rupp MT. *Pharmacist Care Claim Form User's Manual: A Guide to Pharmacist Care Compensation,* 3rd ed. Alexandria, VA: National Community Pharmacists Association, 2000.

Objective information includes observations made and data collected and/or considered by the caregiver that is relevant to the problem including physical exam or assessment, laboratory data, and so on (eg, *Patient presents to the pharmacy in acute distress complaining of flu-like symptoms for the past 2 days. Complexion is pale, skin is warm and dry to the touch, temperature is 101° F orally)*.

The assessment component of the note allows the caregiver to express his/her net conclusion or opinion about the problem based on the subjective and objective information that is available (eg, *Patient's symptoms are consistent with flu)*. The assessment note may be seen as a diagnosis, clinical impression, or a change in the condition of the patient for better or worse.

The plan component of the progress note describes the recommended course of action based on the new information being considered by the caregiver. This may include revising a previous plan or establishing a new one and may contain recommended treatment, patient education/instruction, and/or the need for additional information (eg, *Recommended acetaminophen 650 mg every 4–6 hours, push fluids, and bed rest. If symptoms worsen, or if not improved in 48 hours, patient instructed to see physician)*.

Although the SOAP approach provides a simple, logical structure for documenting clinical encounters with patients, there are some elements that are not applicable to every care-related service performed by the pharmacist. For example, subjective patient information is usually only relevant to situations involving direct patient care. In other situations, such as an intervention to correct a prescription-related problem that is identified during prescription screening and dispensing, subjective patient information would often be unnecessary or irrelevant.[12]

Many permutations of the SOAP approach to clinical documentation have appeared over the years. However, even under different acronyms, most are essentially minor derivations of Weed's simple, yet effective approach. By organizing clinical documentation in a logical and consistent format, SOAP maintains significant advantages over unstructured approaches for ensuring greater accuracy and completeness of a care encounter. Additionally, since the SOAP approach is widely used in the clinical training of many health professionals, it is likely to be more familiar, and therefore more acceptable, to health professionals and claims administrators working for third party payers.

USING ABBREVIATIONS AND SYMBOLS—It is not uncommon for pharmacists and other health professionals to use symbols and abbreviations in their clinical documentation. Used appropriately, symbols and abbreviations can improve the accuracy of documentation while conserving provider time and documentation space. However, used inappropriately, these shortcuts can increase the likelihood of medication errors and other adverse patient outcomes.

Consider the following note: *Pt c/o PND × 5d*. In this note, *PND* could refer to either *paroxysmal nocturnal dyspnea*, or *post nasal drip*. Without additional information, it is impossible to say which with any certainty. Documentation should clarify, not obscure. Ambiguous or equivocal clinical documentation is simply unacceptable. Many commonly used acronyms, symbols, and medical abbreviations have multiple uses and interpretations. For this reason, it is prudent to avoid using them whenever possible. If they are to be used, however, it is important that their meaning is clear and unambiguous. Pharmacists who wish to use symbols and abbreviations in their documentation should adopt and strictly adhere to a standard set of approved symbols and abbreviations in their practices. Excellent references are available to assist in establishing an approved list of symbols and abbreviations for a pharmaceutical care practice.[13]

STANDARDIZED CODING SYSTEMS

The advantage of narrative documentation is that it allows the caregiver to provide detail and nuance to the documentation of clinical observations, impressions, and activities. However, a significant limitation of narrative documentation is the difficulty in transforming it into quantifiable data that are consistent with contemporary computer-based information management and claims administration systems. To do this, it is necessary to create ways to codify key data related to the care provided to the patient. This, in turn, has given rise to standardized coding systems that allow for more efficient documentation and billing of health services.

CODING SYSTEMS TO DOCUMENT PHARMACEUTICAL CARE—The National Council for Prescription Drug Programs (NCPDP) is a standards development organization (SDO) whose membership includes representation from virtually every relevant segment in the US prescription drug delivery system. Since its inception in 1976, the mission of NCPDP has been to create and promote voluntary standards for information transfer in prescription drug benefit program administration. In this capacity, the Council has historically concerned itself primarily with the creation and maintenance of standards for the exchange of information related to the delivery of prescription drug products. NCPDP's Universal Claims Form that was released in 1977 and its more recent electronic counterparts are familiar to most community pharmacists.

In November 1993, NCPDP recognized the need to add the ability to document and bill for pharmaceutical care services to its electronic telecommunication standard. It responded to this emerging need by creating WG-10, the Professional Pharmacy Services (PPS) Work Group. The mission of WG-10 was to:

> *"create a standardized, practical framework that will allow the electronic documentation, storage and transmission of clinical and billing data that describe the delivery of professional pharmacy services."*

Essentially, the mission of the work group was to define and operationalize the pharmacist's prescription-related professional services in a uniform coding system and integrate this system into the electronic claims administration process through the creation of an electronic data interchange (EDI) standard. This standard could then serve as the basis for the efficient communication of information related to the delivery of pharmacists' care-related services to patients. This, in turn, would provide an essential prerequisite for the creation of efficient mechanisms by which pharmacists could routinely document their professional services and, where covered by a patient's health insurance or pharmacy services benefit plan, bill and receive compensation for these services.

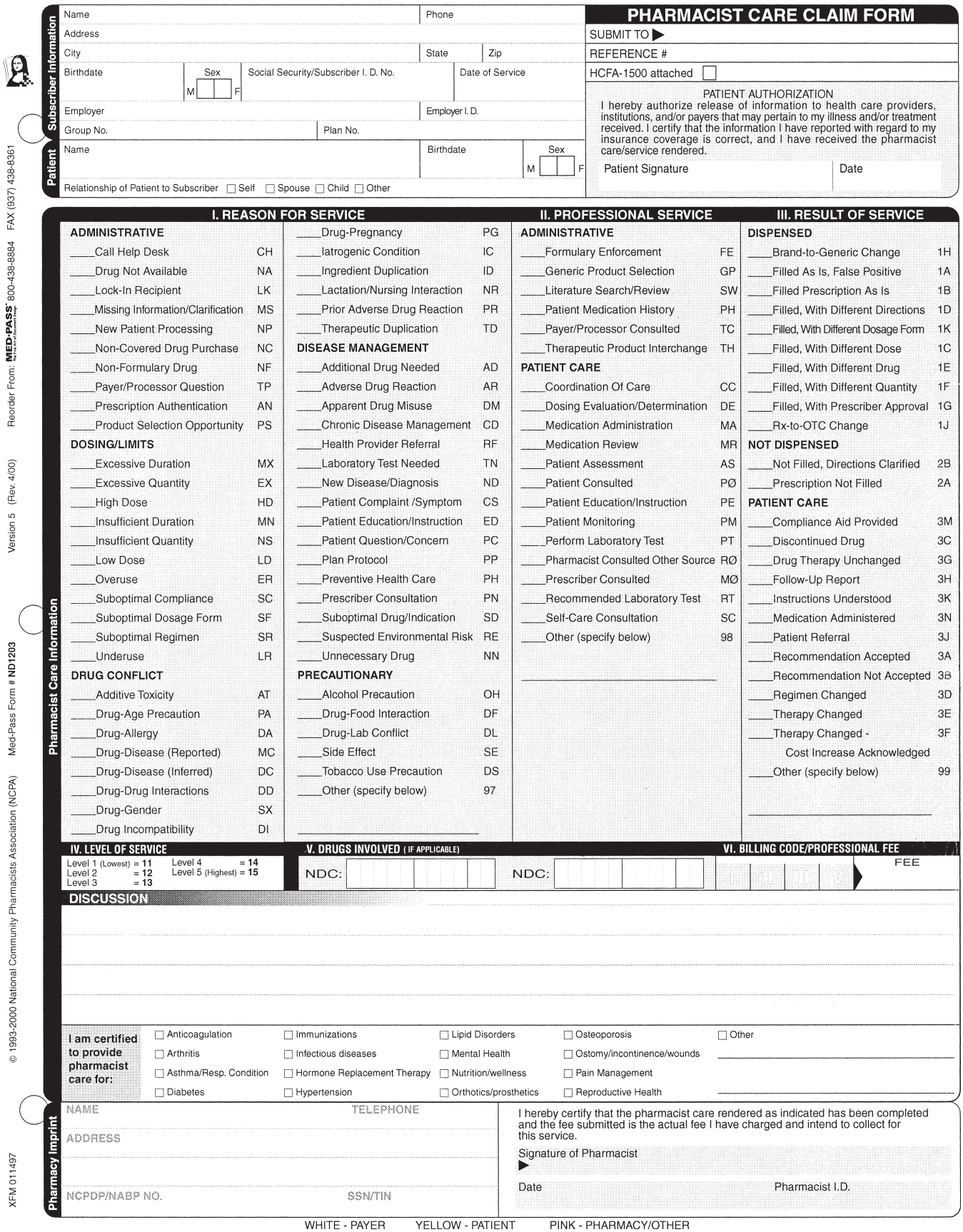
In 1995, the NCPDP approved the addition of the new PPS code set, and billing for professional services became part of NCPDP's electronic telecommunication standard.[14,15] Following NCPDP's approval, the National Community Pharmacists Association (NCPA) modified their popular Pharmacist Care Claim Form (PCCF) to support the NCPDP coding standard, thereby taking an important step toward creating uniformity in how pharmacists document and bill for their professional services. Since this alignment occurred, all subsequent versions of the PCCF have continued to support the PPS coding system. The most recent version of this claim form appears in Figure 117-1. In addition, NCPA publishes a manual on the use of the PCCF.[16]

The core of the PCCF consists of six fields of information:

1. Reason for Service
2. Professional Service
3. Result of Service
4. Level of Service
5. Drugs Involved
6. Billing Codes/Professional Fees

As illustrated on the PCCF in Figure 1, the *Reason for Service* codes are further classified into one of five code groups to better reflect their shared content:

1. Administrative
2. Dosing/Limits
3. Drug Conflict
4. Disease Management
5. Precautionary



PHARMACIST CARE CLAIM FORM

SUBMIT TO ▶

REFERENCE #

HCFA-1500 attached ☐

Subscriber Information

Name | Phone

Address

City | State | Zip

Birthdate | Sex M ☐☐ F | Social Security/Subscriber I. D. No. | Date of Service

Employer | Employer I. D.

Group No. | Plan No.

Patient

Name | Birthdate | Sex M ☐☐ F

Relationship of Patient to Subscriber ☐ Self ☐ Spouse ☐ Child ☐ Other

PATIENT AUTHORIZATION

I hereby authorize release of information to health care providers, institutions, and/or payers that may pertain to my illness and/or treatment received. I certify that the information I have reported with regard to my insurance coverage is correct, and I have received the pharmacist care/service rendered.

Patient Signature | Date

Pharmacist Care Information

I. REASON FOR SERVICE

ADMINISTRATIVE

____Call Help Desk CH
____Drug Not Available NA
____Lock-In Recipient LK
____Missing Information/Clarification MS
____New Patient Processing NP
____Non-Covered Drug Purchase NC
____Non-Formulary Drug NF
____Payer/Processor Question TP
____Prescription Authentication AN
____Product Selection Opportunity PS

DOSING/LIMITS

____Excessive Duration MX
____Excessive Quantity EX
____High Dose HD
____Insufficient Duration MN
____Insufficient Quantity NS
____Low Dose LD
____Overuse ER
____Suboptimal Compliance SC
____Suboptimal Dosage Form SF
____Suboptimal Regimen SR
____Underuse LR

DRUG CONFLICT

____Additive Toxicity AT
____Drug-Age Precaution PA
____Drug-Allergy DA
____Drug-Disease (Reported) MC
____Drug-Disease (Inferred) DC
____Drug-Drug Interactions DD
____Drug-Gender SX
____Drug Incompatibility DI
____Drug-Pregnancy PG
____Iatrogenic Condition IC
____Ingredient Duplication ID
____Lactation/Nursing Interaction NR
____Prior Adverse Drug Reaction PR
____Therapeutic Duplication TD

DISEASE MANAGEMENT

____Additional Drug Needed AD
____Adverse Drug Reaction AR
____Apparent Drug Misuse DM
____Chronic Disease Management CD
____Health Provider Referral RF
____Laboratory Test Needed TN
____New Disease/Diagnosis ND
____Patient Complaint /Symptom CS
____Patient Education/Instruction ED
____Patient Question/Concern PC
____Plan Protocol PP
____Preventive Health Care PH
____Prescriber Consultation PN
____Suboptimal Drug/Indication SD
____Suspected Environmental Risk RE
____Unnecessary Drug NN

PRECAUTIONARY

____Alcohol Precaution OH
____Drug-Food Interaction DF
____Drug-Lab Conflict DL
____Side Effect SE
____Tobacco Use Precaution DS
____Other (specify below) 97

II. PROFESSIONAL SERVICE

ADMINISTRATIVE

____Formulary Enforcement FE
____Generic Product Selection GP
____Literature Search/Review SW
____Patient Medication History PH
____Payer/Processor Consulted TC
____Therapeutic Product Interchange TH

PATIENT CARE

____Coordination Of Care CC
____Dosing Evaluation/Determination DE
____Medication Administration MA
____Medication Review MR
____Patient Assessment AS
____Patient Consulted PØ
____Patient Education/Instruction PE
____Patient Monitoring PM
____Perform Laboratory Test PT
____Pharmacist Consulted Other Source RØ
____Prescriber Consulted MØ
____Recommended Laboratory Test RT
____Self-Care Consultation SC
____Other (specify below) 98

III. RESULT OF SERVICE

DISPENSED

____Brand-to-Generic Change 1H
____Filled As Is, False Positive 1A
____Filled Prescription As Is 1B
____Filled, With Different Directions 1D
____Filled, With Different Dosage Form 1K
____Filled, With Different Dose 1C
____Filled, With Different Drug 1E
____Filled, With Different Quantity 1F
____Filled, With Prescriber Approval 1G
____Rx-to-OTC Change 1J

NOT DISPENSED

____Not Filled, Directions Clarified 2B
____Prescription Not Filled 2A

PATIENT CARE

____Compliance Aid Provided 3M
____Discontinued Drug 3C
____Drug Therapy Unchanged 3G
____Follow-Up Report 3H
____Instructions Understood 3K
____Medication Administered 3N
____Patient Referral 3J
____Recommendation Accepted 3A
____Recommendation Not Accepted 3B
____Regimen Changed 3D
____Therapy Changed 3E
____Therapy Changed - Cost Increase Acknowledged 3F
____Other (specify below) 99

IV. LEVEL OF SERVICE

Level 1 (Lowest) = 11 | Level 4 = 14
Level 2 = 12 | Level 5 (Highest) = 15
Level 3 = 13

V. DRUGS INVOLVED (IF APPLICABLE)

NDC: ☐☐☐☐☐☐☐☐☐☐☐ NDC: ☐☐☐☐☐☐☐☐☐☐☐

VI. BILLING CODE/PROFESSIONAL FEE

FEE

DISCUSSION

I am certified to provide pharmacist care for:

☐ Anticoagulation ☐ Immunizations ☐ Lipid Disorders ☐ Osteoporosis ☐ Other
☐ Arthritis ☐ Infectious diseases ☐ Mental Health ☐ Ostomy/incontinence/wounds
☐ Asthma/Resp. Condition ☐ Hormone Replacement Therapy ☐ Nutrition/wellness ☐ Pain Management
☐ Diabetes ☐ Hypertension ☐ Orthotics/prosthetics ☐ Reproductive Health

Pharmacy Imprint

NAME | TELEPHONE

ADDRESS

NCPDP/NABP NO. | SSN/TIN

I hereby certify that the pharmacist care rendered as indicated has been completed and the fee submitted is the actual fee I have charged and intend to collect for this service.

Signature of Pharmacist ▶

Date | Pharmacist I.D.

WHITE - PAYER YELLOW - PATIENT PINK - PHARMACY/OTHER

Figure 117-1. Pharmacist care claim form (version 5).

Codes in this field are used to indicate the problem or need that stimulated the pharmacist's professional service.

Adjacent to this field on the PCCF are the *Professional Service* codes that describe the professional service(s) that were performed in response to the problem or need that was identified. These services are divided into two groups: administrative and patient care.

The *Result of Service* codes are used to describe the immediate outcomes of the service that was performed. Clearly, many things can and do result from professional services that pharmacists perform during their delivery of care. However, some of these results, such as improved patient health outcomes, can only be determined at some point well after the performance of the service. For this reason, the measurement and recording of true patient health outcomes—while an important part of clinical documentation—is inconsistent with most billing and claims administration systems in which documentation and billing is performed contemporaneously with the delivery of care. As a result, the codes in the *Result of Service* field primarily reflect process or procedural outcomes of the service that was performed, rather than true patient health outcomes.

Values in the *Level of Service* field may be used to describe the intensity of the service that was performed. For any pharmacist service (ie, Reason-Service-Result combination), a number of different levels of service are possible. In contrast to the other fields of information, the definition and rules of assignment for codes in this field are left to the decision of users and their trading partners. In some cases, the level of service may be best represented by the amount of time the pharmacist required to perform the service. Alternatively, it may be based on the complexity of the problem, the level of professional judgment that was required, or the risk that the identified problem represented to the patient. Most pharmacists use the Level of Service field to record the amount of time that was required to perform the service in question. If so, it is important to note that in some cases a pharmacist's service to a patient may be interrupted. This may occur, for example, when a physician is not immediately available and the pharmacist must wait for a return telephone call. When such an interruption occurs, the delay that results should not be considered when assigning level of service unless the pharmacist was actively engaged in the performance of the service during the elapsed time period. For additional guidance on this and other issues, the reader is directed to the *Pharmacist Care Claim Form User's Manual*.[16]

Although not always the case, one or more drug products may be involved in the delivery of a pharmacist service to a patient. If so, the *Drugs Involved* field allows for the identification of up to two specific drug products using the standard 11-character NDC (National Drug Code) as the product identifier. Although many pharmacist services/interventions involve only a single drug product, circumstances may arise in which the pharmacist wishes to identify two drug products with a particular service. Such situations may include the following medication conflicts (ie, Reason for Service):

Additive Toxicity (AT)
Drug-Drug Interactions (DD)
Drug Incompatibility (DI)
Ingredient Duplication (ID)
Prior Adverse Drug Reaction (PR)
Therapeutic Duplication (TD)

In cases of formulary enforcement (NF) or discretionary product selection (PS), this field allows for the identification of both the originally prescribed product and the product that was eventually dispensed.

The *Billing Code* for a pharmacist service on the PCCF is created by transferring the two-character codes from columns I through IV to the appropriately numbered boxes in this field. The resulting 8-character code represents a complete professional pharmacist service. Also included on the PCCF is a section called *Discussion* within which the pharmacist could include a brief narrative summary of the service and/or provide additional information not captured in the codes selected.

THE PHARMACY PRACTICE ACTIVITY CLASSIFICATION—Although NCPDP's PPS code set captures many services pharmacists may perform, it cannot be considered exhaustive in terms of its representation of the pharmacist as a healthcare professional. The single greatest challenge that has historically faced those who would create standard coding systems to document and bill for pharmaceutical care services has been the absence of a comprehensive and widely embraced list of specific activities that pharmacists may perform in the course of fulfilling their professional responsibilities. An important step toward overcoming this barrier was taken in 1998, when ten national professional associations jointly issued the Pharmacy Practice Activity Classification (PPAC).[17]

The PPAC is intended to be an exhaustive classification of activities performed by practicing pharmacists across the continuum of health care settings. Much like a biological taxonomy, the PPAC is organized as a hierarchy. In descending order, they are: domain, class, activity, task and step.

At the highest level in the PPAC are four broad domains of pharmacist activity:

1. Ensuring Appropriate Therapy and Outcomes
2. Dispensing Medications and Devices
3. Health Promotion and Disease Prevention
4. Health Systems Management

Within each domain are more specific classes of activity. Within each class are individual activities, and so on, down to the most specific level in the system which are discrete steps involved in performing a particular activity-related task. An example of the increasingly specific hierarchical nature of the PPAC is

Domain A Ensuring Appropriate Therapy and Outcomes
Class A.2 Ensuring Patient's Understanding And Adherence to His or Her Treatment Plan
Activity A.2.1 Interview patient
Task A.2.1.4 Verify patient understanding and knowledge of treatment plan
Step A.2.1.4.1 Verify that patient can describe the use of new and/or existing medication

Note that the presence of an activity on the PPAC does not necessarily mean it is performed exclusively by pharmacists. Indeed, some activities listed in the system are routinely performed by automated systems or delegated to supportive personnel in many pharmacy practices. These activities were included in the PPAC because it was thought that they remain the professional responsibility of the pharmacist to ensure they are performed correctly, whether the pharmacist is personally performing them, or merely supervising others in their performance.

It is too early to determine what affect, if any, the PPAC will have on future documentation and billing systems for pharmaceutical care. However, its potential to serve as the foundation for a common language with which pharmacists and the pharmacy profession may articulate the professional roles and responsibilities of the pharmacist is significant. It is not unlikely that the PPAC, or some derivative thereof, may eventually serve as the basis for future standardized documentation and billing systems in pharmacy.

FEE SETTING AND THE RESOURCE-BASED RELATIVE VALUE SCALE—To the right of the billing code on the PCCF, an area is provided for the pharmacist to assign a professional fee for the service that was performed. At present, there exists no widely accepted standard for assigning professional fees to pharmacist services. For private pay patients, professional service fees will be set by pharmacists in much the same way that other products and services are priced. Where these services are covered by insurance or third party benefit plans, the pharmacist's professional fees will be determined in negotiation with payers.

Many pharmacists who routinely bill major medical carriers for their services know that under the Medicare program, physicians' fees are set by a Resource-Based Relative Value Scale (RBRVS). Because some have suggested that a similar approach may be used in future payment systems that are

created for pharmaceutical care, it is useful to describe the RBRVS system briefly within the context of this discussion.

By the early 1980s, government third party payers had concluded that the UCR (usual, customary and reasonable) method of compensating physicians and other medical care providers was financially unsound and encouraged abuse. This opinion was particularly prevalent in the Medicare program, where it was decided that a standard fee schedule was needed for physician services. The result was the creation of an ongoing research project at Harvard University known as the Resource-Based Relative Value Scale project.[18]

Essentially, the RBRVS project was an attempt to create a method of reimbursing physician services that is based on the estimated resource input costs required to perform the services. The RBRVS that is used by Medicare to determine physicians' fees defines the resource input costs as consisting of four components:

1. The time required by the physician before, during, and after the service
2. The intensity with which the time was spent
3. The practice costs necessary to supply the service
4. The opportunity costs of additional training or specialization the physician may have been required to complete in order to provide the service.[19]

The RBRVS combines these resource inputs into a model that is intended to reflect the relative costs that efficient physicians would incur in providing a given service if a perfectly competitive market existed. Since it was not considered feasible to gather data on all 7,000 Medicare procedure codes, the researchers surveyed 3,000 physicians in 18 specialties to determine the work necessary to perform over 400 medical services. They then grouped the procedures into broad classes of services that were assumed to be relatively similar in terms of resource inputs and extrapolated the results to procedures that were not surveyed.

The general approach used in the RBRVS has received widespread support from policymakers, and even some physician organizations. As a result, it has been suggested that a similar approach may eventually be applied to determine the professional fees of other providers, including pharmacists.

PHARMACIST CREDENTIALING—It now appears likely that programs to certify pharmacist competency in the performance of certain specialized patient care services will increase in the future. Already, some third party payers require certified evidence of advanced proficiency as a condition of compensation for certain services.

In 1998, two groups were formed to develop consensus and create standards for credentialing pharmacists.[20] The National Institute for Standards in Pharmacist Credentialing (NISPC) was formed through a consortium agreement between the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), and the National Association of Boards of Pharmacy (NABP) to create standards for a series of examinations to credential pharmacists in various specific disease states. A separate group, the Council on Credentialing in Pharmacy (CCP), includes representation from the Academy of Managed Care Pharmacists (AMCP), the American Association of Colleges of Pharmacy (AACP), the American College of Apothecaries (ACA), the American College of Clinical Pharamcy (ACCP), the American Pharmaceutical Association (APhA), the American Society of Consultant Pharmacists (ASCP), and the American Society of Health-System Pharmacists (ASHP). The focus of this group appears to be the certification of generalist practitioners who are capable of providing pharmaceutical care.

Thus, although some disagreement still exists with respect to whether pharmacy should credential practitioners in focused areas of specialty expertise or general pharmaceutical care, there seems to be growing agreement about the need for, and value of, credentialing as a way to ensure a certain minimally acceptable level of proficiency.

The PCCF anticipated this trend and includes a field on the form that allows pharmacists to indicate their certification status in the management of specific disease states. Also included on the PCCF are fields to document the identity of both the pharmacy organization at which the service was provided, and the individual pharmacist who performed the service. Currently, SDOs are working with governmental agencies to create a system of unique provider identification numbers (UPIN) that will allow for the tracking of virtually any billed health care service to the individual who provided the service. This is in keeping with a growing interest among payers for more individual accountability from providers of all health care services.

LIMITATIONS OF THE PPS STANDARD

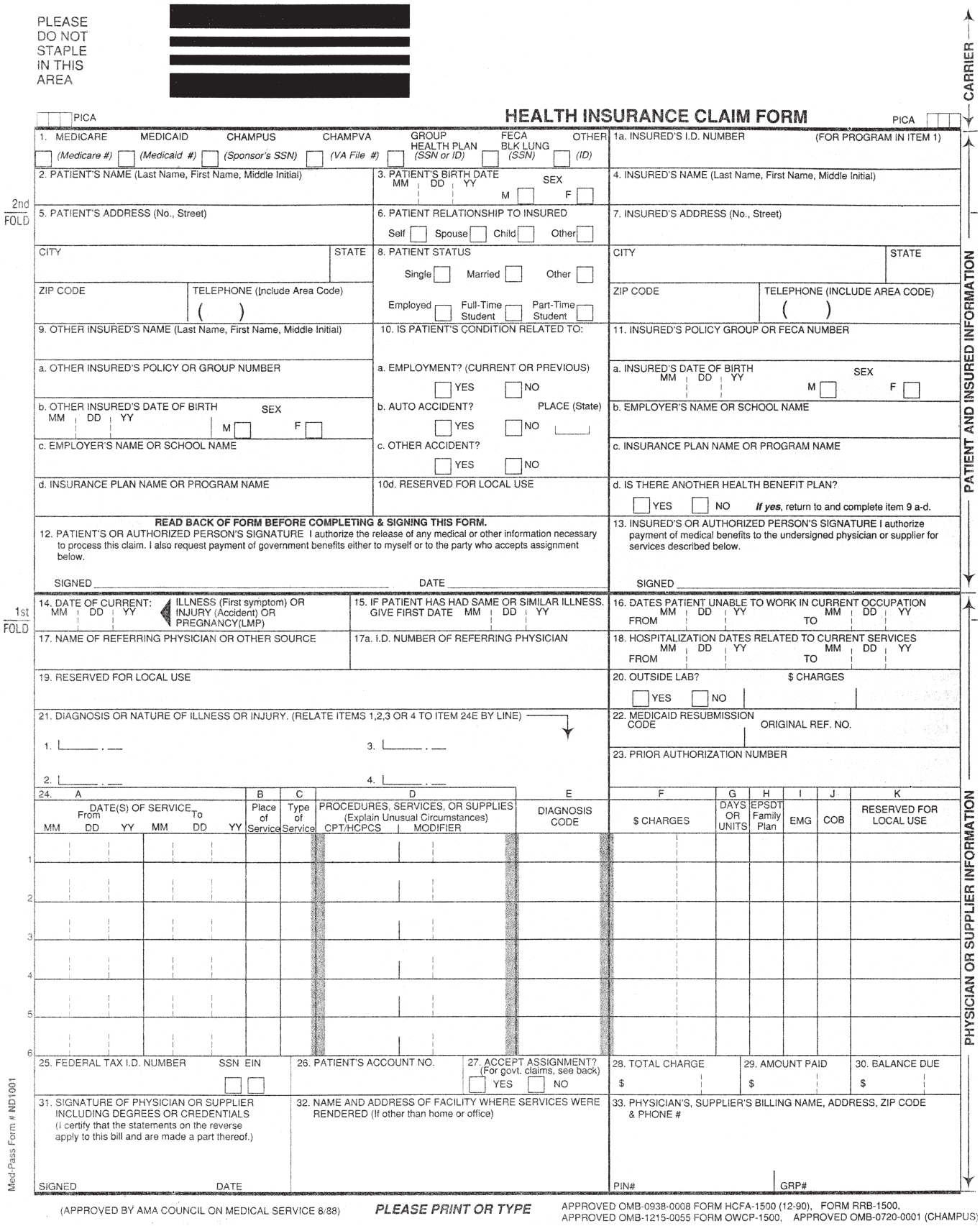
It is important for potential users to recognize the limitations of the PPS coding standard as it is currently configured. It is not the intent of the standard to represent the entirety of pharmaceutical care and the professional roles and responsibilities of pharmacists in all practice settings. The PPS standard was created to support those professional activities and responsibilities that are now, or may be anticipated to soon be included in third party pharmacy service benefit plans in the ambulatory practice setting, especially those services that are traceable to a particular prescription drug claim. It is recognized that pharmacists in certain specialized settings (eg, long-term care, consulting, radiopharmacy) have additional roles and responsibilities that may not be adequately captured in this first version of the PPS standard. Moreover, many professional services of community pharmacists are not performed in relation to a particular prescription drug claim. As discussed below, these limitations of NCPDP's PPS codes has led to the recent adoption of an alternative system that pharmacists may use to bill their professional services that are not traceable to a particular prescription drug claim, the CMS-1500 form and its electronic equivalent, the X12N 837 Health Care Claim.

While not strictly a limitation, an important caveat of the PPS coding standard is that it is not intended to replace more comprehensive narrative documentation by pharmacists of care delivered to their patients. Rather, like all coding systems, the standard is intended to provide an efficient and uniform mechanism for electronically communicating key aspects of this care, primarily for billing purposes. A complete clinical picture should always be recorded by the pharmacist in the patient's pharmacy-based medical record *before* any claims coding mechanism is consulted or applied.

USING THE CMS-1500 TO FILE PHARMACIST CARE CLAIMS—First issued in the early 1980s, the Centers for Medicare and Medicaid Services' (formerly the Health Care Financing Administration) CMS-1500 (ie, *universa*l) claim form is the most widely recognized and accepted format for billing third party payers for health care services. It is required by Medicare and many other third party payers for payment of health care services. Still commonly referred to as the "HCFA-1500" (pronounced hick-fa), the most recent version was released in December, 1990 and is illustrated in Figure 117-2.

In deciding whether to use the CMS-1500 to bill for pharmacist care services, the pharmacist should consider the nature of the service provided, as well as the payer to whom the claim will be submitted. Many pharmacist care services are discrete events that occur during the routine process of providing care, particularly prescription care, to patients. For some of these services, the value that is created is confined primarily to the prescription benefit plan. For example, when a pharmacist recommends a therapeutically equivalent but less expensive product to a prescriber, the value created by the pharmacist is restricted to the differential in the ingredient costs of the two drug products.

In other cases, the value of the pharmacist's professional service goes beyond, or is less likely to be recognized as directly relevant to, the prescription drug benefit. An example would be the pharmacist's involvement in patient education, instruction, or disease state management activities. Since there are often no



PLEASE DO NOT STAPLE IN THIS AREA

[redacted]

PICA

HEALTH INSURANCE CLAIM FORM

PICA

CARRIER

1. MEDICARE (Medicare #) | MEDICAID (Medicaid #) | CHAMPUS (Sponsor's SSN) | CHAMPVA (VA File #) | GROUP HEALTH PLAN (SSN or ID) | FECA BLK LUNG (SSN) | OTHER (ID)

1a. INSURED'S I.D. NUMBER (FOR PROGRAM IN ITEM 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

2nd FOLD

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self | Spouse | Child | Other

7. INSURED'S ADDRESS (No., Street)

CITY | STATE

8. PATIENT STATUS Single | Married | Other; Employed | Full-Time Student | Part-Time Student

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (INCLUDE AREA CODE) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (CURRENT OR PREVIOUS) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. OTHER INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? YES NO PLACE (State)

b. EMPLOYER'S NAME OR SCHOOL NAME

c. EMPLOYER'S NAME OR SCHOOL NAME

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. RESERVED FOR LOCAL USE

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, return to and complete item 9 a-d.

PATIENT AND INSURED INFORMATION

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

1st FOLD

14. DATE OF CURRENT: MM DD YY ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY(LMP)

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS. GIVE FIRST DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE

17a. I.D. NUMBER OF REFERRING PHYSICIAN

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. RESERVED FOR LOCAL USE

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1,2,3 OR 4 TO ITEM 24E BY LINE)

1. ____ 3. ____

2. ____ 4. ____

22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A DATE(S) OF SERVICE From MM DD YY To MM DD YY	B Place of Service	C Type of Service	D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER	E DIAGNOSIS CODE	F $ CHARGES	G DAYS OR UNITS	H EPSDT Family Plan	I EMG	J COB	K RESERVED FOR LOCAL USE
1										
2										
3										
4										
5										
6										

PHYSICIAN OR SUPPLIER INFORMATION

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. BALANCE DUE $

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. NAME AND ADDRESS OF FACILITY WHERE SERVICES WERE RENDERED (If other than home or office)

33. PHYSICIAN'S, SUPPLIER'S BILLING NAME, ADDRESS, ZIP CODE & PHONE #

PIN# GRP#

Med-Pass Form # ND1001

(APPROVED BY AMA COUNCIL ON MEDICAL SERVICE 8/88) *PLEASE PRINT OR TYPE* APPROVED OMB-0938-0008 FORM HCFA-1500 (12-90), FORM RRB-1500, APPROVED OMB-1215-0055 FORM OWCP-1500, APPROVED OMB-0720-0001 (CHAMPUS)

Figure 117-2. CMS-1500 claim form.

"hard dollar" savings to the prescription benefit plan from such services, the value created by the pharmacist is likely to be better recognized and appreciated by that component of the patient's medical insurance plan that is concerned with the total care of the patient, and the total cost of that care. This is usually what is commonly referred to as the *major medical* component of the patient's health insurance plan.

Pharmacists should consider filing their claim with the patient's major medical insurance carrier whenever they provide a service whose primary value is likely to be realized through positive patient health outcomes, or the prevention of negative health outcomes and their related economic sequelae. While each carrier will have its own policies and procedures for filing major medical claims, many require a CMS-1500 to be submitted in the claims packet.

Billing Using the CMS-1500

The CMS-1500 claim form is the most widely recognized and accepted format for billing third party payers for health care services. It is required by Medicare and many other third party payers for payment of health care services. The form consists of 33 boxes or fields of required information. Fields 1–13 contain information about the patient and the insured beneficiary. The remaining 20 fields 14–33 contain information about the provider or supplier of the service. Two fields on the form are particularly important for ensuring prompt and correct payment, field 21 and field 24D.

The first rule of third party payment for health care services is there must have existed a demonstrated medical need for the service that was performed. On the PCCF, need is established by the Reason for Service code that the pharmacist selects. On the CMS-1500, need is established by the patient's diagnosis and related background facts about the condition being treated.

INTERNATIONAL CLASSIFICATION OF DISEASES CODING—Field 21 on the CMS-1500 form is labeled 'Diagnosis or Nature of Illness or Injury.' This field contains four slots, numbered 1–4, for entering patient diagnostic information using the ICD-9-CM (*International Classification of Diseases, 9th Revision, Clinical Modification*) coding system, commonly referred to simply as "ICD-9." This reference is available through a variety of medical publishers.

At least one diagnosis code must be reported on each claim. Up to four codes may be reported if needed to accurately represent the reason for the service that was provided. When more than one is reported, the code which represents the disease, condition or problem that was primarily responsible for the service provided should be listed first, with any additional or supplementary codes listed afterward in order of their proximal relationship to the primary code.

The ICD-9 coding system contains nineteen categories of codes. Categories 1–15 (codes 001–779) identify diseases and related medical conditions. Category 16 (codes 780–799) designates symptoms, signs, and ill-defined conditions. Category 19 (codes 800–999) relates to injury and poisoning. Each of these categories contain numerical codes of 3 to 5 digits, depending upon the level of specificity and precision. For example, undifferentiated asthma is coded as 493 in the ICD-9 system. For asthma with an allergic cause, 493.9 would be the appropriate selection. An additional fifth digit is also available if the patient does or does not have a history of status asthmaticus (ie, 493.91 or 493.90, respectively).

Thus, with each successive digit, the level of diagnostic precision increases. With few exceptions, payers generally require the submission of diagnoses that are coded to at least the fourth digit. Failure to do so will often result in payment delay or rejection. In addition, other common coding problems are:

- The patient's chronic diagnosis which is not the reason for the encounter is incorrectly billed as the primary diagnosis;
- The ICD-9 code that is selected is inaccurate or insufficiently precise (ie, not coded to the fourth or fifth digit when appropriate); and
- A supplementary code is used inappropriately as the primary reason for the encounter.

In addition to the above 17 categories of numerical codes, the ICD-9 system provides two categories of supplementary codes. The first of these is the Supplementary Classification of Factors Influencing Health Status and Contact with Health Services (V01–V82), more commonly known as the "V codes." Of particular interest to pharmacists within the V codes are a series (V73–V82) that are used to classify routine screening examinations, such as those that might be part of a preventive care assessment. For example, there is a special code that is used when screening for diabetes mellitus (V77.1).

The final category of ICD-9 codes is the Supplementary Classification of External Causes of Injury and Poisoning (E800–E999) commonly known as the "E codes." This category allows the classification of environmental events, circumstances, and conditions as the cause of the patient's illness and is generally not used by pharmacists to code for their services.

Because there is no place for narrative description of the patient's condition on the CMS-1500, it is particularly important that code selection is as accurate and specific as possible. It is also for this reason that many pharmacists who bill major medical carriers for their services routinely append additional clinical documentation when they submit a CMS-1500.

CPT CODING—Field 24D on the CMS-1500 form is labeled "Procedures, Services or Supplies." Payers who require the CMS-1500 will usually require the use of Physician's Current Procedural Terms (CPT) codes or CMS's Common Procedure Coding System. Although CMS recently changed its name from the former HCFA, these codes are still commonly referred to as HCPCS (pronounced "hick-picks") codes. As with diagnosis, it is essential that pharmacists thoroughly understand the codes that are used in this field to describe the service that was performed.

The relationship between HCPCS and CPT is illustrated in Figure 117-3. The CPT codes were created by the American Medical Association in 1966 to be a listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. In 1983, HCFA developed HCPCS as a uniform method for health care providers and medical suppliers to code professional services, procedures, and supplies to meet the operational needs of the Medicare and Medicaid programs.

The HCPCS classification is organized into three numbered levels of codes, each of which represents a unique coding system.

Level I of HCPCS is the CPT codes, the maintenance of which continues to be performed by the AMA.

Level II codes were created by HCFA to cover medical services and supplies that are not covered in the CPT codes. Although these codes were primarily intended for use with government payers, they are also recognized by many private insurers.

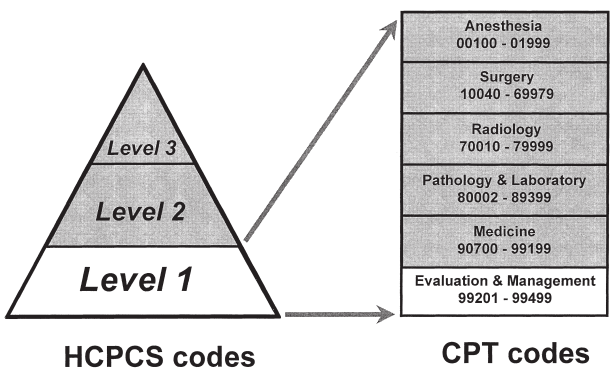


Figure 117-3. Medical care coding systems.

Level III codes were historically assigned by Medicare carriers in individual states and are therefore not common across all insurance carriers. Level III codes are being discontinued under the provisions of the recently enacted HIPAA legislation (see below).

Most pharmacists who wish to bill for their patient care activities will find the CPT codes to be the most useful, especially that section known as the *Evaluation and Management*, or *E&M* codes. As illustrated in Figure 117-3, the E&M codes occupy one of six sections within the CPT coding structure. Each five-digit numerical E&M code begins with a *99* prefix (ie, 99201–99499). The codes are divided into several categories including office visits, hospital visits, and consultations. These categories are further subdivided into two or more subcategories. For example, separate codes are available for an outpatient office visit with a provider depending on whether the patient is established or new to the practice.

E&M code selection is usually based on three key components, with additional considerations becoming relevant only under special circumstances. Once the appropriate category is selected (eg, outpatient office visit with an established patient), the proper code is determined on the basis of:

1. The level of **History** that is taken on the patient (the four levels of History include: Problem Focused, Expanded Problem Focused, Detailed, and Comprehensive.
2. The extent of the **Examination** that was performed (the four Levels of Examination include: Problem Focused, Expanded Problem Focused, Detailed, and Comprehensive).
3. The level of **Medical Decision Making** that was required to perform the service (the four levels of Medical Decision Making include: Straightforward, Low Complexity, Moderate Complexity, and High Complexity.

Selection of the level of medical decision making that was required is itself determined on the basis of three additional considerations:

1. The number of diagnosis or management options
2. The amount and/or complexity of data reviewed
3. The risk of complications and/or morbidity or mortality

Five different codes are available to describe an office visit with a new patient (99201–99205). Likewise, five codes are available to describe an office visit with an established patient (99211–99215). Many pharmacists in the community practice setting will find that these 10 codes most of their needs related to completing a CMS-1500 claim form.

Table 117-1 illustrates how a provider would use the three key components of history, examination, and medical decision making to select the code that best represents the nature of a patient care encounter. For example, 99213 would be the most appropriate code to describe an office visit with an established patient that required expanded problem-focused history and examination and a relatively low level of medical decision making.

Under special circumstances, other considerations become operative in code selection. For example, when counseling or coordination of care activities account for more than 50% of a patient encounter, selection of the proper E&M code from among a sequence involving different levels of care is based exclusively on the amount of time the provider spent with the patient. For example, 99204 would be the most appropriate code to describe an office visit with an established patient that was dominated by counseling and required about 45 minutes to complete.

Also illustrated in Table 117-1 are the *Relative Value Unit* scores (RVUs) that CMS has assigned to each of the codes using the RBRVS discussed above. The resulting RVU score is then regionally adjusted and multiplied by a monetary conversion factor to determine the dollar amount that a provider will be paid for a particular service or procedure under Medicare.

In addition to the 99201–05 and 99211–15 series, there are several sets of CPT codes that are commonly used to report preventive medicine or health services that some pharmacists find useful. Two series of codes, 99381–99387 (new patient) and 99391–99397 (established patient), are used for preventive medicine evaluation and management that includes a comprehensive history and examination, as well as counseling and/or risk factor reduction interventions. However, most pharmacists will find two other series of codes to be more applicable for their preventive health services. The series 99401–99404 are for preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual patient, with separate codes reflecting increasing amounts of time required for the service (eg, 99402 for approximately 30 minutes). Two additional codes are available when similar services are provided to more than one person in a group setting, such as a class. In this case, the code 99411 is used if the service required approximately 30 minutes, while 99412 is available if the service required approximately 60 minutes.

Additional information about CPT/HCPCS coding is available through The American Medical Association, CMS, and various commercial publishers of medical coding materials.

GENERAL PAYMENT PRINCIPLES

As discussed previously, some pharmacist care services are isolated activities that pharmacists perform to correct problems or fulfill needs that have arisen unexpectedly during the course of the practice day. In these cases, it is often unrealistic for the pharmacist to have prenegotiated payment coverage for the service with the payer. As a result, the pharmacist must submit a "cold" claim to the payer in hopes that the information contained on the claim will make a persuasive case for payment. Unfortunately, while proper completion of the required claims forms and aggressive follow-up with the payer can significantly improve the likelihood of receiving at least partial payment, the submission of cold claims to third party payers for pharmacist care activities is still a risky venture under the best of circumstances.

Table 117-1. Selected E&M Codes Used to Bill Pharmaceutical Care

CODES FOR A NEW PATIENT OFFICE VISIT					
E & M CODES	HISTORY	EXAMINATION	MEDICAL DECISION MAKING	TIME	RVUS
99201	Problem Focused	Problem Focused	Straightforward	10 min	.82
99202	Exp. Problem Focused	Exp. Problem Focused	Straightforward	20 min	1.32
99203	Detailed	Detailed	Low Complexity	30 min	1.80
99204	Comprehensive	Comprehensive	Mod. Complexity	45 min	2.66
99205	Comprehensive	Comprehensive	High Complexity	60 min	3.33
CODES FOR AN ESTABLISHED PATIENT OFFICE VISIT					
E & M CODES	HISTORY	EXAMINATION	MEDICAL DECISION MAKING	TIME	RVUS
99211	Minimal problems			5 min	.40
99212	Problem Focused	Problem Focused	Low Complexity	10 min	.71
99213	Exp. Problem Focused	Exp. Problem Focused	Low Complexity	15 min	1.00
99214	Detailed	Detailed	Mod. Complexity	25 min	1.55
99215	Comprehensive	Comprehensive	High Complexity	40 min	2.53

Recognizing this reality, some pharmacists have developed and implemented cohesive pharmacist care *products* in their practices. These products often take the form of specific disease state management or patient education/instruction programs.[21] For these types of services, it is both possible and desirable for the pharmacist to have prenegotiated authorization for payment with selected insurers or managed care organizations whose patients are potential candidates for the service or program in question. These agreements will dramatically improve the efficiency and effectiveness of the claims process.

When it is not possible to prenegotiate payment, the pharmacist has two options. First, the pharmacist can deliver the service and explain to the patient that payment will be sought from their insurer. In this case it is important the patient understands that the ultimate responsibility for payment rests with the patient. Alternatively, it is sometimes possible to delay provision of the service until the payer can be contacted to confirm or deny coverage for the service in question.

HIPAA AND RELATED RECENT EVENTS

In 1996, the 104th Congress passed Public Law 104-191 entitled the "Health Insurance Portability and Accountability Act of 1996." Known informally as HIPAA ("hip-ah"), this law directed the Secretary of HHS to adopt national standards to enable health information, including claims transactions, to be exchanged electronically. The law also requires the creation of regulations to ensure the privacy and security of patients' health information. The final rule for HIPAA was published in August 2000 and was originally set for implementation in October 2002. However, due to the complexity of standardizing the electronic exchange of health information, Congress passed legislation in late 2001 to extend the deadline for compliance of transactions and code sets until October 2003.

While it is still too early to know what the full impact of HIPAA will be, there is little question that it will have a profound affect on how the business of health care is transacted in the electronic environment. Within the context of professional pharmacy services, a particularly interesting development has occurred. As noted above, NCPDP is the standards development organization (SDO) that has historically maintained electronic data interchange standards in pharmacy. In recognition of this status, the HIPAA Final Rule on Standards For Electronic Transactions adopted the NCPDP Telecommunication Standard Format, Version 5.1 as the standard for pharmacy claims. However, another electronic standard, the ASC X12N 837 Health Care Claim, was adopted for professional health care claims that are billed to major medical carriers, including those of pharmacists. X12N is the insurance subcommittee of X12, a standards development organization that is involved in the development of electronic data interchange standards in a variety of industries.

As discussed earlier in this chapter, most pharmacists who are successfully billing third party payers for their professional services are doing so through the major medical carrier using the CMS-1500 universal claim form. Routine payment for professional pharmacy services has simply not made its way into prescription benefit plans in any meaningful way, since most PBMs continue to consider these services beyond the scope of the prescription benefit plans they manage. Since, the X12N 837 claim represents the electronic equivalent of the CMS-1500 form, the HIPAA ruling effectively eliminates NCPDP and its code sets from relevance in the future electronic billing for professional pharmacy services, except where the service is traceable to a particular prescription drug claim, and is billed to a prescription benefit manager (PBM).

As this chapter was being completed, HHS had rejected a petition by NCPDP to add their standard to that of ASC X12N 837 as a HIPAA-compliant standard for professional pharmacy services billing. Although it is possible that this decision may eventually be reconsidered, it now appears that the future of billing for pharmacy-related services will be clearly split between prescription-related services (NCPDP) and the myriad other professional cognitive services that pharmacists perform in their care of patients (X12N).

In preparing for the implementation of HIPAA in early 2002, the NCPA sought collaboration from other national pharmacy associations to join the X12 Pharmacy Advisory Panel it had established. As this chapter was nearing completion, the Panel had been joined by APhA, ASCP, ACCP, and ASHP, with NACDS also considering membership. The Panel was created to advance professional pharmacy services billing via the X12N 837 standard, and to provide oversight and maintenance of the HIPAA-compliant *X12N 837 Health Care Claim: Pharmacy Professional Services Companion Guide* that had been released by NCPA several months earlier. The *Guide* contains the EDI transaction segments and data elements that are germane to pharmacy professional services as billed using the X12N 837 claim, the electronic version of the CMS-1500 claim.

In May 2003, the American Medical Association signaled its acceptance of the X12 Pharmacy Advisory Panel as representing the coding interests of pharmacists by its vote to include the Panel on its Health Care Professionals Advisory Committee (HCPAC). The HCPAC was formed to allow participation by nonphysician health professionals in the AMA's CPT Editorial Panel process which is responsible for maintaining the CPT code set. The addition of pharmacy to the HCPAC represents an important step in the recognition of pharmacists as providers of patient health care services beyond the scope of prescription drug delivery. Membership on the HCPAC also gives pharmacy a vote in the future direction of the CPT codes that most pharmacists use to bill their professional services.

Another event of potentially profound significance to the future of compensation for pharmacist care services occurred on May 25, 2001, when Senator Tim Johnson (D-SD) introduced S. 974 entitled the "Medicare Pharmacist Services Coverage Act" to the 107th Congress. If passed, this legislation would amend Title XVIII of the Social Security Act to provide beneficiaries with coverage for pharmacists' drug therapy management services under Part B of the Medicare program. By recognizing pharmacists as eligible health care providers, an oversight in the original 1965 legislation, this bill would allow pharmacists to obtain provider numbers to bill Medicare directly for their professional services. The bill received two readings before being referred to the Finance Committee where it remained as this chapter neared completion.

CONCLUSIONS

Like pharmacy practice itself, documentation is a learned skill. Increasingly, technology is assisting the pharmacist to accurately and consistently document the care they provide. However, good documenters are not born, they are made. Until recently, pharmacy curricula provided relatively little opportunity for students to develop their written communication skills. The same can be said for the professional careers of most pharmacists. Due to the pharmaceutical care movement and the economic imperatives now facing the profession, these conditions are rapidly changing. Pharmacists who wish to participate fully in the movement toward patient-centered care, and who expect to be paid for their activities, must master the art of clinical documentation and billing.

Pharmacists who wish to pursue compensation for their professional services must recognize that they are still entering largely uncharted waters. Most government and private third party payers still do not have well-defined policies for paying pharmacists for their professional services. This is not to say that payers have no interest in pharmaceutical care. Rather,

for the most part they simply do not understand what it is, or how it will benefit them and their beneficiaries.

In his economic treatise, *Wealth of Nations*, Adam Smith commented on pharmacists and the value of their professional services:

> Apothecaries' profit is become a bye-word, denoting something uncommonly extravagant. This great apparent profit, however, is frequently no more than the reasonable wages of labour. The skill of an apothecary is much nicer and more delicate matter than that of any artificer whatever; and trust which is reposed in him is of much greater importance. He is the physician of the poor in all cases, and of the rich when the distress or danger is not very great. His reward, therefore, ought to be suitable to his skill and his trust, and it arises generally from the price at which he sells his drugs. But the whole drugs which the best employed apothecary, in a large market town, will sell in a year, may not perhaps cost him above thirty or forty pounds. Though he should sell them, therefore, for three or four hundred, or at a thousand percent profit, this may frequently be no more than the reasonable wages of his labour charged, in the only way in which he can charge them, upon the price of his drugs. The greater part of the apparent profit is real wages disguised in the garb of profit.[22]

Although the practice of pharmacy has changed dramatically in the two centuries since those words were written, the basis for compensating pharmacists has not. In general, the value of pharmacists' professional services is still interwoven with, and obscured by, the price of the products they sell. The future of compensation for professional cognitive services must break from this tradition.

The creation of pharmacy services terminology and related electronic claims transmissions standards will help speed the evolution of new payment systems. Likewise, the growing body of research in outcomes assessment and pharmacoeconomics will allow the pharmacy profession to better understand the economic value of pharmaceutical care and better communicate this value to payers. Indeed, demonstrating to payers the value of pharmacists' services represents a priority—perhaps *the* priority—for pharmacy practice-related research in the years ahead.

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CHAPTER 118

Pharmaceutical Risk Management

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THE NEW ERA OF RISK MANAGEMENT

In the United States, drugs are approved only if they are determined to be safe to use for the conditions described in their label. This basic tenet of the Food, Drug and Cosmetic Act has not changed. What has changed though in recent years is the interpretation of the term "safe." Modern concepts of pharmaceutical risk management are based on the premise that drug manufacturers, health care professionals, and patients have a responsibility to minimize the risks of using pharmaceutical products. It is not enough to make drugs minimally safe, they must be as safe as possible over the lifecycle of the product's use.[1–3]

Historically, the Food and Drug Administration (FDA) has interpreted the requirement that a drug must be "safe" to mean that the benefits of a drug outweigh its risks. The determination was made on a "categorical" basis, where the totality of risks was weighted against the totality of benefits when considered for the purposes outlined in the drug product's labeling. If a drug did not meet this criterion, it was not approved or its label was rewritten to narrow the conditions for use. This logic was endemic in the FDA for most of the 20th century. On average, two to four drugs over each 5-year period were withdrawn from the marketplace after post-marketing surveillance data uncovered new risks.[4] Similarly, on occasion, the FDA would require some special "tool" or intervention to improve a product's safety profile. For example, patient package inserts were used to warn women about the risk of birth control pills and a special distribution system was used to limit the dispensing of Clozaril (clozapine) to patients who underwent blood testing that demonstrated that they were not having a serious adverse reaction. However, starting in the early 1990s, this philosophy started to change, as the FDA began to take a more active role in post-marketing surveillance and began instituting a more aggressive "management" process to assure greater safety in the use of marketed drugs. No longer do the manufacturer and FDA provide passive oversight and labeling changes to control risks, now the manufacturer must actively monitor for suspected, but unquantified risks and actively manage and minimize known risks.

PRECURSOR HISTORY

FDA's new concepts for risk management amount to a "cultural shift" in the logic of drug approval and the FDA's role. The key events that led to this change can be traced to a series of reports that highlighted the need for improved medical safety. In 1999, the Institute of Medicine (IOM) released a report entitled, "To Err is Human."[5] This report reviewed the nature and cause of medication errors, estimating that up to 98,000 people died each year due to these errors. In their assessment the IOM included both adverse drug reactions and human errors in drug administration. The report captured the attention of news reporters and the government. Headlines proclaimed alarm at the larger number of fatalities caused by medical errors. Consequently, there was a government-wide initiative started to develop methods and institute procedures to reduce medical errors.

For its part, the FDA was already concerned about medical safety and sought to increase its oversight and control of the safe use of marketed drugs. The IOM report provided impetus and support for an already developing policy of increasingly active intervention. During the 4-year period from 1998 to 2001, at least 10 drugs were withdrawn from the market (Table 118-1). For each preceding 5-year period from 1979 to 1998, on the average only two to four drugs were withdrawn.

Statements made by FDA officials regarding some of these withdrawals suggested that the FDA no longer believed that passive oversight and re-labeling drugs with new warnings was sufficient. Furthermore, the FDA no longer believed that it was sufficient to identify safe conditions of use in the label and that healthcare professionals and patients had to comply with advocated directions of use for the drug to remain on the market.

As a summary of this new philosophy of risk management, the FDA staff issued a report to the Commissioner that highlighted processes for developing risk management systems and signaled new ideas for measuring and intervening to manage risks.[6] (US FDA, 1999). Entitled, "Managing the Risks of Medical Products," the FDA report borrowed heavily from risk management philosophies in other fields, such as environmental risk management and airline safety. It emphasized the process of developing risk management plans to control and manage drug safety.

The risk management "revolution" at the FDA continues today. Under FDA regulations and the Food and Drug Administration's Modernization Act, the FDA may approve new drugs with new restrictions that are intended to assure safe use (Subpart H). These restrictions include limiting distribution to certain facilities or physicians with special training or experience or limiting distribution based on the condition of the performance of specified medical procedures. The regulations specify that the limitations must be commensurate with the specific safety concerns presented by the product. In addition, drugs continue to be approved with restrictions imposed by manufacturers seeking FDA approval.

As discussed below, in March 2003, the FDA released a series of "draft concept papers" focusing on premarketing risk assessment, risk management and pharmacovigilance. After reviewing comments on the concept papers, in May 2004, FDA released a series of Guidances for industry. The risk management guidance contained several revisions that addressed concerns from industry. The draft guidance stated that for certain drugs that pose risk management concerns, there must be a

Table 118-1. Drugs Withdrawn from 1998 to 2001

DRUG	DATE WITHDRAWN
Seldane (terfenadine)	2/98
Posicor (mibefradil)	6/98
Duract (bromphenac)	6/98
Hismanal (astemizole)	6/99
Roxar (grepafloxacin)	11/99
Propulsid (cisapride)	3/00
Rezulin (troglitazone)	3/00
Lotronex (alosetron HCl)	8/00
Raplon (rapacuronium)	3/01
Baycol (cerivaxtatin)	8/01

Risk Minimization Action Plan (Risk MAP) that describes what risks are faces and how they will be handled. The plan must identify a series of "tools" or interventions used to control risk. These tools include a series of informational interventions (to health care providers, patients, or the public) and distribution controls that specific conditions or populations of patient or providers that limit the prescribing or dispensing of the medication. The tools must be pretested, and the plan must be evaluated periodically.

THE FOUR PILLARS OF RISK MANAGEMENT

With the release of the risk management draft guidance the FDA has come to the conclusion that it is necessary to fully consider the risk management process for certain products considered for approval and for continuous marketing. The authors will categorize this process into four key elements: (1) Risk Assessment, (2) Risk Quantification, (3) Development and Implementation of Risk Management Tools (eg, Risk Communication and Distribution and Behavioral Control Systems), and (4) Evaluation of the Effectiveness of these tools and the implementation of design modifications, if necessary. In the section following, the authors review each of these elements in depth.

Risk Assessment

Before even beginning development on a risk management program, it is necessary to understand the nature and magnitude of risks associated with a therapy. Thus, the first part of any risk management program is good risk assessment. The initial step is often referred to as *signal detection*. This means that an analyst must sift through the vast number of real or potential adverse events that can occur to individuals receiving a drug to identify those likely to be a true consequence of taking the drug. This requires careful review of all the available data from multiple sources, good understanding of the underlying disease processes and consequences, non-clinical (animal studies or *in vitro*) experiments, information from similar products, clinical studies including clinical pharmacology trials, and any post-marketing experience, if available.

Risk assessment should be a continuous, on-going effort throughout drug development and needs to involve individuals from multiple disciplines, eg, clinical research, clinical pharmacology, toxicology, and epidemiology). Non-clinical studies provide information on the pharmacological effects of drug (eg, potential molecular targets other than the one desired, cytochrome P450 metabolism). Animal models are often, but not always, consistent with effects in humans and may demonstrate injury in specific organ systems that will heighten concern over a similar effect in humans. However, there is a need to validate all animal models and evaluate results carefully from these models as they may yield both false negatives and false positives.

Clinical trials constitute the bulk of the information available on the safety and efficacy of a new product prior to launch. Usually, these studies are designed to provide the maximum amount of information in a limited time frame while exposing a limited number of individuals to an investigational product. Because of their short time frame and small sample size, these studies are limited in the amount of information they provide about the safety of a new medicine. Current International Conference on Harmonization (ICH), an international regulatory body, requirements for trials of long-term medications to mandate that studies supporting a new drug application include at least 1500 patients on the new drug with 300–600 exposed for at least 6 months and 100 exposed for 12 months or more. With 1500 patients, it is possible to rule an event rate of 1/500, but many of the more serious adverse events that have been highlighted in recent news reports and product withdrawals occurred at less 1/1000 and some even at less than 1/ 10,000.

Phase I studies provide a metabolic profile of the product as well as adverse event potential in special populations (eg, the elderly, those with renal or hepatic impairment). Phase II / III studies can provide information on moderately common adverse events and perhaps provide a signal for the possibility of some less common, but serious, adverse events. In addition to reported adverse events, their number, frequency, and nature, important information can be obtained from inspection of discontinuations due to adverse events, changes in laboratory results, vital signs or symptoms. Careful analyses of phase IIb/III trials can help identify those at highest risks for harm as well as those patients that will receive the most benefit. This information should be included into the package insert to inform the prescriber of the appropriate use of products. Because of their large size, phase IIIb/IV have the potential to identify less common, but not rare, serious adverse events.

Evaluation of a drug's safety is quite a different process than evaluating its efficacy. As opposed to efficacy endpoints, which are well defined and defined with great care to preserve the level of significance, safety endpoints can take many forms, including some previously unrecognized. Instead of one or a very few number of endpoints, safety considerations, including combinations and varying levels of sensitivity, are infinite. If the nominal significance of efficacy of 0.05 is used as a standard, safety comparisons in clinical trials will always yield a number of significant differences. Determining which associations are causal and which are spurious is not a simple process.

Following drug launch, individual occurrences of adverse events in connection with drug use are reported to either the FDA or the drug manufacturer. This voluntary reporting is an excellent signal generating system and has been responsible for the majority of safety alerts that occur in marketed products.[7] However,there is no denominator associated with these events, as the likelihood of a particular drug-event combination being reported has been shown to vary by the nature of the event, length of time the drug is on the market, the drug's market share, the quality of the surveillance system instituted by of the manufacturer, publicity, new knowledge, secular trends, as well as reporting regulations. Another source of difficulty in detecting a possible source of concern is that what is defined as an "event" can be ambiguous. By combining related adverse reaction reporting terms, it is possible to amplify weak safety signals or by separating out individual, but related, reported terms, it is possible to obscure important toxicities. Dividing adverse event terms into sub-terms can divide the same event into many terms, decreasing the magnitude of the signal.

To deal with these confounding effects, spontaneous reports are reviewed on an individual basis for biological/medical plausibility, timing of event in relationship to exposure, possibility of other explanations, and re-challenge and de-challenge effects. Systematic review of large numbers of reports often includes comparing the proportional reporting rates for one drug against the proportional reporting rates of all products.[8] This convention requires generating a proportion or percentage for

each named event or effect compared to total reports for that product and comparing this proportion to a similar proportion developed for all drugs, or specified subset of all drugs.

The FDA maintains an Adverse Event Report System (AERS) of voluntary reports submitted by health care professionals. In addition, all manufacturers are required to submit all domestic adverse drug experiences, whether or not considered drug-related, all serious and unlabeled events from foreign reports and the scientific literature, and all serious, unlabeled events observed in post-marketing studies deemed to be possibly related to the drug under study. The term for this practice of continual monitoring for unwanted, untoward effects of drugs already on the market is pharmacovigilance. Thus, pharmacovigilance refers almost exclusively to analyses of data in spontaneous reporting systems.

Consequently, whether before or after launch of a drug, signal detection rests on careful review, judgment, and experience. Hallmarks of a causal relationship are appropriate time order, consistency, specificity, strength of the association, as well as coherence or medical plausibility.[9]

Risk Quantification

Risk assessment also implies that there is a need to confirm the association between the event and drug exposure and to estimate the magnitude of the risk. These next steps involve an entirely different set of activities and processes. This quantitative exercise can only occur after a signal has been identified, and there is a clear definition of the suspected event. Like measures of efficacy, quantitative estimates of association between a drug and an event requires formal study and analyses. Pharmacoepidemiology is defined as the study of the utilization and effects of drugs in the population at large and usually provides the scientific processes necessary to accurately estimate the probability of these adverse effects (as well as beneficial effects) in the population.

For relatively common events, clinical trials provide a rich source of data with the advantage of an obvious and comparable control group, known exposure, and consistent information on disease severity and co-morbid conditions. Phase IIIb or IV studies, which often are much larger than phase IIb and III studies, can be designed to capture specific information on the event in question. In addition, large, simple studies can be fielded to evaluate the occurrence of a single or very small number of events in a very large number of patients (ie, tens of thousands). However, it is necessary to adequately and accurately "frame the question" (ie, design the study to meet specific objectives) for these or any study looking at a specific association. In randomized studies conducted after the product is on the market, decisions on control or comparison group may be difficult due to ethical or logistical considerations.

One of the most useful developments over the past 20 years has been the advent of computerized billing and payment. These administrative records leave a paper trail of the occurrence of specific events that can be analyzed to provide insights into specific exposure–event relationships. Whether in private insurance, Medicaid or Medicare plans, records of specific prescriptions and specific events can be linked for the same individual. Comparing event rates in those exposed to specific drugs with a similar group not exposed provides evidence for a causal link between drug and adverse event. Because of their vast size, accessibility, and collection of information unbiased by the relationship in question, administrative databases provide the source for the majority of pharmacoepidemiology studies on the risks and benefits of drugs. However, there are other forms of studies, such as a prospective documentation of drug exposure and follow-up for adverse events (ie, often seen in registries) and a case-control methodology that selects patients on the occurrence or non-occurrence of an event and then either searches a database for record of specific drug exposure or queries the individual or surrogate for exposure.

Patient registries are one of the most confusing topics in the realm of risk management as the term is used in many different ways. A registry is merely a group of individuals assembled (and, generally, followed over time) with some common attribute. Common registries are for individuals with specific diseases or specific "exposures," for example, taking a drug. What makes analysis of registries complicated is that often there is no obvious control or comparison group. If the registry is formed because of exposure to a particular drug, there is usually no corresponding cohort of similar individuals unexposed, first, because of the expense in forming and following a cohort may make it extremely costly to create a comparison group (such as a no treatment control group) and, second, even if such a group were formed, it may not provide unbiased data because registries differ from trials in that there is no randomization. People who refuse to take a medicine may be quite different in many ways to people who do. Comparing these two groups may produce "non-equivalent" comparisons where differences among the groups are due to a variety of factors unrelated to the drug in question. For example, patients or their physicians can choose to continue with a drug or switch to another. Likewise those who do not take the drug at the time of initiation of a registry may do so at a later date. On the other hand, a registry offers the advantage of providing prospective and established data for a specific purpose. The desired and necessary information is collected from all members of the cohort with a specific purpose rather than relying on the medical system to collect appropriate information in a consistent manner.

Registries can provide information on the occurrence of specific events, but often lack the ability of generalizing this information to a broader group of patients or groups. Further, many patients may differ in a significant fashion from those that participate in a registry. Information on the absolute risk can be estimated, but the risk differences or risks relative to an unexposed group are difficult to estimate.

Because of the relatively few ways the biologic organism can respond to insults, most drug adverse events fall into a relatively small number of categories.[10] Thus, when patients are taking a number of different medications, it may be very difficult to assign suspicion to one particular product. Also, these events do occur in the absence of exposure to any drug.[11,12] Understanding the background rate of specific events, especially the background rate in patients with specific disease states, is essential for assessing the contribution of drugs to these events. Thus, most analyses provide information on the statistical patient. For example, patients taking statins are more likely to experience liver test elevations than those not on these drugs. But, it is actually difficult to attribute an abnormal test result in an identified patient to their specific use of a statin.

Rigorous risk management plans and post-marketing surveillance can help products in a number of ways. They can dispel suspicion of an association. For example, at the time of the launch of lovastatin, there was concern that it may be associated with lens opacities. This concern arose from a study in dogs. A number of other products had produced a spurious signal in dogs, but this particular result was accompanied by an increased reporting of opacities in a human study population. The results of the latter were confounded by the fact that the report from the dog study occurred between baseline and follow-up lens examinations. The concern raised by the animal study resulted in more intense examination at follow-up and greater reporting of opacities. However, large, carefully designed follow-up studies revealed no increase in opacities with lovastatin.[13,14] Consequently, this resulted in the removal from the package insert of the need to perform slit lamp examination on individuals prescribed lovastatin.

At times, medical and biologic understanding will lag behind application and adverse events will not be reported because they are not believed to have any association with the product. For example, there were little or no reports of renal adverse

events for indomethacin during the first 10 years it was on the market. Only with the increased understanding of a relationship between non-steroidal anti-inflammatory drugs (NSAIDs) and prostaglandin synthesis and prostaglandin and renal function was there recognition that NSAIDs may indeed have an adverse effect on the renal system.[15] Today, there is a clear acceptance that NSAIDs can produce renal failure in a small minority of patients.[16,17]

Because of the need for benefits to exceed the risks with specific products, those products that may most require a comprehensive risk management program are those for treating individuals with non-life-threatening conditions. Of the 16 drugs withdrawn from the market between 1975 and 2000,[18] 10 were for symptomatic or preventive therapies (one for psoriasis, two anti-hypertensive, four NSAID, two antihistamine, one acid/peptic disorders). The remaining six were antibiotics (two) and one each for treatments for congestive heart failure, arrhythmia, depression and type 2 diabetes. In 1997, dexfenfluramine (Redux) made the headlines and caused a major pharmaceutical company to suffer huge losses. This product was indicated for obesity, but a sizeable number of those prescribed the drug were less than 20% overweight and at a much lower risk for major health problems associated with obesity. The fact that the majority of those taking dexfenfluramine were not expected to have a major health impact as a result of their condition meant that the belatedly discovered effect of the drug on heart valves was unacceptable.[19]

No drug is absolutely safe. Relative safety means benefits exceed risks for a defined population and use. Relative benefits and risks differ depending on patient characteristics. Thus, positive benefits *versus* risks may not apply to off-label use. Risks are often classified as pharmacological, that is, those that are the result of the pharmacologic properties of the drug, or idiosyncratic, ie, the mechanism of event is not understood or may result because of some characteristic of the individual.

Risk Communication

It is not enough to learn about risks and quantify their occurrence. One must communicate that information to health care professionals and patients. If the communication is successful, people will become aware of the risk and modify their behavior to avoid safety hazards. Without such communication, there is no hope that patients will change their behavior. The challenge of risk communication is to make people aware of risk issues and to develop messages and select communication channels that will lead to behavior change or adaptation, and the maintenance of those protective behaviors that will avoid adverse safety outcomes continuously.

Risk communication may be conceptualized at a *macro* and a *micro* level. On the macro level, companies must develop a risk communications plan targeted to induce and maintain safe use behaviors. For example, if a drug can be abused/misused, the risk communication plan must convince the individual not to abuse the medication or if the drug may dangerously interact with another medication, the company must develop a communication plan to assure that the patient knows which drugs to avoid. These communications must make people aware of risks. These must also help people understand and identify the conditions that must be avoided. They must persuade people that they are personally susceptible to these dangers. They must convince people of the importance of adopting risk avoidance behaviors. Often, multiple communications (or multiple exposures to the same communication) are necessary to "break through the clutter" of other communications and provide a memorable and convincing message.

The physician and pharmacist have a critical role in this process. They provide the first line of communication for the safe use of drugs. Oral communication is credible, memorable, and may be phrased in an understandable and convincing manner tailored to each individual patient. Written communication is also necessary. Written communication is needed to educate and to remind health professionals of the importance of counseling. Written communication is also important to reinforce the counseling messages of physicians and pharmacists.

In recent years there are several forms of communications developed for patients (often referred to as patient information tools). Many of these tools have slightly different roles in the communications process. Table 118-2 describes some of these tools as well as their distribution method and their purpose. Often, various combinations of these tools are used to reinforce and stimulate conditions necessary for behavioral compliance. For example, some drugs that require medication guides also require the use of wallet cards, patient agreements, informed consent, brochures and/or videos.

The design of a risk communications plan should be based on accomplishing a specific set of goals and objectives. The number, type, and timing of risk communications interventions should be based on a theoretical model of successful communications as well as practical advice gained from understanding the audience for the communications (eg, current beliefs, barriers and facilitators of communications, the skills needed to undertake and maintain behavioral compliance, sub-cultural variations in perceiving and understanding risks, situational constraints in displaying desired behaviors). When developing a risk minimization plan, the FDA requests that companies specify the goals and objectives of the plan and to select and justify the choice of tools. The justification may be based on research supporting the effectiveness of the tool or it may be based on some logic or external (audience) statement of support for the tool.

On a micro level, the individual tools must be designed to accomplish the desired communication goals. To develop risk communication tools, it is essential that there is a clear set of communication objectives (COs). These communication objectives must be enumerated explicitly to assure that the tool is focused on achieving the most important goals. The COs also serve as the basis for evaluation of the tool's impact.

Once the COs are set, the document (or script) is written. There are important document design principles to be followed. Clearly, the documents must be presented in a simple and understandable format. Clear writing principles must be followed such as use of short sentences, avoidance of complex terminol-

Table 118-2. Patient Communications Forms Designed for Risk Communication

FORM (TOOLS)	DISTRIBUTION	PURPOSE
Brochure	Physician	General education (knowledge)
Patient package insert	Package or pharmacist	Risk communication
Medication guide	Package	Risk communication and methods of avoidance
Informed consent	Physician	Acknowledgement of risks
Warning stickers	Package	Risk "signal"
Wallet card	Starter kit	Reminder
Stickers for medication vial	Pharmacist on medication vial	Reminder
Patient agreement or contract	Physician	Behavioral commitment
Decision aid	Physician	Choice of therapy
Video tape or CD	Physician or starter kit	Persuasion or choice of therapy
Recurring interventions (telephone calls)	Telephone	Behavioral maintenance

ogy and emphasizing the most important messages with formatting and graphics. However, the presentation must not be so simplified that the important messages are lost. Further, the information presented must be sufficient to provide the reader with an understanding of what are the meaningful risks, why such risks are significant and how they may be avoided. Human factors psychologists advocate that a complete warning message must contain a clear "signal word" (eg, "warning" or "attention"), it must explicitly cite the risk involved (eg, the drug may cause birth defects), how to avoid the risk (eg, to avoid use if pregnant) and a rationale for the risk to convince readers of the significance of the problem (eg, informing readers that the drug crosses the placental barrier).[20]

To assure that the designed communication delivers the intended messages as defined by the COs, it is important to pretest communications. Qualitative tests (ie, one-on-one interviews) are often used to help formulate question wording and pretest initial questionnaire designs. More formal quantitative comprehension tests use individuals in the target population (ie, consumers in the target market or actual patients). Respondents are asked to read the test materials and answer questions (ie, based on the COs) to test their understanding, interpretation, decision-making, and beliefs about the medication and the material tested. Questions that demonstrate a lack of understanding may lead to design changes in the test materials. However, other considerations, such as the amount and complexity of the materials presented and the nature of the questions themselves must be taken into consideration to determine the meaning of various test scores. Once designed, justified, and tested, the risk communication tools can be produced and distributed in various forms. Eventually, they must be delivered to and read by the intended audience for them to have any impact. According to the FDA's concept paper, the nature of the impact of these tools in the "real world" must be tested (note *Evaluation* below).

DISTRIBUTION AND BEHAVIORAL CONTROL SYSTEMS

Whereas much of what one hopes to accomplish in managing pharmaceutical risks may be realized through carefully designed communications, information dissemination may not be sufficient to lead to behavior change. Often, information is viewed as a "weak intervention." For information to have an impact it must be received, read, understood, motivational, persuasive, remembered and implemented for behavior change to be effective. Furthermore, longer term behavior maintenance means that information must be effective over the long term, often for many years. While voluntary adaptations are viewed as the most positive method of influencing health behavior, it may also be necessary to institute distribution or behavioral control systems that influence risk avoidance behavior.

A distribution system is necessary for a drug to be delivered to the patient. For all prescription drugs, it is necessary for the physician to order a prescription (eg, in writing or verbally) and a pharmacist to dispense the drug. Certain drugs, such as scheduled medicines, also require limits on refills and additional record keeping. For certain risk minimization programs, there have been additional controls developed to minimize "risky" behaviors. For example, for Clozeril (clozapine),where certain blood disorders may resulted from taking the drug, patients are required to submit to monthly blood tests that demonstrate the drug is not having an undesirable effect. This "no blood, no drug" policy has minimized the impact of these problems and permitted a helpful drug to remain on the market. Another example of a distribution control system is the use of a verification sticker program. These are used for certain acne drugs, most notably, Accutane (ie, isotretinoin). In this instance, the drug may have important adverse consequences (eg, causing birth defects if taken during pregnancy). A woman taking Accutane must, therefore, have a monthly pregnancy test to demonstrate that she is not pregnant, and the physician must date and affix a sticker to the prescription (no refills are permitted) that communicates to the pharmacist that the woman is not pregnant. The pharmacist may only dispense the medication if the sticker is attached to the prescription and appropriately dated within 7 days of dispensing.

Other distribution control systems, such as obtaining a prescription for the medication only from a physician who has been certified to prescribe the medicine or providing medication only to a patient who has been certified to receive the prescription have been suggested or implemented by various companies. The logic underpinning such designs is derived from "systems theory," which has been used by various industries (eg, the aircraft industry) to design "safety" into the "systems" used.

Systems theory relies on a number of "design" elements to force an individual to behave in a prescribed fashion. According to systems theory, any activity may be conceived as a "system" that requires actions to occur for the activity to be accomplished. For example, the issuance of a prescription requires the doctor to diagnose an illness (or prescribe a drug to prevent an illness), to choose the medication (along with dosage and directions), to provide the prescription to a patient (or surrogate). Upon delivery to the pharmacy the review and checking of the prescription by pharmacy staff must take place, the retrieval of the medication from storage occurs, the counting of tablets, the labeling of the vial, the temporary storage of the prescription and the dispensing of the prescription to the patient (or surrogate) must take place. There may (and should) be additional stages in this model, such as counseling of patients by physicians and pharmacists, information collection and retrieval, administrative activities for reimbursement and compliance with various laws and regulations and additional risk management activities). However, even this simplified "system" requires many different activities, and mistakes may occur at several different points. To prevent such errors, various procedures may be instituted and controls or design changes implemented. For example, to prevent taking the wrong bottle off the shelve, color-coded bottles may be used or bar codes utilized that necessitate being checked or the institute may implement a mandatory check list of actions to prevent dispensing the wrong medication.

There are a number of "forcing functions" (ie, design features that build in safety) such as having drug names be of a certain font size or that constitute a certain percentage of the front display panel and multiple redundancies (eg, having the drug name on multiple places on the bottle of medicine) that help design safety. At the heart of systems theory is the logic that such procedures must be followed every time an activity is undertaken, or the resulting action cannot take place.

FDA AND THE RISK MANAGEMENT PROGRAM (RMP)

As discussed previously, once the FDA guidance is finalized, certain new drug applications will require a Risk MAP. The purpose of this program will be to propose, design, implement and evaluate a number of interventions intended to minimize the risks of using the drug. In similar fashion to a clinical development program, the Risk MAP will have a defined set of goals and objectives, developed specifically for the drug in question. It is anticipated that this will occur by the end of 2004.

Each Risk MAP must specify the overall goals of the program, (eg, specifying that no pregnant woman be prescribed a specific drug). For each goal, one or more objectives should be specified. These are intermediate steps necessary for achieving the overall goal, for example, specifying that all physicians must fully inform women patients about the risks of taking a drug if pregnant. Finally, a number of tools or interventions must be specified that will aid in obtaining the specified goals and objectives, for example, specifying that there will be a brochure and a video drafted for physicians to distribute to patients. Each of these tools should be justified and pretested to help assure that they will achieve their intended purpose(s).

Evaluation of the Effectiveness of These Tools

One of the important contributions of the FDA draft guidance on risk management was the proposal to evaluate fully the impact of the entire risk minimization program and the impact of the individual tools intended to control risks.

Three types of evaluations are possible. First, individual tools may be pretested as part of the development process. For example, comprehension tests, as discussed previously, may be used to help design impactful communications. Second, a series of interventions may be instituted in a field test (ie, likely, a phase IIIB study). This study may be in the form of a clinical trial where various distribution sites are randomized to deliver various combinations of interventions. By comparing outcomes among sites, the impact of various interventions may be judged. However, care must be taken to assure sufficient power to determine differences among sites and avoiding confounding sites with intervention biases.

Third, the FDA proposed that all Risk MAPs be evaluated fully once implemented. The FDA suggested the use of two different measures of Risk MAP impact and the use of well-defined and validated measures. Based on the evaluation of the Risk MAP, there is a consequent obligation to modify or increase interventions, if not successful. However, few of the interventions implemented in the past to reduce the risks of a drug have been rigorously evaluated. Too often, those that have been evaluated have demonstrated that for all their good intentions, the effect was less than desired. For example, package insert requirements for liver enzyme monitoring are not well followed, even in the face of major media coverage of the risks of hepatic failure.[21] Risk minimization programs must eventually be able to show that they decrease or mitigate the likelihood of adverse events.

Ideally, intervention effectiveness should be evaluated based on ability to decrease actual health outcomes (eg, cases of jaundice, liver disease, and / or liver failures). Often, however, this is impractical, and it may be necessary to monitor surrogates (eg, increases in ALT/AST levels) or process measures (eg, frequency of testing for liver enzyme elevations) or even the comprehension, knowledge, and attitude among patients, prescribers, and pharmacists about the risks and consequences. For outcomes and process measures, the same tools that allow the estimation of risk can be used to estimate the change in risk under a given set of risk management interventions.

The term *registry* often throws terror into the heart of a pharmaceutical marketing director. A very strict risk management program can require all individuals receiving the drug to be followed for appropriateness of treatment and monitoring and/or specific outcomes under conditions of a registry. However, more broadly, the use of a registry provides information on a sample of individuals receiving the medication in question. This sample of individuals can be followed for specific monitoring and/or outcomes such as compliance with laboratory monitoring and/or the effectiveness of that monitoring in preventing one or more clinical adverse events.

In this instance, the criteria for entering the registry is exposure to a particular drug. Although one may wish to recruit all such individuals exposed into the registry, while in all likelihood, one will only be able to recruit a percentage of those individuals. Thus, more commonly, a registry is composed of a sample of willing individuals who have received the drug or have the underlying disease for which the drug may be prescribed.

The same type of observational studies used in assessment of the magnitude of risks, can (and should) be used to monitor the effectiveness of specific interventions. Administrative databases can be used to answer routine queries on the occurrence of contraindicated co-prescribing or overdosing, appropriate monitoring, and associations between prescribing of selected drugs and specific events. Note that such associations do not imply causality. Identical to the analyses for estimating magnitude of risk, analyses should be conducted to estimate the risk under the management program(s). When it is not clear which invention(s) would be most effective, it may be worthwhile to use an experimental design comparing different interventions.

Regardless of evaluation study, interventions need to be assessed on their effectiveness of preventing serious adverse events and on the basis of their cost and burden on the health care system. Too rigorous an intervention may result in many additional visits, tests, and other forms of monitoring. This, in turn, may result is increased mistakes due to increased tasks. Increased costs may make the new therapy of less value than other, less effective therapies and/or raise patient privacy concerns. Other possible decreased benefits that follow from risk management interventions that are too stringent may be decreased patient compliance and decreased drug access to patients that would benefit.

CONCLUSION AND SUMMARY

Risk management is a new and evolving discipline. It is difficult to argue that drugs should be provided to patients in a manner that minimizes potential hazards. The FDA has advanced the public health by fostering greater attention over the discovery, quantification, and management of risks. However, any policy that results in new activities to control one set of hazards may result in creating new, unexpected, hazards. Thus, continuing to evaluate the hazards of drugs and the interventions intended to control these hazards, is essential to assure that the benefits of a Risk Minimization Program will, itself, outweigh its risks.

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CHAPTER 119

Integrated Health Care Delivery Systems

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BACKGROUND

The changing forces responsible for driving the integration of health care systems has led to considerable confusion about integrated health systems (also known as organized health systems), their functions, structure, and processes. In 1996, Shortell et al defined an integrated health system as "a network of organizations that provides or arranges to provide a coordinated continuum of services to a defined population and is willing to be held clinically and fiscally accountable for the outcomes and health status of the population serviced."[1] This definition was stimulated by the belief that the movement toward global capitation and provider-owned health plans would continue to grow. Because, in some cases, there has been movement away from global capitation and provider-owned health plans, Coddington et al defined integrated health systems as those which "provide a comprehensive spectrum of high quality, well-coordinated health care services on a cost-effective basis to residents of its service area.[2] To accomplish this, physicians and hospitals and other health care providers work together for the benefit of the customers. The medical care provided will be enhanced by a commitment to education and research." Although integrated systems in existence today vary widely in their composition, many are comprised of a parent corporation that manages several dissimilar subsidiaries such as hospitals, medical groups, specialty clinics, health plans, home health services, and ambulatory pharmacies as well as components dedicated to improving care through research and education. Systems such as these types are referred to as "vertically integrated" and were formed with the goals of providing high quality, low cost care to populations of patients in broad geographic areas, eliminating duplication of services, and providing care across the continuum (referred to as "seamless" health care).

The impetus for the formation of today's integrated health systems can be traced back to the 1970s when Certificate of Need laws and inpatient care cost ceilings were introduced with the intent of restraining uncontrolled growth in the number of inpatient hospitals beds and resultant increases in health care spending. This led to more care being provided in the outpatient environment as hospitals partnered with private practice physicians in areas such as ambulatory surgery and other outpatient treatment centers to maintain financial viability. In 1982, Diagnosis Related Groups were introduced which resulted in further decreases in hospital census by limiting reimbursement to standard lengths of stay for each condition. To maintain profitability, hospitals sought to capitalize on economies of scale, to increase their patient base, and to leverage purchasing opportunities. Also, in response to inflation in health care spending, the mid-1980s witnessed an increase in the number of patients covered under managed care contracts.

Through the mid-1990s further movement toward integration was driven by several factors.[2] These included a perceived shortage of primary care physicians, the potential for health care reform under the Clinton administration, the perceived need to provide broad geographic coverage, and the desire to offer "single signature contracting" that allows alignment of financial incentives among physicians and hospitals. In addition, it was believed that health plans would not contract with individual physicians or small groups. Larger organized groups capable of capitalizing on the economies of scale and of accepting financial risks for the population developed as "global capitation" was believed to be the future trend. It therefore made sense for physicians and hospitals to work together to compete for dollars awarded on a "per member per month" basis.

Beginning about 1995, forces driving integration of health systems began to change.[2] It became clear that many medical groups and hospitals were not capable of assuming financial risk as evidenced by many large integrated systems experiencing significant financial short falls. Also, declining provider and consumer sentiments regarding managed care and the consumer's desire for increased freedom of choice began to favor larger numbers of specialists or specialty groups, putting organized systems with an emphasis on primary care at a disadvantage. Large integrated systems began to struggle with the complexity of the infrastructure required to manage systems that include such dissimilar entities such as medical groups, hospitals and health plans. Competing interests coupled with the significant challenge and time required to develop successful corporate culture made it difficult for these systems to survive. It is increasingly recognized that discretionary consumer spending on "quality of life" services such as cosmetic surgery, laser eye surgery, complimentary and alternative medicine, infertility treatment, and hearing aids is increasing; integrated systems with a primary care focus may have not have been positioned to meet this demand.

The changing environment of health care has led many integrated systems to re-evaluate their priorities.[2] Current drivers favoring the continued integration of health care systems have been identified. The concept of seamless care continues to be important as consumers appreciate "one stop shopping" where health care is coordinated. Economies of scale, where clinical and administrative services are combined continue to drive integration as well as the ability of integrated systems to provide care to broad geographic areas. This is especially true when integrated systems offer outreach programs to patients in rural areas where such services would not be available otherwise. Improved access to service for patients

needs to be addressed, with the goal being to shorten the time required to get an appointment. A strong regional or national brand name is important in attracting patients and providers alike, and the ability to be recognized for continuous quality improvement has received attention as much focus has been trained on the ability of organizations to provide safe, error-free care. Another factor favoring large integrated systems is that these systems are large enough to have the financial capability to develop information technologies that allow information sharing and automation across the organization. One recent major shift in priority of many integrated health systems is the divestiture of their health plan and a shift toward payer neutral strategies, as it is believed that consumers will play a larger role in selecting their health plans and providers in the future. Although the drivers favoring the integration have changed in recent years, there is still strong rationale favoring an integrated approach to delivering health care.

PHARMACY SERVICES—In a fully integrated system, the pharmacists all work for the same corporation, with the same mission to provide quality, cost-efficient care across the continuum. Ideally, the patient's medical record is available to all caregivers within an integrated system. Pharmacists are then able to assure that the patient's pharmacotherapy plan follows them from the inpatient to the outpatient arena and vice-versa. This gives the integrated health system pharmacist the ability to play a role in the development of care plans in the hospital that will be carried out in the ambulatory arena by another pharmacist who will continue to provide care for the patient. Likewise, information on the patient's pharmacotherapy plan and educational needs that have been assessed and documented by pharmacists working in specialty clinic settings, such as anticoagulation clinics, can be provided by inpatient pharmacists when necessary. This working arrangement allows pharmacists to shift their attention to assuring appropriate pharmacotherapy outcomes from the use of medications as opposed to the traditional focus on drug dispensing and drug price control.

Pharmacists are important leaders in formulary development in integrated systems, as their knowledge and experience in therapeutics and pharmacoeconomics add value to formulary decision-making, development of disease management guidelines, and evaluation of pharmacotherapy outcomes for the system. Formularies and disease management guidelines are not limited to drugs needed for inpatient care, but expand to include agents needed in the outpatient and home-care setting.

An integrated health care system uses the economies of scale to secure contract pricing on pharmaceutical purchases. Because of the structure of an integrated system, just-in-time delivery can be used to provide drugs to the numerous locations where care is provided. This decreases inventory and stocking costs to the system. In this situation, it is essential for the pharmacists to review medication orders and manage the drug use process. The focus of the pharmacist in the integrated system moves from the traditional dispensing activities to the provision of pharmaceutical care.

The pharmacy services in an integrated system may be organized into an assortment of reporting structures. The structure of the Group Health Cooperative of Puget Sound has been described as a matrix. In this integrated system, the pharmacists in the clinics and hospitals report directly to the managers of the facility. There is a matrix relationship between these manager pharmacists and the director of pharmacy administration. In this arrangement the pharmacy administration provides support services, including purchasing and contracting, information system support, development of policies and procedures, support for Pharmacy & Therapeutics Committee activities, long-range planning, and overall support of operations.[3] In the Henry Ford Health System, the pharmacy director of each hospital reports to hospital administration. All ambulatory services are brought together as a product line under the Community Care Services business unit of the system. While the pharmacists in the system are all supportive of the continuum of care, there is no corporate organizational structure supporting the various pharmacy services. The pharmacy directors and managers from the system hospitals, Ambulatory Pharmacy Product Line, and health maintenance organization (HMO) have taken it upon themselves to meet monthly to discuss clinical and operational issues that concern pharmacy services for all patients of the system. It is their goal to support pharmacists as providers of cost-efficient pharmaceutical care and to ensure that optimal patient outcomes are achieved in the integrated system if pharmacists are to continue to play a role in the delivery of health care.

PATIENT-SPECIFIC CARE

Primary Care

Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with the patient, and practicing in the context of family and community.[4] Primary care is the point-of-entry of patient into the health system, where continuity of care is provided over a period of time, and care is comprehensive (medical specialties, nutrition, social) and highly personalized. As such, primary-care practice generally is devoted to internal medicine, family practice, and pediatrics.

Ambulatory care refers more broadly to care that can be delivered in very specific or more general clinic environments and includes emergency rooms and specialty and subspecialty clinics. Primary care serves an important *gatekeeper* role for the health system. The Primary Care team, composed of doctors, nurses, pharmacists, and other health professionals, identifies and manages the patients' health and wellness, intervening to remedy acute illnesses as they occur and referring the patient to more-specialized practitioners or services when needed. As such, the Primary Care team regulates and controls access of the patient to more-specialized health services within the system.

The role of pharmacists has evolved in outpatient environments within integrated health systems. Initially, pharmacists had selective roles within specific clinics, such as anticoagulation or hypertension, which generally developed because of a close working relationship between the physician leadership and the pharmacist. Pharmacists' activities were limited to the therapeutic area of interest of the physician mentor for the clinic. Often, pharmacists started seeing patients with the physician and gradually became recognized by the physician as a capable provider of care. These positions usually were funded through colleges of pharmacy and were limited to pharmacy faculty. The clinics operated as separate functional units, not integrated into the rest of the care of the patient or into the rest of the system of care, for example, the hospital. When outpatient clinics became part of integrated health systems, some traditional models of pharmacist-managed clinics survived. However, the role of pharmacists in primary care clinics in integrated health systems has been expanded to include other activities of focus that meet newly defined patient care or health system needs.

Today, primary-care roles have been chosen deliberately to complement patient-care needs in large, integrated systems. There are several reasons why pharmacist's roles have changed. Health care is now driven by continuous quality improvement. Primary-care clinics are chosen carefully, based on quality-driven analyses to improve the quality of patient care. In 1999, the American Society of Health-System Pharmacists defined minimum practice standards for pharmaceutical services in ambulatory care environments.[5]

HEDIS (Health Plan Employer Data and Information Set) was developed by the National Committee for Quality Assurance (NCQA), an independent, not-for-profit organization dedi-

cated to assessing and reporting on the quality of managed-care plans. The NCQA surveys and accredits managed-care plans much as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits hospitals and home-care agencies. HEDIS incorporates measures related to outcomes or results, as well as the process measures, utilization, and financial data. There are indicators in several domains. Overall outpatient drug use, β-blocker treatment after acute myocardial infarction, appropriate medications for patients with asthma, and antibiotic treatment for children with otitis media are four drug-related indicators. Pharmacists are involved in assimilating overall drug use data and delivering and assessing quality of care delivered to post myocardial infarction, asthma, diabetes, depression, and otitis media patients.

Pharmacists have been identified as one of the important members of the health care team who affect the quality and cost of care.[6] Systems of care, individual patient care, and management of large populations have been improved through pharmacists' involvement. Integrated systems are responsible for the totality of care from birth to death, during wellness and disease, with an emphasis on health wellness and disease prevention. Because of this, pharmacists find themselves in new roles, serving as partners with the patient to encourage the promotion of health and wellness. Table 119-1 compares pharmacist roles in traditional ambulatory-care clinics with those commonly found in integrated health systems.

Quality monitors in place in health systems are designed for continuous assessment of opportunities to improve care of patients across the system. For example, when the Food and Drug Administration (FDA) approved several drug-therapy regimens for the eradication of *Helicobacter pylori* as a cause of peptic ulcer disease, it became clear that health systems, particularly those with managed-care populations, could both improve the quality of care provided and lower the total costs of care by treating patients with antibiotics to eradicate *H. pylori* rather than treating each new ulcer that developed. An appropriate mechanism to identify and treat these patients did not exist. Patients continued to present to their doctors when symptoms of peptic ulcer disease caused them to go to their doctor or emergency room.

Many integrated systems offer *H. pylori* services consisting of teams of nurses and pharmacists, trained to identify patients eligible for treatment from the overall population of patients served by the health system. Identification occurs through the use of large databases on patient characteristics and computerized searches of patient records to identify patients who have had a history of peptic ulcer disease and who may be a candidate to test for the presence of the bacteria. These patients are then called, proactively, into the clinic to be tested for the presence of *H. pylori*. If they are positive, patients are treated with a course of antibiotics and a proton pump inhibitor to eradicate the organism and prevent further recurrence of disease, decline in health, and greater costs associated with acute disease intervention.

The pharmacist-nurse team selects the therapy, usually from a previously developed care plan, algorithm, or care map, and then monitors the patients, interacting with them several times during the course of therapy to ensure compliance and answer any drug- or disease-related questions the patient poses. Patients are followed until their course of therapy is complete, symptoms are resolved, and chronic proton pump inhibitor or histamine-2 antagonist therapy is no longer required. When necessary, reevaluation for the presence of *H. pylori* can occur to determine the possibility of therapeutic failure due to antimicrobial resistance or previously undetected nonadherence to the first eradication regimen.

Pharmacists are participating in smoking cessation programs. Smoking is associated with over $110 billion in annual medical costs in the US. Managed-care systems implement programs to help participating members quit smoking, thereby enhancing their health, decreasing illness risk, and improving quality of life. Pharmacists' roles include identifying patients who may be candidates for nicotine replacement therapy, referring patients with chemical addiction for treatment, teaching patients how to use nicotine patches, lozenges, or gum, and providing realistic expectations about the need for behavioral modification with nicotine replacement products or bupropion (Zyban). Patients are taught to watch for adverse effects in one-on-one contact when the product is dispensed and in-group sessions. As members of the smoking cessation teams, pharmacists work closely with nurses, psychologists, and physicians to monitor patient progress throughout their treatment and for a year following their smoking cessation.

Recently, the role of pharmacists in lipid clinics has been described. Deaths from cardiovascular consequences of hyperlipidemia account for over $100 million annually. While lipid-lowering drugs are being prescribed with increasing frequency, it has been shown that fewer than 50% of treated patients reach and sustain the National Cholesterol Education Program (NCEP) target cholesterol values. There are numerous reports of pharmacist-managed lipid clinics where pharmacists are asked to manage patients on lipid-lowering therapy, educate the patients, adjust doses according to repeat laboratory evaluation, and assess compliance to diet and drug-therapy regimens. While long-term outcome data, such as morbidity and mortality reduction, are not known, improved attainment of cholesterol and triglyceride values has been shown in these disease-specific clinics.

CARE MAPS AND CLINICAL PATHWAYS—Most primary or ambulatory care clinics do not have a specific disease focus. In primary care settings, health care personnel provide more comprehensive care across the complete spectrum of health and disease from birth to death. However, to provide care of this comprehensive magnitude, most integrated health systems have attempted to reduce practice variance by guiding routine diagnosis, intervention, and drug treatment through the use of practice guidelines, clinical pathways, or care maps, coupled with the measurement of achieved outcomes. Reduction in process variance helps to improve the quality of care while decreasing the cost.

In a sense, algorithms, guidelines, and care maps define *best practice* within a range of acceptable choices and allow clinicians to select the patient intervention and monitor the patient's progress through the disease process as guided by the care map's guidelines. Clinical pathways have been referred to in the medical literature by more than 30 different names. Clinical pathways or care maps incorporate goals of treatment based on standards of care, current practice guidelines, scientific evidence, and benchmarking against systems of management used in other health systems.[7]

Table 119-1. Primary Care Roles of Pharmacists

TRADITIONAL PRIMARY CARE ROLES	PRIMARY CARE ROLES IN INTEGRATED HEALTH SYSTEMS
Specific, limited in scope	Broad, integrated into a system of care
Based in a traditional medical specialty	Part of an overall disease management strategy
Chosen by practice interest	Chosen by patient/health system need
Usually single providers of care	Teams of providers delivering care
Monitoring of patients by provider	Measurement of quality and success of service by health system
Unaffected by cost	Driven by value to the patient and health system; quality at lowest cost
Examples: anticoagulation, hypertension,	Examples: smoking cessation, travel, diabetes clinics lipid, *Helicobacter pylori* clinics

Table 119-2. Protocol-Driven Care: Situations Using Care Maps, Algorithms, Guidelines

	REDUCES VARIANCE IN	OUTCOME MEASURES
Primary Care		
Anticoagulation	INR targets Time to therapeutic	Days therapeutic INRs in Range
Asthma	Drug choices Emergency Room visits Monitoring therapy Patient education	FEV1 Readmission rate
Acid peptic disease	Drug choices Diagnosis Cost of therapy Side effects Retreatment	*H Pylori* Eradication Days to pain relief
Acute Care		
Pneumonia	Drug and treatment choices	Time to defervescence
Deep vein thrombosis	Monitoring, dosing	Time to therapeutic APTT/INR, time to ambulation
Myocardial infarction	Thrombolytic protocol Testing Rehabilitation	Time to treatment Length of stay
Tricyclic Overdose	Interventions	Time to recovery

Table 119-2 summarizes examples of situations in which care maps are used as a tool to direct care. Care maps describe pharmacological as well as nonpharmacological therapies, interventions, activities, and outcomes, often throughout the entire course of care (from diagnosis, through admission, and after discharge). They usually are developed for high-cost, high-volume, and/or high-risk diagnoses or procedures. The goals of care maps are to decrease practice variance and, thus, enhance the quality of care, provide continuity of care, decrease care fragmentation (particularly when patient care is handed-off from one service to another), guide the family and patient through expected treatment and progress, optimize cost-effectiveness of health care delivery, and increase satisfaction of patients, families, staff, and physicians.

Importantly, care maps create common expectations and goals previously agreed-upon by the patient and his/her care team. They increase the likelihood that all members of the health care team share responsibility for the care and final outcome of the patient, enhance communication, and promote early problem detection and resolution. Care maps serve as a useful educational tool for new staff and patients.

Care maps generally include specific goals, desired outcomes, and interventions for several domains of care that may include patient education, activity level, discharge planning, medications, nutrition, elimination, diagnostic tests and procedures, and treatments. Table 119-3 depicts standard care map components with example goals, interventions, and documentation strategies shown for deep vein thrombosis (DVT). The goal of the care map is to diagnose, treat and monitor low-risk patients with deep vein thrombosis without hospitalization and to have a rapid, accurate process in place to identify and hospitalize patients with more complex or serious complications of deep vein thrombosis. In both treatment settings, achievement of the desired therapeutic outcome is paramount and assured through a clear delineation of responsibilities and interventions that lead to the desired outcome.

Care maps are developed by a team of individuals who will be involved in the various stages of care of the patient during his or her flow through the process. For the care map depicted in Table 119-3, team members may involve a nurse, pharmacist, physician, social worker, dietitian, and diagnostic radiologist. Each of the team members has responsibility for a component of the care delivered, yet all have shared responsibility for the daily outcomes of interest and the overall treatment outcome. In paperless systems with electronic medical records, team members chart progress electronically; documentation can be performed manually on wall charts.

The care map serves to decrease redundant charting and recording activities and is an easily accessible monitoring and communication tool. At the end of the episode of care, the care map is stored as a permanent part of the medical record.

The role of pharmacists on clinical pathway teams may be as simple as providing consultative advice regarding the drug, intravenous fluids, nutritional products, or their sequencing or as complicated as a day-by-day defined caretaker role of educating the patient and remaining team members about the drug-therapy component of the care map, administering medications, adjusting medication doses, identifying drug-therapy endpoints and monitoring parameters, and performing drug-related monitoring (eg, blood pressure or blood sugar checks). Certain care maps are more conducive to active pharmacist's roles, while others, such as an appendectomy pathway, may leave little need for pharmacist involvement other than the selection and monitoring of analgesic therapy.

DISEASE MANAGEMENT—Disease management deserves mention in primary-care environments, as it is becoming a focal point around which care delivery models of care are developing. To many, disease management is a natural extension of care maps, clinical pathways, and guidelines. Disease management is an evaluative approach to health care delivery that attempts to improve outcomes for patients with a specific disease while optimizing the overall use of health care resources. Outcomes research is a rapidly evolving field that incorporates epidemiology, health services research, health economics, and psychometrics. Measurement of clinical and other outcomes has become important to patients, insurance companies, pharmaceutical companies, and purchasers of health care.

Disease management uses an explicit, systematic, population-based approach to proactively identify patients at risk, intervene with specific programs of care, and measure clinical and other outcomes. The most frequently instituted disease management programs within health systems are for diabetes (83%), asthma (71%), immunization (68%), drug therapy monitoring (58%), hypertension (44%), depression (50%), wellness (36%), anticoagulation management (30%), migraine management (23%), HIV/AIDS (19%), refill clinic (12%), and alternative care (8%). The driving impetus behind disease management programs is reduction of costs, improvement of patient outcomes, improvement of the process of care, and attainment and retention of members.

Candidate diseases for disease management programs are those that consume 80% of the resources and drive up the overall health-system costs. It is estimated that 20% of a selected diseased population is responsible for 80% of the total cost of care for that disease. This concept of 20% of the patients driving 80% of the cost is referred to as the 80-20 rule. The high-use group is the focus of disease management programs that look for opportunities to improve the process of care, education of the patient, drug therapy, and use of expensive resources. The 20% of patients who are high users are often further subdivided to identify the top 5% of patients responsible for 60% of the cost or claims submitted. The top 5% of patients are directed into case management, described in the following section. The remaining high-user patients are managed to obtain the most positive effects on outcomes and cost through innovative monitoring and follow-up.

Disease management tools include guidelines, algorithms, care maps, and a wide variety of patient tools to enhance treatment and drug-therapy adherence. Patients are provided with tools that change behavior, such as participation in support

groups, discounts on health club memberships, access to weight-control programs, and episodic telephone reminder calls to take their medicine and measure the parameter of interest (eg, peak flow for asthma, blood sugar for diabetes).

Selected conditions for disease management programs usually meet several criteria. The total cost of the disease is high; it is prevalent in the population and definable by specific criteria; variation in practice and patient management exists; treatment methods are known, and it is possible to intervene to improve care; and opportunities exist within the system to improve the management of the condition or disease. Once the disease or condition has been selected, preparatory work involves understanding the natural course and cost drivers for the disease, developing guidelines for diagnosis and treatment, modifying patient and physician behavior, and identifying cost-effective care strategies. A measurement system must be in place to determine the effectiveness of implemented strategies and modify approaches for continuous improvement of the management of the condition in question. Figure 119-1 depicts the components of disease management.

In outpatient settings, pharmacists participate in disease management programs through their involvement in patient education, monitoring, and follow-up, as well as by performing tests (eg, blood-pressure monitoring, INR, blood-sugar or cholesterol monitoring). These activities may occur in multidisciplinary clinics or through pharmacies. Even in network pharmacies, technicians are doing more of the dispensing process while the pharmacist's roles are expanding to include reviewing prescriptions, educating patients and other health care workers about drug therapy, and monitoring or enhancing drug-therapy adherence.

Certificate programs are available for pharmacists to provide them with the tools, education, and training necessary to participate effectively in disease management programs. Even without advanced training, pharmacists can participate in disease awareness days and help teach patients about their medications. The National Institutes of Health has defined the pharmacist's role in the management of patients with asthma, in six steps as outlined in Table 119-4.

CASE MANAGEMENT—Case management is a process by which an experienced professional (nurse, doctor, social worker, pharmacist) works with patients, providers, and insurers to coordinate all services deemed necessary to provide the patient with medically appropriate health care. The goals of case management are to provide quality health care while decreasing the cost of providing such care. There are two types of case management: primary-care case management and catastrophic, or high-cost, case management.

In primary-care case management, a physician–care manager, acting as an informed purchaser, coordinates all patient care, referring the patient to specialists or alternative-care providers as needed. This is what has been described previously as primary care. Catastrophic case management usually is conducted by a registered nurse on behalf of the payer. The nurse typically works with the patient, providers, and pharmacists to ensure that care is rendered in a coordinated fashion, according to an established and agreed-upon treatment plan. Candidates for case management are identified through disease management programs or by their primary-care provider and may be patients who fail routine follow-up, who continue to consume an exceptionally high proportion of medical and financial resources, or those for whom the quality of care has been adversely affected by circumstances beyond the management of the routine delivery system.

Case managers often follow patients over the full course of their treatment, which may improve the continuity of care and increase patient compliance with care methods while reducing costs. The financial goals of most case management programs are to keep patients out of the hospital and emergency department by appropriately increasing the ambulatory care support and drug therapy. Thus, outpatient drug costs may increase to decrease other healthcare costs. Case managers involve pharmacists in redesigning drug-therapy regimens to offer equally effective, lower-cost alternatives for patients who consume high resources, for example, generic equivalents rather than branded drugs and first-generation products rather than high-cost new-release and potentially unproven therapeutic alternatives.

Case management, disease management, guidelines, care maps, and other tools of organizing the provision of care have arisen as a result of managed care. Managed care attempts to offer a coordinated approach to the delivery and financing of health care services that balance price restraint and resource management with access to quality health care. Aspects of managed care are prevalent in primary-care settings of large integrated health systems. Even those without his/her own HMO is focused on providing best value to their patients; best value is highest quality at the lowest cost.

DATA REPORTING AND MEASUREMENT—Pharmacists and other health care providers need access to data and information to have an effective impact on care in a population of patients served by a large integrated health system. On a micro-level, individual practitioners can improve the quality of care of their own patients. To evaluate and improve individual patient care, pharmacists need access to the medical record, drug-dispensing records, laboratory results, and diagnostic reports. These are readily available in most systems. On a macro-level, an individual can improve the quality of care in a population of patients. When health systems are responsible for the lives and outcomes of their patients and they assume the financial risk for providing the care to these patients, health care is managed. Managed care requires access to databases that reveal information about the patients, the way that treatments and drugs are used, and their outcomes, so that global decisions about care delivery can be made. Databases generally fall into four major areas: medical claims data, pharmacy claims data, member eligibility data, and provider data.[8] Protection of patient privacy, as required by the Health Insurance Portability and Accountability Act (HIPAA), must be assured whenever health care workers access or utilize patient data. Health systems are required to notify patients of their rights to privacy and document that patients have received notification. HIPAA requirements are discussed more fully in Chapter 111: *Laws Governing Pharmacy*.

A claim is information submitted by a provider (doctor) or a covered person to establish that medical services were provided, from which processing for payment to the provider or covered person is made. Claims databases allow health systems, including managed-care organizations, to generate descriptive statistics on patients, providers, and diseases; to conduct comprehensive cost and resource-use analyses; and to build economic models of diseases.

Health care databases allow pharmacists to examine the effectiveness of a treatment to be assessed and the effects of drug-switching patterns within disease categories to be measured. These data are used to determine the cost and outcome implications of new treatments and formulary changes, as well as for monitoring disease management programs. Data are formatted in rows of transactions each time a service is provided to a patient. The medical claims data may outline claims related to hospitalization, procedures, diagnostic tests, use of medical facilities, and visits to clinics or emergency rooms. The pharmacy claims data outline each prescription date written, date filled, drug, dose, patient information, prescribing physician, ingredient cost, amount paid, and copayment for plans in which the patient pays a portion of the total prescription fee.

Member eligibility data pertain to the patient's enrollment history, benefit plan and code, employer, primary-care provider, and personal data such as address, telephone number, gender, dependents in the household, and social security number.

The provider information includes multiple physician identifiers such as state license numbers, drug enforcement administration (DEA) numbers, and federal tax identification numbers as well as physician demographic information.

Table 119-3. Care Map Template: Deep Vein Thrombosis

Patient Presents with Signs and
Determine risk of complications and

LOW RISK: OUTPATIENT DIAGNOSIS, MANAGEMENT AND TREATMENT				
DOMAIN OF CARE	PRE-ADMISSION	DAY 1	DAY 5 TO GOAL INR	GOAL INR TO END OF TREATMENT
Outcomes	Prepare to send the patient home and arrange follow-up	Confirm diagnosis	Attain therapeutic INR. Swelling and discomfort alleviated.	INRs Q2 week, then monthly
Level of Care	Moderate	Minimal	None	None
Patient Education	Discuss possible diagnosis and OPD management.	Discuss doppler results and duration of LMWH. Dietary and warfarin drug interaction counseling. Training for LMWH self-injection.	Duration of oral anticoagulation.	Reinforce dietary and drug interactions
Activity Level	As tolerated	As tolerated	As tolerated	As tolerated
Discharge Planning	Identify insurance coverage for LMWH and Home Health Care	Confirm that patient has necessary resources for OPD management. Triage to anticoagulation clinic.	None	None
Medications	LMWH admin: _____	Continue LMWH for 5 days or until INR at goal. Administer first dose of warfarin. Time warf: _____	Adjust warfarin dose daily in response to INR. Continue LMWH.	Warfarin to Goal INR
Nutrition	Regular oral diet	Regular oral diet. Counsel food interactions	Regular oral diet. Reinforce food interactions.	Regular oral diet. Reinforce food interactions.
Elimination	Stool softeners ordered as needed.	Normal elimination	Normal elimination	Normal elimination
Diagnostics/ Procedures	Schedule venous doppler for next day (Day 1). Appoint time: _____	Perform doppler. Baseline LFTs, CBC, INR.	INR	INR
Treatments	Recommend leg elevation for next 12–24 hours.	None	None	None

There are many limitations to health care databases. Services not covered by the health plan may be omitted, coding errors can and do occur, and specific information about disease severity is not available, thus requiring chart review or other patient-specific inquiries to evaluate true efficacy. Because of these limitations, many health systems have developed additional, more specific and probing reporting systems to key into areas of focus. A summary of sample pharmacy-related reports for a large integrated health system is outlined in Table 119-5.

The reports in Table 119-5 are reviewed by pharmacists and used to educate prescribers about their drug use. Opportunities are identified to reduce drug costs and increase formulary compliance and quality, using methods referred to as counter detailing. Large databases are useful for describing patient, provider, and disease characteristics and estimating the implications of a change in the formulary; measuring the effects of treatment guidelines; and monitoring disease management programs.

Data and measurement are an important part of the role that pharmacists play in integrated health systems, not only because of access to necessary data, but also because of understanding of the relationships between the data and patient, provider, or health system. Colleagues ask pharmacists to evaluate how drugs are being used and to assist them in interpreting data to identify opportunities to change prescribing guidelines, modify a care map or disease management program, and assess overall compliance with system guidelines.

DOCUMENTATION—"If it isn't documented, it didn't happen." In every role within health systems including primary care, acute care, long-term care, and home care, pharmacists need to document their activities, findings, interventions, and outcomes of interventions. There are regulatory, ethical, and communication-mandated reasons for documentation. Documentation may be as simple as jotting a note to a physician to remind him or her to change the dose of a drug at the patient's next visit or be a formal summary of a drug-therapy plan in a patient's chart. Much documentation is now electronic.

Pharmacy order entry systems allow for free text entry to note specific information regarding a patient or prescription, such as allergy, brand preference, characteristics, or name clarifications. However, most pharmacy order entry systems fall short of facilitating complete documentation of the provision of care or advice to a patient, patient's family, provider, or other health professional. Pharmacy departments often design their own systems to capture the activities and ensure that employee productivity can be measured and strategic decisions about deployment of personnel and development of new services can occur. In fee-for-service environments, documentation systems are used to generate bills for reimbursement of services. Docu-

Symptoms Consistent with DVT
underlying conditions

HIGH RISK: ADMIT FOR DIAGNOSIS, INITIAL MANAGEMENT AND TREATMENT				
PRE-ADMISSION	DAY 1	DAY 2-GOAL INR	DISCHARGE	DISCHARGE TO END OF TREATMENT
Admission, diagnostics, drugs within 1 hr; Time to ER: _____ Time of Admiss: _____	Ambulation; Maintain therapeutic APTT; Initiate warfarin; APTT: ___; Time war:___	Maintain therapeutic APTT until INR therapeutic.	Educated patient at INR goal without DVT symptoms.	Maintain goal INR
High	Moderate	Moderate	None	None
Orientation to the unit and disease process and diagnostics	Drugs and monitoring tests. Teaching done: _____	Reinforce risk of bleeding, frequency of monitoring on warfarin. Post-test score:_____	Reinforce risk of bleeding and anticoagulation clinic process.	Reinforce dietary and drug interactions
Restricted	As tolerated once APTT at goal.	As tolerated	As tolerated	As tolerated
Identify insurance and living environment	Provision for home care as needed. Disposition:_____	Triage to anticoagulation clinic for OPD follow-up.	Plan for discharge medications and family pick-up.	None
I.V. heparin protocol. Target APTT 1.5 – 2.5 x control within 16 hr; Time Heparin: _____	I.V. heparin per protocol. P.O. warfarin per protocol. Goal INR: 2–3	I.V. heparin per protocol. P.O. warfarin per protocol. Goal INR: 2–3	Warfarin Rx written and filled.	Warfarin to goal INR
Regular diet ordered & initiated	Regular oral diet. Counsel food interactions	Regular oral diet. Reinforce food interactions.	Regular oral diet. Reinforce food interactions.	Reinforce dietary and drug interactions
Evaluated and stool softeners ordered as needed	Normal elimination	Normal elimination	Normal elimination	Normal elimination
Venous doppler within 6 hours. Doppler: ___	Monitor for signs of PE; VQ scan or angiogram if indicated	INR	INR	INR
Leg elevated until heparin APTT therapeutic	Upper body exercises	None	None	None

mentation is an important part of every practicing pharmacist's activities. Each of the following aspects should be documented for every intervention:

1. The nature of the pharmacist intervention (eg, prescribing error, prescribing omission, drug-therapy monitoring, or drug interaction);
2. What service the pharmacist performed;
3. The outcome of the intervention; and
4. What drugs were involved in the intervention.

Most pharmacists in primary-care settings are actively identifying, preventing, resolving, and documenting adverse drug reactions. Documentation involves system-specific reporting mechanisms, such as to a quality committee, and then the use of the FDA's MedWatch form for serious adverse drug or device reactions. In particular, the FDA is interested in drugs and devices that have been released within the last 24 months and those associated with therapeutic interchange programs.

Table 119-6 summarizes activities performed by primary-care pharmacists in the US and their frequency, based on type of integrated health system practice. Most of the activities listed in Table 119-6 have been discussed or are covered under *System Supportive Roles for Patient Care*. Academic detailing, or counter detailing, is a common function in managed-care settings of integrated health systems as a means to educate prescribers about system-wide formulary drugs and approved guidelines.

Pharmacists are trained to make appointments with physicians to review new drug guidelines and formulary additions. They emphasize the proper use, dosing, and supportive data, much as a pharmaceutical company representative would for a new drug. More importantly, health system pharmacists discuss drugs that are not on formulary and patterns of drug use that are inconsistent with system guidelines, to seek conformance of practice. Counter detailing, used in conjunction with prescribers' profiles or report cards, are effective methods to drive drug use toward system-chosen options.

Acute Care

The term *acute care* embraces the hospitalization phase of health and disease. It represents a very short time and small

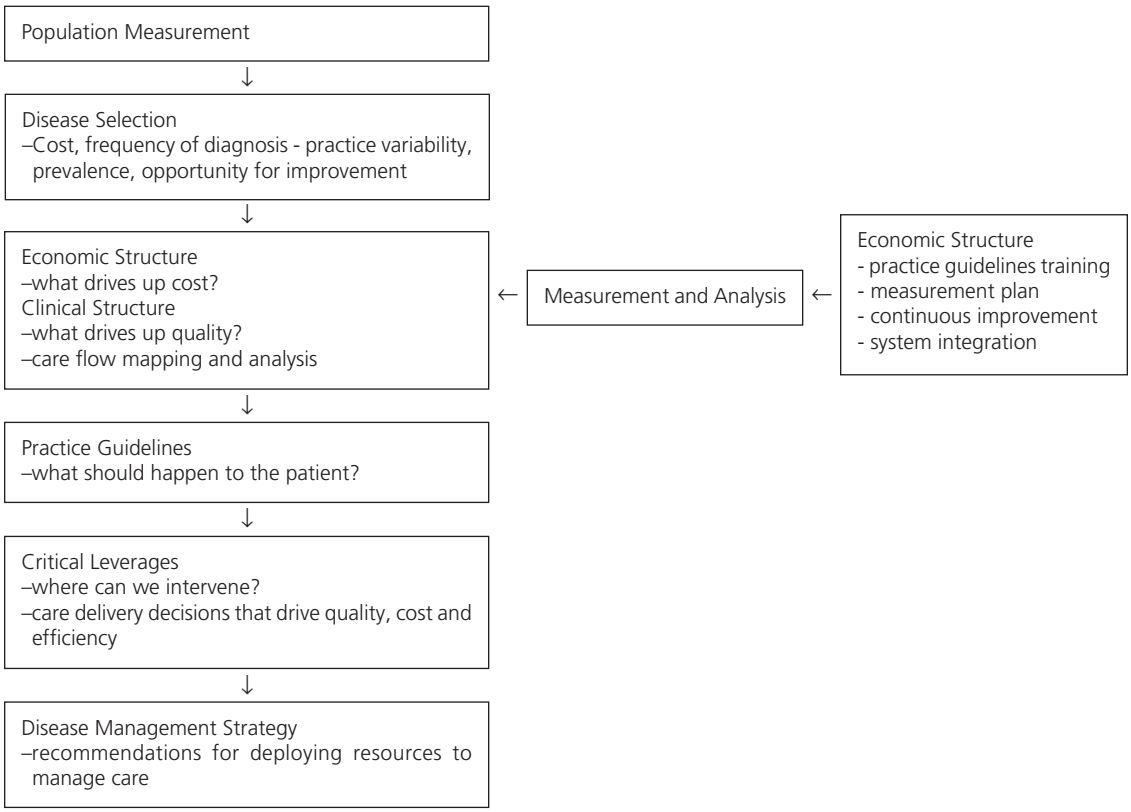

Figure 119-1. Disease management.

component of the total spectrum of health care management for most people. The goals of integrated health systems and managed-care organizations are to optimize health and wellness programs to minimize the number of occasions people need acute care. Acute-care needs may arise at any time from birth to death, but generally are concentrated toward the end of life. High costs result from hospitalizations and use of specialized services and technology. Therefore, the impetus is on disease prevention and health promotion to keep people out of the hospital. In integrated health systems, costs are shifted from inpatient (acute care) to outpatient (primary care) to manage patients in their homes and community settings.

Although the acute-care, or hospital, component of most integrated systems is being decreased to control costs, it remains the most sophisticated clinical segment of any health care system and cares for patients during the most acutely ill phases of their lives. Likewise, the sophistication of acute-care pharmacy services is high, with significant areas of expertise and specialization in both the distributive and the clinical roles assumed by pharmacists.

MULTIDISCIPLINARY TEAMS—As in primary care, the process of care delivery in acute-care settings is often organized around teams of providers, which may consist of nurses, physicians, respiratory therapists, and pharmacists. Whereas centralized pharmacy or decentralized pharmacy satellites provide unit-dose intravenous and oral medications to patients, clinical pharmacists are redeployed from these operational areas to serve as members of multidisciplinary-care teams. Pharmacists may be assigned to teams based on therapeutic focus, geographical proximity, or service-alignment and serve important roles to ensure that quality pharmaceutical care is achieved. While they may enter or verify the entry of drug orders into the computer, they typically do not distribute, admix, or dispense drugs. The distributive functions are generally performed centrally and supported by automated devices and technical support staff.

Clinical acute-care pharmacists have evolved into roles that have been shown to contribute significantly to the overall quality of the care delivered to hospitalized patients. The major focus of care, independent of the therapeutic focus area, is to ensure that optimal pharmaceutical care is delivered. Pharmacists are held accountable by their team and pharmacy administration to ensure that the drugs are given responsibly for the purpose of achieving a definite outcome that will improve the patient's quality of life, cure disease, eliminate symptoms, slow disease progress, or prevent disease.[9]

Pharmacists work proactively with their health care team to identify, solve, prevent, and document drug-related problems. Drug-related problems include untreated indications, improper

Table 119-4. Asthma Management

Educate the Patient
• Proper use of inhalers, and peak flow meters
• Drug information
Assess and Monitor Disease Severity
• Discuss symptoms and monitoring of symptoms
Avoid or Control Precipitating Factors
• Advocacy to limit allergen exposure
Establish Medication Plans for Chronic Management
• Review medication plan with team to optimize drug therapy
Establish plans for Monitoring Exacerbations
• Outline steps for caregiver and patient to take when exacerbations occur
Provide Regular Follow-up Care
• Participate in follow-up visits to reinforce drug therapy principles

Table 119-5. Database Reports

REPORT NAME	REPORT DESCRIPTION	FREQUENCY OF REPORTING
MAC Savings	Maximum allowable cost vs. HCFA vs. average wholesale price	Monthly
Member Utilization	Top 100 members with highest utilization ranked by benefit value	Monthly
Brand Generic	Generic utilization summary by clinic	Monthly
Drug Usage Product Ranking*	Top 2000 drugs dispensed by generic product index number and total ingredient cost	Monthly and quarterly
Drug Usage Therapeutic Class	Drug usage ranked by therapeutic class	Monthly and quarterly
Financial Pharmacy Provider	Listing of pharmacies where members have Rxs filled	Monthly and quarterly
Pharmacy Errors	Pharmacy online adjudication errors	Monthly and quarterly
Prescriber Activity	Prescribers' Rx activities by DEA # and # of members	Quarterly
Prescriber Utilization by Cost	Top 200 prescribers' usage of pharmaceuticals by cost	Monthly and quarterly
Prescriber Utilization* by Volume	Top 200 prescribers' usage of pharmaceuticals by volume	Monthly and quarterly
Prescriber Formulary Compliance	Top 200 prescribers ranked by formulary noncompliance	Monthly
Prescriber Detail by Member Cost of Claims*	Total claims paid exceeding $500 by patient, pharmacy, doctor, drug name, quantity and days supply	Monthly

drug selection, subtherapeutic dosage, failure to receive drugs, overdosage, adverse drug reactions, drug interactions, and drug use without indications. The pharmacist team member has the drug-therapy expertise and is relied upon by the team for information and collaboration when treatment plans are being made and modified.

Pharmacists often are assigned to a particular service or team and develop specialty expertise for an area of practice, such as intensive-care medicine, transplant surgery, or bone marrow transplantation. Patients in these clinical settings require intense, specialized care because of the severity of their illness. Pharmacists on these teams are often responsible for writing drug and nutrition orders and monitoring the patients continuously during their acute phase. In this team structure, pharmacists may cover for each other when one is scheduled off, but the service coverage is continuous.

Other predominant roles for hospital pharmacists have included alignment with a service that cares for only one aspect of the patients' needs during their hospitalization. Teams such as the nutrition or pain team focus on a narrow aspect of the patient needs, while the primary team provides the overall patient care. On these teams, nurses, pharmacists, dietitians, or physician's assistants may have interchangeable roles that complement each other. When one is scheduled off, another team member picks up the responsibilities of the missing member, but it may be someone with a different background training and discipline. On teams of this nature, cross-functional training allows role integration of all team members and maximal team efficiency.

PATIENT-FOCUSED CARE—Over the past decade, the term *patient-focused care* was coined to represent the consumer (customer)-driven need for all hospitals to provide care in a friendlier, more efficient, and more continuous way to patients. As health care has become more competitive and patients can shop for health systems, many hospitals have re-engineered their care-delivery process to make the hospital stay more pleasant for the patients and easier for the staff. The goal of patient-focused care is to provide high-quality, compassionate, and cost-effective care to patients and improve customer satisfaction. The goal is accomplished through bringing the services to the bedside of the patient rather than taking the patient off the unit to other services.

A common theme of the patient-focused care model involves the use of small interdisciplinary teams responsible for continuity of care of the patient from admission to discharge. A key component of patient-focused care is the creation of multiskilled teams of individuals who share responsibility and expertise in providing care and making care decisions at the bed-

Table 119-6. Percentage of Ambulatory Pharmacists Performing Function by Health-System Type

FUNCTION	STAFF OR GROUP HMO	IPA	HOSPITAL-BASED	PHYSICIAN-BASED
Make pharmaceutical decisions for large populations	55	67	37	46
Monitor patient outcomes	80	74	68	62
Monitor medication compliance	93	77	75	76
Conduct wellness and prevention programs	63	61	57	56
Conduct specialized clinics	46	28	36	29
Track adverse drug reactions	98	66	89	82
Prepare home infusion medications	43	26	50	41
Use pharmacoeconomic data for formulary decision-making	73	86	70	79
Provide written information with each new Rx	87	53	83	82
Provide oral counseling with each new Rx	88	54	84	79
Collect HEDIS* Data	69	71	24	18
Provide physician profiles or report cards	71	76	38	47
Design pharmacy benefits	61	71	26	41
Negotiate pharmaceutical contracts	61	57	44	50
Write medication orders	22	15	50	41
Conduct medication management programs (DUE)	90	74	76	71
Have prescribing authority	20	6	20	12
Conduct academic detailing	65	69	44	56

* HEDIS = Health Plan Employer Data and Information Set.

side. The patient's exposure is maximized to a smaller number of caretakers, and the number of care steps is minimized to reduce fragmentation of services. Care partners are cross-trained to draw blood, perform x-rays, change and bathe patients, and assist the nurse in other patient-related activities. The pharmacist, nurse, and physician collaborate to formulate drug-therapy plans, diagnostic testing, follow-up, and endpoints. Much of the care is directed by care maps and monitored by flow charts in each patient's room. Patient-focused care is an operational restructuring that centers on the patient as opposed to the current emphasis on departments and caregivers.

A 2000 survey, published by Raehl and Bond, revealed that 26% of US hospital pharmacy departments were operating in a predominant patient-focused system, with traditional departments remaining as core (ie, smaller, flatter) structures.[10] The survey demonstrated that pharmacists were involved in providing direct patient care in 85% of the hospitals operating in a patient-focused model, and pharmacy personnel almost always reported through traditional pharmacy department channels.

In some patient-focused care implementation projects, pharmacy roles and responsibilities were significantly expanded to include obtaining a complete medication history, assisting in the development of drug treatment plans, implementing drug-therapy plans, assisting in evaluating and modifying drug therapy, educating patients throughout their hospital stay about their drug therapy, preparing patients for discharge, and follow-up by telephone after discharge. A small decentralized pharmacy was located on each patient care unit. First doses and urgently needed medications were prepared by a technician and checked by the patient-focused care pharmacist before they are given to the patient with the remaining doses are prepared centrally and redistributed to the patient-focused care unit on a 24-hour schedule. Expanded responsibilities led to increased numbers of pharmacists and pharmacy technicians required to perform the defined work.

Although data have shown that patients on patient-focused care units have shorter average hospital stays, have fewer follow-up emergency room visits and are readmitted less often than control patients, severe economic pressures and workforce shortages have forced the dissolution of patient-focused care models in some cases. This has been due primarily to the unfavorable reimbursement environment in health care, the labor intense nature of the patient-focused care model as well inefficiencies and the inability to realize anticipated savings resulting from decentralization of care processes.

PROTOCOL-DRIVEN CARE—The opportunity for variance in practice exists in the hospital as it does in the primary-care setting. Guidelines, protocols, and decision algorithms have been in use in hospitals for many years to attempt to improve the consistency of care, reduce the likelihood of errors, and reduce costs. Care maps that outline care steps from admission to discharge are in place for all facets of care in most hospitals. Care maps can be a helpful bridge between the acute-care and primary-care settings.

The pharmacist's role in acute-care protocols can be quite extensive. In the inpatient treatment arm of the deep vein thrombosis care map shown in Table 119-3, the pharmacist takes a complete medication history, works collaboratively with the team to initiate and optimize heparin therapy, educates the patient daily about various aspects of heparin and warfarin therapy, ensures early initiation of warfarin therapy with a sufficient heparin overlap period, and performs discharge medication counseling and follow-up with the patient's local pharmacy. In each step, the pharmacist, just like other team members, documents the outcomes she/he is responsible for achieving, on the care map.

Protocol-driven care facilitates drug-therapy decisions within a range of acceptable choices predicted to include 90% of patient situations. For example, the deep vein thrombosis protocol denotes starting and maintenance dosing of heparin, the frequency of APTT monitoring, and suggested dosing adjustments in response to resultant APTT values. With this information and their professional training and background, pharmacists can make dosing and monitoring adjustments without necessarily consulting with the rest of the team. Protocol-driven prescribing is effective because the protocols are developed in advance for noncontroversial treatments, within which clear-cut decisions can be made.

When patients deviate from the range of choices outlined in the protocol, the team reassembles to discuss alternative treatment choices and designs a new plan to get the patient back on course. Protocols do not cover all possible clinical situations, but are designed to provide a framework of care for most situations that arise. Protocol-driven prescribing allows autonomy of choice within a range of acceptable choices outlined in the protocol but prevents aberrant decisions that may jeopardize patient care.[7]

In large integrated health systems, the opportunity exists to make the transition from inpatient (acute care) to outpatient (primary care) as seamless as possible. The patient should not experience an interruption in the way care is delivered or the level of knowledge and sophistication of the team members at each phase of care. To provide seamless care, sophisticated technology and information systems are needed to share medical and drug information through the transition. Corporate alignment of the financial and reporting structures of individuals in acute-care and primary-care environments is necessary to facilitate smooth patient transition. Successful integration is difficult to achieve, even in the most highly developed health systems, because of the magnitude and complexity of the components.

COST-JUSTIFICATION Documentation is an essential component of the pharmacist's responsibilities in the acute phase of care. Through years of careful documentation of the impact of pharmacy services on overall care of patients, it has been shown that care is improved and costs are reduced. For every dollar spent on pharmacists, anywhere from 1.7 to 17 times that much money is saved in drug-therapy-related expenses.[6] Documentation allows effective communication between services, teams, and health care providers. Documentation provides a mechanism to create optimal staffing patterns for patients of different acuity of illness and therapeutic focus. Through documentation, pharmacists can verify the impact they have for promotion, annual performance review, and internal recognition.

Many approaches have been taken to document acute-care pharmacy services. Both manual and automated systems exist that summarize problems identified, interventions taken, and outcomes associated with the interventions. In most cases, the problems and interventions relate to the drug-related problems described by pharmaceutical care. However, in certain areas of practice, pharmacists have developed extended patient-care roles and may be administering medications or performing procedures. Pharmacists may have a role in research protocols that must be documented in the patient's medical record and the research records. Pharmacists routinely leave notes in patients' charts and care maps and consult notes, and many are involved in writing drug orders. Each of these mechanisms is important documentation of care rendered. Documentation is critical in all facets of pharmacy practice.

Long-Term, Hospice, and Home Care

Home care is the provision of resources for medical care in the patient's home. Services include skilled nursing care, intravenous medications and nutrition, physical and occupational therapy, rehabilitation care, and respiratory care. Pharmacists work with home care nurses to streamline drug therapy and minimize the risk of drug-related problems. Hospice care is any comprehensive program that provides specialized care to terminally ill patients. Hospice programs offer medical, sociological, and psychological services to patients in the institutional and home setting. Long-term care's goal is to help people with

disabilities be as independent as possible; thus it is focused more on caring than on curing. Long-term care provides assistance and care for persons with chronic disabilities and is needed by persons who require help with the activities of daily living or who suffer from cognitive impairment. Long-term care is not limited to the elderly, but the need for long-term care is more prevalent in the elderly. Pharmacists provide dispensing and clinical services to hospice and long-term care facilities. Given that medication safety is of great concern in elderly and compromised patients, drug therapy should be evaluated carefully to assure that the fewest possible drugs at the lowest effective doses are used.

Integrated health systems usually offer these areas of care to patients, as well as primary and acute care. Home care is becoming increasingly important to facilitate the transfer from acute care back to the home and primary-care setting. Pharmacists have important roles in all three care phases, as drug therapy is usually involved. Table 119-7 summarizes predominant pharmacy roles in home care, hospice, and long-term care settings.

Education

The role that pharmacists have in educating patients, physicians, and other health care workers in health systems is so important that it warrants separate mention. The educational role spans all facets of practice in integrated systems.

PATIENTS—Many physicians leave patient's drug education to the pharmacist, as their direct contact time with patients is limited increasingly by the need to enhance productivity. The pharmacist is the patients' last professional contact before they take a medication and has the opportunity and responsibility to safeguard the patients' health and to help ensure the success of the drug therapy. In the past, pressure to educate patients came from the federal government via the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) and FDA Guidelines. Now, patients demand information about the safe and effective use of their medications. It is desirable for pharmacists to provide credible, accurate information rather than allowing the patient to default to easily available and potentially suspect drug information available through the Internet.

The simplest form of patient education is counseling at the time of dispensing the prescription. At minimum patients should know how to take their medicine, how often, how much, what to do if a dose is missed, what side effects to watch for, food and drug interactions of significance, and how to store the medication. Consumers are being told that the pharmacist should answer questions about prescription and over-the-counter products, that they will discuss drug-therapy concerns privately with the patient that pharmacy systems screen for potentially serious drug interactions and that pharmacy prices should be reasonably competitive. While written materials can supplement the oral personal communication between the pharmacist and patient, they should not substitute for one-on-one interaction. Only through probing and the use of open-ended questions can pharmacists determine true patient understanding about their medications and reinforce important concepts.

Nonadherence to prescription medications has been estimated to cost $50 billion in the US annually, with another $50 billion in indirect costs, such as lost productivity and time lost from work or school. Pharmacist counseling has been shown to improve adherence to medications. Six important factors in ensuring patient compliance to drug therapy are stage of therapy, literacy level, age, cultural and language issues, gender, and readiness to comply. When filling first prescriptions or for newly diagnosed patients is the best time to ask the three "prime", important questions:

What did your doctor tell you this medicine is for?
How did he or she tell you to take the medication?
What did the doctor tell you to expect the medication?

For patients who have been taking the same medication for years, it is simple to reinforce compliance and elicit any problems the patient may have been having with their drug therapy.

A second important factor is the literacy level of the patient. As many as 40 million American adults are functionally illiterate, and 50 million more are marginally literate. There are several age-related factors that affect medication compliance. Children need to be supervised by their parents when taking medications, teenagers need to understand the importance of proper use, middle- and older-age patients may have special communications needs and consume a higher proportion of medications in society. Increased age is associated with memory problems, hearing and physical impairments, and comprehension issues, all of which can interfere with medication compliance.

Patients from different cultural backgrounds may have different perceptions about health care, and language barriers further compound the conveyance of clear concise directions about medications. Lastly, gender and readiness to comply are inherent characteristics that pharmacists must assess before developing an approach to communicating with patients.

Once information about these six important factors affecting medication compliance is known, pharmacists are prepared to counsel patients effectively about their medication. These six factors pertain to all pharmacy practice settings within integrated systems. Whether in a clinic pharmacy, inpatient, or home setting, the pharmacist should seek a quiet, private area where the patient can be seated comfortably (or lie down if still infirm). Patients must be comfortable to be prepared to receive information and ask questions or they will not listen, go elsewhere for information, or fail to comply.

Pharmacists participate in a wide variety of patient educational experiences other than counseling at the time of dispensing. Brown bag lunches are used when the patients bring in their medication and pharmacists discuss what the drugs are and how they are used and answer questions patients may have about their drug therapy. Therapeutically focused workshops

Table 119-7. Home Care, Hospice Care, and Long-Term Care

FUNCTIONS	HOME CARE	HOSPICE CARE	LONG-TERM CARE
Intravenous admixture	X	X	X
Medication preparation and dispensing	X	X	X
Therapeutic drug monitoring	X		X
Drug therapy review	X	X	X
Dosing, monitoring and follow-up of medications and nutrition therapy	X		X
Tracking adverse drug reactions	X	X	X
Development of drug therapy protocols	X	X	X
Develop of team-based treatment plans	X	X	X
Drug use evaluation	X	X	X
Patient/family education	X	X	X
Protocol-driven prescribing	X	X	X
Communication liaison between acute care and primary care	X		

or lectures are offered to patients recovering from stroke, myocardial infarction, and other disabilities to offer information about drug therapy for these disorders. Large group sessions for recovering alcoholics, smokers, diabetics, asthmatics, and patients with other conditions are used to bring several health care professionals together and offer information to patients. Dietitians, pharmacists, nurses, and others lead discussions with patients and answer questions they have about their disease process, diet, and drugs. All of these formats in which pharmacists share information with patients help to establish the pharmacist as a trusted professional and reputable source of information.

Other important educational topics for patients who receive care in integrated health systems are to improve overall understanding about medication programs, benefits, formularies, and cost considerations. Physicians often are asked to prescribe drugs listed on a formulary of choices, to use generic alternatives whenever possible, and less expensive branded drugs when the health system is at risk for the cost of care delivered. Managed-care organizations employ therapeutic substitutions or switch programs to increase the use of *best-value* medications for their patients. Most patients have insufficient understanding about these processes and decisions and frequently label them managed-care *rip-offs* that cheapen health care. Proactive educational mailings, brochures, and discussions with patients often allay their concern that less-expensive drug choices are inferior. Seminars, use of the Internet, and video summaries of this information can be helpful adjunctive ways of conveying information to patients in this high-technology era of medicine.

Particularly useful tools for patient education are the telephone, fax machines, and electronic mail (e-mail). Patients really appreciate personal follow-up and inquiry regarding their medications. In many integrated systems in which pharmacists are truly and responsibly providing pharmaceutical care, follow-up telephone calls asking how the patient is doing, if he or she is having any problems with the medication or has any other questions are a service that greatly enhances customer satisfaction, loyalty, and compliance. A surprisingly large number of patients have access to fax machines and e-mail, which provides another electronic avenue for communication and follow-up without interfering with their day or inconveniencing the pharmacist.

PHYSICIANS AND OTHER HEALTH CARE WORKERS—Ongoing education to physicians and other health care workers allows a bond of learning, growth, and service to develop that is valued and deeply respected by other health-system colleagues. Physicians rely on pharmacists, other colleagues, and pharmaceutical representatives for most of their updates on new drugs and therapeutics. They attend professional meetings infrequently enough that this form of continuing education is of limited use. Unfortunately, the pharmaceutical industry has been very effective in scheduling visits and employing strategies to educate physicians about new drugs and motivate their use, even in instances where the new drug adds little value to available treatments. Pharmacists can be effective in conveying a balance between the drug company's marketing information and the medical literature and help to ensure that the information prescribers receive is consistent with health-system guidelines on drug use.

As a part of the health care team, pharmacists may be asked to convey information more formally, in lectures or journal clubs, to the prescribers and the rest of the team. Pharmacists benefit from honing their presentation skills (the ability to design and convey information effectively with limited time), in oral and written formats. Interpretation of the medical literature, biostatistical design, and trial methodologies are important features of providing drug information accurately and effectively.

Information to prescribers can take the form of newsletters, written guidelines, monographs, or electronic transmissions. All communication media should be explored to ensure maximal exposure for transmission of educational materials to prescribers and other health care professionals. As health professionals who subscribe to lifelong learning, pharmacists can contribute meaningfully to the education of other professionals and patients in their system.

SYSTEM SUPPORT FOR PATIENT CARE

Information Systems

One important asset in an integrated system is the information about patient health care usage and the cost of health care. Today this information is best stored, sorted, and analyzed through the use of computers. Medical informatics is an information science specialty that is defined as the use of a computer-assisted systems approach to obtain, process, store, retrieve, manipulate, analyze, and distribute data.[11] In an integrated system, the availability of data allows the information to be placed on a network that can be accessed by all providers in the system and further facilitate care across the continuum.

With system computer access a pharmacist in a satellite ambulatory site can access the patient's hospital records, get information regarding the nature of a drug reaction, and thus take action to avoid an allergic reaction. Computerization and information systems can be used to streamline medication dispensing, freeing the pharmacist for more involvement in providing patient care. Additionally, computers and information systems can assist pharmacists in the provision of cognitive services, as the rapid availability of current, accurate medical information is the basis for these services.

Network computers can facilitate communication with system employees. Workers can send e-mail to each other detailing specific encounters with patients. Frequently in integrated systems, employees are distributed over a large geographic area that limits communication between these providers of care over the continuum. Network e-mail provides an open line of communication between these workers and can lead to better working relationships. Managers can use mail lists to inform all employees quickly of procedural changes or other necessary information that can aid in the efficient provision of patient care. This electronic exchange of information allows faster and less cumbersome exchange of information.

In some cases the Internet may be used to provide access to system information. There is great concern regarding the use of the Internet as a conduit to supply patient and medical information because of the ability of unauthorized persons to access the information. Thus, information provided on the Internet by integrated systems is presented in three levels of complexity.

Some systems only maintain a Web page that provides general information about the system and the services provided. At the next level of complexity the system provides guidelines and policies in a password-protected area to limit access to authorized users. It is on this level that systems are most likely to provide information. The highest level of complexity also requires the highest level of security, as here access to patient medical information is available to authorized employees with passwords. It is becoming common for patients to have access to their own health page through secure sites that integrate appropriate medical, drug, and financial information. Given the raised conscientiousness regarding protected health information, health systems have improved confidentiality to assure compliance with HIPAA.

There are three types of databases that are used by pharmacists in an integrated system: administrative, bibliographic, and point-of-care.[12]

ADMINISTRATIVE DATABASES—Hospital and ambulatory pharmacies have used computers regularly for prescription order entry since the 1970s. These information systems were first developed to perform the administrative task of providing accurate billing for medication. The costs for these com-

puter systems were offset by the capture of lost charges. In addition, the computers provided accurate labels and work lists for medication cart filling and IV admixture preparation. Reports that assess drug quantity use for inventory control can be generated with this information. From a clinical standpoint, early programs began providing patient profiles for pharmacists to review for drug interactions and allergies.

In the hospital setting, computer administrative databases can provide information about which agents are carried on the formulary. Similarly, in the ambulatory setting computer links can verify the insurance eligibility of the patient as well as identify formulary agents that are covered by the patient's insurance plan. In both settings, computer programs can be used in billing the insurance company for the drug costs. While pharmacy administrative databases developed separately in inpatient and ambulatory settings, the information available and the use of the computer hardware are similar.

While these computers are expensive, the economy of scale provided by the integrated system allows the large amount of capital needed to purchase this equipment. The volume of units dispensed in an integrated system also justifies the expenditure on the computerized equipment that can dispense medications for cost-efficiency while allowing the implementation of just-in-time inventory to control drug costs further. Besides controlling drug costs, these computerized systems can add efficiency and accuracy to work performed by caregivers, further improving the quality of the health care services provided by the integrated system.

Administrative databases also can be used by pharmacists for medication use review. Through the use of prescription data, reports can be run that identify prescribing patterns of physicians. This information can be used to determine if the physician is adhering to formulary or to practice prescribing recommendations, and proper follow-up education can take place. In some integrated health systems, an individual physician's compensation may be tied to the adherence to formulary or guidelines.

Administrative databases can be used to identify patients needing specific interventions. For example, pharmacists may feel there is a need for additional counseling of patients with hyperlipidemia. To locate these patients, the pharmacy database can be queried to identify all patients taking an antihyperlipidemic agent. This query may identify more patients than one pharmacist can counsel in a reasonable amount of time. The pharmacist may further choose to work with only the patients taking these agents who have coronary heart disease. These patients can be identified by crossing the prescription database information with a diagnostic code. As the pharmacist only wishes to work with the patients who have not reached goal values, the identified lipid test results can be extracted from the system's laboratory database. The pharmacist has identified the system's patients who will be best served by the pharmaceutical intervention through the use of database queries.

BIBLIOGRAPHIC DATABASES—Bibliographic databases provide pharmacists with easy access to medical information that previously required a trip to a medical library and hours of exhausting searching. By placing these databases on the system's network, pharmacists and other caregivers can access this information at their particular site. MEDLINE and International Pharmaceutical Abstracts are examples of databases that track the biomedical literature. There is an assortment of similar databases available to search specific areas of interest, which include allied health care journals.

The literature citations found through the database searches can serve to support clinical decision-making for individual patients as well as the development of treatment guidelines for the integrated delivery system.

POINT-OF-CARE DATABASES—Point-of-care databases provide clinical decision support at the patient's bedside or in the clinic setting and can be useful tools for pharmacists providing pharmaceutical care. These databases use information derived from administrative databases, bibliographic databases, and official FDA labeling. Clinical screening databases and references databases are the two types of point-of-care databases that pharmacists find useful.

The clinical screening databases are used to screen for drug-related problems such as drug interactions and allergy contraindications. For example, the patient's administrative data may contain information indicating the presence of a penicillin allergy. With the link to the clinical screening database, when an order for penicillin is entered on this patient, a flag will appear alerting the pharmacist to the problem and will not permit dispensing of the penicillin without further action by the pharmacist. At this point, the cognitive function of the pharmacist is activated, as the problem must be investigated and needs decisions by the pharmacist to verify the allergy and discuss an alternate drug choice with the physician. The same scenario would take place if the clinical screening database identified a drug interaction. Clinical screening databases can aid in the direction of pharmacist interventions.

The earliest reference database was Micromedex, which provides an assortment of drug and poison control information in database form. Other reference databases are electronic versions of commonly used pharmacy reference books, such as the *American Hospital Formulary Service, Facts and Comparisons,* and *USP Drug Information*.

There are several advantages to common databases. All system caregivers have access to the same information, which can be updated at one central location in a timely manner with placement of the database on the network. With published information, updates are usually only available once a year, and the work required to distribute a large number of books through a system can be cumbersome. Thus, the process of disseminating information is improved through computerization. Databases allow quick retrieval of the needed information through the use of search engines, thus allowing a decision to be made quickly at the point-of-care. It is important to note that patient information is also available in several of these databases. Network availability of patient instruction sheets allows all caregivers access to the same teaching tools, so the information given to patients will be common wherever they are seen in the system.

THE MEDICAL RECORD—As the integrated health care system is the keeper of all data associated with the care of the patient, the use of computerized patient medical records on the system's network makes this information readily accessible to caregivers across the system. Previously, patient's paper charts were delivered from site to site as the patient was seen as an inpatient and in the outpatient clinic. The paper method requires time and resources to transport patient information, and often the chart and the patient are not in the same place at the same time. Without valuable historic care information, the clinician is forced to provide care based on limited information, thus sometimes providing fragmented care. With the use of computerized, networked medical records, an integrated system can deliver seamless, efficient care.

Further efficiencies can be realized in an integrated system, as all data developed using different information systems can be organized in one location. For example, the laboratory and pharmacy databases can be programmed to dump their data directly into the medical record's database, eliminating the need to access a different computer system or different software to gain access to test results and prescription information. Pharmacists can enter notes in the medical record about pharmaceutical care provided to the patient, so that physicians and other caregivers can review these valuable activities.

COMPUTERIZATION—As an integrated system is the provider of *seamless* health care, information systems provide the backbone to this provision of care. By the virtue that information of all types is available on patients for caregivers to use, the expense of network computerization is required to use this data efficiently in providing patient care. It is important for pharmacists to be involved with the development and use of

information systems in the integrated system. Computerization and automated dispensing systems can be used for accurate dispensing of medication. With dispensing tasks provided by technology, the pharmacist can use information in the decision-making functions required to provide pharmaceutical care.

INTEGRATION OF TECHNOLOGY AND AUTOMATION INTO PRACTICE

As technology and automation continue to be increasingly used in health care and other industries, so has the responsibility of pharmacists to understand and integrate these systems into their practice. When used appropriately, automation and information technology can be powerful tools in integrating and managing data, increasing quality and efficiency and assuring safety while helping contain costs. In addition to incorporating automation and information technology into individual practice areas such as inpatient and ambulatory pharmacy practices, integrated health systems face the additional challenge of assuring that these technologies complement practice in all areas and assist in the provision of seamless care throughout the continuum.

In the inpatient acute care environment, several types of automation are employed for medication dispensing and compounding. Automated medication dispensing cabinets (eg, SurMed, others) are frequently employed to make many medications available on the patient care unit while offering a degree of medication control. Some institutions use these devices for dispensing controlled substances or floor stock mediations only, while others use them for up to 90% of all first doses dispensed. Ideally, these devices communicate with the pharmacy information management system via an interface so that all orders may be reviewed and approved by a pharmacist prior to being removed by a nurse for administration to a patient. The main advantage of these cabinets is that medications are immediately available on the patient care unit and medication charge capture and inventory record keeping is enhanced. They also improve the accountability of controlled substances. These advantages must be balanced against the increased potential for medication errors to occur, the need to maintain several locations for medication inventories, the workload associated with maintaining and stocking the cabinets as well as the impact on nursing workload. Although these devices allow access to the medication more quickly, they may actually require the nurse to do more work as he or she must spend time accessing the machine for each dose. This can be especially problematic if insufficient numbers of cabinets are available in each area, requiring the nurse to travel significant distances to retrieve medications.

Some pharmacists believe that automated medication dispensing devices should be used only in conjunction with Point-of-Care medication administration error prevention (eg, Bridge Drug Management System, Acu-Scan Rx) systems. Point-of-Care systems employ palm-size devices that provide the nurse with real-time access to the patient's medication profile and/or medication administration record. Through the use of barcode technology, the system assists the caregiver in verifying that the right drug is given in the right dose to the right patient at the right time. With this system, the nurse scans the barcode on the medication as well as the barcode on the patient's wristband. Using a radio frequency telecommunications network, the hand held device communicates with the pharmacy computer system to verify the dose to be administered against the patient's medication profile and allergies. Once verification takes place, the nurse administers the medication and uses the hand held device to record that the dose has been administered. One of the major hurdles to implementation of Point-of-Care technology is that not all medications are bar coded and no standard symbology for bar coding of drugs has been adopted. In addition, radio frequency networks are not yet installed in many hospitals. Once these problems have been sufficiently addressed, the use of Point of Care error prevention systems are likely to gain more widespread use and allow the increased use of automated dispensing cabinets.

Another widely used automated methodology in the inpatient environment is the use of robotics for packaging and dispensing of unit-dose medications and total parenteral nutrition (TPN) solutions. Robot Rx and the ATC Profile are examples of machines employed in central pharmacy environments. The Robot Rx has the capability of packaging and bar coding of medications, dispensing first doses, filling unit dose medication carts as well as handling medication returns and removing outdated inventory. It also is capable of preparing supplies of medications for restocking of automated dispensing cabinets. Disadvantages of this system include large space requirements and the "double-packaging" medications to assure that a bar code is affixed. The ATC profile is capable of packaging and bar coding of medications in patient-specific single or multiple dose strips, which are easy for the nurse to find and identify. This machine is used primarily to increase the efficiency of unit dose cart filling, although the potential for first dose dispensing exists. The main disadvantage of the ATC profile is the large number of medication returns that must be put away manually.

Many inpatient pharmacy areas employ automation for preparation or IV solutions or TPN solutions. These systems allow mass production of TPN base solutions and are also capable or adding electrolytes and other additives. These systems reduce the amount of technician time required to prepare solutions and reduce the amount of pharmacist time required for checking of final products. The cost-effectiveness of such devices depends on the number of TPN solutions prepared by any given institution.

One of the most exciting forms of technology now beginning to be employed by inpatient clinical pharmacists is the use of clinical decision support algorithms for drug therapy monitoring. Through the integration of databases such as the patient's medication profile, lab information, and demographic data, users are able to create "rules" which identify drug therapy-related problems. An example would include identification of a patient on a drug such as cefotetan (which interferes with production of carboxylated clotting factor) whose INR becomes elevated. Violation of this "rule" results in a clinical alert, which appears on the pharmacy computer system, notifying the clinical pharmacist that intervention may be warranted. This system has the potential to reduce dramatically the amount of time a clinical pharmacist spends manually reviewing databases and patient profiles to identify actual or potential problems, and allows pharmacists to spend more time making actual interventions. Ideally, the same system utilized to identify drug-related problems is also used to document and tabulate pharmacist interventions, resulting in further efficiency gains.

Automation and other technologies are also employed in the ambulatory setting of integrated health systems. Automation in ambulatory pharmacies range from systems designed to count tablets and capsules to nearly full automation of the dispensing process. Some systems offer visual imaging to assist the pharmacist in verifying the accuracy of the filling process while other systems employ bar code technology to verify the NDC barcode on the labeled package matches the NDC on the manufacturer's package. These features reduce the possibility of a product picking error from reaching the patient.

Technology is available that allows dispensing of prescriptions within medical clinics or physician offices. Some systems allow physicians to transmit medication orders electronically to a pharmacy, where the pharmacist enters the information into the patients medication profile, then electronically activates an automated dispensing machine located in the medical clinic or physician's office, which results in the dispensing of prepackaged and labeled prescriptions which are then provided to the patient by the physician or his representative. The person

dispensing the prescription scans a barcode on the dispensed product, which allows verification that the correct drug has been dispensed. Other systems bypass the pharmacist altogether and allow the physician to dispense pre-packaged, prelabeled, bar-coded medications directly to the patient. These systems also allow the physician to adjudicate claims with the patient's third party payer. A drawback to the above systems includes the requirement to fill relatively large numbers of prescriptions to cost-justify the technology. Also, because not all drugs are stocked in these machines, and because some medications must still be provided by traditional pharmacies, patient profiles maintained by stand alone systems in physician offices will not allow drug interaction checking against a complete patient profile in many instances.

Computerized Prescriber Order Entry (CPOE) is a technology whereby a prescriber directly enters orders into a computerized database. These orders are then sent to a pharmacy computer system via an interface. The pharmacist then reviews the order, and if appropriate, approves the order and dispenses the medication or allows the medication to be dispensed or retrieved from an automated dispensing device. Some CPOE systems allow for screening of drug interactions and identify and correct potential errors such as incorrect doses, routes, or frequencies before they occur. The time taken for the order to be received in the pharmacy is reduced, and legibility problems are avoided. In the inpatient environment, CPOE offers the advantage of selection of predefined treatment order sets, increasing compliance with disease management guidelines. In both the inpatient and ambulatory settings, CPOE can enhance prescriber compliance with system and payer formularies. The ideal CPOE system integrates the patient's medication profile, laboratory and other pertinent patient information into one database to allow the clinician access to all pertinent information at the time the prescription is written.

Implementation of automation impacts the manner in which pharmacy is practiced, in both the inpatient and outpatient settings. Most enhanced automated technologies, if implemented appropriately, will reduce the number of pharmacists and technicians required to perform basic functions associated with medication dispensing and distribution. This is thought by many as an opportunity to spend more time providing direct patient care activities such as patient counseling, performing pharmacotherapy histories, participating in patient care rounds, or participating in disease management activities. The extent to which pharmacists are successful in these endeavors is dependent on their willingness and ability to market the value of providing such services to institutional administrators and payers. Also, it is important that pharmacists assure that automation is implemented and utilized appropriately and that policies and procedures designed to assure safe and appropriate use of these systems.

Outcomes Management

Pharmacoeconomics can be thought of as the description and analysis of the cost of drug therapy to health care systems and society.[13] Further, pharmacoeconomics identifies, measures, and compares the costs, benefits, and risks of drugs and pharmacy services. These techniques are used in an integrated health care system to ensure selection of quality, cost-efficient treatment.

Traditionally, medical decision-making was focused on the clinical indicators of disease and the outcomes of treatment. In other words, this information answered the question, *Did the patient get better with the treatment?* If the answer was *yes,* the treatment was considered acceptable and useful. The issues of quality and cost-efficiency were not addressed with this type of analysis. Indeed, information currently presented to the FDA for drug product approval does no more than illustrate that the drug made the patient *better* or at least caused no harm.

In an integrated health care system interested in providing the best quality and cost-efficient care, decision-making based solely on clinical outcomes is limited in its usefulness and may in fact be detrimental to the overall health of the system. Thus, the framework for decision-making is broadened to include measures of economic and humanistic outcomes to deal with the limitations of the traditional approach. Here the drug or pharmacy intervention is analyzed not just to determine if the patients got better but how much better they got in terms of health care resource use (economic outcomes) and patient satisfaction (humanistic outcomes). This broadening of approach is synonymous with the broadening of approach to health care taken by an integrated system. In a fragmented health care delivery system decisions are made only on the basis of their effect on the care given. It is only appropriate that integrated systems adopt the new, broader decision-making framework, as it is concerned about delivery of quality, cost-efficient across the continuum.

THE OUTCOMES MANAGEMENT MODEL—The outcomes management model combines the techniques of outcomes research with the Plan-Do-Check-Act (PDCA) process model for quality improvement. Outcome management allows the important issues of efficiency, capability, efficacy, and productivity to be addressed.[14] Outcomes research is aimed at building theories and models for evaluating effective drug treatment protocols, successful treatment interventions, and optimal therapeutic outcomes. Outcomes researchers translate these theories into models for measuring the effectiveness of drugs and procedures as summarized by Vermeulen et al, in 2000.[15]

Outcomes management is the daily application of these models in the integrated health care delivery system. Outcomes management can be used to identify areas of patient care in which a treatment guideline, a clinical pharmacy service, or an operational improvement is needed to ensure the delivery of quality, cost-efficient patient care. It can identify best-practice options that can be implemented throughout the system.

Once a guideline, service, or operational improvement is designed, a parallel research design should be developed to collect and analyze the outcomes of the intervention. Both the process improvement and its evaluation should be launched simultaneously. This allows outcomes data to be collected to determine the effect of the intervention from the beginning of the process. Analysis of the data is conducted using accepted statistical techniques. Feedback is provided to the decision-makers as well as those involved in the planning and implementation of the process-improvement plan so that modification can be made to further this process. When changes are made, the outcomes management model begins again and continuously cycles, providing continuous improvement to the process.

APPLICATIONS—*Guidelines, Critical Pathways, and Treatment Protocols*—Outcomes data such as treatment failures, overuse of laboratory tests, or prolonged lengths of stay in the hospital are measures of treatment outcomes that can signal a need for a guideline, pathway, or protocol. These outliers in care can indicate the need for structured use of medication to optimize effectiveness. For example, one institution noted increasing costs for low-osmolality contrast media. Evaluation of use indicated that the use of this agent over the conventional high-osmolality contrast media had not affected the rate of adverse drug reactions reported to be a benefit of the low-osmolality agent. A guideline was implemented regarding the targeted use of these agents to ensure that those who would benefit most from the more-costly agents would receive them. At the time the guidelines were implemented, an outcomes study also was begun. The outcomes study indicated that drug costs were decreased by limiting the use of the agent, without negative effect on patient outcomes.[16]

Medication Safety—Although the benefits of clinical pharmacy services may be obvious to pharmacists, the use of the outcomes management model allows demonstration of the beneficial impact of these services on clinical, economic, and

humanistic outcomes. In an integrated system the impact of these services over the continuum of care can be measured, and cost savings can be captured. For example, a high number of inpatient admissions (economic outcome) for bleeding among patients on warfarin therapy (clinical outcome) can signal the need for better patient education on the monitoring and use of the drug. With this information, a pharmacy manager can identify and assemble a multidisciplinary team to improve the process of outpatient warfarin. When the intervention is implemented, the clinic pharmacist can collect outcomes data on the patients participating in the modified clinic process. A decrease in bleeding episodes after implementation can be attributed to the process improvement.

OPERATIONAL IMPROVEMENTS—The need to change the organization of pharmacy tasks can be identified through economic outcomes such as increased overtime payroll. The pharmacy manager also may determine the need for a reorganization of work assignments when work is not being accomplished and the departmental goals are not being met. For example, the manager may be interested in the purchase of a robotic dispensing machine to free up pharmacists for clinical functions. To develop the plan for the purchase of the robot, an economic model can be developed to determine if the traditional methods of dispensing or the robotic dispensing machine is the most efficient use of capital. Once the decision is made, continuous collection of outcomes data relating to dispensing as well as clinical services can be gathered. Outcomes assessment can be used to support the continuation of the program or signal other changes that need to be made in the process.

BENEFIT MANAGEMENT—The activities involved in pharmacy benefit management began when insurance companies decided to pay for prescription medication as part of the covered benefits. Early management included activities involved with prescription dispensing and the payment to the retail drug stores for prescription costs covered under the plan. The management of this benefit became more important as insurance providers found that the costs of the pharmacy benefit continued to climb. Today, pharmacy benefit management entails a host of activities that now span the scope from dispensing drugs to the management of outcomes.

As controlling drug costs is important to insurance carriers, it likewise has become important to integrated health care systems that wish to provide cost-efficient care. Also, as most integrated systems are involved with managed-care plans that capitate the pharmacy benefit, the importance of maximizing the investment in prescription drugs for the provision of optimal health care outcomes becomes critical.

The degree of system integration and resources available will determine whether the integrated system entirely manages the benefit itself or contracts with a company that offers various services for pharmacy benefit management. These companies are called pharmacy benefit managers (PBMs). A survey conducted in 2001 revealed that PBMs are primarily involved in claims adjudication, while some are involved in providing disease management programs for their managed care organization or integrated system.[17] The activities involved in pharmacy benefit management have been described in four levels of sophistication.[18] There are varying degrees of each level of activity used in the management in an integrated system. Systems may pick and choose which services will be provided internally and externally through contracts with PBMs.

Level 1 (Managed Costs)—At this basic level of service, the focus is on managing costs of prescription drugs and handling the technical aspects of paying pharmacy claims, including reporting usage information. While an integrated system usually provides ambulatory prescription services through system-owned pharmacies, in most systems there are some patients who receive medication through retail pharmacies. In either case, the pharmacists filling the prescription need access to information about the insurance coverage—whether the patient and the particular medication are covered—before the service is rendered. Further, the pharmacist also needs a mechanism to process the claim for payment of the service.

All of these activities are best carried out through the use of a computerized system. As this is a highly technical function, it is less expensive for a system to contract with a PBM or other company with these skills and equipment for claims processing. For the integrated system to try to set up its own claims-processing activities would require huge capital costs for a hardware system that by the nature of the advances in computer systems would become obsolete quickly. Additionally, PBMs have provider customer-support personnel to handle problems arising from equipment problems and verification of coverage.

Another activity involved in managing the cost of prescriptions at Level 1 of benefit management involves controlling the costs of the drugs themselves. An integrated health system usually represents a large patient population and thus a significant amount of prescription usage. This fact can be used as leverage with pharmaceutical companies to secure product discounts. Additionally, the use of formularies can ensure that the patients only receive coverage for prescriptions for agents with low contract prices. Encouragement to use generic products is another way to hold down prescription drug prices. Limiting the quantities of drugs available for a given period of time, controls individual prescription costs. For example, new prescriptions may be limited to a 30-day supply.

A copayment often is used to interest patients in holding down the price of prescriptions. In some cases tiering of copayments is used to encourage patients to accept a less expensive alternative. For example, a drug may be available as a branded drug and a generic. The copayment is higher if the patient insists on receiving the branded product and reduced if the generic is accepted.

Level 2 (Managed Utilization)—At this point of managing the pharmacy benefit, the emphasis shifts to utilization review, optimal use, and standards of care. Here information about the types and volume of drugs prescribed and the prescribing patterns of individual physicians is shared with the payers and the physicians. The use of this information is intended to educate the physician about the use of cost-effective therapy. In some integrated systems, physician compensation is tied to compliance with prescription formularies and the use of lower-cost medications.

Therapeutic interchange of medication is implemented at this level to ensure that products chosen as the most cost-effective in their class are used. In some cases, the dispensing pharmacist is required to call prescribing physicians to inform them of the change in medication. In some integrated systems, with the appropriate legal arrangements with medical staff, therapeutic interchange can be automatically implemented much like is performed currently in hospitals under the authority of the Pharmacy and Therapeutics Committee and the hospital's Medical Executive Board.

While activities in Level 2 do not require the equipment of Level 1, they do require expertise in drug use evaluation and physician education. Integrated-system pharmacists with a background in hospital pharmacy may be likely candidates to provide these services to the system. These pharmacists understand the work required in performing utilization review and the techniques for presenting this information to physicians, which easily can be expanded to take on the additional aspect of ambulatory care. However, if personnel with this expertise are not available in the system, these functions can be contracted to a PBM.

Level 3 (Managed Therapy)—Level 3 focuses on disease management and how drug therapy is integrated into overall management. This approach is more comprehensive than the drug-focused approach of Level 2. In disease management, the front-line health care provider and the patients become involved in the care program. With disease management, providers develop guidelines or treatment pathways to reflect best practice in the treatment of a specific disease. It is important that pharmacists, as the integrated delivery system's drug experts, become involved in these activities. Patients also are given the responsibility of carrying out their treatment at home and learning how to manage their disease.

Integrated systems with pharmacists who have expertise in the development of guidelines and experience in working with patient-care teams can provide these services internally. It is important for the pharmacy manager to claim these activities for the pharmacy, as this is the future of pharmacy practice. As the patient is involved in the disease management process, the pharmacist has long been established as the patient's ongoing contact within health care. This relationship should be nurtured and used as a mechanism to establish system pharmacists as important participants in disease management.

Level 4 (Managed Outcomes)—The managed outcomes phase occurs when the integrated health system is able to apply treatment guidelines for multiple disease states across the patient base and use outcomes analysis to demonstrate the value of the care. This level of activity requires that the first three levels of pharmacy benefit management be firmly in place. This requires integrated data links of prescrip-

tion and medical information that is often only available in an integrated system. Success at this level is not merely defined as the ability to manipulate data for outcomes analysis, but the ability to use this information to ensure the provision of quality care. As this level provides assurance of the provision of quality, cost-efficient care, integrated systems are striving to reach this level of function in the management of the pharmacy benefit.

FORMULARIES—Formularies represent a tool for pharmacy benefit management at its basic level and have been used since the 1950s to control drug costs and reduce performance variance in hospitals. Formularies in hospitals have developed from a list of drugs stocked in the institutions to an entire system to optimize patient care through effective, safe, and cost-effective use of drugs.[19] As the integrated system is interested in providing quality, cost-efficient drug therapy, the use of pharmacoeconomic techniques in the formulary decision-making process is necessary. Pharmacoeconomics goes beyond the traditional analysis of efficacy and safety to include costs of treatment and thus provide a global assessment of the medication. This type of analysis assigns a value to drug treatment so that the agent can be compared more equitably with other therapies.

These techniques for drug evaluation and formulary decision- making have been adopted in the integrated health care systems and managed-care organizations and outlined in detail in a 2000 publication of the Academy of Managed Care Pharmacy.[20] The changes in the drug evaluation process include the concerns of providing care across the continuum. The structure of the Pharmacy and Therapeutics Committee is changed for the integrated system to include an appropriate balance of primary-care physicians and specialists. Often the pharmacy representation will be expanded to include institutional and ambulatory pharmacists. Administrators involved with the managed-care plans for the system are often included. In some cases a PBM is contracted to provide formulary management. In this case, the PBM has its own Pharmacy and Therapeutics Committee and formulary of approved agents.

Formularies are described according to access the prescribers have to various drug entities. The control over access originally was intended merely to control drug costs; today the control is maintained to ensure the use of the most cost-effective agents and reduce process variation through statistical process control.

Open Formulary—This formulary is usually a comprehensive list of prescription products available, without restrictions on the choice of agent. Often within the open formulary, certain products are considered preferred as more cost-effective agents. These products are promoted for use to prescribers through newsletters and preferred products lists. Dispensing pharmacists may receive computerized messages encouraging them to contact the prescriber to switch to these agents when a nonpreferred agent is prescribed. Because there are no restrictions enforced, this type of formulary has limited impact on prescribing and thus little effect in managing the pharmacy benefit.

Closed Formulary—This formulary is a limited list of drugs chosen for inclusion by the Pharmacy and Therapeutics Committee. Typically, these formularies limit selection to between 300 and 1000 dosage forms. Usually, these formularies offer several choices of agents in each therapeutic category. In a health plan using the closed formulary, only drugs on the formulary drug list will be covered.

A mechanism must be in place to provide authorization when a patient requires a nonformulary agent. A letter of medical necessity from the prescribing physician or documentation of treatment failure on the covered agents may be needed to gain authorization for use.

Closed systems require more efforts to administer than the open system. The physician must be educated as to which medications are acceptable. The dispensing pharmacists become involved in contacting the physician if a nonformulary agent is prescribed. While this physician contact may take time, this provides the pharmacist an opportunity to work with the physician to improve care. Thus, these additional activities at the prescribing and dispensing phases contribute to more-effective drug choices and the control of costs, thus better control of the benefit.

For many years employers were required to provide open formularies as part of their employee benefit packages, because of union demands. However, as the pressure to control drug costs is increasing, more plans and in turn integrated systems are closing their formularies.

Restrictions—Within either formulary structure, other mechanisms of restriction may be used to direct therapeutic use and control costs. Restrictions often are placed on specific agents that are not considered to be used for problems covered by the health care insurance. For example, retinoic acid is used for both acne and age-related skin wrinkling. This drug treatment may not be covered for patients over 35 who would be suspected of using the product for wrinkles. As many plans do not cover plastic surgery for the same problem, it may be determined that use of this agent also is not covered. Some medications may have a lifetime cap, such as nicotine patches. In this way, the attempt is made to cover patches only for patients who are truly making an effort to stop smoking and not for those who are using the patches in situations in which smoking is not allowed.

A common restriction is the requirement for generic dispensing when the agents are available. Generic drug usage can provide the same therapeutic outcome at as much as a 60% saving in drug costs. In some cases, the branded drug may be available to patients if they are willing to pay the difference in price.

Prior authorization is used to direct proper care and control costs of drugs. In this case the prescriber must contact the insurer with specific information about the patient's condition. If previously set requirements are met, the prescription is authorized for coverage.

Drugs are sometimes restricted to specific physicians for use. These are usually very expensive medications that require a high level of expertise to prescribe and monitor the treatment. In many cases these restrictions require the primary-care physician to attempt treatment with a commonly used drug before referral to the specialist who has access to the restricted agent. While this may have limited effect on drug costs, it helps ensure safe and effective use of these specialized agents for the appropriate patients.

Incentives—The use of economic incentives to the integrated system or patient to promote use of preferred agents is one way to manage the pharmacy benefit. For the integrated system, the incentive is some form of risk-sharing agreement with the managed-care organization. In this case, part of the capitation for the patient is withheld to cover prescription costs. If the actual prescription costs are less than the withheld amount, the remainder is returned to the system.

The incentive for pharmacists may be an increase in the dispensing fee when generic drugs are used. A newer trend is to provide pharmacists incentives for cognitive services employed when changing an agent to a formulary or preferred product.

Patients may receive an incentive though a graduated system of copayments. Use of generic drugs may come with a lower copayment than use of branded agents. Preferred agents have a lower copayment than nonpreferred agents. Nonformulary agents may not be covered at all, thus encouraging the patient to have the prescriber select a covered medication.

The impact of these various incentives will influence drug costs to varying degrees. For physicians who are employees of integrated system and not direct recipients of the capitation fees, the shared risk incentive may have little effect unless the system explains the impact on the revenues and financial health of the system. The incentive will only influence pharmacists if the money offered is seen as a sufficient amount to cover the time involved in contacting the physician to switch a prescription. Patients who have no direct control on what is prescribed may in fact be irritated when they present a prescription for a nonformulary agent and are asked to pay for their medication.

BENEFIT MANAGEMENT COMPANIES—While PBMs can provide the total scope of services to the integrated health care system, there are many things to be considered when contracting for business services. Although there is little question that PBMs can provide claims processing with their computer systems, the practicality of using their services for some of the higher levels of pharmacy benefit management is less certain.

Much of the expertise needed to develop treatment protocols and disease-management plans often lies in the integrated health care system itself. The practitioners know their own unique patient population and, through personal interaction, understand local needs. This understanding can be valuable in developing the correct treatment plans to optimize outcomes in the specific patient population. While there is always a cost involved in developing these programs, the system has to determine whether internal development or external development (PBM) will provide the best product for the investment.

It is important to consider that whoever develops the treatment plan it will be the system's caregivers who will implement it. They must understand the plan and take ownership of it to implement the plan for optimal patient outcomes.

When pharmacy benefit management moves to Levels 3 and 4, there is a great deal of internal system information that must be used in decision-making and analysis. When this is done internally the issues of confidentiality remain in the system. When a PBM is involved in these activities, the system's confidential information must be provided to the PBM. While these confidentiality issues can be dealt with in contracts, the sharing of proprietary information in the competitive field of health care becomes a significant concern to the administrators of an integrated health care system.

HEALTH PROFESSIONAL EDUCATION—This chapter has discussed numerous mechanisms that are developed in integrated health care systems to ensure the provision of quality, cost-efficient care. These mechanisms are only helpful to this end if they are understood and adopted by practitioners at the point of care. To make these tools useful, the integrated system must develop an educational program for physicians, pharmacists, other health care providers, and patients. Pharmacists have an assortment of skills that can be used for these tasks. Pharmacy managers in integrated systems should work with administration to establish pharmacists as leaders in these educational roles.

Group Meetings—An efficient way to reach a large number of people is through group meetings. These educational meetings should be conducted throughout the integrated system for physicians, allied health care professionals, pharmacists, and patients. If geographically, it is not practical to have all department personnel in one place, the use of multimedia in the form of teleconferencing or videotape presentations can provide an education forum.

Medical staffs in integrated health care systems meet on a regular basis to discuss clinic procedures and day-to-day operational activities. This forum provides an opportune time for pharmacists to present information regarding formulary procedure, formulary agents, treatment guidelines, and disease management. As the practitioners are discussing the operation of their clinic, it is an easy transition to provide clinical information for incorporation into their daily treatment practices.

In the integrated health care system, patients are important players in their own care, and education of patients also must be considered. Often support groups meet, providing a forum to provide new information about services and treatment to a significant number of patients.

One-on-One Meetings—The pharmaceutical industry has long used this method to educate physicians about the use of their products. When pharmacists use this forum, it has been referred to as academic, or counter, detailing. The use of the term *counter* is meant to indicate the pharmacist is speaking against the information provided by the manufacturer. This is not always the case. The difference between detailing by the pharmaceutical sales force and that by the integrated-system pharmacist usually involves the purpose of the detailing activity. The salesperson is encouraging the use of the product for company profit, whereas the pharmacist is encouraging the use of the product that will provide quality, cost-efficient care for the patient. Sometimes the same product meets these two objectives, and then the two detailing activities do not run *counter* to each other. When this situation occurs it may be helpful for the system to use pharmaceutical sales representatives to educate the physicians on the use of agents. However, caution is advised, as their ultimate goal is maximal usage of their product, and the system's goal is optimal use of the proper treatment.

Pharmacists can use the same techniques used by the sales representatives in detailing activity. However, the discussion between the pharmacist and the physician can be more open, as topics for discussion are not governed by federal law as they are with the pharmaceutical representative. Pharmacists can provide the physician with system documents describing treatment as well as journal articles. Pharmacists can discuss actual system costs and use patterns to illustrate which drugs can provide care at lower costs. These educational sessions can serve to bolster the physician-pharmacist relationship and demonstrate the pharmacists' expertise in drug therapy.

Patient counseling frequently takes place in a one-on-one manner at the time of prescription dispensing. While this is an excellent time to educate the patient, it may not be optimal, as the pharmacy is often the last stop in the patient visit. Pharmacists in integrated health care systems are frequently in the clinic areas. Patient educational sessions can take place during the course of the office visit. This situation may prove optimal, as the physician, pharmacist, and patient are in the same locale to address treatment goals and changes in therapy.

Materials—In the hospital setting, the term *the formulary* has not only referred to the list of approved drug products, but also to a published document. Most formulary books not only contained the list of approved drugs, but also policies and procedures regarding pharmacy services and prescription writing along with guidelines and protocols. Encouraging the use of this book as a source of prescribing information can be helpful in educating physicians and other health care practitioners about the use of drugs in the system.

As integrated health systems computerize information systems, formularies can be placed in this environment for easier access by practitioners around the system. Besides the benefit of access, this electronic information can be more easily updated than the traditional printed format, which was updated usually once a year. Besides access to the formulary, other information regarding disease management and patient care can be provided in this format.

In systems where computer access is not readily available to all system care providers, a newsletter can be helpful in providing practical information in the patient-care areas. This document provides information in a short, easy-to-read format that can be posted in the patient-care work areas for easy access.

Many prescribers have integrated electronic drug information and hand-held prescribing technology in personal device assistants (PDAs). Comprehensive drug information databases that provide drug doses, side effects, indications, cost, contraindications and formulary alternatives are available for a wide range of national and statewide insurance plans. For example, in Michigan the formularies of all of the large HMOs are available at no cost to the users through ePocrates as a simple download from http://www.ePocrates.com. Other programs have established direct links to CPOE applications such that the physician can step out to dictate his/her patient note and send the prescription to the patient's pharmacy through infrared wireless technology (Fig 119-2).

Patient education materials should not be limited to those handed out at the time the drug is dispensed, nor limited to information on drugs alone. Information should be provided to patients on their disease and how their treatment plan works to control or eliminate their health problem. Much of this information is available from the various disease research and ad-

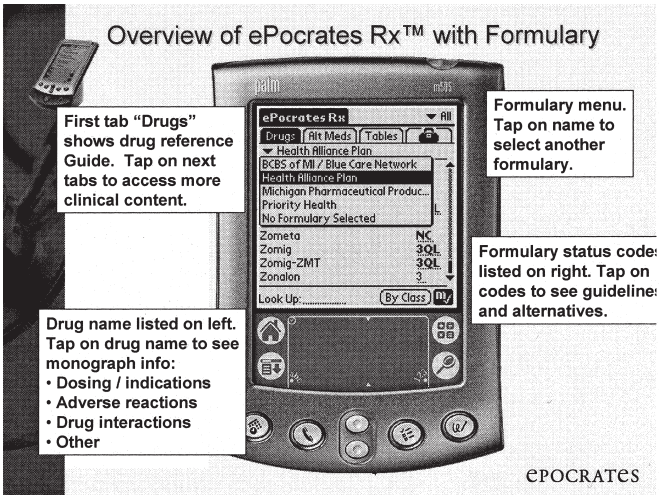

Figure 119-2. Personal device assistant with formularies (courtesy, ePocrates, Inc.).

vocacy groups such as the American Heart Association and American Diabetes Association and through government agencies. This information can be provided to patients in the clinics or mailed to the patient's home as a method of follow-up to one-on-one counseling. Physicians can download and print relevant materials from the Internet to support the patient's educational needs or refer them to high-quality web sites where credible information about their disease process or drug therapy is available.

ACHIEVING BUSINESS RESULTS

Pharmacy as a Business

HEALTH CARE BUSINESS—Business is a system of inputs and outputs in which monetary, human, and material resources are converted into the output or product. To continue to do business those outputs must be of value to the market in which they are sold, so that more resources can be purchased and more products can be produced. In other words, you have to make money to stay in business. While relating this to health care at one time seemed less than ethical, in today's health care environment this statement rings true. It is to this end that integrated health care systems have developed for the purpose of providing a quality product (health care) for a price that is considered competitive in the marketplace.

Pharmacists in integrated health care systems have the same mission to provide quality, cost-efficient care to the patients of the system. In pharmacy, the inputs include the skills of the pharmacists, medications, equipment, and supplies. The outputs include the products used, the goods (prescription and other medications) and services (drug-therapy monitoring) needed to provide patients with pharmaceutical care. In an integrated system the pharmacists must work to ensure seamless delivery of this care across the continuum. The coordination of these functions is the responsibility of the pharmacy management. If management is successful, it will have used the resources available, provided the proper patient care, and generated a profit to the system to save on overall costs. By understanding this concept it is easy to deduce that the concept of providing pharmaceutical care goes hand-in-hand with the business concept of serving the patient's needs with the resources available.

TOTAL QUALITY MANAGEMENT—While business is still defined as a system of inputs and outputs, the way business is conducted in the US has changed over the past several decades as foreign competition has entered and taken a front seat in world markets. The industry hit hardest by these changing concepts was the automobile manufacturers. The once world leaders in the industry, General Motors, Ford, and Chrysler, found that the Japanese were beginning to steal market share from them easily, in the late 1970s. As the problem grew, the industry giants realized that the competition was producing a better-quality, more cost-efficient product that the customers wanted. The carmakers realized that the way the Japanese handled the process of inputs and outputs was different. The Japanese after World War II sought the help of an American, Edward Demming, who helped them reconstruct the way business was run with a system called Total Quality Management (TQM). With this concept, business runs in a streamline manner. Employees who work daily with the product are asked for input about how to make the product better. Customers are asked how they feel about the product or service. The information from both these parties is taken into consideration and implemented to improve the product continuously. Efficiency in production is stressed. Just-in-time inventory concept is embraced. *Benchmarking* is used. This practice identifies the best practices of business and uses them as a standard for comparison with how a specific company is performing. As the auto industry adopted these concepts, it began to regain lost business in world markets. These concepts of running a quality, cost-efficient business are shared by integrated health care delivery systems, thus the adoption of TQM and the associated techniques was natural for the modern health care business. The Malcolm Baldridge Awards are now given to businesses for their achievement in the implementation and adoption of the TQM concepts. The health care industry participates in this awards process, and thus health care systems that achieve these highly prized honors are considered leaders in the field.

As health care delivery embraces the concept of customer satisfaction, it is important to consider who customers of an integrated system are. Health care is a unique industry in that the consumers of the service often do not pay for the service—someone else does. Although the patients are the customers of the service, their satisfaction with the service is still important, as there are competitors for their business. These customers have personal concerns for quality.

The other very important customer is the payer, who may be an employer group or health plan. This customer's focal concern is the cost of health care. If the payer is not satisfied with the cost of health care products and services provided by the system, it will take its business elsewhere. In this case, the payer looks at health care as a business commodity and expects the health care system to operate under the same business constraints as the payer does. That is, to provide a quality product in a cost-efficient manner. Thus, again this concept of using the structure of an integrated health care system as a quality, cost-efficient method to provide health care is in concert with the concerns of the potential customers, which is good business.

Many large employer groups have embraced exceptionally high standards of quality in their manufacturing and engineering areas. Health care, unlike manufacturing, is struggling to achieve "zero defect" outcomes. Corporations like General Electric, Ford Motor Corporation, and Motorola have adopted a quality philosophy and methodology called *Six-Sigma.* In *Six-Sigma,* systematic and statistically-based processes are applied to relevant defects in performance, driven by customer expectations. *Six-Sigma* methodologies aim to reduce the variation in clinical and business process which give rise to long cycle times, high cost and poor outcomes.[21] A process that operates at true *Six-Sigma* levels is producing acceptable quality levels over 99.99% of the time or producing no more than 3.4 defects per million events. In health care, 19% of medications dispensed in hospitals result in an error equating to a Sigma level of 2.4. Integrated delivery systems have far to go to achieve the level of quality performance expected by purchasers of health care. Pharmacists can have a pivotal role in achieving *Six-Sigma* quality due to the ease of access to data, knowledge of statistics and high ethical standards.

FUNCTIONAL AREAS—Pharmacy managers in an integrated system are faced with balancing the various inputs and demand for the different outputs to provide a quality, cost-efficient pharmacy service. There must be a business focus that ensures that monetary, human, and material resources (inputs) are allocated to the areas where they are most needed. Sound business practices of budgeting and quality control, among others, can be used to identify, monitor, and suggest change in pharmacy operations. Use of business plans, including long-range planning, is important for pharmacy managers to keep pharmacy practice on course with its goals and the goals of the integrated system. When pharmacy services are running smoothly, the system has another service that it can point to in its constant effort to stay competitive in the marketplace.

For the pharmacy manager, there is much to juggle to allow pharmaceutical care to establish and maintain its place in an integrated system. The plan may be for pharmacists to become involved in an academic detailing program with the system's physicians. In an effort to run a streamlined operation, no additional personnel will be made available for this task. The pharmacy manager then must use business skills to analyze the current work patterns, locate inefficiencies, and improve the process so that the existing pharmacists have time to take on these new tasks.

Accounting and Finance—Just as pharmacy departments in integrated systems take a different form, accounting in these systems takes a different approach to what is considered fiscally sound operations. In an integrated system, the money spent on expensive medications in the inpatient setting can save money in the consumption of the outpatient dollar. As the integrated system handles care through the continuum, the value of these expensive medications can be realized. Expensive drugs, which are given to inpatients, may save money for the system's ambulatory business units or *vice versa*.

Because of the ability of an integrated system to spread costs as well as savings across these systems, pharmacists working in these systems must broaden their fiscal management. In a system, pharmacy managers must have an understanding of purchasing, billing, and accounting as it applies to pharmacy throughout the system. Justification of fiscal losses in one site must be balanced in pharmacy savings at another point of care, and as saving health care use dollars in other facets of care, for example, office visits or decreased readmission rates.

Managed care has been an important driving force in the establishment of integrated systems for the provision of quality because of payment methods offered by the plans to health care providers who wish to contract with the plan. In this contractual agreement, the health care provider agrees to provide health care services in return for payment from the managed-care plan. This differs from the traditional relationship between providers and traditional insurance in that payment is not made on an occurrence basis, but on a monthly basis. Managed-care payment is made on a monthly basis for an agreed-upon fee that is called a per member per month (PMPM) fee. Under this structure the variation in the plan's costs only depend on the number of members enrolled, not on the number of services or complexity of services provided. Thus, if the patients use fewer services or the integrated system can run more efficiently, the system makes money. On the other hand, care is based on a PMPM for all care, it is common to if the patients require more services, the managed-care plan pays out no more money.

While the overall coverage in managed care is based on a PMPM for all care, it is common to have the pharmacy fees carved out from the total health-care benefit payment. The principles of services utilization under managed care apply to the pharmacy benefit as they did to the total health care benefit. If pharmacy services can provide prescription and pharmaceutical care at costs less than the amount paid by the managed-care plan, the pharmacy makes money. Thus, it is important for the pharmacy manager to understand this concept and understand why it is important to select the most cost-efficient agents for use in the managed-care population.

Human Resources—Efficiencies across the system are important to reach the goal of quality, cost-efficient care. This principle holds true when it comes to handling human resource issues in the pharmacy. To provide cost-efficient care, the system cannot afford to employ personnel who are not equipped to perform the tasks required. As integrated systems have changed the way health care is delivered, it is important for pharmacy managers to understand that these changes may be difficult for employees to understand and, thus, are not working to their optimal efficiencies. The pharmacy manager must find new ways to find qualified people, develop and motivate staff, and retain qualified people. These requirements do not differ from the human resource function of any business; however, as health care is rapidly changing, it becomes critical for the integrated system pharmacy management to be quicker and more innovative in these human resource functions.

Operations—Operations management is the organizing of the process that turns the inputs into the outputs. In the case of pharmacy services in the integrated system, pharmacy management is required so that the process takes the skills of the pharmacist and the medications and turns them into a quality, cost-efficient product of pharmaceutical care.

To provide these services the managers must look at pharmacy activities across the system and determine if all operations are running efficiently. In those areas where weaknesses are found, the operation is evaluated, and changes are made to improve services. The benefit from an integrated system is that pharmacists with various types of expertise can be called upon for assistance.

An integrated system is usually in a better position to adopt the use of computers and automation for dispensing medication and information to help the pharmacist. With computer links and automated dispensing units, pharmacist time can be freed up for patient counseling and physician education. In this way, the pharmacists can assist physicians in the choice of the most cost-efficient medication and help the patient use the drug for the best health care outcome. Thus, better operational management can play an important role in ensuring that quality, cost-efficient pharmaceutical care is delivered by the system.

Marketing—Marketing usually is associated with advertising or personnel selling a product or services. Marketing of pharmacy services in an integrated health care system is of critical importance for the survival of pharmacists as health care providers. A key factor in a successful business is to provide goods or services that have value to the customer. As integrated health care systems are run in a cost-efficient manner, any service or product that is not viewed as adding value to health care will be eliminated. In discussing marketing of pharmacy services it is important to consider the customers of pharmacy services in the integrated system.

Marketing plays an important role in developing the trust of health care providers. If the health care team sees the pharmacist as someone providing a valued service by working as a member of the team, the value of pharmacy involvement in patient care is accepted. In an integrated health care system, this involvement may be as simple as providing information regarding drug interactions to avoid negative outcomes or as complex as a pharmacist overseeing the complete care of a patient in a warfarin clinic. Through pharmacy marketing these services are accepted by the decision-makers of the system as quality, cost-efficient efforts needed to maintain the level of care demanded by the integrated system.

To ensure that pharmacy services are being provided to meet patient needs, marketing activities include identifying target markets for services, developing a product mix to satisfy these target markets, ensuring convenience and competitive pricing of products and services, and promoting pharmacy services. This reflects mostly on the quality initiative of an integrated health care system.

THE MANAGEMENT PROCESS—Bringing these functions together to run a quality, cost-efficient pharmacy service in one setting is a challenge. When the various types of pharmacy services provided in an integrated health care system are considered, the task appears overwhelming. Thus, the management process requires a directed, organized effort that can be sustained over the continuum of care for a long period of time. A good pharmacy manager prepares plans and organizes resources, especially the staff, in a way to bring together the talents to achieve the goal of providing quality, cost-efficient pharmaceutical care by directing their activities and controlling their activities. In an integrated system the use of TQM concepts indicates that the manager solicits input from the employees and customers of the service to ensure the best process.

PLANNING—Planning is the most critical element to ensure a successful operation. It requires that internal strengths and weaknesses of pharmacy services in the system be evaluated. In an integrated system, this review is expanded beyond the pharmacy alone and must include evaluation of pharmacy's interactions with the overall provision of health care. The operation and plans for expansion for the health care system as a whole must be understood for the pharmacy manager to plan for the pharmacy operations required over the continuum of care. Once the pharmacy's place in the overall business plan for the integrated system is understood, the manager can set goals for the department and develop policies, procedures, and business strategies to carry out the plan.

Organizing—Once the plan for action is determined, the pharmacy manager must organize pharmacy resources to accomplish the stated objectives. This involves identifying the tasks to complete, assigning tasks to individuals, and defining methods of accountability. Cooperation of pharmacists around the system is often required to complete a single process, thus organizations take on a broader scope than in the traditional health care delivery.

Staffing—Staffing involves identifying and providing the human resource needs for the system's pharmacy services. While the hiring and training of pharmacists in an integrated system is parallel to the process in any business, it is important to employ personnel who grasp the concepts of providing care across the continuum. In this situation, the qualified employees possess good communication skills and interest in working with the entire health care team to provide quality, cost-efficient care.

Directing—Directing involves keeping personnel focused on attaining system goals. This can be difficult in an integrated system, as sometimes it is difficult for employees to understand that the small part of the overall care process to which they contribute plays an important function in ensuring that quality, cost-efficient service is provided. While planning and organizing are management functions that usually take place before a process is implemented, directing the process is a continuing function of the pharmacy manager. Further, it is important to direct employee focus to the accomplishments required to reach the long-term plan. Integrated systems experience constant change as they grow through mergers and acquisitions. It is during these times of change that the manager must be especially diligent in directing the focus of integrated health care system pharmacy personnel.

Control—The controlling process involves periodic assessment of the work process. While directing activities is a day-to-day activity of business management, control through the use of reports and reviews ensures that the pharmacy's activities are on the correct course to achieve goals. This periodic assessment also is important because change in integrated health systems is continual. These periodic assessments can allow for review of the pharmacy process goals alongside the system's changing goals. This management function can signal the need to return to planning or organization to meet the new situation.

DEVELOPING A BUSINESS PLAN—If an integrated system is to use its resources for the best achievable outcomes, clear goals and a clear plan to achieve these goals are critical. A universal goal of integrated health care delivery systems is to provide quality, cost-efficient health care services to all patients. With this clearly understood system goal in mind, pharmacy management can develop a strategic plan that allows the manager to focus on the pharmacy's strengths, reduce weaknesses, bring together resources, and direct pharmacy to initiate a process that will ensure the delivery of quality, cost-efficient pharmaceutical care. Business goals generally are categorized as outcomes management, expense management, and profit. As managed care and its concern with quality play a major role in the provision of care in the integrated system, outcomes management that uses traditional measures of economic and clinical outcomes along with humanistic outcomes is becoming the benchmark method for determining if an integrated system is meeting its goals.

Outcomes—By using the outcomes management model, the pharmacy manager can determine the need for a pharmacy intervention to improve patient care. By assessing clinical, economic, and humanistic outcomes, the pharmacists can determine if treatment is being maximized throughout the integrated system. Once the diagnosis is completed, a plan of action can be implemented. An important component of the plan is a method of collecting specific outcome information that will allow measurement of the effect of the intervention on outcomes. With this outcome data in hand, the manager can perform an analysis to determine the success or failure of the process. This analysis can reveal where improvement is needed. After improvements are made, the cycle of analysis continues to repeat itself. This technique allows managers to identify what works and what does not and to improve the planning and the process over time. As the outcomes management model involves continuous process improvement, it is recognized as an important tool to ensure quality, cost-efficient service in integrated health care delivery systems.

Expenses—In traditional pharmacy practice, expense management was tied solely to meeting an assigned budget for pharmacy purchases and personnel costs. In an integrated health care system, these remain important, but the costs and savings in other health care costs, such as additional office visits or decrease in length of hospitalization, can be factored into the pharmacy budget. As the integrated system recognizes savings across the system, pharmacy managers must be in tune with system accounting to identify savings in other costs that can be attributed to the use of expensive drugs or pharmacy services.

Profit—Profit is a simple concept of business, in which the cost to produce the product is less than the value the product is sold for in the marketplace. In the traditional pharmacy setting, pharmacists worked hard to procure drugs for the least possible cost while ensuring that the payers paid more for drugs than the purchase price and the cost to run the pharmacy. While this concept of pharmacy profit is still important today, it is measured differently because of the influence of managed care. While some customers of an integrated system may still pay for individual services, more and more patients have managed pharmacy coverage by which the pharmacist is paid a set PMPM. The key to profits here is to ensure that drug and business expenses are less than the PMPM payment. As always, the pharmacy manager who can best control the costs of doing business has the best chance of maintaining the profit needed to stay in business.

SECURING THE FUTURE—While the basic principles of business apply to the operation of any pharmacy service, diligence in applying these principles to pharmacy services in an integrated health care system is critical. While drugs are an acceptable product used to treat disease and illness, the services of a pharmacist may not be understood as clearly and thus valued by either those who are running the health care system or those paying for the pharmacy benefit. If pharmacy is viewed only as a service that delivers drugs, integrated-systems managers will see the economy of replacing pharmacists with technicians who can operate automated dispensing machines.

In an integrated system, an effective pharmacy manager uses sound business principles to show the systems administrator that pharmacists are the most appropriate managers of the pharmacy business within the organization. To do this, the manager must begin by using sound business principles to procure drug stock efficiently at the best price. While a pharmacy focus on drug-inventory management may seem misdirected, one must understand that those running integrated systems are often businessmen first. It is efficient spending of health care dollars on drugs, which is the quickest, easiest, and most traditional measure of an efficient business operation. A pharmacy manager who can use business principles to establish sound drug-inventory management will establish credibility with the system administrators.

This credibility establishes a foundation from which the pharmacist can work to establish or expand pharmacy services in the direct patient-care arena. This is where the use of sound business techniques becomes particularly important to pharmacists. For example, if it were proposed that a pharmacist be placed in a clinic to monitor patients on warfarin therapy, this would make good business sense, as it would be less expensive to have a pharmacist monitor these patients than the physician. Further, twice as many patients could be cared for, as both physicians and pharmacists see patients; that would increase patient satisfaction with access to health care providers. However, a nurse could be seen as able to provide the same care as the pharmacist at a lower cost. This is where the pharmacy manager can use techniques of outcomes research and pharmacoeconomi1cs to give support to the sound business decision that a pharmacist can provide quality, cost-efficient care in this role. The outcomes management model further provides the tools to reaffirm the soundness of this decision, as the actual intervention is continually monitored and improved to ensure continuing quality, cost-efficient patient care. It is only through the use of sound business techniques that the pharmacist will win and keep a place within the integrated health system's provider team.

Pharmacy managers in integrated health care systems are running a pharmacy business as part of a very large business that delivers health care across the continuum. As part of this integrated business, the pharmacy manager is required to interact with many business managers who handle other facets of health care delivery. It is important for the pharmacy manager to understand what these other managers value in the operation of the delivery system, to function as a team player to ensure the provision of quality, cost-efficient health care, the product of the integrated health care delivery system. It is through the marriage of leadership skills with data and measurements, continuous quality improvement, employee-mindedness, and strategic thinking that business results are achieved and customer satisfaction is optimized.

CHALLENGES

Integrated health delivery systems face enormous future challenges. Many of these are in various stages of integration. During the process of integration through mergers, acquisitions, and joint ventures, vision and strategy must be communicated clearly to employees, the community, and health system stakeholders. Change is occurring rapidly in health care. Communication plans are essential to allay the anxiety of pharmacists and other health care workers. Organizational structures must be designed to achieve both vision and strategy. Relationships between system components must be well defined and understood. In professions such as pharmacy, corporate committees can be developed to help develop a strategy and vision for pharmacy throughout the health system. Physician involvement is needed to align pharmacy services with medical need and to ensure medical staff support of system wide formulary and drug use policies and guidelines. Information systems must be integrated, and common databases are needed for shared information across facilities. Physician order entry systems with links to physician offices, clinics, and the hospitals in the system are needed to reduce practice variance and enhance quality. Cross-functional training of pharmacists to bridge clinical roles in acute and primary-care settings with common goals defined and clear time lines are needed. Staff development, education, and retooling are needed to ensure shared expectations, skills, and competence. A process for evaluation and continuous process improvement will help to ensure continued alignment of processes with visions and goals. Pharmacists in health systems are part of the continuing vortex of change and as such must be prepared for dynamic, responsive role shifts as system goals are defined and redefined, and functions merged.

Another future challenge for pharmacists in health systems is the change in the delivery of services and care. The term *era of telemedicine or cybermedicine* has been coined to represent the way that patients seek and receive information about their health and medications. Electronic and Internet capabilities have put vast information in the hands of the consumer. This represents both an advantage and a challenge. As discussed, the electronic and cyber educational opportunities are enormous. Patients can be directed to databases and Web pages of the health system where guidelines, helpful hints, and online chat rooms with pharmacists and other professionals facilitate the exchange of information and knowledge. The opportunity may represent a threat to health systems that have not prepared for this wave of communication, as patients may find erroneous sources of information. The public wants to be educated about drugs and will find a means of gaining necessary information. The challenge to pharmacists in health systems is to ensure that patients are provided with accurate information consistent with safe, effective drug use.

The pharmaceutical industry is positioned to continue advertising directly to consumers. Television, magazines, direct-to-home mailings, help-lines, and other strategies are used to gain access to consumers. While physicians previously were seen as the customers of the pharmaceutical industry, patients are now the target. Lay people, with no medical training, are being barraged with information about drugs and messages to ask their physician to prescribe new drug therapies. Direct-to-consumer advertising presents a large challenge to health-system pharmacists. It forces pharmacists to stay up-to-date on all newly released drugs and devices, because often patients will question pharmacists about new entrants to the market. Pharmacists may have to counter consumer requests with alternative formulary choices and provide sufficient explanation to satisfy patients about the choices made by health-system formulary committees. Pharmacists are asked about new drugs about which little or no information is known, and they are expected to have answers.

In a more global sense, drug-purchasing agreements and formularies will continue to merge to gain increasingly larger market shares. As a result of increasing costs of providing medical and pharmacy services to patients, employers may begin contracting directly with health systems for health services rather than going through an insurance plan. For systems that own their own HMOs, this may be happening already, but future alliances will occur to cut out the middle provider. Contracts may be negotiated this way to reduce the cost of providing care and improve access of the purchaser's employees to the medical care by ensuring exclusivity with the health system. Pharmacists will be asked to provide pharmacy services directly to large companies (eg, General Motors, IBM, General Electric) rather than to individual patients. As a part of this service, the pharmacy benefits, drugs provided, educational offerings, and clinical services will all have to be tailored to meet the needs of the new purchasers of health care.

Pharmacists continue to play a pivotal role in the evolution of care delivered by health systems. To prepare for future challenges, pharmacists will need enhanced development of analytical, business, and financial skills. Knowledge of marketing strategies may be important, as direct-to-consumer advertising

from pharmacies to patients may play a role in maintaining and growing business. Customer satisfaction will be improved through extended clinical and educational services offered to patients. System-wide integration will require that pharmacists serve on committees and teams ensure alignment of financial, informational, and technological systems; clinical services; job descriptions; and care delivery. Pharmacists with leadership skills will help shape the vision for corporate pharmacy integration and are needed to plan for pharmacy in the 21st century.

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PART **8C**

Patient Care

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CHAPTER 120

Specialization in Pharmacy Practice

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Compared with many other professions, only recently has the profession of pharmacy entered the arena of advanced level credentialing. Formally, the medical profession has been recognizing specialty practice for nearly 100 years. Several other health professions (eg, nursing, optometry, dentistry) also demonstrate a long history of advanced level credentialing of qualified members. In fact, specialization in the healing arts is probably as old as the first declaration by a priest or shaman that he possessed special knowledge, insight, and power to heal. Therefore, he differed from other members of the tribe and was so recognized.[1]

HISTORY OF SPECIALIZATION IN MEDICINE

Specialization in medicine enjoys a long history. Medicine's evolution to its currently high credentialed state provides an interesting study in the professional, economic, and political forces that influence such a transformation. While there are major differences between medicine and many other health professions, medicine can serve as a model for other professions seeking to have credentialed specialists.

In medicine, the growth of specialization began in the 1920s and 1930s and is directly connected to the development of medical science and the resulting improvements made in medical care delivery. In the US, the growth of medical specialization is largely due to the physician's need to master the special tools and skills needed to deliver quality health care and the intricacies of social, political, and economic forces.

Most specialty areas developed around organ systems (eg, ophthalmology, otolaryngology, urology, neurosurgery, gastroenterology, cardiology); however, physicians were the only assessors of their own qualifications to practice a given specialty. There was no formal system to assure the public that the heart specialist was different from the general practitioner or that a physician claiming to be a specialist was indeed qualified. Consequently, specialty societies and medical education institutions collaborated on developing boards to define specialty qualifications and to issue credentials that would assure the public of the specialist's qualifications. The American Board of Ophthalmology established in 1917 was the first specialty board in the US.[2] It established the guidelines for the education, training, and evaluation of candidates desiring certification to practice ophthalmology. The second specialty board, the American Board of Otolaryngology was established in 1924. The third and fourth boards, the American Board of Obstetrics and Gynecology and the American Board of Dermatology and Syphilology, were established in 1930 and 1932, respectively. These were followed by several other specialties, such as, the American Board of Internal Medicine in 1936 and the American Board of Surgery in 1937.

The objectives of each specialty board were to elevate the standards of a specialty area, to familiarize the public with its aims and ideals, to protect the public against irresponsible and unqualified practitioners, to receive applications for examinations in a specialty area, to conduct examinations of such applicants, and to issue certificates of qualification in a specialty area. Since 1934, official recognition of specialty boards in medicine has been achieved by the collaborative efforts of the American Board of Medical Specialties and the American Medical Association (AMA) Council on Medical Education. The American Board of Medical Specialties (ABMS) approves 24 medical specialties. This organization has become the standard by which the profession and the public recognize physician specialists in the US.[3] In addition to the 24 ABMS member boards, approximately 180 non-ABMS boards issue specialty certification.

The establishment of board certification for physician specialists was based on the concept that a physician, who successfully met certain predetermined qualifications and attained the requisite level of knowledge, skill, and experience in a well-defined specialized area of medicine, would be a better practitioner than one who did not meet these qualifications. The implication was that a specialist would produce better health care outcomes, less morbidity, and/or greater efficiency in providing health care. However, while intuitively logical, this concept has not been validated by any studies.[4] One may argue that physicians with specialties provide state-of-the-art knowledge and that the patients ultimately benefit from specialist-dominated care. On the other hand, there may be instances where the sophisticated, expensive, specialist-dominated care may not produce any better health outcomes than did other, simpler, less-expensive health care delivery systems.

VALUE OF SPECIALIZATION IN MEDICINE

Although board certification is not required for an individual physician to practice medicine, the value of specialty certification in medicine, at least in medically sophisticated societies, is quite clear. Most hospitals and managed care organizations require that at least a certain percentage of their staff be board certified. Specialty board certification status for a physician is often used as a standard of excellence. Most hospitals, managed care organizations and health insurance plans require board certification for physicians for them to obtain clinical privileges and hospital appointments. Furthermore, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance embrace medical specialty board certification by incorporating it into their accreditation standards.[5] Commonly, the public also

views medical specialty board certification as a measure of a physician's clinical expertise.

HISTORY OF SPECIALIZATION IN PHARMACY

The Basis of Specialization

For most of its history as a profession, pharmacy was relatively undifferentiated. Prior to the mid-1900s, most pharmacists concentrated on providing drug products to patients in response to the order of a physician or other credentialed prescriber. The emergence of practice differentiation really began to be recognized in the late 1960s and early 1970s. In a 1968 editorial, Paul Parker described hospital pharmacists who had developed unique roles that were distinctive from the traditional dispensing roles of the pharmacist.[6] These pioneering "clinical pharmacists" participated with physicians in therapeutic decision-making, and Parker suggested that their level of knowledge and practice skills required special educational and experiential preparation. Further, he encouraged hospital pharmacists to organize their departments to recognize and utilize these emerging "specialists" and proposed that the medical model of service organization might be applicable to pharmacy.[6] Shortly thereafter, the Study Commission on Pharmacy, known synonymously as the Millis commission, was commissioned by the American Association of Colleges of Pharmacy (AACP). Its report, published in 1975, acknowledged that differentiation in pharmacy practice was occurring and that this differentiation was, in general, expected and desirable. While not specifying specialty practice areas, the commission suggested that a structure be established to oversee all pharmacist credentialing.

In a series of editorials between 1974 and 1976, Donald Francke outlined his concept of a structure for the practice of pharmacy.[7] Specialization was addressed as part of the continuum of education, and he identified the pharmacotherapeutic specialist, the clinical radiopharmacist specialist, the drug information specialist, the pediatric clinical pharmacy specialist, and the pharmacy practice specialist, among others.[7]

Task Force on Specialization in Pharmacy–Role of APhA

Perceiving the evolving interest in differentiated practice within the pharmacy profession, the Board of Trustees of the American Pharmaceutical Association (APhA; now the American Pharmacists Association) appointed a Task Force on Specialties in Pharmacy in early 1973. This group was charged to (1) identify existing or potential areas of specialization (or, alternatively, to determine that there were no specialties and that the practice of pharmacy was not likely to become specialized); (2) propose a means by which specialties could be identified; and (3) develop the means by which individuals could become recognized as specialists, as well as recommendations for recertification.

The Task Force published its report in 1974.[8] While not concluding whether specialties existed at that time, it did determine that one or more specialties would develop in the near future and that there was need for an independent agency to recognize these specialists. It made several recommendations concerning the recognition process and proposed the establishment of a Board of Pharmaceutical Specialties (BPS) to develop the mechanism to identify specialty practice areas and recognize individual specialists.

Development of the Board of Pharmaceutical Specialties

The Board of Pharmaceutical Specialties was officially established on January 5, 1976, when APhA members approved the BPS bylaws within the APhA structure. The initial mission of BPS was based on responsibilities outlined in its bylaws. (1) BPS recognizes appropriate specialties in pharmacy practice using specific criteria developed for this purpose. *These criteria are discussed below in the Petition Process.* (2) BPS sets standards for certification and recertification of pharmacists in designated areas of specialty practice. *This is achieved primarily by individual specialty councils, within the BPS structure, which make recommendations to the full Board.* (3) BPS administers the process of examination and evaluation of individuals who seek certification and recertification as specialists. (4) BPS serves as an information clearinghouse and coordinating agency for organizations and pharmacists with regard to the specialty practice of pharmacy.

The organizational relationship of the BPS to the APhA was intended to provide financial and administrative support for the young organization, while ensuring that decisions regarding recognition of specialties and specialists would be independent. To this end, BPS bylaws provide for a nine-member Board, comprised of six pharmacists and three non-pharmacists (ie, two other health professions members and one public/consumer member. The Board is appointed by the APhA Board of Trustees, but is independently responsible for administering the specialty certification process. This Board is advised by Specialty Councils, representing each recognized specialty. The Specialty Councils are comprised of six pharmacists from the specialty practice area itself, and three pharmacists representing the profession in general. The Specialty Council Chairs (ie, currently numbering five and representing the specialties of Nuclear Pharmacy, Nutrition Support Pharmacy, Oncology Pharmacy, Pharmacotherapy, and Psychiatric Pharmacy) as well as the Executive Director/Secretary of BPS (an administrative staff position) serve as *ex-officio* members of the Board of Pharmaceutical Specialties.

The initial membership of the Board of Pharmaceutical Specialties included:

R. Paul Baumgartner, Jr., PharmD
Carl G Britto, BS
Maureen M Fink, BS (Vice Chair)
Thomas D Foster, PharmD
John D James, BS
Warren E Weaver, PhD (Chair)
Erma Angevine, BA
Charlotte Cumbie-Doster, RN, EdD
Rosemary A Gellene, MD

BPS New Specialty Petition Process

A key role of the Board of Pharmaceutical Specialties is the recognition of new specialties within the profession. To its credit, the founders of BPS sought to make this a very formal and participative process for the pharmacy profession. Seven criteria for recognition of a new specialty were established, which remain in effect today.[9] These criteria must be addressed in detail in a petition that is submitted to BPS by an organization or group seeking recognition of a new specialty in pharmacy. A more detailed description of the petition process is available from BPS and on its web site, which provides additional guidelines for needed supporting information under each criterion. The BPS criteria that must be met for a new specialty are as follows:

1. The profession of pharmacy **needs** specifically trained practitioners in the specialty practice area to fulfill the responsibilities of the profession in improving the health and welfare of the public. Licensed pharmacists or other health care professionals cannot provide the level of services that pharmacist specialists can, and pharmacy's responsibilities may not be fulfilled effectively without their contributions.
2. A **clear, significant demand** for the specialty is made by the public and health care systems.
3. A **reasonable number** of pharmacist specialists practice in and **devote significant time** to provision of services in the specialty area.

4. Practice in the specialty area requires **specialized knowledge** of pharmaceutical sciences based upon the biological, physical, and behavioral sciences. The specialty may not be based solely on the practice environment or managerial, procedural, or technical services.
5. Pharmacists in the specialty practice area perform **specialized functions,** acquired through education and training beyond the basic level attained by licensed pharmacists.
6. Pharmacy schools and other organizations offer **education and training** in the specialty practice area.
7. **Transmission of knowledge** in the specialty practice area occurs through books, journals, symposia, professional meetings, and other formal media or mechanisms.

Petition Review and Approval

When the BPS receives a petition proposing a new specialty, a formal review process begins. If an initial staff and Board review indicate that the petition is complete and reasonably addresses the criteria, the petition is released for review and comment by the profession and the public. At least two open hearings, usually at major pharmacy meetings, are held to solicit input from the pharmacy profession, other health professions, third-party payers, and the public. Finally, the Board will consider the detailed information in the petition and any comments provided during the review period to determine whether the criteria for establishment of a new specialty have been met. The Board's decision is appealable in accordance with established BPS appeals policy. Once a new specialty has been approved, the initial Specialty Council is appointed. The organization or group that submitted the petition appoints the six specialist members to the Council, and BPS appoints the three non-specialist pharmacist members. After the first certification examination is administered and the first group of specialists is certified, all new specialist members of a Specialty Council are required to hold the certification. One of the initial charges to this Council is to work with the BPS, the sponsoring organization and others within and outside the profession to develop initial funding to establish the specialty. The other major charge is to work with the BPS testing consultant to develop the process itself.

Establishment of a Specialty Certification Process

Across all professional fields, there are relatively consistent procedures that need to be followed in the development and implementation of an advanced practice certification process. To be respected and successful, a certification examination must be psychometrically sound and legally defensible. This process begins when the BPS, and the profession determines that the legitimate criteria for the establishment of the specialty have been met. An early responsibility of the Specialty Council is to work with the testing consultant to conduct a role delineation study, also known as a job analysis. Usually, this is a very comprehensive survey designed to identify what specific knowledge, skills, and tasks characterize the specialty and can be used to differentiate between practitioners who are and are not at the specialist level. This is administered to a large group of pharmacists, some of whom are generally believed to be practicing at the specialist level, and some who are thought not to be practicing at that level.

When appropriately analyzed, the results of this study form the Content Outline or Examination Specifications for the specialty's certification examination, which determines what types of questions should comprise the examination. Next, the Council convenes groups of knowledgeable individuals to draft questions (also known as test items) that meet established test specifications. When appropriate, test items are based on evidence-based clinical practice guidelines and randomized clinical trial data, and each item is referenced for validation purposes. Following an extensive review, these questions are used to create the specialty examination itself. All BPS specialty certification examinations consist of 200 multiple-choice questions. Each has four possible answers, only one of which is correct. After the first examination has been drafted, the Council and other experts conduct a passing point study, which results in a psychometrically valid passing score. A passing point study involves determining what fraction of minimally competent practitioners would likely select the correct answer for each item. BPS and most similar advanced practice certifications utilize a Criterion referenced scoring system, rather than the more familiar Norm referenced system more common in academic institutions. Detailed discussion of these systems in included on the BPS website (http://www.bpsweb.org) and educational testing references. Recertification in all five BPS specialties is required every 7 years. Recertification examinations consist of 100 multiple choice questions in the same format as the original certification examination. When available, a BPS-approved professional development program may be substituted for the written recertification examination.

Evolution of Specialties

In the pre-BPS discussions across the pharmacy profession, several potential specialties were identified. It was not surprising that Nuclear Pharmacy emerged as the first petition to be submitted to the BPS. A section on Nuclear Pharmacy had been established within the APhA structure in 1975, and there was little debate that specialized knowledge and skill was required to practice nuclear pharmacy safely and competently. The community of nuclear pharmacy practitioners was relatively small and close-knit, and the APhA was in an excellent position to assist BPS to develop the specialty.[10] It was nearly 12 years, however, before any other specialties were proposed. Since that time, however, four additional specialties have been recognized. Those petitions were submitted by three other major professional organizations, marking the profession's recognition that the BPS could ideally serve the entire pharmacy profession as its specialty certification body. Although other certifications have emerged in recent years under other auspices, BPS remains the only organization in pharmacy offering specialty level certification.

The bar graph (Fig 120-1) illustrates the development and growth of specialties in pharmacy since 1995. Note that numbers represent individuals currently certified by BPS as of the year indicated. Individuals who failed to recertify when required are removed from these totals.

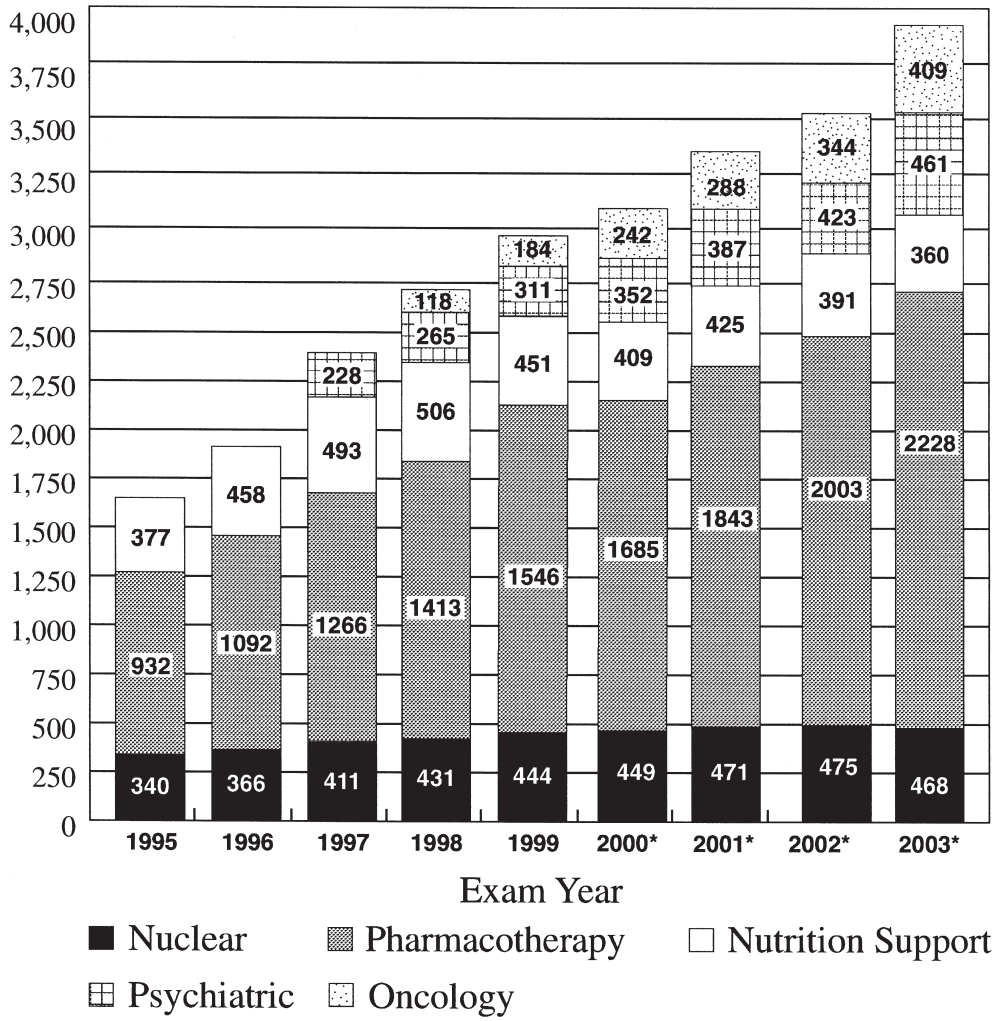
CURRENT SPECIALTIES IN PHARMACY

Nuclear Pharmacy

1. Supporting Organization(s)
   American Pharmaceutical Association
2. Year of Specialty Recognition: 1978
3. Description of the Specialty:
   Nuclear Pharmacy seeks to improve and promote the public health through the safe and effective use of radioactive drugs for diagnosis and therapy. A nuclear pharmacist, as a member of the nuclear medicine team, specializes in the procurement, compounding, quality control testing, dispensing, distribution, and monitoring of radiopharmaceuticals. In addition, the nuclear pharmacist provides consultation regarding health and safety issues, as well as the use of non-radioactive drugs and patient care. Those who are granted certification in this specialty may use the designation Board Certified Nuclear Pharmacist and the initials BCNP, as long as certification is valid.
4. Eligibility Requirements:
   The minimum requirements for certification in nuclear pharmacy are:
   - Graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or an alternative educational program accepted by BPS (eg, pharmacy school outside of USA)

Pharmacists Certified by the Board of Pharmaceutical Specialties

The table below illustrates the numbers of pharmacist specialists holding BPS certification in each of the years noted. This graph demonstrates the growth in specialization in the five recognized areas for which testing programs have been implemented.



*individuals who failed to recertify have been excluded from these figures.

Figure 120-1. Pharmacists certified by the Board of Pharmaceutical Specialties.

- Current, active license to practice pharmacy
- 4,000 hours of training/experience in nuclear pharmacy practice
- Achieving a passing score on the Nuclear Pharmacy Specialty Certification Examination.

The required 4,000 hours of experience may be earned in a variety of settings.

Academic-up to 2,000 hours:

- Undergraduate courses in nuclear pharmacy: up to 100 hours experience for every quarter credit hour or 150 hours experience for every semester credit hour, to a maximum of 1,500 hours
- Postgraduate courses in nuclear pharmacy: up to 100 hours experience for every quarter credit hour or 150 hours experience for every semester credit hour, to a maximum of 1,500 hours
- MS or PhD degree in nuclear pharmacy: 2,000 hours
- Successful completion of the Nuclear Pharmacy Certificate Program offered by Purdue University (217 hours) or The Ohio State University (214 hours). Credit for other courses will be assessed on a case-by-case basis.

Training/Practice-up to 4,000 hours:

- Residency in nuclear pharmacy: hour-for-hour credit to a maximum of 2,000 hours
- Internship to satisfy requirements of state boards of pharmacy: hour-for-hour credit in a licensed nuclear pharmacy or facility authorized to handle radioactive materials, to a maximum of 2,000 hours
- Nuclear pharmacy practice: hour-for-hour credit in a licensed nuclear pharmacy or health care facility approved by state or federal agencies to handle radioactive materials, to a maximum of 4,000 hours.

5. Examination Content
   - Procurement of radiopharmaceuticals (6% of the examination)
   - Compounding of radiopharmaceuticals (20% of the examination)
   - Quality Assurance of radiopharmaceuticals (15% of the examination)
   - Dispensing of radiopharmaceuticals (20% of the examination)
   - Distribution of radiopharmaceuticals (5% of the examination)

- Health and Safety associated with radiopharmaceuticals (15% of the examination)
- Provision of Information and Consultation (15% of the examination)
- Monitoring Patient Outcomes (2% of the examination)
- Research and Development (2% of the examination)

6. Recertification
Recertification for Board Certified Nuclear Pharmacists (BCNP) is a three-step process:
   - Self-evaluation: Review of the nuclear pharmacy practice activities/functions that have changed since initial certification or last recertification.
   - Peer review: Documentation of nuclear pharmacy practice over the seven year certification period.
   - Formal Assessment: This assessment of a practitioner's knowledge and skills will be accomplished through one of two methods: 1) achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination; OR 2) earning 70 hours of continuing education credit provided by a professional development program approved by BPS.
   - A current, active license to practice pharmacy is required for recertification.
   - As part of the recertification process, every BCNP is asked to complete an annual practice report form provided by BPS. At time of recertification, the BCNP must also certify that the candidate is not under suspension by the Nuclear Regulatory Commission or their state radiation control organization.
7. Members of the first Specialty Council
All appointed in 1978: (* = non-specialist member)
David R. Allen, PhD
*Horace Aslin, BS
Ronald J. Callahan, MS
James R. Cooper, PharmD
Thomas Deutsch, BS
Rodney D. Ice, PhD
*John Romankiewicz, PharmD
Stanley M. Shaw, PhD
*Margaret C. Yarborough, BS

Nutrition Support Pharmacy

1. Supporting Organization(s)
American Society of Health-System Pharmacists and American Society for Parenteral and Enteral Nutrition
2. Year of Recognition: 1988
3. Description of the Specialty:
Nutrition support pharmacy addresses the care of patients who receive specialized nutrition support, including parenteral and enteral nutrition. The nutrition support pharmacist has responsibility for promoting maintenance and/or restoration of optimal nutritional status, designing and modifying treatment according to the needs of the patient. The nutrition support pharmacist has responsibility for direct patient care and often functions as a member of a multidisciplinary nutrition support team. Those who are granted certification in this specialty may use the designation Board Certified Nutrition Support Pharmacist and the initials BCNSP, as long as certification is valid.
4. Eligibility Requirements
The minimum requirements for this specialty certification are:
   - Graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or an alternative educational program accepted by BPS (eg, pharmacy school outside of USA).
   - Current, active license to practice pharmacy.
   - Completion of three (3) years practice experience with substantial time spent in nutrition support pharmacy activities
     OR
     Completion of a specialty residency in nutrition support pharmacy practice plus one (1) additional year of practice with substantial time spent in nutrition support pharmacy activities
     OR
     Completion of a nutrition support fellowship plus one (1) additional year of practice experience with substantial time spent in nutrition support pharmacy activities
     OR
     Completion of BOTH a specialty residency in nutrition support pharmacy practice AND a nutrition support fellowship (no additional year of experience required).
   - Achieving a passing score on the Nutrition Support Pharmacy Specialty Certification Examination
5. Examination Content
Domain 1: Provision of individualized nutrition support care to patients
   - Subdomain A: Assessment of the patient (17% of the examination)
   - Subdomain B: Development and Implementation of a therapeutic plan (22% of the examination)
   - Subdomain C: Monitoring and Management of the patient (39% of the examination)

   Domain 2: Management of nutrition support services (13% of the examination)
   Domain 3: Advancement of nutrition support pharmacy practice (9% of the examination)
6. Recertification
Recertification for Board Certified Nutrition Support Pharmacists (BCNSP) is based on the following activities:
   - Earning a minimum of 3.0 continuing education units (CEU) in nutrition support with no less than 1.0 CEU earned every two years. These CEUs must be from providers approved by the American Council on Pharmaceutical Education (ACPE). NOTE: 1.0 CEU equals 10 hours of approved continuing education.
   - Achieving a passing score on the 100-item, multiple-choice recertification examination, which is based on the content outline of the certification examination
   - A current, active license to practice pharmacy is required for recertification.
7. Members of the first Specialty Council
All appointed in 1989: (* = non-specialist member)
Joseph S. Bertino, PharmD
Lawrence A. Robinson, PharmD
*Stephen M. Caiola, MS
Michael D. Reed, PharmD
Deborah B. Thorn, MBA
*Ellen A. Leitinger, PharmD
Beverly J. Holcombe, PharmD
Kathleen M. Strausburg, MS
*James A. Ponto, MS

Pharmacotherapy

1. Supporting Organization(s)
American College of Clinical Pharmacy
2. Year of Recognition: 1988
3. Description of the Specialty:
Pharmacotherapy is that area of pharmacy practice that is responsible for ensuring the safe, appropriate, and economical use of drugs in patient care. The pharmacotherapy specialist has responsibility for direct patient care, often functions as a member of a multidisciplinary team and is frequently the primary source of drug information for other healthcare professionals. Those who are granted certification in this specialty may use the designation Board Certified Pharmacotherapy Specialist and the initials BCPS, as long as certification is valid.
4. Eligibility Requirements
The minimum requirements for this specialty certification are:
   - Graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or an alternative educational program accepted by BPS (eg, pharmacy school outside the USA)
   - Current, active license to practice pharmacy
   - *Bachelor of Science in Pharmacy degree (or equivalent) plus a, b, or c below.
     a. Five (5) years of practice with substantial component (>50%) of patient care activities in pharmacotherapy
        OR
     b. Completion of a Pharmacy Practice or Specialty Residency and three additional years of practice with a substantial component (>50%) of patient care activities in pharmacotherapy
        OR
     c. Completion of BOTH a Pharmacy Practice Residency and a Specialty Residency with a substantial component (>50%) of patient care activities in pharmacotherapy

     *Doctor of Pharmacy degree plus a or b below.

a. Three (3) years of practice experience with a substantial component (>50%) of patient care activities in pharmacotherapy
OR
b. Completion of a Pharmacy Practice or Specialty Residency with a substantial component (>50%) of patient care activities in pharmacotherapy

- Achieving a passing score on the Pharmacotherapy Specialty Certification Examination

*One of these two requirements must be met in order to be certified.

5. Examination Content
Domain 1: Collect and interpret data to design, recommend, implement, monitor, and modify patient-specific pharmacotherapy in collaboration with other health care professionals to optimize drug therapy (55% of the examination)
Domain 2: Retrieve, generate, interpret, and disseminate knowledge in pharmacotherapy (30% of the examination)
Domain 3: Design, recommend, implement, monitor and modify system specific policies and procedures in collaboration with other professionals/administrators to optimize health care (15% of the examination)
6. Recertification
Recertification for Board Certified Pharmacotherapy Specialists (BCPS) is an assessment of a practitioner's knowledge and skills through one of two methods:
- Achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination;
OR
- Earning 120 hours of continuing education credit provided by a professional development program approved by BPS.
- A current, active license to practice pharmacy is required for recertification.

7. Members of the first Specialty Council
All appointed in 1989: (* = non-specialist member)
David R. Rush, PharmD
Robert L. Talbert, PharmD
*William C. Porter, PharmD
Peter Gal, PharmD
Peter H. Vlasses, PharmD
*William A. Smith, PharmD
George E. Dukes, PharmD
Barbara J. Zarowitz, PharmD
*William A. Miller, PharmD

Psychiatric Pharmacy

1. Supporting Organization(s)
American Society of Health-System Pharmacists
2. Year of Recognition: 1994
3. Description of the Specialty:
Psychiatric pharmacy addresses the pharmaceutical care of patients with psychiatric-related illnesses. As a member of a multidisciplinary treatment team, the psychiatric pharmacy specialist is often responsible for optimizing drug treatment and patient care by conducting such activities as monitoring patient response, patient assessment, recognizing drug-induced problems, and recommending appropriate treatment plans. Those who are granted certification in this specialty may use the designation Board Certified Psychiatric Pharmacist and the initials BCPP, as long as certification is valid.
4. Eligibility Requirements
The minimum requirements for this specialty certification are:
- Graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or an alternative educational program accepted by BPS (eg, pharmacy school outside the USA)
- Current, active license to practice pharmacy
- Completion of four (4) years of practice with substantial time spent in psychiatric pharmacy practice
OR
- Completion of a specialty residency in psychiatric pharmacy plus one (1) additional year of practice with substantial time spent in psychiatric pharmacy
- Achieving a passing score on the Psychiatric Pharmacy Specialty Certification Examination

5. Examination Content
Domain 1: Collaborate with other health professionals in pursuing optimal drug therapy for neuropsychiatric patients; this requires that the psychiatric pharmacist collect and interpret pertinent clinical data, and assume personal responsibility for successful drug therapy outcomes (ie, through the recommendation, design, implementation, monitoring, and modification of pharmacotherapeutic plans for the patient) (75% of the examination)
Domain 2: Interpret, generate and/or disseminate knowledge in neuropsychiatric pharmacy (20% of the examination)
Domain 3: In collaboration with other professionals/administrators, recommend, design, implement, monitor, and modify systems and policies to optimize the use of drugs in the treatment of neuropsychiatric patients (5% of the examination)
6. Recertification
Recertification of Board Certified Psychiatric Pharmacists (BCPP) requires an assessment of a practitioner's knowledge and skills through one of two methods:
- Achieving a passing score on the 100-item multiple choice recertification examination, based on the content outline of the certification examination;
OR
- Earning 120 hours of continuing education credit provided by a professional development program approved by BPS.
- A current, active license to practice pharmacy is required for recertification.

7. Members of the first Specialty Council
Appointed in 1994: (* = non-specialist member)
M. Lynn Crismon, PharmD
Martha P. Fankhauser, MS
*George H. Hinkle, MS
Michael W. Jann, PharmD
*Howard A. Juni, PharmD
Raymond C. Love, PharmD
*Max D. Ray, PharmD
Glen L. Stimmel, PharmD
Barbara G. Wells, PharmD

Oncology Pharmacy

1. Supporting Organization(s)
American Society of Health-System Pharmacists
2. Year of Recognition: 1996
3. Description of the Specialty:
Oncology pharmacy specialists recommend, design, implement, monitor and modify pharmacotherapeutic plans to optimize outcomes in patients with malignant diseases. Those who are granted certification in this specialty may use the designation Board Certified Oncology Pharmacist and the initials BCOP, as long as certification is valid.
4. Eligibility Requirements
The minimum requirements for this specialty certification are:
- Graduation from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or an alternative educational program accepted by BPS (eg, pharmacy school outside the USA)
- Current, active license to practice pharmacy
- Completion of three (3) years of practice with substantial time spent in oncology pharmacy
OR
- Completion of a specialty residency in oncology pharmacy plus one (1) additional year of practice with substantial time spent in oncology pharmacy
- Achieving a passing score on the Oncology Pharmacy Specialty Certification Examination

5. Examination Content
Domain 1: Collaborate with other health professionals in pursuing optimal drug therapy for patients with cancer. This requires that the oncology pharmacist collects and interprets pertinent clinical data, and assumes personal responsibility for successful drug therapy outcomes. (60% of the examination)
Domain 2: Interpret, generate and/or disseminate knowledge in oncology as it applies to oncology pharmacy practice. (20% of the examination)
Domain 3: In collaboration with other professionals, patients, and the public, recommend, design, implement, monitor, and

modify systems and policies to optimize the use of drugs in patients with cancer. (15% of the examination)
Domain 4: Collaborate with other professionals and the public in addressing public health issues (eg, risk factors, prevention, screening, cancer survivorship) as they relate to oncology pharmacy practice. (5% of the examination)

6. Recertification
Recertification for Board Certified Oncology Pharmacists (BCOP) requires achieving a passing score on the 100-item, multiple-choice recertification examination, which is based on the content outline of the certification examination. As of the summer, 2003, a professional development option for recertification of BCOP is under development.
A current, active license to practice pharmacy is required for recertification.
7. Members of the first Specialty Council
Appointed in 1997: (* = non-specialist member)
*Samuel C. Augustine, PharmD
Carol M. Balmer, PharmD
*Toby Clark, MS
Rebecca S. Finley, PharmD
Barry R. Goldspiel, PharmD
Robert J. Ignoffo, PharmD
Jim M. Koeller, PharmD
Celeste M. Lindley, PharmD
*Kathleen M. Strausburg, MS

ADDED QUALIFICATIONS PROCESS AND CURRENTLY RECOGNIZED AREAS

In 1997, BPS approved a process for the recognition of Added Qualifications in an existing specialty. Added Qualifications provides a method to document further differentiation of practitioners within BPS-recognized specialties.[11] BPS issued its *Petitioner Information for Added Qualifications in Infectious Diseases* document in August 1997. This was followed by the publishing of several articles, meetings with interested organizations, and other informational activities. Conferral of added qualifications requires submission of a $100 fee and a structured portfolio, which is reviewed by the pertinent BPS Specialty Council and scored in accordance with published criteria. Added Qualifications must be reaffirmed every 7 years, just as BPS certification in a primary specialty.

In May 1998, the Society of Infectious Diseases Pharmacists submitted a petition for Added Qualifications in Infectious Diseases Pharmacotherapy. The petition, including the portfolio review process, was approved by BPS in March 1999. In March 2000, the American College of Clinical Pharmacy (ACCP) submitted a petition to BPS, requesting designation of cardiology as a second area of Added Qualifications within Pharmacotherapy. The petition, including the portfolio review process, was approved by BPS in October 2000.

As of spring 2003, 40 Board Certified Pharmacotherapy Specialists held Added Qualifications in Infectious Diseases, and 21 held Added Qualifications in Cardiology. To date, no other petitions for Added Qualifications have been presented to BPS, although pharmacist groups have expressed interest in establishment of a program for Pediatrics (within pharmacotherapy), Positron Emitting Tomography (within Nuclear Pharmacy), bone marrow transplant (within Oncology), and some others.

THE BPS SPECIALTY CERTIFICATION PROCESS

Currently, BPS specialty certification and recertification examinations are administered once annually, on the first Saturday in October. The application deadline is the preceding August 1. Examination sites are established in approximately 18 cities in the continental United States. Additional, "alternate sites" may be established in other US cities, at the request of 10 or more candidates, and in foreign countries. In recent years, BPS has had a total of approximately 28 sites each year worldwide.

Complete examination information, including a Candidate's Guide, Specialty Content Outlines, current fees, and application materials are available upon request from BPS or at the website, www.bpsweb.org. First-time applicants are encouraged to apply on-line.

As previously described, each BPS specialty certification examination consists of 200 multiple choice questions, each having only one correct answer. Written recertification examinations consist of 100 questions. Short practice tests for each specialty are posted on the BPS website to illustrate the construction of the questions and their content.

Candidates are informed in writing of their performance on each domain of the examination, and successful candidates are awarded a BPS certificate. A BPS certification or recertification examination may be retaken if necessary at reduced fee.

THE VALUE OF SPECIALTY CERTIFICATION IN PHARMACY

As in other professions where specialty certification has become established, this rigorous process provides value and benefit to society, to the pharmacy profession, and to the certified individuals.

Society

The existence of pharmacists who have demonstrated an advanced level of practice knowledge and skill has clearly resulted in improved pharmaceutical care for patients. Numerous studies have investigated the positive impact of clinically trained pharmacists in inpatient and ambulatory care settings.[12] Pharmacists who are able to interact with other health professionals in planning and implementing therapy contribute special expertise in areas that complement the skills of their colleagues. As the recognized "drug experts," they can also help to ensure that patients maximize the potential benefits of therapy. While there have been few direct studies of the impact of specialty certification in pharmacy (or in medicine, for that matter) on patient outcomes, available evidence suggests that training and experience are important determinants of quality care. Specialty certification provides an objective, independent measure of knowledge and experience against an established standard. High quality certification programs in all fields maintain that their first obligation is to society, and ensure that their programs meet that goal.

The Pharmacy Profession

As the numbers of BPS-certified pharmacists have grown within the pharmacy profession, the value of this credential has been increasingly recognized. Just as in other health professions, increasingly, specialty board certification is viewed as an important qualification for clinical faculty in pharmacy schools.[13] BPS certification has also been accepted by several schools as a measure of the clinical expertise of applicants to non-traditional PharmD programs, often exempting them from certain didactic requirements. Specialty board certification is a respected model of clinical expertise in institutional settings where clinical privileges are required to perform some patient-care services. When other health professionals understand that pharmacists can also meet this rigorous standard, the status of the profession and pharmacists' ability to participate fully in patient care increases.

The Individual

Specialty certification confers many potential benefits for the pharmacist. Positive recognition by patients, colleagues, and employers often brings psychological "enrichment" and reward

to pharmacists who have worked hard to develop and document their expertise. There are also increasing instances of monetary reward for specialty certification. Some examples include: Bonus pay for members of the uniformed services and pharmacists in many institutional systems; hiring or promotion preference, particularly for professionally challenging clinical specialist positions; reimbursement of costs for certification and/or recertification; eligibility for participation in collaborative practice or other arrangements where payment for pharmaceutical services is possible. As specialty certification becomes more common in pharmacy, recognition of its value to the individual pharmacist will also increase, just as it has for medicine and other health professions.

OTHER CREDENTIALS IN PHARMACY

Specialty certification is but one of several options open to pharmacists seeking to advance professionally after their initial entry into practice. Other credentials available include:

- Formal post-graduate degree programs
- Residency or fellowship training
- Certificate training programs
- Multi-disciplinary certification programs (eg, Certified Diabetes Educator)
- Non-specialty certification programs (eg, Certified Disease Manager; Certified Geriatric Pharmacist)

Detailed discussion of these opportunities is beyond the scope of this chapter. Attainment of some of these credentials may help prepare or qualify a pharmacist for BPS Specialty Certification.

COUNCIL ON CREDENTIALING IN PHARMACY

Because of the multiplicity of credentials available to pharmacists, several of the major membership organizations in pharmacy joined to establish the Council on Credentialing in Pharmacy in 1997. This organization provides a forum for discussion, planning, and dissemination of information within and outside the pharmacy profession on the topic of credentialing for pharmacists and pharmacy technicians. The Council's Reference paper on Pharmacy Credentialing has become an important resource on the topic.[14]

FUTURE OF SPECIALIZATION

Pharmaceutical care and the services offered by pharmacists will continue to evolve and increase in complexity and sophistication. For example, between 1993 and 2003, the Food and Drug Administration approved more than 300 new drugs, biologicals, and vaccines that prevent and treat over 150 conditions.[15] Many of these are new molecular entities and not oral dosing forms, and require greater expertise in their preparation and administration than older products. Furthermore, as pharmacy and the rest of medicine move into the era of pharmacogenomics and gene therapy, new and expanded skills and knowledge will be required to utilize new tools in the therapeutic armamentarium safely and effectively. As has occurred with other health professions, pharmacy will most likely respond to these challenges by increasing specialization. Further, health care systems, payers, and patients will continue to demand greater knowledge and skill *and documentation of that knowledge and skill* from those professionals responsible for drug therapy management.

In less than a decade (1995–2003) the number of board certified specialists in pharmacy has grown by nearly 240% (ie, from 1649 to 3926); however, many pharmacists have not sought specialty credentialing. As of the year 2004, fewer than 5% of practicing pharmacists have sought any type of advanced practice certification, and optimal recognition and acceptance of specialization has clearly not yet arrived. The future of specialty certification will ultimately be defined by many factors, including attainment of provider status for pharmacists to be recognized by Combined Medicare-Medicaid Services, continued development of collaborative prescriptive practices (ie, currently, more than 40 states have such legislation), further expansion of postgraduate training programs including new degrees and specialty practice residencies, employer practices, and society's acceptance of new roles and practices for pharmacists. Over the past two decades, the growth in pharmacy residents has been impressive, from 356 to 1080 or approximately 300%.[16] As more and more students continue to seek postgraduate training to differentiate themselves from the typical graduate, the number of pharmacy practice residencies and specialty practice residencies will expand. A new cadre of specialty-trained practitioners will help drive the process of specialty recognition.

While it is uncertain which areas of pharmacy practice will be recognized as specialties for the future, discussion has centered around compounding, pain management or palliative care, and perhaps, ambulatory or primary care. Each new specialty must satisfy all seven criteria for recognition by BPS and ultimately the pharmacy profession, and this process will maintain the high standards set forth by the visionaries who began this process nearly three decades ago.

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