

# SAFETY BRIEF

## MECHANICAL ENGINEERING

**Triodyne Inc.****Officers**

Ralph L. Barnett  
Dolores Gildin  
S. Carl Uzgiris

**Mechanical Engineering**

Peter Barroso Jr.  
Dennis B. Brickman  
Elizabeth J. Buhrmaster  
Michael A. Dilch  
Christopher W. Ferrone  
Claudine P. Giebs  
Suzanne A. Glowiak  
Crispin Hales  
Lee Halvorson  
Gary M. Hutter  
Brian D. King  
Dror Kopernik  
Woodrow Nelson  
Steven R. Schmid  
R. Kevin Smith  
William G. Switalski  
Andrew H. Tudor  
James R. Wingfield  
Leonard Zelek

**Library Services**

Sharon Meyer  
Betty Bellows  
Meredith L. Hamilton  
Cheryl Hansen  
Antonia M. Johns  
Norene Kramer  
Scott Kramer  
Molly Kravetz  
Florence Lasky  
Kimberly Last  
Shirley W. Rutenberg  
Annette Schubert  
Jackie Schwartz  
Louise M. Stefani

**Information Products****Expert Transcript Center (ETC)**

Meredith L. Hamilton  
Glenn Werner  
Shirley Werner

**Contract Services**

Beth A. Hamilton

**Graphic Communications**

Mary A. Misiewicz  
Charles D'Ecotiss  
Anthony Provenzano  
Lynn Wallace-Mills  
Thomas E. Zabinski

**Model Laboratory**

2721 Alison Lane  
Wilmette, IL 60091-2101  
Robert Kaplan  
Bill Brown  
Mario Visocnik

**Vehicle Laboratory**

Charles Sinkovits

**Photographic Laboratory**

7903 Beckwith Road  
Morton Grove, IL 60053  
Larry Good

**Business Systems**

Maryalyce Skree-Hauser  
Sharon L. Mathews  
Chris Ann Gonatas  
Janet Heckenbach  
Karen Kotsovetis

## ENVIRONMENTAL ENGINEERING.

**Triodyne Environmental Engineering, Inc.**

5950 West Touhy Avenue  
Niles, IL 60648-4610  
(708) 647-6748  
FAX: (708) 647-2047

**Officers/Directors**

Gary M. Hutter  
Ralph L. Barnett  
S. Carl Uzgiris

**Engineering/Science**

John P. Bederka  
Richard Gullickson  
James T. O'Donnell  
Audrone M. Stake

**Library/Research Services**

Shelley Hamilton

January 1990

**Triodyne Inc.**

Consulting Engineers and Scientists

5950 West Touhy Avenue Niles, IL 60648-4610 (708) 677-4730

FAX: (708) 647-2047

V.5 N.4 Reprint

## SAFETY RESEARCH

**Institute for Advanced Safety Studies**

5950 West Touhy Avenue  
Niles, IL 60648-4610  
(708) 647-1101

**Chairman of the Board**  
Ralph L. Barnett

**Executive Director**  
Leslie A. Savage

**Director of Research**  
Thomas E. Waterman

**Information Services**  
Beth A. Hamilton

## FIRE AND EXPLOSION:

**Triodyne Fire & Explosion Engineers, Inc.**

2907 Butterfield Road  
Suite 120  
Oak Brook, IL 60521-1175  
(708) 573-7707  
FAX: (708) 573-7731

**Officers/Directors**

John A. Campbell  
Reed B. Varley  
Ralph L. Barnett  
S. Carl Uzgiris

**Chicago Office**

John A. Campbell  
Thomas H. Miller  
Kim R. Miniszewski  
James H. Shanley, Jr.

**Miami Office**

1110 Brickell Avenue  
Suite 430  
Miami, FL 33131-3135  
(305) 374-4091  
FAX: (305) 358-9615  
Reed B. Varley

**Laboratory/Library**

5950 West Touhy Avenue  
Niles, IL 60648-4610  
(708) 677-4730  
Cheryl Hansen

## MANUFACTURING.

**Alliance Tool & Mfg. Inc.**

91 East Wilcox Street  
Maywood, IL 60153-2397  
(312) 261-1712  
FAX: (708) 345-4004

**Officers**

S. Carl Uzgiris  
Ralph L. Barnett

**General Manager**

Ramesh Ganghi

**Plant Manager**

Larry Shelley

**Founders/Consultants**

Joseph Gansacz  
Albert Kanikula

## CONSULTANTS:

R. A. Budenholzer, Ph.D.  
Power and Energy

R. A. Damijonaitis  
Mathematical Modeling  
Digital Design

David W. Levinson, Ph.D.  
Senior Metallurgical  
Advisor

W. Patrick Mc Vay  
Medical Device  
Engineering Consultant

James T. O'Donnell, Ph.D.  
Pharmacology

**MEDICAL SERIES**

## Status of Standards of Practice in Pharmacy

By James T. O'Donnell

### Abstract

*Forces affecting standards, including laws and regulations, accrediting agencies, relevant literature, legal opinions, and professional organizations, are discussed. Compliance is evaluated. The promulgation of standards is examined from positive and negative viewpoints.*

### Biography

Dr. James O'Donnell is a pharmacist, pharmacologist, and nutritionist. He is presently Assistant Professor of Pharmacology at Rush Medical College, Chicago, Illinois; Editor-in-Chief for the *Journal of Pharmacy Practice*; and pharmacy editor for *Infusion*. His practice experience includes institutional, community, long term, and home care pharmacy practice. Dr. O'Donnell is a Triodyne Inc. consultant in matters of pharmaceutical and alcohol effects. He is a frequent lecturer on drug effects, pharmacy practice, effects of alcohol, and responsibilities of pharmacists. He has authored more than 70 publications and is a member of the boards of the Illinois Pharmacists Association, the Illinois Council of Hospital Pharmacists, and the Greater Chicago Illinois Pharmacists Association.

Reprinted with the permission of W.B. Saunders Company from the *Journal of Pharmacy Practice*, Volume 1, Issue 1, August, 1988.

Circulation: 30,311

No Charge

The first article in this issue focused on the historical development of standards in pharmacy.\* This article will present definitions, forces affecting standards (including laws and regulations), accrediting bodies, published literature, pharmacy organization standards, and legal opinions. These are displayed in Table 1. The focus and effects of many of these various forces will be analyzed and discussed. Evaluation of compliance of various standards is made, and finally a discussion of the positive and negative sides to promulgation of standards is presented.

### Standards in Other Professions

Initially, a review of standards of practice in other health professions, namely medicine and nursing, was planned, with an intention to compare and contrast those with pharmacy standards. Literature research showed that published standards in medicine are practically nonexistent. Standards in nursing as defined by the American Nurses Association address the functions and roles of the nursing standards of practice:

*"Nursing's concern for the quality of its services constitutes the heart of its responsibility to the public. The more expertise required to perform the service, the greater society's dependence upon those who carry it out. Nursing must control its practice in order to guarantee the quality of its service to the public. Behind that guarantee are the standards of the profession, which are directed toward assurance that service of a good quality will be provided. This is essential both for the protection of the public and for the profession itself. A profession which does not maintain the confidence of the public will soon cease to be a social force."*<sup>1</sup>

Standards have been developed by several specialty areas of nursing practice including, but not limited to, critical care, pediatrics, psychiatric, and emergency nursing practice. Similarities can be demonstrated between the standards for the American College of Clinical Pharmacy (ACCP) minimal standards and those of the nursing specialty groups. The ACCP standards will be discussed later.

\*O'Donnell, J.T.: History of the Development of Standards of Practice in the Profession of Pharmacy. *Journal of Pharmacy Practice* 1:1, pp. 3-10, August, 1988.

**Table 1.**  
**Sources of Standards Affecting Pharmacy Practice**

<b>Statutes</b>	State <ul style="list-style-type: none"> <li>• Pharmacy practice acts</li> </ul>
	Federal <ul style="list-style-type: none"> <li>• Food, Drug, and Cosmetic Act</li> <li>• Controlled Substance Act</li> <li>• Alcohol and Treasury</li> </ul>
<b>Regulations</b>	Board of Pharmacy
	Health Departments Health and Human Services
<b>Accrediting Agencies</b>	Joint Commission on Accreditation of Healthcare Organizations
	American Society of Hospital Pharmacist Residency Accreditation Specialty Boards <ul style="list-style-type: none"> <li>• Board of Pharmaceutical Specialties</li> </ul>
<b>Organizations</b>	American Pharmaceutical Association
	American Society of Hospital Pharmacists American College of Clinical Pharmacists American College of Apothecaries American Society of Consulting Pharmacists
<b>Literature</b>	Journals
	Textbooks Handbooks
<b>Legal Opinions</b>	Law Reviews
	Court Opinions

### Development of Standards

The term "profession" is defined as a vocation in which a professed knowledge of some department of learning is used in its application to the affairs of others, or in the practice of an art founded upon it. An organized profession requires more than the mere existence of an intellectual discipline. The essence of professionalism is the relationship of trust that exists between the practitioner and the person who receives his advice or services. The recipient, relying entirely on the knowledge of the practitioner, must be able to have complete trust in the practitioner's services and impartial advice. It follows that there must be an established minimum standard of knowledge for practitioners, and that there must be agreement among them about standards of behavior in their professional work. This means that there must be a body that determines the standard of education and

establishes the code of conduct, and that this body must be representative of practitioners and be subject to their collective control.

If the characteristics described are accepted as the elements of a profession, then pharmacy meets the essential requirements, as follows:

(1) **An intellectual discipline and a standard of knowledge.** Pharmacy is of ancient origin. Today a university degree in pharmacy followed by an examination and including some extern or clerkship training is required by all jurisdictions before licensure to practice is granted.

(2) **A representative body of practitioners.** In contrast to Great Britain, which has the Pharmaceutical Society of Great Britain as its representative body, the United States has a general body, The

American Pharmaceutical Association (APhA), the national professional society of pharmacists, and also several other organizations that represent pharmacists by practice type, interest, and/or location. Membership in these organizations is voluntary. To a greater or lesser extent these organizations promulgate standards of practice.

**(3) Standards of Practice.** These are accepted standards of practice known throughout the profession. They are intended to express the collective views of members of the profession and have been approved by governing bodies of the respective organizations.

### What are Standards

Standards are criteria for professional practice. They represent an acknowledged measure of comparison for quantitative or qualitative value and can be used by members of the profession at all levels. In addition, other health care professionals, institutions, and regulatory bodies are provided with a reference of expectation of the profession. Standards increase accountability of the profession to the public by articulating, supporting, and protecting the rights of patients:

*"Society gives professions the right to govern their concerns and empowers the professions to manage their own functions. The professions, in turn, are responsible to society for their actions. Because of this relationship, the professions must regulate themselves in order to insure the quality of the services provided."*<sup>2</sup>

Metcalfe delineates the establishment and implementation of standards of practice as prime functions of a professional organization:

*"The responsibilities inherent in carrying out these functions are to establish, maintain, and improve standards; to hold members accountable for using standards; to educate the public to appreciate the standards; to protect the public from individuals who have not attained the standards or willfully do not follow them; and to protect individual members of the profession from each other."*<sup>2</sup>



### Licensure, Certification, and Accreditation

The functions of a profession also include the professional definition and regulation of both generalist and specialist practice. Professional regulation is achieved largely through standard setting and credentialing of individuals and institutions by means of licensure, certification and through the adoption of ethical codes and norms of conduct.<sup>3</sup> In addition to the standards of professional practice, education and organization standards must be used in accreditation of education and service programs.

Review of specialty standards developed and proposed in pharmacy [Board of Pharmaceutical Specialties (BPS), radio-pharmacy, nutrition support, pharmacotherapy, minimum standards for clinical pharmacy in hospitals] demonstrate this standards and credentialing process.

Standards are used in all aspects of quality assurance (QA) including peer review. The term QA is now widely used to cover a variety of tasks, activities, roles, and functions. It has become an all purpose term, and it connotes an ideal. Assistance or enhancement in quality is probably the most that can be achieved in light of present knowledge.<sup>4</sup>

### Accreditation by JCAHO and ASHP

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) standards for accreditation are primarily structural in nature and address services provided in organized health care settings. The JCAHO has developed accreditation standards for hospitals, home care, long-term care, psychiatric and mental health care, and hospice care. The JCAHO standard setting process involves participating institutions, health

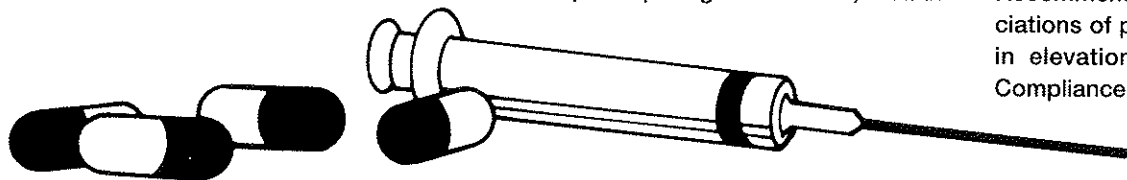
care professional organizations, and government agencies in the development and field review of the accreditation standards. The accreditation standards are drafted by the respective professional and technical advisory committees to the accreditation programs. In some cases, a specific professional and technical advisory committee is consulted. The American Society of Hospital Pharmacists (ASHP) is consulted for the pharmacy standards of JCAHO.

In 1957, the American Hospital Association (AHA) and the ASHP called for greater involvement by hospital pharmacists in the control of drugs in the institutional setting by voting "to urge hospital pharmacists, through appropriate channels, to extend their responsibilities to include participation in programs dealing with the safe handling of drugs throughout the hospital."<sup>13</sup> Since then, traditional patterns for the delivery of pharmaceutical services have given way to new concepts. These new concepts have resulted in greater involvement by the pharmacist in an institution's patient care areas and the recognition of a need for a clinical component to pharmaceutical services and drug control in the institution. This clinical service component recognizes the need for pharmacy students to be patient oriented as well as product oriented.

The ASHP Statement on Clinical Functions in Institutional Pharmacy Practice serves to define the advanced roles for pharmacists in organized health care settings, and thus helps to elevate standards:

*"Contemporary pharmaceutical services include clinical functions such as drug related decision making and patient care activities such as preparation, distribution, and control...Each director of pharmaceutical services is responsible for establishing and maintaining an appropriate clinical services program. The ASHP believes that pharmacists must be able to develop and provide clinical pharmacy services, and it supports and endorses the several specific clinical functions."*<sup>13</sup>

Recommendations by professional associations of practitioners are the first step in elevation of standards of practice. Compliance with these recommendations



is examined later in this article by examining the Stolar ASHP reviews.

## Standard of Care

The standard of care required of the practicing pharmacist encompasses myriad definitions. It can be defined in general terms, such as a high degree of care and skill, or it can be defined in specific terms, such as in the sale of drugs when the pharmacist has a social duty to be familiar with drugs and to be able to distinguish one from another.<sup>5</sup> Another facet of the standard of care that is applicable to pharmacists is that it is based, usually by the court, on what the majority of pharmacists would do under like circumstances. At one time, the comparison was made on the local or community level; however, in general the criteria today is much broader, and the courts view the practice of the profession as a whole on a nationwide basis.

The standard of care is really a measure by which the court determines if the duty is fulfilled, and this standard may vary depending on the type of duty involved. The practicing pharmacist has the duty to qualify himself or herself by attaining and maintaining an acceptable level or professional competence and by using such skill and precaution in the preparation, compounding, dispensing, labeling and sale of drugs and medical devices—whether pursuant to prescription or not—so as to prevent injury or death to all who are exposed to his or her professional services. If the pharmacist is an owner, operator, or director of a pharmacy, he or she has additional duties: to employ only qualified individuals and to manage responsibly the incidental operation of a business establishment.<sup>6</sup> Negligence exists when a standard of care has been breached, resulting in harm to someone.

## Laws and Regulations

The pharmacist must be aware of and comply with the laws, regulations, and standards governing the profession. Many of these standards and regulations deal with aspects of drug control. Among the agencies and organizations affecting institutional pharmacy practice are those described below.

### *Regulatory Agencies and Organizations*

The U.S. government, through its Food

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

### *State Boards of Pharmacy*

The state board of pharmacy is the agency of state government responsible for regulating pharmacy practice within the state. Practitioners, institutions, and community pharmacies must obtain licenses from the board to practice pharmacy or provide pharmacy services in the state. State boards of pharmacy promulgate numerous regulations pertaining to drug dispensing and control. The pharmacy practice act and accompanying rules and regulations are considered to be minimums. In some states, the state board of health licenses the hospital pharmacy separately or through a license that includes all departments of the hospital. In others, there are separate classes of pharmacy licenses, including retail, hospital, parenteral, and nuclear.

Standards and guidelines for pharmaceutical services have been established by the JCAHO and the ASHP. The United States Pharmacopoeial Convention also promulgates certain pharmacy practice procedures as well as official standards for drugs and drug testing. Professional practice guidelines and standards generally do not have the force of the law, but rather are intended to assist pharmacists in achieving the highest level of practice. They may, however, be used in legal proceedings as evidence of what constitutes acceptable practice as determined by the profession itself.<sup>7</sup>

General practitioners of pharmacy are not held to the higher standard applicable to experts. This does not mean, however, that general practitioners can disregard an area of practice in which experts exist. For example, the general practitioner of pharmacy probably has a legal duty to detect harmful drug interactions. Whether a pharmacist practicing in an institution will be held to a higher stand-

ard of care than the standard for a pharmacist practicing in a community pharmacy is not clear; no cases directly addressing that point are known. Nonetheless, a good argument can be made for applying a higher standard to pharmacists practicing in institutions.

The JCAHO standards pertain to the minimal services required of pharmaceutical services in hospitals and in extended care facilities. New JCAHO home care standards, which now incorporate pharmacy, are examined later in this issue.\* The Social Security Administration has also devised minimum standards for such services in hospitals and in extended care facilities for those institutions' qualification in the Medicare program. These are a few examples of the standards of practice that are currently in force. Other examples might include the pharmacy service procedural manuals that are developed by pharmacy and therapeutics committees in hospitals or by pharmacy corporations offering contract pharmacy service of ambulatory care, i.e., large chain pharmacy corporations, Health Maintenance Organizations (HMOs).

## Promulgation of Standards by Professional Organizations

"Every profession must have a measure by which to judge its practice."<sup>8</sup> Metcalf delineates the establishment and implementation of standards of practice as prime functions of a professional organization.

*"The responsibilities inherent in carrying out these functions are to establish, maintain, and improve standards; to hold members accountable for using standards; to educate the public to appreciate the standards; to protect the public from individuals who have not attained the standards or willfully do not follow them; and to protect individual members of the profession from each other."*

The APhA and the AACP promulgated the Standards of Practice for the Profession of Pharmacy in 1979.<sup>8</sup> The introductory statements are reproduced here in their entirety so that the reader can benefit from the initial intent of the organizations promulgating these standards: (see next page)

\*Bing, C.M.: Intergration of Standards Into High-tech Home Care Pharmacy Practice. *Journal of Pharmacy* 1:1, pp. 45-52, August, 1988.

## Introductory Statements to the 1979 Standards of Practice for the Profession of Pharmacy

New "Standards of Practice" for the profession of pharmacy have been completed after six grueling years of work and an investment by the American Pharmaceutical Association and the American Association of Colleges of Pharmacy of more than \$250,000.

These Standards...should provide the cornerstone for the future practice of pharmacy. They describe in generic terms what a pharmacist does in fulfilling the basic responsibilities of the profession.

The Standards have been developed at an opportune time: They will enable the profession to inform the federal government and other official agencies dealing with health care matters on exactly what constitutes comprehensive pharmaceutical service; third party payors will understand better what they should be paying for. The schools and colleges of pharmacy will be able to scrutinize their curricula to determine the relevancy of subject matter in their educational programs. Providers of continuing education will be able to identify practitioner needs more accurately and design programs around uniformly acceptable objectives.

The Standards also will provide bases for promoting the pharmacist's role to the public. People will learn what they can expect and what they may legitimately demand in the way of pharmaceutical service. Regulatory boards can use them to review the pertinence and relevance of licensing examinations. And pharmacists will be in the enviable position of defining for other health care practitioners the scope of pharmacy practice, showing them clearly where the pharmacist's responsibilities lie in relation to the roles of these colleagues.

The immediate use to which the Standards can be put is pharmacist self assessment of both practice and ability to provide needed services. As they now exist, the Standards tell what pharmacists do. They give the pharmacist a basis of reference by describing the kinds of functions being performed by other similarly trained health professionals who collectively are called pharmacists. Thus the Standards point out to all pharmacists the nature of comprehensive pharmaceutical service, and they provide adequate guidance for pharmacists to investigate and prepare for delivering any new service. The standards can also be used for peer review. Peer review is of primary importance in assessing and monitoring the quality of pharmacy practice. It is the process by which the pharmacist actively engaged in the practice

systematically assesses, monitors, and makes judgments about the quality of pharmacy care provided to patients or clients by other peers using the standards of practice. The primary purposes of peer review are:

- a. to judge the quality of service provided
- b. to contribute to the improvement of the delivery of services by the expeditious identification and correction of decision-making problems and service deficiencies. Peer review emphasizes the interrelationship of structure, process, and outcome elements in the standards of pharmacy practice from the perspective of the decision-making process. To make the Standards work, more comprehensive procedures will require cooperation within the profession of pharmacy—from practitioners, educators, and professional associations.

First, the Standards of Practice must be widely disseminated . . . Standards of practice are expected to be as dynamic as the profession of pharmacy itself.

Second, practitioners must be given an opportunity to determine, in a confidential and voluntary way, how well they fulfill the responsibilities covered by the Standards.

Third, programs designed to "fill the gap" in the pharmacist's self-appraised competence must be made accessible to practitioners. As feedback of pharmacist's self assessment activities reaches the providers of continuing professional education, these educators will be responsible for establishing programs that will help practitioners maintain their competence to practice.

Finally, pharmacists should be able to determine how well they have developed their new competencies. Methods by which practitioners can demonstrate that they maintain the needed competencies of a pharmacist will have to be explored. The profession has completed the first phase of its continuing competence in Pharmacy Project with the publication of the Standards of Practice. Eventually, through the initiative of individual pharmacists as well as collective action by the profession, pharmacists will be able to use the Standards to identify their own educational needs and map out their own learning programs to maintain competence. In so doing, they and the profession will move closer to the goal of having pharmacists assume primary responsibility for their own ongoing professional education.

Our focus is on Standards of Practice as they relate to patient care functions (i.e., Section III). Section IV, Education of Pharmacists, will be addressed in a future issue. It has been suggested that documentation and publishing standards will expose pharmacists to malpractice litigation. These standards have been in print for over nine years now. In lieu of published guidelines, which can be viewed and measured, a pharmacist would be defending himself in a vacuum against a claim that he did not perform up to a standard, if there were not a standard of reference.

Kalman and Schlegel<sup>9</sup> previously had defined the practice standards as the degree of adherence to defined criteria. Criteria, when fulfilled, are indicative of quality service. To illustrate, they considered the function of the pharmacist to collect and record data about the health status of the patient as part of the overall responsibility to monitor patient drug therapy. A standard of practice would indicate *what* information should be collected, *when* and *how often*, and how the record should be maintained. They describe practice standards as essential because they address basic concepts of quality: quality of professional preparedness (competence), quality of service provided (performance), and quality of educational outcomes (programming). Standards provide a yardstick by which quality may be measured.

They further describe practice standards as more than statements of intent. They are statements of action. Why statements of action and not statements of knowledge? Statements of knowledge tell what the pharmacist *should* know. Whether the pharmacist acts on that knowledge is a different matter.

Kalman and Schlegel advise that we should not wait for the courts to set our practice standards. According to the former Chief Justice of the United States, Warren Burger, the pharmacist is similar to the law clerk who goes to the library and finds the right book; that is, the pharmacist accurately transfers the drug from one container to another and dispenses it. The profession was outraged by the Justice's comments.<sup>10</sup>

Had the court in Ingram and Jones looked to the Standards, and held these standards, they would have recognized that

**Table 2.**

Percentage Reporting	Clinical Service
11%	A. Preparation of written medication histories on admission
35%	B. Counseling of patients on their medications either during their stay or at discharge
61%	C. Concurrent, routine monitoring of the drug therapy of patients
19%	D. Rounds with the medical and nursing staffs, with pharmacists taking an active part in the educational discourse during rounds and at subsequent conferences dealing with the patient's drug therapies
45%	E. Pharmacokinetics or nutritional support consultations

pharmacists do in fact have a higher duty that is commensurate with their education and training.<sup>11</sup>

### ASHP Practice Standards

Baumgartner<sup>12</sup> describes the ASHP practice standards as an excellent starting point and reference for the pharmacist who is supporting an old service or justifying a new one, or in the preparation of a policy and procedure. He describes the ASHP Practice standards as the result of long and hard efforts to "lay bare many of the matters associated with institutional pharmacy practice" (p. 1). The ASHP Practice Standards provide a point of reference for pharmacists' use in evaluating institutional programs and services. The documents that comprise this publication are defined as follows:<sup>13</sup>

**ASHP Statement:** A declaration and explanation of basic philosophy or principle; must be approved by the Board of Directors and the House of Delegates.

**ASHP Guideline:** General advice on the implementation of pharmacy practice programs; must be approved by the Board of Directors.

ASHP Technical Assistance Bulletin: Specific, detailed advice on pharmacy programs or functions developed by an ASHP staff division in consultation with experts; must be approved by the Board of Directors.

The ASHP Goals for Institutional Pharmacy includes assurance of a high quality of professional practice through the establishment and maintenance of standards of professional ethics, education, and attainments and through the promotion of economic welfare....More broadly, the Society's primary purpose is the advancement of rational, patient-oriented drug therapy in hospitals and other organized health care settings.<sup>14</sup>

One of the stated objectives of the Canadian Society of Hospital Pharmacy is to raise the standard of proficiency (practice) among hospital pharmacists in Canada. Their discussion serves well to explain the process of change and to define guidelines. The Canadian Society first determined what should be done to improve the standards of performance in specific areas of practice. It was recognized that changes were needed to accomplish this goal.

---

*"In lieu of published guidelines, which can be viewed and measured, a pharmacist would be defending himself in a vacuum against a claim that he did not perform up to a standard, if there were not a standard of reference."*

---

A method of changing standards of practice is by the use of guidelines—lines by which one is guided or indications or outlines of policy or conduct. It is within this context that guidelines may be used to establish and improve standards of hospital pharmacy practice. The development of guidelines on a particular aspect of practice of a time-consuming task that requires the efforts of many people. Guidelines should reflect the views of experienced practitioners on what is not only highly desirable, but what is reasonable in the sense of standards of performance that may be attained with reasonable resources.<sup>15</sup>

The law expects much more from the professional than mere observance of rules and regulations enshrined within written legislation. It expects the observance of reasonable standards of practice, based on current professional opinion of what is reasonable. Although guidelines may not have true legal stature in that their adoption cannot be demanded by law, the courts consider that those who do not observe them may be negligent in the practice of their profession.

Recognizing the legal implications of guidelines and standards of practice, pharmacists are obliged to take them seriously. Guidelines are not something to be accepted or rejected at the whim of the individual pharmacist. Rather, they are standards of performance that can be ignored only at the risk of being negligent by providing patients with a standard of pharmacy service below that commonly accepted as reasonable.

## Are the ASHP Practice Standards "Standards of Practice"?

Standards are criteria for professional practice. They represent an acknowledged measure of comparison for quantitative or qualitative value and can be used by members of the profession at all levels. In addition, other health care professionals, institutions, and regulatory bodies are provided with a reference of expectation of the profession. Standards increase accountability of the profession to the public by articulating, supporting, and protecting the rights of patients.

The ASHP periodically surveys hospital pharmacy practitioners in a mail survey of pharmaceutical services in short-term hospitals. Stolar recently reported the results of the ASHP National Survey of Hospital Pharmaceutical Services-1987.<sup>16</sup>

from 1.8% in 1985); 24% reported having no clinical services (versus 38% in 1985). Nineteen percent said their departments had one or more clinical specialists. Stolar concluded that drug control in community hospitals is improving, and clinical services are more widespread. Twenty percent of respondents had comprehensive pharmaceutical services, defined as complete UDD and complete IVA plus three or more clinical services.

The clinical services listed and the percent reporting are as follows in Table 2. Table 3 presents percentages of respondents having clinical pharmacy services in 1987 and previous surveys.<sup>16</sup> These surveys serve to demonstrate the growth of clinical, patient-related services.

The reader can assess how they compare to other practitioners and practice

---

*"Although guidelines may not have true legal stature... the courts consider that those who do not observe them may be negligent in the practice of their profession."*

---

A sample of 875 hospitals was selected randomly from among the estimated 5,600 US short-term hospitals that employ a pharmacist on at least a part-time basis. The survey had a 71.1% response. Nearly three fourths of the respondents had complete unit dose drug distribution services (UDD), 68% reported complete intravenous (IV) admixture services (IVA), and 57% reported both complete UDD and IVA. Nearly 5% of respondents offered five specified clinical services (up

sites. Surely, the achievement of the Practice Standards (which are being surveyed), is not always within the control of the individual practitioner, since resource availability and allocation by the institution is a key factor. Yet some would argue that by publishing Practice Standards, pharmacists are exposing themselves to unnecessary liability and litigation exposure! Surely, the ASHP Practice Standards are the recommendations for practice, and surely the insti-

**Table 3.**  
**Percentages of Respondents Having Clinical Pharmacy Services in 1987 and Previous Surveys<sup>a,b</sup>**

Year	Drug Histories	Counseling	Drug Therapy Monitoring	Rounds	Pharmacokinetic Or Nutritional Consultations <sup>c</sup>	None	Any 3
1987	10.9 ± 2.3	35.2 ± 3.3	61.3 ± 4.8	19.4 ± 4.3	45.4 ± 4.0	23.8 ± 5.2	15.1 ± 3.8
1985	9.2 ± 3.3	25.5 ± 4.3	45.5 ± 4.2	12.7 ± 3.4	23.1 ± 2.8	38.4 ± 4.6	9.8 ± 3.1
1982	5.0 ± 2.0	20.8 ± 4.3	26.7 ± 4.1	13.0 ± 4.3	18.7 ± 2.9	—	11.0 ± 2.2
1978	4.1 ± 1.8	10.8 ± 3.6	15.0 ± 3.1	6.2 ± 1.6	—	—	3.8 ± 2.1

<sup>a</sup>The 1987 survey asked whether the clinical services were provided to all or only selected patients, but previous surveys did not.

<sup>b</sup>Service provided to either all or selected patients; expressed as percentage ± 3 S.E.

<sup>c</sup>Before 1987, the survey asked about only pharmacokinetics consultations and did not include nutritional consultations. Reprinted with permission.<sup>16</sup>

**Table 4. Literature Sources That May be Used to Determine Pharmacists' Standards of Practice**

Title	Publisher
<b>Compendia and Handbooks</b>	
Pharmacy Law Digest	Facts and Comparisons
USPDI	US Pharmacopeia
Hospital Law Manual	Aspen
Drug Product Liability	Matthew Bender
Drug Interaction Facts	Mediphor
Handbook of Institutional Pharmacy Practice	Williams & Wilkins
Sourcebook of Unit-Dose Drug Distribution	ASHP
Trissel's Handbook on Injectable Drugs	ASHP
Individualizing Drug Therapy Practicable	
Applications of Drug Monitoring	Gross Townsend Frank
<b>Books</b>	
Sterile Dosage Forms	Lea & Febiger
Cancer Chemotherapy Handbook	Elsevier
Medical Malpractice: Pharmacy Law	Shepard's McGraw Hill
Remington Pharmaceutical Sciences	Mack
The Practice of Pharmacy	Harvey Whitney
Pharmacy Practice for Trial Lawyers	Hickmon
Pharmacy and the Law	Aspen
Medication Errors	Stickley
Applied Therapeutics for Clinical Pharmacists	Applied Therapeutics
<b>Journals</b>	
American Pharmacist	APhA
American Journal of Hospital Pharmacy	ASHP
Drug Intelligence and Clinical Pharmacy	Harvey Whitney
Food Drug and Cosmetic Law Journal	Food Drug Law Institute
The Consultant Pharmacist	ASCP

tutional pharmacy practice community does not meet these recommendations. That is apparent by the ASHP's survey. Does that mean that the institutional pharmacy community is practicing below the standard? On the contrary, I would suggest that the Standards are set by the survey to assess and measure what the majority of practitioners do in their practice.

## Literature

The above discussion of the ASHP reviews serves to demonstrate the effect of journal publications as a chronicle of what particular standard exists. Journals for most national and state pharmacy associations and specialty groups from time to time will publish surveys (like the

ASHP reviews), or individual practitioners' descriptions of the states of their own practices. Material presented in textbooks used in professional training, as well as in handbooks used in graduate training and practice will also serve as documentation of standards of practice to be followed by pharmacists. Practitioners use these references as source materials, and most likely, these treatises will be reviewed by others to determine whether or not a particular standard exists. Table 4 lists literature sources that may be used to determine standards of practice for pharmacists. An example follows.

A hospital, its pharmacists, and its nurses were named in a malpractice action following ototoxicity in a newborn who

was treated with gentamicin. Selection of and need for the drug were not the issues. The complaint claimed that the pharmacists deviated from an accepted standard of care that existed at the time of the occurrence, holding pharmacists to a standard to recommend that blood level monitoring for gentamicin be recommended and performed for any patient receiving aminoglycosides. The literature describing the availability and utility of serum monitoring of gentamicin levels was presented as evidence of an existing standard of care, with particular emphasis on one handbook, which stated:

*"Careful serum monitoring and dosage adjustments are necessary to prevent further drug accumulation and progressive toxicity....Careful monitoring of the renal function and serum aminoglycoside concentrations early in therapy can minimize several of these risk factors....An age related difference in gentamicin half lives was reported. Infants younger than seven days had significantly longer half lives than infants older than seven days. This variation in half life with age may be a function of renal maturity. These data indicate a wide variation in aminoglycoside distribution volumes and half lives. Generally, initial doses of 2 to 2.5 mg/kg are required, with careful serum level monitoring to determine subsequent dosage requirements (p 127)."*<sup>17</sup>

This particular publication was presented as a state-of-the-art, practical compendium, written and reviewed by practicing clinical pharmacists with expertise in therapeutic drug monitoring. It was well referenced in the primary literature, which had been developed by over 1,000 presentations and publications involving aminoglycoside kinetics and the need for serum monitoring to insure safety and efficacy.

This particular issue focuses upon another publication which may be used to establish a standard of care, that is, the drug manufacturer's package insert literature. It has been held that a physician's deviation from a manufacturer's recommendations is prima facie evidence of negligence (and thus standard of care) if the patient's injury resulted from the physician's failure to adhere to the recommendations.<sup>18</sup> This was the holding in *Mulder v. Parke Davis*,<sup>19</sup> where a physician excessively prescribed an antibiotic in a manner warned against in the

manufacturer's literature. In the aminoglycoside case discussed above, the manufacturer of gentamicin recommended "Serum concentrations of aminoglycosides should be monitored when feasible to assure adequate levels and to avoid potentially toxic levels."<sup>20</sup>

In another action, a pharmacist filled prescriptions for Ventolin inhaler (albuterol; Glaxo, Research Triangle Park, NC)

and practice areas, a clinical pharmacy program that is integrated with the clinical services of other departments in the health care setting (e.g., medicine, surgery, laboratory, nursing) can fulfill these standards. They describe these practice standards as applying to all organized health care facilities that provide inpatient or outpatient care, and apply to all subspecialties of medical and surgical practice.<sup>22</sup>

---

***"It has been held that a physician's deviation from a manufacturer's recommendations is prima facie evidence of negligence (and thus standard of care) if the patient's injury resulted from the physician's failure to adhere to the recommendations."***<sup>18</sup>

---

and Viskin (pindolol; Sandoz, East Hanover, NJ), a beta blocker. The patient suffered acute bronchospasm, and died within a short time after taking the Viskin. It certainly is well known that Ventolin is indicated for treatment of bronchospastic disease [i.e., asthma and chronic obstructive pulmonary disease (COPD)]. The manufacturer's insert for Viskin states: "is contraindicated in (1) bronchial asthma" and further "Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) patients with bronchospastic diseases should in general not receive beta-blockers."<sup>21</sup> In this case, the pharmacist is being specifically held to a standard created by the manufacturer's package insert, as well as other published standards of care.

#### **Minimum Practice Standards for Clinical Pharmacy Specialists with Interpretation for Organized Health Care Settings**

The ACCP recently promulgated minimum standards of practice for institutions. Their stated purpose of minimum practice standards for clinical pharmacy specialists was to delineate for health-care setting administrators and practitioners those specialized functions and activities that may be considered essential to provision of clinical pharmacy services. They define clinical pharmacy practice as a specialized discipline in which the desired endpoint is to provide optimal patient care. The standards discussed the various approaches by which patient care may be influenced. Through delineation of responsibilities

and Portions of the ACCP Standards are reproduced with permission<sup>22</sup>:

*"A clinical pharmacy program should at minimum provide the following services:*

*(1) design, recommend, implement, monitor, and alter pharmacotherapeutic plans based on acquired patient specific information in selected patient groups;*

*2) interpret and apply pharmacokinetics drug data to the design of patient specific drug dosage regimens;*

*(3) retrieve and evaluate drug literature as a means of providing patient specific drug information to health professionals and patients; and*

*(4) educate health professionals, practitioners, students, patients, and the public regarding applied pharmacotherapeutics."*

---

***"If this role of the clinical pharmacist is accepted by the hospitals, plaintiffs may have even more choices for potential defendants when a drug injury occurs."***

---

It is interesting to note the wording in these ACCP minimum standards, which refer to "facility" providing or having, and "programs," in contrast to the APhA/ACCP Standards which describe what the pharmacist must do. A further contrast, this time with the ASHP Practice Standards, is that if clinical pharmacy programs are to be practiced, the preceding four standards are the minimums.

#### **Do Clinical Pharmacy Services Lead to Increased Liability?**

The continuing development of the role of the clinical pharmacists may have a wide reaching repercussion on drug injuries, because every hospital and organized health care setting ultimately may be required to have a drug surveillance agent who reviews the charts of patients and detects indications of drug injuries before serious damage occurs.<sup>23</sup> According to the *Drug Product Liability Compendium*, a reference commonly used by attorneys in drug cases, a new role for the pharmacist as a clinical pharmacologist (clinical pharmacist) has been described.<sup>24</sup> The practitioner is now learning at the patient bedside about the effects of drugs to develop expertise in evaluating drug interactions and drug injuries. It has been argued that the physician is too busy to evaluate carefully the effect of prescribed drugs on his or her patient. A third party who is skilled in evaluating drug effects can act as a check on the physician's prescribing practices and help reduce drug injuries. This proposal has taken the pharmacist a step further into medicine.<sup>25,26</sup> If this role of the clinical pharmacist is accepted by the hospitals, plaintiffs may have even more choices for potential defendants when a drug injury occurs. So if an institution claims to provide such services, it must in fact provide them because it will be held accountable if a drug injury occurs. If an institution does not provide these services and the majority of hospitals begin to do so (a standard), then a nonparticipating institution may still be held accountable just as if it had provided these services. James C. Simmons<sup>27</sup> states:

*"Our court system of civil justice currently is playing a major role in dictating the rights, liabilities, duties and obligations of all health professionals, including pharmacists....As the pharmacist seeks ways to provide professional service commensurate with his educated capacity, civil litigation will play a profound and dramatic part in establishing the parameters within which he will be ex-*

pected to practice. As the public becomes aware of the pharmacist's education and ability, and as more pharmacists reach out in search of new ways to use it, the civil law will naturally keep up with the pharmacist's assumption of responsibility and will dictate a corresponding assumption of liability...the civil law, which dictates the standard of practice for all professionals will actively participate...by litigating the guidelines that establish minimum standards required of all pharmacists (p. 730)."

Webster maintains that pharmacists should view the increased risk of litigation (being sued) as a positive factor.<sup>28</sup> He states that as long as pharmacists are able to walk into a courtroom and convince a judge and jury that they had no duty to the patient—no duty to warn, no duty to counsel, no duty to question the appropriateness of a prescription—that this profession has not advanced past what Kalidonis<sup>29</sup> has described as a "field not ready to be a profession."

Is there increased liability of pharmacists arising from announcements of new standards and codes of practice? There is, according to Frank Duckworth, phar-

Because of the explosion in tort litigation, Duckworth advised that this is not the time for pharmacists to impose on themselves poorly defined legal duties. He recognized that pharmacists yearn for expanded patient roles, that expanded clinical roles for pharmacists have become ingrained in the educational system and have been encouraged by professional leaders at the state and national levels. Both the Bachelor of Science and Doctor of Pharmacy programs include major clinical components that are expanded constantly. Duckworth further acknowledged that most students are taught patient instruction and warnings, in contrast to 20 years ago when the pharmacy student was told not to provide any information to the patient but to refer the patient back to his or her physician.

He does note that Health Care Financing Administration (HCFA) regulations require pharmacists to review patient records in skilled nursing facilities<sup>33</sup> and will shortly require this review in intermediate care as well.<sup>34</sup> Duckworth admits that a few states have initiated regulations that the pharmacists provide consultation to the patient with each dispensed prescription.

---

*"...standards should be flexible enough to allow for the adoption of improvements in technology and not hold the practice to the time the standards (regulations) are developed."<sup>36</sup>*

---

macist/attorney and President of the Food Drug Law Institute. He states that colleges and universities are establishing new standards for the practice of pharmacy that call upon pharmacists to counsel patients about drugs dispensed upon prescription. These

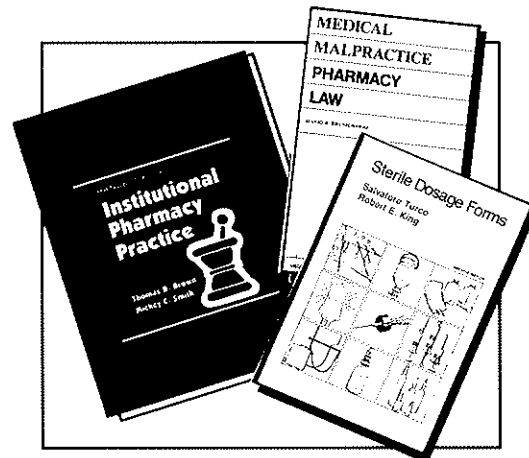
*".....so called standards will inevitably create legal duties of the types that have produced disaster for physicians and manufacturers. The law looks to statements by professional groups or institutions of standards of practice or codes of conduct as one of the main sources of legal duties to which members of the profession must conform."<sup>30</sup>*

A skillful plaintiff's attorney may well be able to do so by marshalling support from published standards.<sup>31,32</sup>

He recognizes that there is a definite trend toward patient counseling, but warns that it is a creation of a legal duty without clear parameters and therefore is unwise and hazardous.

He goes on to state, "As a lawyer, I am absolutely appalled that the pharmacy profession would deliberately go out and create a duty to warn patients in connection with the filling of prescriptions, where no such duty now exists, and thereby subject themselves to liability such as that occurring in the Benedictin cases in the District of Columbia."

Duckworth readily admits that the education and practice of pharmacists involves counseling patients and a greater involvement in their drug therapy than



that of the pharmacist of the 1950s and 1960s whose only duty was to fill the prescription accurately. Yet he states that there is no duty, since the courts have said there is no duty, based on court cases. I submit to the readers that the duty and standard is developed by those who practice, not by those who evaluate us from the court, and that if reasonable standards are developed and promulgated, then it will be clear to lawyers, judges, plaintiffs, and anyone else who looks to determine what pharmacists duties are, and that unnecessary prosecution of liability claims will be averted. The point I would make in disagreement with Duckworth is that many pharmacists will limit their practice in a naive fear of litigation.

Development and promulgation of standards will set the tone for practice. Considering the large number of pharmacists employed by corporations (chains, hospitals, HMOs), who have essentially nonprofessional corporate managers, failure to provide established promulgated standards describing the expanded roles will relegate the pharmacist to filling the prescription only, since the courts and lawyers, in their ultimate wisdom, have ruled that pharmacists have no duty to warn!

Duckworth predicts increased risks of litigation and of liability in the litigation as a result of expanded practice, such as drug product selection and patient counseling. In Illinois, no lawsuits related to drug product substitution have even been filed in the eleven years since the passage of the drug substitution legislation. Pharmacists in Illinois are specifically immune by statute when performing generic substitution; however, no reports of litigation from other states were apparent to this investigator, other than incidents involving illegally manufactured

drugs. In my opinion, this fear of litigation has been instigated by those companies desirous of maintaining trade name monopolies. Simmons recently confirmed this opinion.<sup>35</sup> Duckworth states these risks will be increased far more if the profession imposes on pharmacists an enlarged and undefined duty to warn and to counsel patients. He must realize that the standards do exist. Is he suggesting that by not promulgating, pharmacists who do not live up to the current, day-to-day expanded practice will somehow be immune from liability?

Duckworth quotes several duties and phrases from the APhA Standards of Practice for the Profession of Pharmacy, and suggests that retail pharmacists do not live up to the functions described. If they are held to a legal duty to do these things, "they are in a heap of trouble." He is clear to note that benefit may flow from pharmacists' expanding roles and counselling patients, but the overriding theme is not to label something as a Standard or Code when it is only something "that would be nice" because pharmacists may be held to a legal duty for a level of practice that has not or cannot be attained. Leeds elsewhere in this issue analyzes these APhA standards, and concludes that the very survival of the independent practitioner lies in offering pharmacy services at levels described in the standards.\*

In what this author considers an unusual report, two New Jersey pharmacists have criticized the State-mandated standards for IV additive (IVA) services. Pharma-

cists Polillo and Ferri of the Garden State Community Hospital of Marlton, NJ complained about specific requirements for "almost forcing hospital pharmacies to have separate IVA services, rather than to dispense IV additive medication into patients' drawers." They note it took ten years to implement the standards that now could serve to limit current technology, such as prefilled syringes, syringe pump systems, Add-Vantage (Abbott Labs, North Chicago, IL), and other similar new drug delivery technology. These are described as rigid protocols concerning the preparation, labeling, and dispensing of IV medication. These standards force the director of pharmacy to continue to think of IVAs as separate ritualistic area of practice.

Implementation of standards by state agencies may be viewed as helpful to upgrade standards when they are not able to do so on a voluntary basis due to structure limitations (i.e., hospital administration failure to provide resources for practice expansion); however, as Polillo and Ferri point out, the standards should be flexible enough to allow for the adoption of improvements in technology and not hold the practice to the time the standards (regulations) are developed.<sup>36</sup>

Changes may be effected by making a regulation or bylaw under provisions of existing pharmacy legislation. Thus, certain activities are required by law with little room for the exercise of judgment to fit individual situations. Such a method of effecting change has its place, but should be reserved for those situations where no other method will produce the desired results.<sup>15</sup>

A review of existing standards in pharmacy has addressed the effects of laws, regulation, and accrediting agencies. No one seems to question or debate the status of these in determining standards. In reality, these are minimum standards and requirements. On the contrary, the published and promulgated standards of practice, and practice standards of the major pharmacy organizations in the United States are framed to protect the patient, ensure safe and effective drug therapy, and advance the profession. It is apparent that not all of the published standards are, in fact, standards: that is, they are not practiced by the majority of reasonable and prudent pharmacists. It is also apparent, however, reflecting on history as well as the past short 20 years, that the standards and the practice have progressed, and will progress further.

It should be evident that there is a diversity of use of the word "standard." This may be confusing, and in deference to Duckworth this author agrees that there is confusion and that standards should be realistic. If they are recommendations, and not standards, then they should be identified as desirable goals and not as standards of everyday practice.

Pharmacists should be encouraged to be familiar with and apply the standards to the profession of pharmacy routinely in daily practice.

**Editor: Paula Barnett**

Illustrated and produced by Triodyne Graphic Communications Group.  
Copyright © 1990 Triodyne Inc. All Rights Reserved. No portion of this publication may be reproduced by any process without written permission of Triodyne Inc., 5950 West Touhy Avenue, Niles, IL 60648-4610 (708) 677-4730. Direct all inquiries to Triodyne Graphic Communications Group.

\*Leeds, N.H.: Standards of Practice for Community Pharmacy. *Journal of Pharmacy* 1:1, pp. 41-44, August, 1988.



## REFERENCES

1. American Nurses Association: Standards of Nursing Practice. Kansas City, MO American Nurses Association, 1973, p 1.
2. Donabedian A: The Nursing Audit: Profile for Excellence. New York, Appleton-Century Crofts, 1972, 1.
3. Tyles MM: The anatomy of a profession. Presented at the National Federation of Specialty Nursing Organizations Meeting, Portland, OR, June 24, 1983.
4. Donabedian A: in Graham N: Quality Assurance in Hospitals. Rockville, MD, Aspen Systems Corp., 1982, p 26.
5. *Spry v. Kiser* 102 S.E. 708 (N.C. 1920).
6. Willig SH: Legal considerations for the pharmacist undertaking new drug consultation responsibilities. *Food, Drug, and Cosmetic Law* 25:444-452, 1970.
7. ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control. *Am J Hosp Pharm* 37:1097-1103, 1980.
8. Kalman SH, Schlegel JF: Standards of practice for the profession of pharmacy. *Am Pharm* 19:133, 1979.
9. Kalman, SH, Schlegel JF: Measuring up: Don't let the courts set practice standards. *Am Pharm* 18:184, 1978.
10. "The Burger opinion: What pharmacists had to say," *J AM Pharm Assoc* 16:492-493, 1976 (editorial).
11. O'Donnell JT: The role of the clinical pharmacist in risk management. *Top Hosp Pharm Manage* 5:37-45, 1986.
12. Baumgartner TG: Practice standards. *Fl J Hosp Pharm* 4:vii-ix, 1984 (editorial).
13. Practice Standards of the American Society of Hospital Pharmacists 1987-1988. American Society of Hospital Pharmacists Bethesda, MD, 1987, p 6.
14. Anonymous: Directions for the American Society of Hospital Pharmacists in organized health care delivery. *Am J Hosp Pharm* 32:702-703, 1975.
15. Summers JL: Guidelines. *Can J Hosp Pharm* 30:65, 1977 (editorial).
16. Stolar MH: ASHP National Survey of Hospital Pharmaceutical Services—1987. *Am J Hosp Pharm* 45:801-818, 1988.
17. Cipolle RJ, Zaske DE, Crossley K: Gentamicin/Tobramycin: Therapeutic use and serum concentration monitoring, in Taylor WJ, Finn AI (eds), *Individualizing Drug Therapy: Practical Applications of Drug Monitoring*. New York, Gross Townsend Frank, 1981.
18. Bushwood DB: Medical Malpractice, Pharmacy Law. Colorado Springs, CO, Shepard's/McGraw-Hill, 1986, p 20.
19. 288 Minn 332, 181 NW2d 882, 1970.
20. Garamycin Package Insert. Kenilworth NJ, Schering Corp, 1981.
21. Viskin Package Insert. East Hanover, NJ, Sandoz, 1985.
22. American College of Clinical Pharmacy. Minimum practice standards for clinical pharmacy specialists with interpretation for organized health care settings. *Drug Intell Clin Pharm* 21:645-47, 1987.
23. Fink JL: Liability of the pharmacist as a therapeutic consultant. *Am J Hosp Pharm* 38:218-22, 1981.
24. Dixon M: Drug Product Liability. New York, Matthew Bender, 1982.
25. Biles JA: The doctor of pharmacy. *JAMA* 9:1157-1159, 1983.
26. Lundberg GD: The clinical pharmacist. *JAMA* 9:1193, 1983.
27. Simmons JC: Pharmacy and the civil law. *J Am Pharm Assoc NS* 17:730-734, 1977.
28. Webster RT: Risky business: Just what pharmacy needs, Fineberg J (ed.). *PAS Washington Line Pharmacy Association Services*. Fineberg J (ed): 3, 1988.
29. Kalidonis G: Pharmacy: A field not quite ready to be a profession, in Great Lakes Regional Conference on Clinical Pharmacy Practice. Arlington, VA, Illinois Council of Hospital Pharmacists, 1987, pp 25-80.
30. Duckworth FA: The potential liability of pharmacists arising from announcements of new standards and codes of practice. *Food Drug Cosm Law J* 43:1-15, 1988.
31. Fink JL, III: The pharmacist's liability for drug interactions. *J. Postgrad Pharm* 1:8, 1979.
32. Fink JL III: Legal standard of due care for pharmacists in institutional practice. *Am J Hosp Pharm* 37:1546-1549, 1980.
33. 42 C.F.R. 405.1127(a) 1987.
34. 53 Fed. Reg. 22,638, 1987.
35. Simmons JC: Trends in pharmacy malpractice. Seminar, American Society of Pharmacy Law/American Pharmaceutical Association Annual Meeting, Atlanta, GA, March 1988.
36. Polillo PC, Ferri L: New Jersey standards affect dispensing of I.V. admixtures. *Am J. Hosp Pharm* 44:2486-2487, 1987 (letter).