

Practice Advisory on Collaborative Drug Therapy Management

I. Introduction

Collaborative drug therapy management (CDTM) is a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy.¹ In this role, pharmacists augment the physician, applying their specific drug therapy knowledge, skills and abilities to complement other types of care provided by collaborating professionals.¹ People may refer to CDTM differently and use terms such as collaborative practice agreements or collaborative practice. The CDTM designation is used primarily because it is descriptive of the usual scope of the practice agreement between the physician and the pharmacist, i.e., the management of patient drug therapy regimens.

Because these arrangements typically allow pharmacists to engage in professional activities that fall outside of traditional pharmacy practice laws, authorization in each individual state has been required to establish laws governing how CDTM can be administered in a given state. Authority for collaborative drug therapy management is generally found in the state pharmacy practice act and/or through regulations promulgated by state boards of pharmacy. As of this writing, 46 states have authorized CDTM arrangements between pharmacists and physicians.¹ These regulations establish the criteria for participation and the range of services that the pharmacists may provide when working under such agreements.

Responsibilities placed upon pharmacists working with physicians under CDTM agreements can include:

- Implementing or modifying drug therapy of individual patients or groups of patients (patients with diabetes, asthma, hypertension, etc);
- Ordering and evaluating the results of laboratory tests directly relating to drug therapy;
- Administration of medications, including immunizations.

The following activities (within most pharmacists' usual scope of practice) are also integral to meeting the responsibilities delineated above:

- Collecting and reviewing patient drug histories;
- Obtaining and checking vital signs;
- Performing physical assessment consistent with the disease state and drug therapy;
- Evaluating and rendering advice regarding adjustments in the patient's drug regimen.

II. Collaborative Drug Therapy Management and Managed Care Organizations

Managed care organizations have three primary goals in managing the health of their enrollees: improving the quality of patient outcomes, increasing patient satisfaction and managing costs. CDTM agreements between physicians and pharmacists serving a managed care organization's enrollees can contribute to each of those goals. CDTM agreements take maximum advantage of the physician's training and expertise in disease diagnosis and the pharmacist's training and expertise in drug therapy and disease management.

This collaboration allows the physician and pharmacist to share the responsibility for patient outcomes.

CDTM:

- Makes drug therapy changes easier, more efficient and convenient for the patient, pharmacist and physician
- Expands the ability of health care professionals to provide optimal care for their patients;
- Provides a means for physicians to satisfy the unmet needs or unsolved problems of their patients;
- Reinforces relationships between pharmacists and physicians;
- Extends access to health education, health screening and other services to underserved populations in minority communities, in poorer areas, in urban centers, in rural areas and in institutions where physician access is limited.

As such, the return on investment calculated by the managed care organization is expected to be positive and may allow for the organization to take a proactive role in proposing new CDTM arrangements between willing physicians and pharmacists to be used within a managed care organization.

A large array of CDTM arrangements exists within health plans, including:

- Emergency contraception
- Asthma therapy management
- Immunization administration
- Hypertension therapy management
- Dyslipidemia therapy management
- Warfarin/anticoagulant therapy management
- Diabetic therapy management
- Depression therapy management
- Smoking cessation therapy
- Flu/antiviral therapy

These programs have been shown to be successful in managing therapy in a wide variety of medical conditions. CDTM programs improve the quality of medication therapy, and improve the satisfaction of the patient, physician and pharmacist.^{1,2,3,4} In addition to pharmacy organizations, CDTM programs have been recognized by the American College of Physicians, the American Society of Internal Medicine and the Infectious Diseases Society of America.⁵ Each organization has issued statements in support of the value of CDTM programs.

What are the benefits to patients?

- Increased access to health care
- Enhanced patient care through optimized drug therapy management
- Decreased drug-related problems (adverse drug reactions, drug interactions, poor compliance, etc.) through the use of scientifically designed drug therapy protocols and management
- Reduced costs through optimal use of medications and minimization of drug related problems
- Pharmacist identification of underlying conditions that require the care of a physician.

What are the benefits to physicians?

- Reduced visits for chronic disease patients, freeing more time for physician patient interaction and for management of complex case
- Delegation of medication management to the drug therapy specialist, the pharmacist, who has unique skills and knowledge that can be used to support the physician's therapy strategies
- Referral of patients by pharmacists to physicians
- Enhanced ability to achieve pay-for-performance goals

What are the benefits to pharmacists?

- Allows pharmacists to move from a product-oriented service to a patient-focused practice using their unique knowledge to improve clinical outcomes
- Allows pharmacists to demonstrate their value as an integral part of the health care team

What are the benefits to health plans/managed care organizations?

- Utilizing the pharmacotherapy skills of the pharmacist to decrease chronic disease physician visits for medication therapy related issues
- Enhanced drug therapy outcomes through optimization of drug therapy regimens
- Improved patient satisfaction
- Reduced costs of care
- More targeted physician referrals

What is the potential liability to a pharmacy?

CDTM arrangements include an added potential of practice liability to the pharmacist caring for patients under a CDTM agreement. Health care professionals have a duty to provide patient care in a manner consistent with applicable laws, medical evidence and standard of care. If practitioners, within the scope of a CDTM setting, are found to be negligent, pharmacists and physicians are placed at risk of legal repercussions consistent with any harm done to a patient. Since each CDTM agreement is unique, and each state allowing CDTM does so under its own laws, it is not possible to identify specific risk issues in the context of this document.

III. Differences between Medication Therapy Management and CDTM

In discussions involving CDTM, a common question that arises is the distinction between CDTM and medication therapy management (MTM). Medication therapy management is a distinct service or group of services that optimize therapeutic drug outcomes for individual patients. MTM services are independent of, but can occur in conjunction with the provision of a medication.

As many of the services provided under MTM are consistent with CDTM activities, the terms CDTM and MTM have at times been used interchangeably. However, the two programs should not be thought of as one in the same, as several important distinctions exist.

In contrast to CDTM, MTM services do not require the development of formal practice agreements between individual pharmacists and physicians or groups of pharmacists and physicians, and MTM services may be provided by other ancillary health care personnel. In addition, individual state pharmacy

practice laws do not establish the scope of MTM services that may be offered unlike CDTM requirement. It is assumed that pharmacists practicing under MTM agreements will abide by existing state pharmacy practice laws.

The distinction between CDTM and MTM programs is important given that formalized agreements between physicians and pharmacists are not required for MTM and the scope of services provided under CDTM is typically broader than those for MTM.

IV. Considerations for Successful CDTM Programs

CDTM agreements are formalized, written documents outlining the scope of services to be provided by each party. Sections of a CDTM agreement typically include:

- Overview of program
- The purpose of the agreement
- Criteria for patient inclusion
- Responsibilities of the involved professionals
- Monitoring and treatment guidelines
- Detailed instructions as to how to operate the CDTM agreement, including referral back to physician
- Training requirements
- Quality improvement process

Effective CDTM agreements require the presence of the following key elements:

1. An environment whereby one or more pharmacist(s) and one or more physician(s) have professional relationships sufficient to allow pharmacists under a written and signed agreement to perform certain patient care functions under certain specified conditions;
2. Access to patients and pertinent information from their medical records;
3. Access to pertinent patient laboratory tests and results;
4. The knowledge, skills and ability to perform authorized functions;
5. Documentation and communication of pertinent information for the patient's medical record;
6. Accountability for the quality measures;
7. The ability to be reimbursed for drug therapy management activities;
8. Commitment of the time and resources necessary to achieve stated goals and objectives.

Within health care systems, such as health maintenance organizations, the relationships between pharmacists and physicians, developed through the normal course of patient care activities, may be strong enough to allow quick transitions to formal CDTM agreements. Outside of such organizations, in a community setting, pharmacists wishing to develop CDTM arrangements with local physicians must first develop credibility and rapport through a communication plan. The plan should include basic information about the range of services offered, the benefit to the physician and patient, and a means to identify areas how the program could benefit a physician's practice.

In addition to a successful physician communication strategy, patient communication must also be put in place. In many instances, patients will be unfamiliar with the role of the pharmacist outside the traditional

drug dispensing function. Education about how a CDTM program will benefit the patient through improved compliance, decreased medication costs and improved outcomes should be undertaken. Patients should understand that drug therapy management services administered under a CDTM agreement require compensation and patient-specific information.

Compensation

Compensation may depend on the type of managed care organization model. In a group model managed care environment, CDTM pharmacists can work as do other nonphysician health care providers with advanced training, as part of a patient care team. In a fee-for-service environment, pharmacists have three options: they can work as part of a physicians' group practice and file for payment under the physician's provider number; they may be recognized as a provider and bill a managed care organization directly; or patients can pay cash for their services. Pharmacists are not currently recognized as a provider under Medicare and, therefore, cannot bill Medicare directly for services under the Part B benefit. In the first scenario, a pharmacist would file a "level 2" visit claim for a typical anticoagulation visit, and the reimbursement would return to the practice for which the pharmacist works. Pharmacists who are not directly employed by the medical group or work in an individual practice setting in ambulatory settings (e.g., community pharmacy) may establish provider status with payors and bill directly under the medical reimbursement system.⁶ Additionally, pharmacists sometimes electronically bill for CDTM services as a component of a patient's drug benefit using a pharmacy claims system.

While physician office billing functions are well supported, pharmacist billing functions for non-distributive services are typically not well defined, nor are they well supported by care systems. As such, the three billing scenarios described above may all be necessary when providing services to a range of patients enrolled in different medical and pharmacy benefit plans, as determined by the benefit plan design.

As of May 23, 2007 all claims for CDTM activities must be submitted under a provider's National Provider Identification (NPI) code number. NPI status may be granted to both individuals and organizations. Therefore, individual pharmacists and the pharmacy practice site may each have unique identifier status. Health plans may have a limited network of pharmacists that provide CDTM activities and may require an NPI number for reimbursement.

Operation of a successful CDTM program must include adequate resource allocation to provide patient care activities, administrative functions and marketing/communication activities. In addition, there should be a means of calculating the return on investment gained through decreased use of other health care resources such as physician office visits, emergency room visits, hospitalizations and medications.

V. Examples of CDTM Use in Managed Care Settings

CDTM arrangements appear very differently across various managed care settings. Two examples can be demonstrated in programs involving patients of Blue Cross Blue Shield of Minnesota and Scott & White Health Plan.

In 1999, Fairview Health Services of Minneapolis-St. Paul established a CDTM program in six primary care clinics called the Collaborative Practice of Pharmaceutical Care. Through 2004 the Fairview CDTM practice has led to improvements in patients' goals of therapy achieved and identification and resolution of

more than 12,000 drug therapy problems in 4000 patients receiving CDTM services.⁷ Through a collaborative practice agreement signed by the medical director of Fairview Clinics and individual “certified pharmaceutical care practitioners,” these specially trained pharmacists were authorized to provide pharmaceutical care services to patients in Fairview Clinics and Pharmacies. These “pharmaceutical care services” were defined as “a practice in which a practitioner takes responsibility for all of a patient’s drug-related needs and is held accountable for this commitment.”⁸ Blue Cross Blue Shield of Minnesota and Prime Therapeutics have worked with the University of Minnesota and Fairview Health Services to design a study to measure the outcomes of the program. Results from this study are pending.

Scott & White Health Plan implemented a CDTM program for members meeting certain criteria. This program initially focused on diabetes and heart failure (CHF), and now includes asthma. In this program, Scott & White Health Plan members meet with a pharmacist monthly and are then eligible for copayment waivers of medications and supplies for the identified disease state. The care is provided in Scott & White retail pharmacies, and the pharmacists are working under a collaborative practice agreement with the Scott & White physicians. The pharmacies are billing for pharmacist services.⁹ A study was conducted to evaluate the impact of the pharmacist-run medication management program on medication adherence and to measure the effect of the medication management program on medical utilization costs and glycemic control. In a preliminary analysis of results patients in the intervention group demonstrated an improvement in medication adherence and a trend of greater decline in hemoglobin A1c compared to controls after 12 months of enrollment in the medication management program.^{10,11}

In a 2011 update, Scott & White indicated that the program was still operational for diabetes for the fourth year, and for asthmatic patients and patients with refractory hypertension. A clinical and economic evaluation was completed for the diabetes group with the intervention group showing a 58 percent greater sustained reduction in hemoglobin A1c (HbA1c) over a two year period compared to matched controls. The health economic outcomes associated with the diabetic program showed a significant reduction in inpatient medical costs in the intervention group while the medication costs and the outpatient costs were greater in the intervention group. The average reduction in total medical costs during the second year of management in the intervention group vs the control group reflected a reduction of \$1,800 per enrolled diabetic per year over their matched controls. For the 400 patients currently enrolled in the program that reflects an annual savings of \$720,000 per year for the intervention group. Savings are inclusive of all costs associated with administering the program, including copay waivers and visit charges for the monthly pharmacist visit.¹²

VI. Conclusion

CDTM agreements in which pharmacists use their therapy expertise to provide drug therapy management services under formal agreements with physicians have been demonstrated to increase the quality of patient medication therapy while decreasing costs and improving patient, physician and pharmacist satisfaction. These agreements are dependent upon state specific regulations governing the depth and breadth of services provided and are allowable in 46 states as of this writing.

The future of CDTM is dependent upon pharmacist practitioners accepting the challenge of assuming both the risks and benefits of providing patient care activities outside the normal scope of prescription dispensing practice. Yet the challenges are well within the scope of expertise for the pharmacist. As

additional reports show positive outcomes for patients cared for through these arrangements, continued expansion is expected.

¹ Finley PR, et al. Impact of a collaborative pharmacy practice model on the treatment of depression in primary care. *Am J Health-Syst Pharm.* 2002; 59:1518-26.

² Kiel PJ, McCord, AD. Collaborative practice agreement for diabetes management. *A J Health-Syst Pharm.* 2006; 63:209-210.

³ Schumock, GT, ,et al. Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996-2000. *Pharmacotherapy* 2003;23(1):113-32.

⁴ Thomas J, et al., Survey of pharmacist collaborative drug therapy management in hospitals. *Am J Health-Syst Pharm.* 2006; 63:2489-99.

⁵ Hammond R W, et al.

⁶ Koch KE, "Trends in Collaborative Drug Therapy Management" *Drug Benefit Trends* 12(1):45-54, 2000.

⁷ Isetts B, et al. "Effects of collaborative drug therapy management of patients' perceptions of care and health-related quality of life." *Research in Social and Administrative Pharmacy.* 2(2006) 129 – 142.

⁸ Collaborative Practice Agreement for the Provision of Pharmaceutical Care: Agreement Between Fairview Clinics and Fairview Pharmacy Services. Received via e-mail from Brian Isetts, January 8, 2008.

⁹ Information received via e-mail from Tricia Tabor, Scott & White Health Plan, January 10, 2008.

¹⁰ Hanson K, et al. "Evaluation of medication adherence and economic outcomes of a member benefit medication management program for high-risk managed care patients with diabetes." Poster presented at the American Society of Health-System Pharmacists Mid-year Clinical Meeting, December 2007.

¹¹ Klein M, et al. "Evaluation of medication adherence and economic outcomes of a member benefit medication management program for high-risk managed care patients with diabetes." Poster presented at the American Society of Health-System Pharmacists Mid-year Clinical Meeting, December 2007.

¹² Information received via e-mail from Paul Godley, Scott & White Health Plan, December 19, 2011.