ACCP Position Statement

Collaborative Drug Therapy Management by Pharmacists—2003

American College of Clinical Pharmacy

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The American College of Clinical Pharmacy (ACCP) published its initial position statement on collaborative drug therapy management by pharmacists in 1997.[1] Since that time both the public and the evolving health care delivery system have become increasingly aware of both the benefits and risks posed by the growing role of pharmacotherapy in patient care. In that same period, more than 250 new drugs were approved by the Food and Drug Administration,[2] the Institute of Medicine released two important reports on the issues of preventable errors and needed changes in health care systems,[3, 4] and expenditures for drugs increased an average of 17%/year—among the highest increases for any component of health care.[5] Clearly, drug therapy has become one of the cornerstones of modern health care delivery. Consequently, effective and rational management of increasingly complex drug therapies is now essential both to the health and welfare of patients and to the efficient economic performance of health care systems and organizations of all types.

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Because of their knowledge and skills in drug therapy and their accessibility to patients, pharmacists with the requisite clinical training and professional education are positioned to help patients, other health care professionals, and the health care system achieve more effective and efficient drug therapy outcomes. In recognition of this valuable role, more than 75% of states have enacted legislation or made changes in state medical and pharmacy practice acts that provide for an increased level of pharmacist involvement in the collaborative management of patients' drug therapy. The attributes of state and federal acts and regulations are summarized in Table 1.

Definitions

In presentations made in December 1998 to the National Association of Boards of Pharmacy (NABP) and its Task Force on Collaborative Practice Agreements, ACCP provided the following definitions for the consideration of NABP in its work with state boards of pharmacy and others:

- Collaborative drug therapy management (CDTM) by pharmacists: a collaborative practice agreement between one or more physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens. (This definition is consistent with that of the

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice

State	Alaska	Arizona	Arkansas	California
Year	2002	2000	1997	1981, 2002
Types of collaborative practice agreements	Written protocols	Written protocols (drug therapy management agreement)	Protocol for each specific patient	Policies, procedures, protocols
Level of review or approval required	Physician, Board of Pharmacy	Physician, Board of Pharmacy, Drug Therapy Management Advisory Committee	Physician	Facility
Drugs included	All	All	All	All
Environments	All	Health care institutions: hospitals, staff model health care organizations, nursing care institutions, community health centers	All	1981: Licensed health care facilities, licensed clinics, providers who contract with licensed health care service plans 2002: Expanded to all settings
Educational requirements, demonstrated competencies	No additional educational requirements necessary	One of the following: (1) pharmacy practice residency accredited by ASHP or APhA; (2) current BPS specialty board certification or Certified Geriatric Pharmacist; (3) Pharm.D. degree and completion of an ACPE-approved certificate program in each area of practice covered in the drug therapy management agreement; (4) B.S. in Pharmacy, satisfactory completion of an ACPE-approved certificate program in each area of practice covered in the drug therapy management agreement, and appropriate credentialing issued by the governing body of a qualifying Arizona practice site	Must be credentialed in one of the following areas of disease state management: asthma, anticoagulation therapy, diabetes mellitus, dyslipidemia Copy of credential must be kept on file at the Board of Pharmacy	Clinical residency or clinical experience as specified by facility 2002: Training course required for emergency contraception in community pharmacies; protocol kept with authorized prescriber
Other aspects addressed	Initiating and modifying drug therapy	Implementing, monitoring, and modifying drug therapy	Completion of course approved by Board of Pharmacy enables pharmacist to administer certain drugs, including immunizations and vaccinations to patients aged 18 yrs and older	Administering injections, patient assessment, ordering laboratory tests, initiating and adjusting drug regimens
Comments	Regulations, not statute		Those completing diabetes mellitus training eligible for reimbursement from insurance companies	

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Connecticut	Florida	Georgia	Hawaii
Year	2002	1986, 1997	2000	1997, 2002
Types of collaborative practice agreements	Written protocols specific to patient	Formulary only (mostly OTC); legislation to establish protocols introduced in 1997	Protocol	Policies, procedures, protocols
Level of review or approval required	Physician; available for inspection by Department of Public Health and Consumer Protection	None	Physician	Health care professionals, facility administrator
Drugs included	All	1986: Specified formulary only, no narcotics or injectables 1997: All	All	All
Environments	Hospital: inpatient	Pharmacies	All	1997: Hospital 2002: All settings
Educational requirements, demonstrated competencies	Determined by institution; criteria filed with Commission of Pharmacy	No additional, except: CE course required to order laboratory tests; smoking cessation certification required to prescribe nicotine transdermal systems	Course of study approved by Board of Pharmacy; annual CE on modification of drug therapy	Requirements to administer drugs: BCLS certification and training for injectables
Other aspects addressed	Implementing, modifying, and discontinuing drug therapy; administering doses; ordering laboratory tests	For OTC formulary: no pregnant or nursing women; drug supplies for less than 34 days only; no refills		Patient assessment, ordering laboratory tests, administering drugs and injectables, modifying drug therapy
Comments			2002: Awaiting regulations	

Collaborative Pharmacy Practice contained in the NABP Model State Pharmacy Practice Act.)

- Drug therapy management protocol: a written plan that delegates legal prescriptive authority to pharmacists under designated circumstances. It serves to guide their conduct, direct the course of action, and delineate the functions, procedures, and decision criteria to be followed. It has been mutually agreed upon by the collaborating physicians and pharmacists, and has been reviewed by an appropriate body responsible for quality assurance within the practitioners' practice setting.

At the national level, legislation introduced in 2001 and 2003 in both the United States Senate and House of Representatives proposed to amend the Social Security Act to recognize pharmacists as health care providers for Medicare patients. In June 2002, the Medicare Payment Advisory Commission issued a report to Congress encouraging the Secretary of Health and Human Services to evaluate existing models of CDTM by pharmacists in anticipation of likely changes in the Medicare program. Earlier in 2002, the American College of Physicians (ACP) and the American Society of Internal Medicine (ASIM) issued a joint policy statement that contained qualified support for the concept of CDTM in certain practice settings.[6] Thus it is being increasingly recognized by others that interdisciplinary collaborative practice among pharmacists and physicians can improve drug use in patient care.

ACCP Position Statement

The ACCP advocates the role of qualified pharmacists in CDTM in all practice settings. Pharmacists, practicing with physicians and other health care professionals in an interdisciplinary, collaborative manner, improve pharmacotherapeutic outcomes and provide increased value and efficiency to the health care system. With very few exceptions, the pharmacist's role in drug therapy management should be

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Idaho	Illinois	Indiana	Iowa
Year	1998	Not applicable	1996	1996
Types of collaborative practice agreements	Written protocols	Pharmacist may practice CDTM if acting as agent of prescriber	Policies, procedures, protocols	Written protocol
Level of review or approval required	Physician	Not applicable	Hospital and admitting practitioner	Physician
Drugs included	All	Not applicable	All except narcotics	All
Environments	All	All	Acute care settings; private mental health institutions	Retail and health-system pharmacies that meet eligibility requirements for the Medicaid demonstration project
Educational requirements, demonstrated competencies	No additional educational requirements necessary	No additional educational requirements necessary	No additional educational requirements necessary	No additional educational requirements necessary
Other aspects addressed	Initiate and modify drug therapy, patient assessment, ordering laboratory tests	None	Changing duration of therapy, drug strengths, dosage forms, frequencies or routes of administration; stopping and adding drugs	Implementing and modifying drug therapy, clinical assessment, ordering laboratory tests
Comments	Regulations, not statute	Not addressed in laws or regulations		Guideline, not statute, and hence subject to interpretation

based on a collaborative agreement between each pharmacist and physician where physician-patient, physician-pharmacist, and pharmacist-patient relationships exist.

History of Pharmacist Collaborative Drug Therapy Management in the United States

The passage of the Federal Food, Drug and Cosmetic (FDC) Act of 1938 and the Durham-Humphrey amendment of 1951 led to the legal separation of prescribing (by physicians) and dispensing of drugs (by pharmacists). Before these acts, pharmacists could prescribe drugs legally. In the 1951 act, prescription drugs were differentiated from nonlegend, over-the-counter drugs, and it became illegal for pharmacists to refill legend drugs without authorization from a patient's physician.[7, 8] These restrictions were deemed to be in the best interest of patients and the health care system. The 1997 ACCP position paper on CDTM outlined these events in more detail.[1] Since that time, pharmacist involvement in drug therapy management has evolved in a manner that integrates pharmacists' services with those provided by physicians and other health care providers. This collaborative practice approach has developed in an attempt to improve efficiency and quality of care.

More recently, pharmacists have gained recognition as drug therapy experts at the national level. One example that continues to serve as a template for new CDTM programs is that developed by the Indian Health Service (IHS). In the 1960s, pharmacists in the IHS began assuming an active role in drug therapy management. In 1973, under a grant from the National Center for Health Services Research and Development, the IHS developed the Pharmacist Practitioner Program, in which specially trained pharmacists provided drug therapy management services in collaboration with physicians.[9, 10] A 1-year review of this program found that quality of care, as judged by physicians, was satisfactory and patient acceptance was excellent.[11]

A later report demonstrated that pharmacists were able to provide patient monitoring between physician visits, extending the interval needed between physician visits.[12] 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, the results of a study were published in which clinical pharmacists, working within physician-supervised protocols, managed the

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Kansas	Kentucky	Louisiana	Maryland
Year	1996	1996	1999	2002
Types of collaborative practice agreements	Medical Practice Act interpreted to permit delegation to pharmacist	Collaborative care agreements	Written protocols	Therapy management contract
Level of review or approval required	None	None	State Board of Medical Examiners and Board of Pharmacy	Board of Physician Quality Assurance and Board of Pharmacy
Drugs included	All	All; narcotics not specified	All	All
Environments	All	All	All	All; therapy contracts not required for institutional settings
Educational requirements, demonstrated competencies	No additional educational requirements necessary	No additional educational requirements necessary	No additional educational requirements necessary	Pharm.D. or equivalent training
Other aspects addressed	Copy of protocol for immunizations kept at primary care provider's office Information reported to state immunization registry	Physical assessment; ordering clinical tests; initiating, continuing, or stopping drug therapy; drug modification and monitoring; therapeutic interchange	None	Modifying, continuing, and discontinuing drug therapy; ordering laboratory tests; patient care monitoring
Comments			2002: Regulations are required to enact CDTM; regulations not yet written	$500 fee to Board for each pharmacist/physician agreement that has to be reviewed 2002: Regulations being drafted

drug therapy of patients in a skilled nursing facility.[13] The results of this controlled study indicated that patients in the group managed by pharmacists had significantly fewer deaths, were discharged more often to lower levels of care, and were prescribed fewer drugs than the patients in the traditional care group. The estimated health care savings due to clinical pharmacists' management of drug therapy in a skilled nursing facility were $70,000/year (in 1984 dollars) for every 100 beds. In 1995, the Veterans Health Administration began allowing pharmacists with advanced training to participate in CDTM, with scope of practice determined at the practice site.

The 1997 position statement described in detail the success and expansion of early CDTM pilot projects in California, Washington, and Florida.[14–18] The Health Manpower Experimental Act of 1972, a unique experiment in California, allowed students of the allied health professions to be trained in areas that were then beyond their legal scope of practice. In 1977, California Assembly Bill 717 was introduced, authorizing drug therapy management by only those pharmacists involved with the pilot projects. The project was so successful in saving health care dollars that legislation was passed in 1981 allowing all pharmacists practicing in California-licensed acute and intermediate health care facilities to provide drug therapy management.[14] Pharmacists, pursuant to a prescriber's order, were authorized to adjust drug dosage, order laboratory tests, perform physical assessments, and administer drugs. In the intervening years the law has been expanded twice. In 1983, pharmacists were further authorized to initiate drug therapy.[15–18] By 1994, the types of practice sites covered by the authorization had been expanded to include clinics and systems licensed as health care plans (e.g., managed care organizations). The site- and practice-specific protocols range from pharmacist-managed nutritional support in the inpatient setting to antihypertensive drug management in the outpatient setting.[15–18]

Other jurisdictions followed California's lead. The state of Washington first authorized pharmacist participation in drug therapy

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Michigan	Minnesota	Mississippi	Montana
Year	1991, under state public health code	1998	1987	2001
Types of collaborative practice agreements	Responsibility delegated by M.D. or D.O.	Written patient-specific protocol with dentist, optometrist, physician, podiatrist, or veterinarian	Guidelines, protocols	Written protocol
Level of review or approval required	None	None	Board of Pharmacy	None
Drugs included	All, except C-II drugs and anabolic steroids	All	All	All
Environments	All; Medical Practice Act interpreted to permit delegation to pharmacist	All	Institutional settings; in outpatient settings, specific protocols required for each patient	All
Educational requirements, demonstrated competencies	No additional educational requirements necessary	No additional educational requirements necessary	Study course (of at least 20 hrs) approved by Board of Pharmacy	No additional educational requirements necessary
Other aspects addressed	Pharmacist must record the name of the delegating M.D. or. D.O.on the prescription	Administering first doses and medical emergencies, modifying drug therapy	Initiating and modifying drug therapy, administering doses, ordering laboratory tests	Initiating and modifying drug therapy, administering doses, including immunizations for patients ≥ 18 yrs old

management under protocol in 1979. Currently, pharmacists in Washington provide these services in institutions, managed care clinics, and community settings.[19, 20] In 1986, the Florida legislature created a third class of drugs for pharmacists to use in treating patients with acute illnesses.[21] Florida pharmacists are authorized to use this formulary independently in the management of minor illnesses. At the time of publication of the previous CDTM position paper, 14 states and the federal government had adopted legislation or regulations authorizing pharmacists to engage in CDTM. By the end of 2002, 38 states allowed for various types of CDTM authority within the scope of practice of pharmacists (Table 1).

Evolving View of Health Care

Health care costs have continued to rise since the previous ACCP position statement.[1] It has been projected that, in the United States, health care expenditures will reach $3.1 trillion and will constitute 17.7% of the gross domestic product by 2012.[22] In addition, it is estimated that prescription drug costs will increase from $121.5 billion in 2001 to $445.9 billion in 2012. These projections have led to greater scrutiny regarding health care system expenditures.

The issue of patient safety also has gained considerable attention. In 1999, the Institute of Medicine released its landmark study concerning medical errors. The report estimated that such errors cost the health care system $17–29 billion/year and that at least 44,000 deaths/year occur in hospitals as the result of these errors.[3] In response to this report, the Patient Safety Task Force was established by the Department of Health and Human Services to coordinate data collection and analysis to meet the stated goal of reducing medical errors by 50% by 2004.[23]

National pharmacy organizations such as ACCP have taken the opportunity presented by the report's findings to clarify and promote the role and responsibilities of pharmacists in improving patient safety as it relates to the use of pharmacotherapy. Given the growing emphasis on patient safety and medication errors in the health care system, it is appropriate that pharmacists should play an increasingly important role in patient care, especially through CDTM. Greater pharmacist involvement can be accomplished through a variety of activities ranging from direct patient care to policy development at the local, state, and national levels. By practicing in a collaborative

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Nebraska	Nevada	New Mexico	North Carolina
Year	1998	1990	1993, 2002	1999
Types of collaborative practice agreements	Not addressed	Protocols	1993: Protocols 2002: Specific vaccination and emergency contraception protocols	Written protocol
Level of review or approval required	None	Available for inspection by Board of Pharmacy	Board of Pharmacy-approved practitioner license	Medical Board and Board of Pharmacy
Drugs included	All	All, except narcotics	All	All
Environments	All	Licensed medical facilities: hospitals, hospices, managed care settings, home health care, skilled nursing facilities	All	All
Educational requirements, demonstrated competencies	No additional educational requirements necessary	No additional educational requirements necessary	Pharmacist clinician: 60 hrs of physical assessment with either 9 mo of clinical experience or physician-supervised preceptorship of 150 hrs and 300 patient contacts plus pass a Board-approved examination Pharmacists certified by Indian Health Service Pharmacist Practitioner Program must have 600 patient contacts within the past 2 yrs and an affidavit from supervising physician Certification renewed annually by completing an extra 10 contact hrs of ACPE credit beyond the 16 hrs required for licensure For vaccination and emergency contraception protocols, pharmacist clinician designation not necessary but must complete Board-approved courses	Meets one of the following: (1) BCPS certification; (2) Certified Geriatric Practitioner; (3) ASHP residency; (4) Pharm.D. degree; (5) 3 yrs of clinical experience and approved certificate program in area of practice; (6) B.S. Pharmacy, 5 yrs of clinical experience, and two certificate programs Clinical Pharmacy Practitioner designation renewed annually Thirty-five contact hrs of continuing education
Other aspects addressed	Administering doses, including immunizations	Initiating, modifying, and monitoring drug therapy	Monitoring drug therapy, ordering laboratory tests, patient assessment, prescribing and modifying drug therapy Practitioner and pharmacist clinician must meet every 2 wks to discuss patient management (every 60 days in nursing homes)	Initiating and modifying drug therapy, ordering laboratory tests

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	North Dakota	Ohio	Oregon	Pennsylvania
Year	1995, 2001	1999	1980	2002
Types of collaborative practice agreements	Collaborative agreement with licensed physician	Depends on setting; outpatient: consult agreement signed by pharmacist, physician, and patient; hospital inpatient and long-term care: policies for agreements set by facility	Patient-specific written protocols	Written protocols
Level of review or approval required	Board of Pharmacy and Board of Medical Examiners	Depends on setting; outpatient: physician; hospital: approval by facility; long term care: policies developed by facility are approved by Board of Pharmacy	None Protocols on file at Board of Pharmacy	Physician protocols on file at Board of Pharmacy and Board of Medicine
Drugs included	All, except narcotics	All	All	All
Environments	Institutional settings: hospitals, skilled nursing facilities, swing bed facilities, clinics	All	All	Institutional settings
Educational requirements, demonstrated competencies	For authority to initiate drug therapy: (1) Doctor of Science (Sc.D.), Ph.D. in Clinical Pharmacy, M.S. in Pharmacy, or Pharm.D. degree; or (2) certified as specialist by Board of Pharmaceutical Specialties; or (3) completed an accredited fellowship or residency No additional educational requirements necessary to modify drug therapy 2001: To perform CLIA-waived laboratory tests, must complete Board-approved course and instrument training plus earn CLIA certificate 2001: To administer injectables and immunizations, must complete Board-approved course and BCLS	Depends on setting; outpatient and long-term care: no additional; hospital inpatient: competencies set by facility Specific course required for administration of immunizations	No additional educational requirements necessary	No additional; State Board of Pharmacy to establish educational guidelines for authority to administer injectables
Other aspects addressed	Pharmacist must notify physician when initiating or modifying drug therapy; physician limited to collaborative agreements with no more than three pharmacists 2001: Authority to perform CLIA-waived laboratory tests and administer drugs and immunizations	Outpatient: monitoring and modifying drug therapy; hospital inpatient: allows pharmacist to act as agent of physician		Administering injectables, ordering laboratory tests Pharmacist must carry liability insurance
Comments			Regulations, not statute	

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Rhode Island	South Carolina	South Dakota	Texas
Year	2001	1998	1993	1995
Types of collaborative practice agreements	Written protocols	Not explicitly addressed	Protocols	Written protocols with specific physicians
Level of review or approval required	None	Not addressed	Practitioner or the legal authority of the licensed health facility	Must be available for inspection by Board of Pharmacy
Drugs included	All	Not explicitly addressed	All, except narcotics	All
Environments	All	Not explicitly addressed	All	All
Educational requirements, demonstrated competencies	Advanced training: residency or board certification or certification from an accredited professional organization or educational institution	Not addressed	No additional educational requirements necessary	Specific clinical continuing education (6 contact hrs)
Other aspects addressed		As of 2002, the Board of Pharmacy has not taken a stance on interpretation of the statute	Administering, initiating, and modifying drug therapy; research investigators	Administration, physical assessment, ordering laboratory tests, implementing and modifying drug therapy Written protocol defined as a physician's order, standing order, standing delegation order, or other identified protocol

relationship with other health care providers, pharmacists can improve the safety, quality, and efficiency of drug use and overall health care.

Review of Progress Since the Last Position Statement

The body of evidence and literature supporting the role of pharmacists in improving patient and health care outcomes has increased steadily since 1997. In the hospital setting, four clinical pharmacy services are associated with lower mortality rates: clinical research, drug information, drug histories on admission, and participation in a cardiopulmonary resuscitation team.[24] Investigators also have shown that medication errors occur in about 5% of patients admitted to hospitals.[25] Institutions that deployed pharmacists in patient care areas reduced the risk of errors that adversely affected patient outcomes by 94% over those that did not. Other researchers have demonstrated that acceptance of pharmacists' recommendations concerning drug therapy reduced the rate of medication errors in an intensive care unit.[26] In outpatient and community environments, pharmacists' drug therapy management services have achieved improved patient outcomes related to dyslipidemia, heart failure, anticoagulation, asthma, diabetes mellitus, and other disease states, as well as improved rates of immunization.[27–38] These mounting data further support the benefit of including pharmacists as collaborative members of the health care team.

The previous ACCP position statement described the 1995 Pew Health Professions Commission report that sought to characterize the future of the health professions in the United States.[39] The commission predicted a shift toward a health care system that would emphasize enhanced integration and collaboration among health care professionals, provide a more diverse skill mix, and result in more efficient delivery of health care. To accomplish this paradigm, the commission suggested that health professionals redesign the organization of their workplace, redefine their scopes of practice, "rightsize" their workforce, and restructure their professional education programs.[39]

In 1998, the Pew Commission's fourth and final report in the series recommended further changes in the education and training of health professionals to accommodate future health care system needs.[40] The report suggested that, from its observations, the best integrated health delivery systems used interdisciplinary teams in

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Utah	Vermont	Virginia	Washington
Year	2001	1992	1999	1979
Types of collaborative practice agreements	Written protocols	Drug or dosing protocols	Written protocol with M.D., D.O., or podiatrist	Protocols
Level of review or approval required	Outpatient: Division of Occupational and Professional Licensing and Physician's Licensing Board Inpatient: facility approval	Medical staff of institution	Board of Pharmacy and Board of Medicine	Board of Pharmacy
Drugs included	All	All	All	All
Environments	All	Institutional settings	All; protocols not required in inpatient facilities	All
Educational requirements, demonstrated competencies	No additional, except training and BCLS certification required for drug administration	No additional educational requirements necessary	No additional educational requirements necessary	No additional educational requirements necessary
Other aspects addressed	Administering prescription drug therapy	Adjusting doses, VT BReg 4.512: "This section should not be construed as giving prescribing privileges to pharmacists"	Modifying and discontinuing drug therapy, ordering laboratory tests Requires written consent from patient on file $750 fee to Board for each protocol that has to be reviewed	Initiating and modifying drug therapy, physical assessment, ordering laboratory tests Protocols must be renewed every 2 yrs
Comments		Regulation, rather than statute		

the delivery of care. The commission therefore recommended that training programs for health professionals incorporate a strong interdisciplinary focus. Advantages of the interdisciplinary team approach noted in the report included more efficient use of resources, avoidance of mistakes and duplication of services, and encouragement of collaboration, consultation, and brainstorming by coordinating the expertise of several health professionals. Specifically for the profession of pharmacy, the Pew Commission advised the pharmacy education community to focus its curricular reform on the changing roles and responsibilities of pharmacists, the evolution of practice settings, development of teamwork skills, and collaboration with other health professionals. In addition, the opportunity for active practitioners to develop clinical skills was encouraged to extend roles beyond dispensing.

A significant driving force behind the ongoing demand for health care reform in the United States is the trillion-dollar price tag for health care as well as the rate of growth of this market. The cost of health care is expected to continue to increase moderately and steadily over the next several years. In a market-driven health care economy, three principal values exist: managing and, if possible, lowering costs; increasing patient satisfaction; and improving the quality of patient outcomes. These values are consistent with efforts to achieve more integration of services and collaboration among providers. By 2005, health maintenance organizations will provide health insurance coverage to most of the commercial market and one fourth of the Medicare market.[40] In capitated managed care systems, cost consciousness is a priority, occurring in tandem with the provision of high quality health care. Even in noncapitated health systems, cost containment is important to keep health care affordable and prevent premium increases. Health care providers increasingly are looking to pharmacists to monitor and manage drug therapy for both greater cost-effectiveness and improved patient outcomes.

By 2010, the life expectancy of women and men in the United States is predicted to be 86 years and 76 years, respectively. A large portion of the population includes the "baby boomers," who will begin to turn 65 during that year.[41]

Table 1. Attributes of State and Federal Regulations Governing Collaborative Practice (continued)

State	Wisconsin	Wyoming	Federal Government
Year	2000	1999	1995
Types of collaborative practice agreements	Medical Practice Act interpreted to permit delegation to pharmacist	Written protocols	Protocols within scope of practice After June 30, 2004, the pharmacist must be licensed in a state that has CDTM in the scope of practice
Level of review or approval required	None	Physician	Appropriate facility-based authorizing body or chief of staff
Drugs included	All	All	All, except narcotics
Environments	All	All	All
Educational requirements, demonstrated competencies	No additional educational requirements necessary	No additional educational requirements necessary	M.S. degree, Pharm.D. degree, accredited residency, specialty board certification, or 2 yrs of clinical experience
Other aspects addressed		Initiating and modifying drug therapy, physical assessment, ordering laboratory tests	No protocol or cosignature required within scope of practice; policies required to assure practice is within identified scope of practice After June 30, 2004, prescribing authority for nonphysician clinicians is based on the individual's state licensure, registration, or certification
Comments	Guideline, rather than statute		1995 regulation was to expire December 31, 2001; recent action extends until June 30, 2004

ASHP = American Society of Health-System Pharmacists; APhA = American Pharmaceutical Association; BPS = Board of Pharmaceutical Specialties; ACPE = American Council on Pharmaceutical Education; OTC = over-the-counter; CE = continuing education; BCLS = basic cardiac life support; CDTM = collaborative drug therapy management; BCPS = Board-Certified Pharmacotherapy Specialist; CLIA = Clinical Laboratories Improvement Amendments of 1988.

With the U.S. population living longer, increased numbers of people will develop chronic medical conditions, the most common treatment for which is pharmacotherapy. This increased need for services and care could be met more effectively by pharmacists providing CDTM to that population.

The Institute of Medicine report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, identified a shortage of interdisciplinary programs in the health care system that could address many of the needs of patients with chronic medical conditions.[4] As new drugs become available, the risk of prescribing errors increases. Again, pharmacists working within CDTM arrangements should be able to reduce the number of medication errors substantially, contributing to better patient outcomes and improved management of health care expenditures.

Information technology advances also have had a dramatic impact on health care systems. Patients with computer access are actively seeking out disease and drug information independent of the advice they seek from their health care providers. Direct-to-consumer advertising also has dramatically influenced patient interest and questions regarding disease state and drug management. One positive result of this movement is the emphasis on patients taking more responsibility for their own health care. Increased participation in health care decision making should positively influence relationships among patients and health care providers. Self-participation and shared responsibility for health care by patients may reduce the risk of medical errors, while stimulating health care providers to stay abreast of new therapies and the literature supporting or refuting emerging health care practices. Using counseling and education techniques, pharmacists are well suited to help patients manage and better use the wealth of health information afforded by technology and direct-to-consumer advertising.

Evolving View of Collaborative Drug Therapy Management

In providing CDTM, an interdisciplinary approach is essential, with health care professionals sharing responsibility for assuring better patient outcomes. In this role, pharmacists act not as physician substitutes or extenders, but as physician enhancers, applying their specific drug therapy knowledge, skills, and abilities to complement the other types of care provided by

the collaborating professionals. The typical CDTM arrangement delegates drug therapy management authority from a physician to a pharmacist within the terms of a formal agreement. The authority can include initiating, modifying, and monitoring drug therapy, ordering and performing laboratory and related tests, assessing patients and their response to therapy, counseling and educating patients, and administering drugs. Collaborative agreements vary significantly based on state legislation, practice environments, and the education and training of the pharmacist.

Impact of Pharmacists Performing Collaborative Drug Therapy Management

The number and types of CDTM practices has increased substantially since 1997. Pharmacists in a variety of practice settings are providing clinical services through arrangements structured with individual physicians, physician groups, and institutions. The body of evidence in support of pharmacists providing clinical services has grown. Economic, clinical and humanistic outcome assessments have been performed in many practice environments.

Much of the evidence supporting pharmacist involvement in CDTM is derived from experience in ambulatory care settings. In a 1999 review, 95 studies were identified, including 21 that represented community pharmacy practice.[42] The goal of the investigation was to identify gaps in the literature regarding clinical, economic, and humanistic outcomes analyses. The research methods of each study was analyzed to develop recommendations for future endeavors. All three types of outcomes, as well as combined outcomes, have been addressed in the pharmacy literature; however, no single report has addressed all three areas. The research methods included surveys, retrospective reviews, prospective open-label trials, and randomized, controlled studies. Despite efforts to control for confounders and biases, methodologic flaws were appreciated. Most of the studies reported positive outcomes resulting from pharmacist interventions; however, the impact of methodologic flaws remains unclear. To ensure the integrity of future investigations, the authors recommended more randomized, controlled, multicenter trials, with power analyses.[42] Collaboration among pharmacy practitioners (i.e., multicenter analyses), as well as combined clinical, economic and humanistic outcomes assessments, were highly encouraged.

In a similar analysis, previous recommendations regarding ambulatory clinical pharmacy services were updated.[43] Insight regarding how ambulatory practice has changed over the past decade was provided along with recommendations to ensure continued expansion and success. Advice was provided regarding how to overcome stereotypical perceptions often encountered during communications with the lay public, insurers, and legislators. The authors evaluated outcomes assessments from different ambulatory care settings, describing positive findings and pitfalls. Similar to the 1999 review, concerns related to research design and methodologic parity were described, as were recommendations for randomized, controlled, multicenter trials, specifically with respect to identifying the effects clinical pharmacy services have on morbidity and mortality. A study that demonstrated that clinical pharmacy services improved morbidity and mortality in patients with heart failure was highlighted.[30] Another study showed similar improvements in patients with coronary heart disease.[27]

In 1996, the results of an analysis of economic evaluations of clinical pharmacy services from 1988–1995 were published.[44] In 2003, an update of this analysis compared and contrasted the original findings with 59 newly identified, more recently published studies.[45] A trend toward more reports from ambulatory settings (including community practice) was noted. The number of pharmacotherapeutic or disease management programs had increased, with less emphasis on specialized and targeted drug programs. These changes are consistent with those being seen in clinical practice. Inclusion of studies and reports from other countries was a new addition, thus emphasizing the expansion of CDTM.

Similar to the previous analysis,[44] 85% of the studies in the 2003 analysis[45] reported positive results. Median cost-benefit analysis data remained consistent (4.09:1 vs 4.68:1 for previous and 2003 analyses, respectively); however, mean values changed dramatically (16.7:1 vs 5.54:1, respectively), which was attributed to a lone outlier in the original analysis. Limitations were discussed, one of which was the need for enhanced efforts when developing research protocols. Recommendations were consistent with those presented previously.

In an effort to promote the merits of contemporary pharmacist patient care services to legislative officials and others, 10 national pharmacy organizations joined forces in 1999 to form the

Alliance for Pharmaceutical Care. One document developed by the Alliance, "Evidence of the Value of the Pharmacist,"[38] summarized some of the key literature supporting the efforts of pharmacists from the past decade.[26–37]

As noted earlier, the ACP-ASIM recently released a position statement that provides positive, if somewhat narrow, support of CDTM.[6] However, this was not the first position statement from a nonpharmacy group regarding CDTM. In 1997, the Infectious Diseases Society of America (IDSA) published a document noting physician support for CDTM. Whereas the ACP-ASIM statement was more global in focus, the IDSA document specifically addressed collaboration among hospital (clinical) pharmacists and infectious diseases specialists (physicians).[46] It is important to note that the overall tone of the ACP-ASIM paper suggests enhanced appreciation and understanding of pharmacist roles and responsibilities.

Requirements for Collaborative Drug Therapy Management

For pharmacists to participate effectively in CDTM, the following conditions should exist: a collaborative practice environment; access to patients; access to medical records; a defined level of education, training, knowledge, skills, and abilities; documentation of clinical activities; and payment for pharmacists' activities.

Collaborative Practice Environment

To promote the development of CDTM agreements with providers, the pharmacy profession needs to correct the misperception among some audiences that pharmacists have limited clinical training and experience. The profession must educate and convince the public, legislators, and health care practitioners about pharmacists' professional qualifications and expertise. Without support from these groups, support for collaborative practice arrangements will be limited.

When developing CDTM, the pharmacist's scope of practice should be defined clearly, delineating routine and nonroutine professional duties and responsibilities. Other health care providers, such as nurse practitioners and physician assistants, may be involved in CDTM agreements. Clear and consistent communication between each of these providers can help alleviate turf battles and promote a collaborative environment. Better understanding of the various skill sets and knowledge of different practitioners is essential so that roles and responsibilities are understood. For example, pharmacists are well suited for drug therapy management responsibilities, especially with respect to chronic disease states. Nurse practitioners and physician assistants may better serve patients through activities in screening, triage, and treatment of acute illnesses. The role of these physician extenders cannot be understated. Interaction and mutual support between these individuals and pharmacists are important, as is consistent and active communication with physicians.

Access to Patients and Medical Records

Direct communication with patients is imperative for pharmacists to function successfully as drug therapy managers. In addition to an established agreement with a physician, a pharmacist-patient relationship is a key element of CDTM. In this relationship, the patient grants the pharmacist responsibility to perform services and the pharmacist promises competency in the performance of these services. Physicians and patients should understand that this relationship complements, rather than replaces, the physician-patient relationship.

The pharmacist must have access to medical records that include the patient's medical history, problem lists, progress notes, laboratory and procedure results, and drug history. The CDTM agreements also should address patient privacy and confidentiality issues. Pharmacists working in a health-system environment may have easy access to computerized medical records. Other practice settings may involve obstacles to access that need to be overcome. This is one area where pharmacy organizations can facilitate CDTM by promoting and assisting with the sharing of medical information through support of new technologies.

Education, Training, Knowledge, Skills, and Ability

Pharmacists are uniquely trained for the task of CDTM. The American Council on Pharmaceutical Education (ACPE) implemented revised accreditation standards for professional degree programs in pharmacy in 1998. Pharmacy education now consists of at least 2 years of a college prepharmacy curriculum, followed by a 4-year professional program with extensive training in pharmacology and pharmaceutical

sciences, biomedical sciences, therapeutics, physical assessment, and clinical experiential training. Successful completion of this curriculum leads to the Doctor of Pharmacy (Pharm.D.) degree, now the sole degree offered by U.S. colleges and schools of pharmacy. Specific areas and examples of core curricula required under the ACPE standards for Doctor of Pharmacy programs can be found on the ACPE Web site (http://www.acpe-accredit.org/).

Most pharmacy curricula now include active learning and problem-based learning components, which develop students' abilities to critically analyze data (i.e., critical thinking) and improve skills in providing individualized drug therapy management services. Additional training in patient interviewing, counseling, and patient assessment have resulted in competency to collect patient data, enhance patient adherence to a therapeutic plan, and monitor drug therapy for response to therapy and avoidance of adverse effects. Experiential training has been incorporated into the early years of the educational process to help students apply didactic learning to patient care. Advanced experiences demonstrating interdisciplinary and collaborative practice further enhance clinical skills and foster the concept of working as part of a health care team.

Many pharmacists complete postgraduate residencies and fellowships to obtain advanced clinical training. Generalized and disease- or discipline-specific programs are available. Some pharmacists who graduated from professional programs with a bachelor's degree in pharmacy (i.e., before the national shift in the pharmacy education curriculum) have obtained the necessary knowledge, skills and abilities through nontraditional Doctor of Pharmacy programs, postgraduate education, or various types of certificate programs that help them to achieve the necessary competencies for a specific disease state.

Pharmacists may pursue additional voluntary credentials that can highlight their ability to provide CDTM and other patient care services. The Board of Pharmaceutical Specialties offers board certification for the following pharmacy specialties: nuclear pharmacy, nutrition support, oncology, pharmacotherapy, and psychiatric pharmacy. The American Society of Consultant Pharmacists offers certification in geriatric pharmacy. In the late 1990s, the National Association of Boards of Pharmacy, as part of the National Institute for Standards in Pharmacist Credentialing, developed disease state management certification examinations for anticoagulation, asthma, diabetes mellitus, and hyperlipidemia. This process was stimulated as a result of the establishment of a Mississippi Medicaid project, which was initiated several years before to evaluate the delivery of targeted disease and drug therapy management services to Medicaid recipients. In addition, pharmacists can obtain certification as diabetes educators or asthma educators in programs established for a wide range of health professionals interested in advanced skills.

All of these credentials can help to identify those pharmacists who are qualified to provide CDTM. Ultimately, of course, the credentials or specific education and training requirements for an individual collaborative practice agreement should be determined by the collaborating practitioners at the practice site.

Documentation of Activities and Quality Assurance

Timely and appropriate documentation of all activities related to CDTM is essential to both quality and professional acceptance. Policies and procedures should be in place to ensure that the documentation is shared appropriately and available to other providers caring for the patient. Conformity with the Health Information, Portability and Accountability Act (HIPAA), regulations, and guidelines for patient privacy and confidentiality should be incorporated into the plan. Pharmacists engaged in CDTM should meet all relevant standards for quality assurance and adhere to the same measures of quality as other health professionals in the practice setting. Supervision and quality improvement activities are site specific and will differ greatly among settings and health systems. Mechanisms to measure and ensure quality should be developed as an integral part of the CDTM agreement. Measuring adherence to practice guidelines and comparing patient outcomes to benchmark data or literature reports is essential and should be identical to the process developed for other health care professionals. Pharmacists should be able to provide at least the same quality of care and achievement of outcomes as other providers.

Payment for Services

Several national pharmacy organizations, including ACCP, continue to seek recognition of pharmacists as providers of patient care services

within both federal and private health care payment systems. Appropriate payment for pharmacists' CDTM and other direct patient care services will be a logical result of this recognition. Without reform of the payment system for pharmacists' services, which is based almost exclusively on the sale of drugs, the inclusion of CDTM will be difficult, if not impossible, to accomplish. All practitioners within a given practice setting must be able to generate revenue sufficient to support the direct and indirect costs of their practice activities, including salaries, staff support, supplies, technology support, and other expenses.

Summary

Since publication of the initial ACCP position statement on CDTM by pharmacists in 1997, the public, government, and much of the health care community at large have come to better appreciate the growing complexity of providing effective and safe drug therapy in today's health care environment. Increased interest in the issues of cost and quality of drug use is evident in the increasing coverage of the issue in the lay press and professional literature. This represents real progress, as well as real opportunity, for pharmacists. It also heightens the potential for a better understanding of the vital role that pharmacists can play in addressing these concerns.

The percentage of patients who take several drugs for chronic diseases will continue to increase. Based on current trends, the number of patients who lack adequate access to care, or who receive either suboptimal, inappropriate, or unnecessarily expensive drug therapy for their acute and chronic diseases, will increase. Even as financial and human resources are increasingly strained within the current health care system, costs will continue to rise unless changes are made.

Fortunately, qualified pharmacists are prepared, capable, and willing to help address a significant portion of these challenges. The public, many health care providers, some legislators, and a few insurers now recognize that pharmacists, because of their education and training in drug therapy, are well positioned both to accept additional responsibility for patient care and to provide services that make a real difference in health care quality and outcomes. The health care programs administered by the U.S. Public Health Service, the armed forces, and the Veterans Health Administration, as well as 38 states, now support pharmacist participation in CDTM. Pharmacists, working in an interdisciplinary structure with physicians and other health care providers, have demonstrated that they can improve the effectiveness, efficiency, and safety of drug therapy by providing CDTM. It is time to incorporate this valuable professional skill of the contemporary pharmacist as a core component of the delivery of health care services.

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