ACCP POSITION STATEMENT

Collaborative Drug Therapy Management by Pharmacists

American College of Clinical Pharmacy

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The traditional system of providing drug therapy to patients, in which only certain health care professionals are authorized to initiate drug therapy, is under attack at many levels. The processes of drug prescribing, dispensing, administration, monitoring, and dosage adjustment, as practiced in this traditional system, occur in a disjointed fashion that frequently results in avoidable drug-related problems that contribute significantly to poor patient outcomes and increased medical costs.[1]

Collaborative drug therapy management, characterized by an interdisciplinary approach to patient care, is emerging as a solution that can maximize the patient's health-related quality of life, reduce the frequency of avoidable drug-related problems, and improve societal benefits from pharmaceuticals. In this approach to care, drug therapy decision making and management are coordinated collaboratively by pharmacists, physicians, other health care professionals, and the patient.

Many pharmacists with sufficient clinical training have or are willing to assume this level of responsibility for the patients they serve. When participating in collaborative drug therapy management, pharmacists share the responsibility for patient outcomes, not just by providing basic dispensing functions and drug information services, but by solving patient- and medication-related problems and by making decisions regarding drug prescribing, monitoring, and drug regimen adjustments.

This statement represents the position of the American College of Clinical Pharmacy (ACCP) on the role of pharmacists in collaborative drug therapy management. Furthermore, a model for collaborative management of drug therapy is described and endorsed as a way to enhance the quality of patient care within health care systems.

ACCP Position Statement

The American College of Clinical Pharmacy advocates the role of qualified pharmacists as capable collaborative drug therapy managers. Furthermore, ACCP supports the pharmacists' role in collaborative drug therapy management to improve patient outcomes and increase efficiencies in the health care system. To participate in collaborative drug therapy management, pharmacists must have access to patients and patient health information, conduct patient assessments, document activities, and undergo quality assurance programs on these activities. Scope of practice statements, identifying pharmacists' professional authority and responsibility, shall be based on the pharmacist's credentials and the nature of the collaborative arrangement within the health care environment or system.

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History of Pharmacist Prescribing in the United States

Regulation of pharmacist prescribing in the modern health care system of the United States can be traced to passage of the Federal Food, Drug, and Cosmetic (FDC) Act of 1938. This act was introduced to address concerns surrounding the availability of a growing therapeutic armamentarium of antimicrobial agents, led by introduction of the sulfonamides in 1935. Following a disaster in which 107 people died from consuming a toxic base used to compound a sulfanilamide elixir, Congress passed the FDC Act of 1938. The Food and Drug Administration (FDA) then issued regulations to enforce this legislation. The 1938 act deemed as misbranded any drug that failed to carry adequate directions for use or failed to warn patients about potential lack of safety. Any drug could be exempt from the requirement of adequate directions for use if, because of its potential for toxicity or misuse, it was to be used under the supervision of a physician. Regulations mandated these exempted agents carry the wording, "Caution: to be used only by or on the prescription of a physician, dentist, or veterinarian." Another provision was the wording, "Warning—may be habit forming," required on certain narcotic and hypnotic drugs. These regulations became the forerunner to our present-day system for designating prescription drugs and controlled substances. Until this time, pharmacists had been able to prescribe medications legally.

The activity of pharmacists refilling, and thereby continuing, a patient's medications without authorization from the patient's physician was a secondary issue in the 1938 FDC debates. Although not defined as unlawful in 1938, the practice of pharmacists providing refills of medications directly to patients was not favored by the FDA. No definition had differentiated a prescription drug from a non-legend, over-the-counter, drug. The two classes of drugs were not legally differentiated until passage of the Durham-Humphrey Amendment in 1951. At that time, it became illegal for pharmacists to refill legend drugs without authorization from the patient's physician.[2, 3] Thus, the practice of physician prescribing and pharmacist dispensing became law. Many regulations endorsed by today's state boards of pharmacy are resultant attempts to define these distinctions clearly.

During this same period, the preparation of medications was increasingly assumed by pharmaceutical manufacturing companies, thereby lessening the role of individual pharmacists in product manufacturing. Thus, pharmacists were no longer taking an active role in initiating or continuing prescription drug therapy, and were also spending less time in the final preparation of the pharmaceutical product.

In the 1960s and 1970s, pharmacists began to assume roles as direct patient care providers in rural settings within the Indian Health Service. The activity of pharmacist prescribing was first documented in this setting. As early as 1977, Brands described pharmacist practitioners in the Indian Health Service who were trained to diagnose and treat acute, self-limiting diseases and chronic diseases in ambulatory patients.[4] A 1-year review of patients cared for by this arrangement found that 70% of the patients in this group were cared for solely by pharmacists. Quality of care was satisfactory and patient acceptance was excellent. In a similar fashion, Erickson described a program in the same Indian Health Service setting that demonstrated pharmacists were able to provide patient monitoring between physician visits and were also able to extend the interval between physician visits.[5]

In 1972, individual states began exploring the issue of pharmacist prescribing, heralded by the Health Manpower Experimental Act of 1972, a unique experiment in California. Health Manpower Pilot Projects were created with the purpose of training students of the allied health professions in areas that were then beyond their legal scope of practice. To include prescribing by pharmacists, nurses, and physician assistants in these pilot projects, the California Assembly Bill 717 was introduced in 1977, with a provision for sunsetting in 1983. The bill authorized prescriptive authority only to those directly involved with the pilot projects. The project was so successful in saving health care dollars[6] that the California Pharmacists Association, with assistance from the California Society of Hospital Pharmacists, introduced legislation in 1981 to enable prescribing by all pharmacists in the state. This legislation allowed registered pharmacists functioning in licensed acute and intermediate health care facilities to adjust the dosage of a patient's drug regimen pursuant to a prescriber's authorization, order laboratory tests, perform physical assessments, and administer medications. This law has been expanded twice since then and now enables pharmacists to initiate drug therapy

(1983) and expands the types of practice sites to include clinics and systems licensed as health care service plans (e.g., managed care organizations; 1994). The specific duties outlined by each protocol are site- and practice-specific. Traditionally, they have ranged from pharmacist-managed nutritional support prescribing in the inpatient setting to antihypertensive medication management in the outpatient setting.[7–10]

Eventually, pharmacists have gained recognition as drug therapy experts at the national level. In 1974, the Department of Health, Education, and Welfare enacted a drug regimen review regulation for nursing homes in an attempt to improve the quality of drug prescribing in that health care setting. In 1984, Thompson and associates published the results of a study of clinical pharmacists who prescribed under physician protocol in a skilled nursing facility.[11] The findings of this controlled study indicated that patients in the prescribing clinical pharmacists' group had significantly fewer deaths, more patients discharged to lower levels of care, and fewer drugs per patient than the patients in the traditional care group. The estimated health care savings due to clinical pharmacists prescribing in a skilled nursing facility were $70,000 annually (in 1984 dollars) for every 100 beds.

Legislation enabling pharmacists to prescribe under protocol was first passed in the state of Washington in 1979. Since then, it has been amended several times to clarify or expand the types and numbers of protocols. Currently, the Washington State Board of Pharmacy has over 70 protocols on file, conducted by over 425 pharmacists practicing in 60 locations throughout the state. Although the protocols were initially used in institutions, most are now used in managed care and community settings. In clinic settings, these protocols have been found to create efficiencies in prescribing antimicrobial and anticoagulation regimens.[12, 13] In the community pharmacy setting, protocols are used for prescribing refills and for monitoring drug therapy of chronic disease states.

The third state to provide prescriptive authority to pharmacists was Florida. Taking a different approach, the Florida legislature created a third class of drugs in 1986. In contrast to the California and Washington provisions for prescribing under protocol, Florida pharmacists enjoy independent prescribing from within a limited formulary. Certain drugs within the following categories are included in this formulary: oral, urinary, and otic analgesics; hemorrhoid medications; antinausea preparations; antihistamines and decongestants; anthelmintics; topical antifungals and antimicrobials; topical antiinflammatory preparations; otic antifungals and antimicrobials; keratolytics; vitamins with fluoride; lindane shampoos; antidiarrheals; smoking cessation products; and ophthalmics. The formulary is subject to specific conditions spelled out in the state's pharmacy practice act. The legislation has been amended frequently.[14]

In 1995, the Veterans Health Administration (VHA) updated the granting of prescribing authority for practitioners in the Veterans Affairs (VA) system. "General guidelines for establishing medication prescribing authority for clinical nurse specialists, nurse practitioners, clinical pharmacy specialists, and physician assistants," VHA Directive 10-95-019, reviews and clarifies the prescribing role of these practitioners within the VA health care system. Clinical pharmacy specialists are defined as those with Master of Science or Doctor of Pharmacy degrees, pharmacists who have completed an accredited residency, specialty board-certified pharmacists, or pharmacists with equivalent experience. The scope of practice for each type of practitioner is determined by the practice site. The scope of practice statement identifies each individual's prescriptive authority and describes routine and nonroutine professional duties and general areas of responsibility. Prescriptions written by authorized practitioners within their approved scope of practice do not require a physician cosignature. Because states cannot regulate the activities of the federal government or its employees when acting within the scope of their employment, state laws and regulations related to medication orders and prescriptions do not affect scope of practice statements in the VA system.

With early models in place and numerous studies documenting success, momentum has mounted to support the pharmacist's role in collaborative drug therapy management. States are continuing to enact or pursue legislation to enable pharmacists to prescribe as part of collaborative drug therapy management agreements. Currently, 14 states and the federal government have enacted legislation allowing some form of collaborative prescribing for pharmacists. Table 1 provides some specific attributes of these laws.

Impact of Pharmacists Performing Collaborative Drug Therapy Management

Since the late 1970s, many studies have been

published that document the success of pharmacists' management of specific types of patients, drugs, disease states, and specific patient problems and issues. Outcomes measured have included increased patient safety and satisfaction, reduced health care costs, and improved efficiencies.[15–22]

Recently, a summary and critique of 104 studies that assessed the economic outcomes of clinical pharmacy services from 1988–1995 was published.[23] The clinical pharmacy services evaluated could be classified into four main categories—disease state management (4%), general pharmacotherapeutic monitoring (36%), pharmacokinetic monitoring (13%), and targeted drug programs (47%). The services were provided in a variety of health care settings, including university, community, and government hospitals; health maintenance organizations; and community pharmacies.

Outcomes, or consequences, of the services described were considered in all 104 papers. Nineteen (18%) of the papers were found to be full economic analyses because they considered two or more alternatives to care and measured both input costs and outcomes. The most common outcomes measured were drug costs avoided, length of hospital stay, use of nonpharmaceutical resources, rates of adverse drug reactions, frequency of pharmacist-driven therapeutic interventions, and qualitative changes in prescribing patterns. In 93 (89%) of the papers, beneficial financial impacts of clinical pharmacy services were described.

In seven papers, the study design was sufficiently rigorous to allow the results to be expressed as a benefit to cost ratio. The calculated benefit to cost ratios for these seven studies ranged from 1.08:1 to 75.84:1 (mean 16.7:1). In other words, for every dollar invested in clinical pharmacy services, on average, $16.70 of benefit was realized. Overall, the body of literature contains a wealth of information pertinent to the value of the clinical practice of pharmacy.

Evolving View of Health Care

In November, 1995, the Pew Health Professions Commission released its third report describing the future of the health professions in the United States.[24] The changes foreseen by the Pew Commission come from the backdrop of failed government-driven health care reform and the emergence of market-driven health care reform. Table 2 illustrates the shifting paradigm in health care as outlined by the Pew Commission.

The driving force behind health care reform in the United States is the trillion-dollar health care market and the rate of growth of this market. The rate of growth of health care resource utilization competes for other needed programs in both the private and public sectors. These expenditures are brought to the forefront by the fact that, compared with all other industrialized countries, the United States spends more of its gross national product on health care (nearly $3000/person versus $2000/person or less in all other countries), yet realizes no proportional improvement in quality of life.[25] In a market-driven health care economy, three principal values exist: (1) holding or lowering costs; (2) increasing patient satisfaction; and (3) improving the quality of patient outcomes.

The shift to create this new system will be accomplished by more integration and collaboration, as opposed to fragmentation. The steps in this change are occurring at an increasingly rapid pace. This is evidenced by the current movement of health care into a managed care environment. What these changes mean for health care systems and for pharmacists, in particular, are not absolutely clear, but the implications are that the next generation of health professionals will be practicing in an environment that is more intensively managed. In addition, exploration into changing the roles of health professionals to provide a more diverse skill mix within the health care team and more efficient delivery of integrated health care appears to be essential.

The Pew Commission has suggested that to meet these challenges, health professionals will have to redesign the way their work is organized, re-regulate the ways in which they are permitted to practice, right-size the health professional workforce, and restructure health professional education.

This re-regulation of health professions has direct bearing on the need for collaborative drug therapy management and prescriptive authority for pharmacists. As discussed earlier, our present prescriptive authority regulations evolved to protect consumers from misbranded and dangerous medications. However, at this juncture, the current process of drug prescribing, dispensing, administration, and consumption may, in fact, actually provide barriers to effective and efficient health care delivery. Current practice acts do not recognize overlapping or

Table 1. Attributes of State and Federal Regulations Governing Pharmacist Prescribing

State	Arkansas	California	Florida	Indiana	Kentucky	Michigan	Mississippi
Year	1997	1981	1986	1996	1996	1991, under state public health code	1987
Types of Collaborative Practice Agreements	Protocol for each specific patient	Policies, procedures, protocols	Formulary only; legislation to establish protocols introduced in 1997	Policies, procedures, protocols	Collaborative care agreements	Responsibility delegated by M.D. or D.O.	Guidelines, protocols
Level of Review or Approval Required	Physician	Facility	None	Hospital and admitting practitioner	Yet to be determined by Board of Pharmacy	None	Board of Pharmacy
Medications Included	All	All	Specified formulary only; no narcotics or injectables	All, except narcotics	All; narcotics not specified	All, except C-II drugs and anabolic steroids	All
Environments	All settings	Licensed health care facilities, licensed clinics, providers who contract with licensed health care service plans	Pharmacies	Acute care settings, private mental health institutions	All settings	All settings	Institutional settings; in outpatient settings, specific signed protocols required for each patient
Educational Requirements/ Demonstrated Competencies	Those completing diabetes mellitus training eligible for reimbursement from insurance companies	Clinical residency or clinical experience as specified by the facility	No additional	No additional	No additional	None specified	Study course (of at least 20 CEUs) approved by Board of Pharmacy
Other Aspects Addressed	Completion of course approved by Board of Pharmacy enables pharmacist to administer certain medications, including immunizations and vaccinations, to patients age 18 years or older	Administering injections; patient assessment; laboratory tests; initiating and adjusting drug regimens	No pregnant or nursing women; only drug supplies for less than 34 days; no refills	Changing duration of therapy, drug strengths, dosage forms, frequencies or routes of administration; stopping and adding drugs	Physical assessment; ordering clinical tests; initiating, continuing, or stopping drug therapy; drug modification and monitoring; therapeutic interchange	Pharmacist must record the name of the delegating M.D. or D.O. on the prescription	Initiating and modifying drug therapy

Table 1. Attributes of State and Federal Regulations Governing Pharmacist Prescribing (continued)

Nevada	New Mexico	North Dakota	Oregon	South Dakota	Texas	Washington	Federal Government
1990	1993	1995	1980	1993	1995	1979	1995
Protocols	Protocols	Collaborative agreement with licensed physician	Protocols or on a case-by-case basis	Protocols	Written protocols with specific physicians	Protocols	Protocols within scope of practice
Available for inspection by Board of Pharmacy	Board of Pharmacy approves practitioner license	Board of Pharmacy and Board of Medical Examiners	None	Practitioner or the legal authority of the licensed health facility	Must be available for inspection by Board of Pharmacy	Board of Pharmacy	Appropriate facility-based authorizing body or chief of staff
All, except narcotics	All	All, except narcotics	All	All, except narcotics	All	All	All, except narcotics
Licensed medical facilities (hospitals, hospices, managed care settings, home health care, skilled nursing facilities)	All settings	Institutional settings (hospitals, skilled nursing facilities, swing bed facilities)	All settings	All settings	All settings	All settings	All settings
No additional	Additional training equivalent to that of a physician assistant (60 hours of physical assessment; 9 months of clinical experience or M.D. preceptorship)	No additional	No additional	No additional	Specific clinical continuing education	No additional	M.S. degree, Pharm.D. degree, accredited residency, specialty board certification, or 2 years of clinical experience
Initiating, modifying, and monitoring drug therapy	Monitoring drug therapy; ordering laboratory tests; patient assessment; prescribing and modifying drug therapy	Pharmacist must notify physician when he/she initiates or modifies drug therapy	Further rulings expected in 1997	Administering, initiating, and modifying drug therapy; research investigators	Written protocol defined as a physician's order, standing order, standing delegation order, or other protocol	Initiating and modifying drug therapy; protocols must be renewed every 2 years	No protocol or cosignature required within scope of practice; policies required to assure practice is within identified scope of practice

Table 2. The Shifting Paradigm in Health Care

1945–Present	Future
Specialization	Primary care
Cost unaware	Cost accountable
Technology-driven	Humanely balanced
Institution-based	Community-focused
Professionally driven	Managerially driven
Individual care	Population health
Acute	Chronic
Treatment	Management and prevention
Individual providers	Team providers
Competitive	Collaborative

innovative scopes of practice based on demonstrated competency.[24] In addition, the current health care system is not oriented toward managing and monitoring chronic medication therapy. Rather, the focus has traditionally been toward managing acute medical events.[26]

Although pharmacists have traditionally assessed patients and assisted in drug therapy decision making, they have been given little autonomy to manage common and chronic disease states without the direct concurrence of a physician. Without authority to initiate and change medication regimens, many pharmacists must still contact a licensed prescriber as a step in solving drug-related problems they have identified. Scope of practice statements defining professional duties and general areas of responsibility are a logical way to improve access and continuity of patient care. Once considered only a hindrance to practicing disease and drug management, the inability of pharmacists to prescribe medications may well be considered both time and cost impediments to the delivery of quality and cost-efficient patient care in evolving health care delivery systems.

Pharmacy has embraced the philosophy that the provision of pharmaceutical care represents the principal mission of the profession.[27] Core activities of pharmacists who provide pharmaceutical care include the following: (1) participating in drug therapy decisions; (2) selecting drug products; (3) determining doses and dosage schedules; (4) preparing and providing drug products; (5) providing drug information and education; and (6) monitoring and assessing outcomes of drug therapy.

These types of activities can help solve significant problems in our health care system.

Table 3. Tasks Associated with Provision of Pharmaceutical Care

Interview patients to obtain information pertinent to product selection, dosage determination, and usage of current and past prescription and over-the-counter products
Initiate requests for, or perform, and interpret results from appropriate laboratory and other diagnostic studies needed to select, initiate, monitor, and modify drug therapy
Renew or rewrite prescriptions for continuation of drug therapy in accordance with established therapeutic endpoints or patient appointment status
Measure vital signs and perform physical examinations of relevant organ systems and other patient assessments for the purpose of initiating, monitoring, and adjusting drug therapy
Evaluate the patient's responses to therapy
Provide oral and written recommendations for corrective actions for drug-related problems
Document all patient care activities through orders and notes in the patient's medical record
Select, initiate, monitor, continue, modify, and administer medication therapy to prevent disease or adverse reactions; resolve drug-related problems; or improve cost-effectiveness
Implement treatment guidelines, protocols, formulary changes, or critical pathways for therapy, as approved by an authorized health system provider or committee
Provide patient education, identify expected outcomes of therapy, select monitoring parameters, and develop follow-up plans for drug therapy
Provide direct patient care for appropriate disease management, either under protocol, policy, or guidelines
Provide highly specialized inservice education and training to other health care professionals
Develop medication use evaluation criteria and other quality improvement measures to assess the use of drug therapy by other providers
Design, conduct, and coordinate clinical research projects under FDA guidelines and procedures of the institutional review board

Adapted from reference 28.

Table 4. Definitions of Prescribing Activities

Select	When pharmacotherapy is necessary, and after review of an individual patient's history, medical status, presenting symptoms, and current drug regimen, the clinician chooses the best drug regimen among available therapeutic options.
Initiate	After selecting the best drug therapy for an individual patient, the clinician also determines the most appropriate initial dose and dosage schedule and writes an order or prescription.
Monitor	Once drug therapy is initiated, the clinician evaluates response, adverse effects, therapeutic outcomes, and adherence to determine if the drug, dose, or dosage schedule can be continued or needs to be modified.
Continue	After monitoring the current drug therapy of a patient, the clinician decides to renew or continue the same drug, dose, and dosage schedule.
Modify	After monitoring a patient's drug therapy, the clinician decides to make an adjustment in dose and/or dosage schedule, or may add, discontinue, or change drug therapy.
Administer	Regardless of who initiates a patient's drug therapy, the clinician gives the drug directly to the patient, including all routes of administration.

Some examples of tasks associated with the provision of pharmaceutical care are listed in Table 3.[28] Many of these examples are necessary to help patients use their medications optimally, but are prohibited by some state pharmacy statutes and regulations.

Evolving View of Prescribing

Defining Prescribing

Today, prescribing is no longer the act of writing medication instructions. Prescribing encompasses multiple complex tasks, and as a term, it inadequately describes the numerous activities needed to provide drug therapy that achieves the defined outcomes that improve a patient's quality of life. The process of prescribing is more appropriately described by a broad set of activities that include selecting, initiating, monitoring, continuing, modifying, and administering drug therapy. Table 4 provides definitions of these prescribing activities. To select, initiate, and monitor drug therapy, the practitioner must be able to order and interpret laboratory tests, and perform patient assessments related to drug therapy management. This set of prescribing activities suggests that the focus of a practitioner's responsibility is on drug therapy management to improve patient outcomes.

Defining Collaborative Relationships

Some individuals have advocated that pharmacists be granted independent prescriptive authority—that is, authority to prescribe medications independent of a defined collaborative relationship with an individual physician or medical group. Indeed, the system operative in Florida represents a form of independent prescriptive authority for pharmacists, albeit limited to a select formulary of drugs. Others have argued that pharmacists should function in a dependent role where prescriptive authority is delegated by a physician or other independent prescriber to another health care professional whom that prescriber believes possesses the professional skills and judgment necessary to perform these delegated duties.

However, the terms "dependent" and "independent prescribing authority" do not adequately reflect the collaborative relationship needed for pharmacists to contribute fully to the drug use process. A collaborative practice maximizes physician training and expertise in diagnosis, and pharmacist training and expertise in drug therapy and disease management. In most successful examples, the pharmacist and the physician have entered into a collaborative practice agreement or protocol under which the physician diagnoses and may make an initial treatment decision, and then authorizes the pharmacist to select, monitor, modify, and discontinue medications as necessary to achieve favorable patient outcomes. The physician and pharmacist then share the risk and responsibility for patient outcomes.[29]

Two additional factors support collaborative, rather than independent, management of patients by pharmacists. First, pharmacists have limited training in diagnosis. While physical diagnosis is a systematic process of organ system review, the pharmacist's assessment of physical findings is often targeted to a specific organ system or disease state. Except for acute self-limiting diseases or conditions identified during drug therapy monitoring, such as adverse drug reactions or inadequate responses, pharmacists

are not trained to be diagnosticians. Second, a collaborative environment is the nature of current and future health care delivery systems. In fact, the future holds a marked increase in the extent of collaborative and managed health care delivery for all providers. All health care providers will be interdependent and will function in a collaborative fashion. The debate regarding dependent versus independent practice should be put to rest; instead, pharmacists should strive for collaboration with shared responsibilities and risks.

Prescriptive authority is not necessary to perform many duties involved in selecting, initiating, monitoring, continuing, modifying, and administering drug therapy. Nor is the ability to initiate drug therapy a prerequisite condition for pharmacists to establish a therapeutic relationship with a patient, solve drug-related problems, assume responsibility for therapeutic outcomes, or improve a patient's quality of life. However, when legally available, initiating drug therapy changes through collaborative drug therapy management agreements makes provision of care easier, more efficient, and convenient. Given the complexity of drug therapy decision making, evolving health care systems, and historic development of prescriptive authority, it may benefit society to review the scopes of practice of all health professionals, including the efficiencies gained by a collaborative health care team.

The above discussion has focused on collaboration between pharmacists and physicians. However, optimal patient care and efficiency are most likely to result when effective collaboration exists among all the health professions. For example, there is no reason why nurse practitioners and pharmacists, or physician assistants and pharmacists, cannot collaboratively provide care for many patients with acute and chronic illnesses.

Requirements for Collaborative Drug Therapy Management

In order for pharmacists to participate effectively in collaborative drug therapy management in a timely and cost-efficient manner, several conditions must exist: (1) a collaborative practice environment; (2) access to patients; (3) access to medical records; (4) knowledge, skills, and ability; (5) documentation of activities; and (6) compensation for their activities.

Collaborative Practice Environment

The pharmacist wanting to participate in collaborative drug therapy management first needs to identify a physician or practitioner group who wishes to collaborate with the pharmacist. The physician or health system will identify patient populations, disease states, specific drugs, and certain drug-related issues in which other health professionals wish to practice collaboratively with pharmacists. A description of routine and nonroutine professional duties and general areas of responsibility become the approved scope of practice for that pharmacist. The physician or health system needs to be willing to share responsibility for the pharmacist's actions. The environment may be an acute care hospital, a transitional care facility, a nursing home, a clinic, or a community pharmacy, as long as the remaining conditions are also met.

Access to Patients

Direct communication with patients is imperative for pharmacists to function successfully as collaborative drug therapy managers. In fact, it is best to establish an agreement with the patient describing the ideal conditions under which care should be rendered. Within this relationship, the patient grants the pharmacist responsibility, and the pharmacist in turn promises competency to perform the service, along with a willingness to assume responsibility, to the patient. This agreement codifies the direct relationships between patients and pharmacists, and heightens awareness of both groups to the responsibility assumed by the pharmacist in caring for the patient. The goal should be the establishment of a permanent and ongoing relationship that takes place over time. These relationships should complement, but not replace, those of patients and physicians.

Access to Medical Records

Access to a patient's medical records is essential to the provision of collaborative drug therapy management. In fact, it is only under these conditions, wherein the pharmacist has adequate knowledge of the patient and the patient's history, disease states, drug therapy, and laboratory and procedure results, that quality care can be rendered. Much work is being done in this area, via computerization of medical records and network facilitation of electronic data, to ensure this key element is in place to facilitate patient care by health care providers.

Table 5. Areas and Content of Core Pharmacy Curriculum Adopted in 1997 by the American Council on Pharmaceutical Education

Biomedical Sciences	Anatomy, physiology, pathophysiology, microbiology, immunology, biochemistry, molecular biology, biostatistics
Pharmaceutical Sciences	Medicinal chemistry, pharmacognosy, pharmacology, toxicology, pharmaceutics, biopharmaceutics, pharmacokinetics
Behavioral, Social, and Administrative Pharmacy Sciences	Health care economics, pharmacoeconomics, practice management, communications, pharmacy history, ethics, social and behavioral applications and laws of practice
Pharmacy Practice	Dispensing, drug administration, epidemiology, pediatrics, geriatrics, gerontology, nutrition, health promotion and disease prevention, physical assessment, emergency first-care, clinical laboratory medicine, clinical pharmacokinetics, patient evaluation and ordering medications, pharmacotherapeutics, disease-state management, outcomes documentation, self care and non-prescription drugs, drug information and literature evaluation
Professional Experience	Introductory and advanced practice experiences throughout the curriculum as a continuum, in a variety of practice settings

Adapted from reference 30.

Knowledge, Skills, and Ability

In many ways, the pharmacist is uniquely trained for the task of collaborative drug therapy management. Contemporary pharmacy education has provided pharmacists with more extensive and in-depth training in pharmacology and drug therapy management than any other health professional. Other health professionals who have prescriptive authority, such as nurse practitioners and physician assistants, have far less education in drug therapy management. Areas and examples of core curricula required under the 1997 American Council on Pharmaceutical Education requirements for Doctor of Pharmacy programs are listed in Table 5.[30]

Documentation of Activities

When pharmacists participate in any aspect of collaborative drug therapy management, they must document their activities in the patient's medical record. This information should, in turn, be available to other care providers within the health care system. Within the collaborative drug therapy management agreement, the frequency of communication with the collaborative team should also be established.

Compensation

In a vertically integrated managed health care system, the historical fee-for-service system of compensation is not operative. Therefore, pharmacists, either as primary care providers or as disease management specialists within a provider group, should expect to join with other health professionals on a collaborative team. Within a managed care contract, the pharmacist, along with other team members, assumes risk and responsibility for providing health care to patients in that system. Compensation from managed care payers will be on a contractual basis for team services. Demonstration of improved outcomes will be integral to continuing contracts.[31] Specific duties and privileges will be defined by the scope of practice within the specific health care system, partly based on the mix of health care providers present and the type of patients for whom the system provides care. Collaborative drug therapy management will not lead to a fee-for-service form of compensation for clinical pharmacy services within a managed care environment. It is possible that it may do so in other types of health care systems.

Competencies, Setting, Credentialing, and Quality Assessment

Competence assessment is essential when pharmacists assume collaborative drug therapy management activities, especially when such activities are new. Many methods exist to certify competence, such as granting clinical privileges or determining scope of practice in a health system via committee,[32] completing certificate programs for specific disease states, demonstrating knowledge and patient care skills, or earning national certification in a specialty via competency-based processes. The nature of the collaborative relationship will determine the appropriate mechanism for assessing competence. In addition, competencies may vary based on

which prescribing activities are needed or how the scope of practice for each pharmacist is written. For example, initiating and modifying drug therapy may require competencies different than those necessary for administering, continuing, or monitoring drug therapy.

Pharmacists, by nature of their education and licensure, should be able to perform many of these functions without any additional demonstration of competence. The entire spectrum of prescribing activities is appropriate for any qualified licensed pharmacist in any practice setting as long as a collaborative relationship with other health care providers is established, access to relevant patient information exists, and ongoing competence and quality are assessed.

Pharmacists engaged in collaborative drug therapy management activities should be held accountable to the same quality assurance monitors and measures as other health professionals in their setting. Thus, supervision and quality assessment of activities are setting specific and will differ greatly among settings and health systems. Mechanisms to measure and ensure quality should be developed and put into place at the time the collaborative arrangement is established. These mechanisms should follow the same outline as those developed and used for other health professionals.

Summary and Conclusions

The practice of pharmacy and the provision of health care in the United States have changed dramatically over the past 60 years. Reports in the literature documenting pharmacists functioning in primary care roles and as prescribers of medications appeared as early as the 1970s. Reports of these early efforts, now renamed as efforts in collaborative drug therapy management, have demonstrated increased efficiencies in the health care system, while maintaining quality of care and patient satisfaction. At least 14 states and the federal government have authorized some form of pharmacist involvement in collaborative drug therapy management, and many other states are seeking to institute enabling legislation and regulations. Opportunities for pharmacists to increase efficiencies, decrease drug-related morbidity, and improve patient outcomes are abundant.

Not only has the role of the pharmacist evolved, but market-driven forces have caused the entire health care system in the United States to become more collaborative in nature. Pharmacists now have an opportunity to participate in collaborative drug therapy management and contribute to the quality of patient care in concert with other health care professionals.

In order to function successfully in a collaborative environment, the pharmacist must practice in a setting where teamwork is fostered, be able to establish a covenantal relationship with the patient, and have access to the patient's medical records. Because collaborative drug therapy management involves multiple complex tasks, the process may be more easily defined by describing the activities involved in the process—selecting, initiating, monitoring, continuing, modifying, and administering drug therapy. Ideally, these responsibilities should also include ordering, performing, and interpreting medication-related laboratory tests and procedures, along with performing patient assessment tasks related to drug therapy. By virtue of their extensive training in all relevant aspects of drug therapy management, pharmacists are well qualified and well equipped to provide collaborative drug therapy management services to patients.

Collaborative drug therapy management is most successful when the nature of the collaborative arrangement, the competencies and credentialing required, and the quality assurance checks that will be used to assess performance are defined at the outset in each specific setting.

In this era of rapid evolution in health care, the provision of collaborative drug therapy management by pharmacists can contribute to the efficacious, efficient, and cost-effective use of health care resources to improve patient outcomes in the United States.

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