

ACCP WHITE PAPER

Collaborative Drug Therapy Management and Comprehensive Medication Management—2015

American College of Clinical Pharmacy

Sarah E. McBane*, Anna L. Dopp, Andrew Abe, Sandra Benavides, Elizabeth A. Chester, Dave L. Dixon, Michaelia Dunn, Melissa D. Johnson, Sarah J. Nigro, Tracie Rothrock-Christian, Amy H. Schwartz, Kim Thrasher, and Scot Walker

The American College of Clinical Pharmacy (ACCP) previously published position statements on collaborative drug therapy management (CDTM) in 1997 and 2003. Since 2003, significant federal and state legislation addressing CDTM has evolved and expanded throughout the United States. CDTM is well suited to facilitate the delivery of comprehensive medication management (CMM) by clinical pharmacists. CMM, defined by ACCP as a core component of the standards of practice for clinical pharmacists, is designed to optimize medication-related outcomes in collaborative practice environments. New models of care delivery emphasize patient-centered, team-based care and increasingly link payment to the achievement of positive economic, clinical, and humanistic outcomes. Hence clinical pharmacists practicing under CDTM agreements or through other privileging processes are well positioned to provide CMM. The economic value of clinical pharmacists in team-based settings is well documented. However, patient access to CMM remains limited due to lack of payer recognition of the value of clinical pharmacists in collaborative care settings and current health care payment policy. Therefore, the clinical pharmacy discipline must continue to establish and expand its use of CDTM agreements and other collaborative privileging mechanisms to provide CMM. Continued growth in the provision of CMM by appropriately qualified clinical pharmacists in collaborative practice settings will enhance recognition of their positive impact on medication-related outcomes.

KEY WORDS collaborative drug therapy management, comprehensive medication management, collaborative practice, clinical pharmacist, clinical pharmacy.

(*Pharmacotherapy* 2015;35(4):e39–e50) doi: 10.1002/phar.1563

The American College of Clinical Pharmacy (ACCP) published in 2003 an update to its position statement on collaborative drug therapy management (CDTM).^{1, 2} Since 2003, significant federal legislation calling for monumental changes in the U.S. health care system has been passed. The Medicare Modernization Act (MMA) of 2003 was the largest reconstruction of Medicare in the program's history and included Medicare Part D, a voluntary prescription drug benefit. Medicare Part D prescription drug plans were also required, effective in 2006, to offer medication therapy management (MTM) services to beneficiaries.³ Although this provision created an opportunity for pharmacists to offer and be

reimbursed for such services, it invoked restrictions that limit patient access to MTM services, such as the patient's underlying disease state(s), number of medications, and eligibility (i.e., patient age).³ Furthermore, the legislation does not specify which health care providers should provide MTM or the process by which MTM services should be delivered.

The Affordable Care Act (ACA), passed in 2010, aims to improve care for individuals, improve overall health for populations, and decrease health care costs.⁴ Essential components of the ACA intended to ensure that more Americans have health insurance are the individual coverage mandate and the expansion of

Medicaid coverage. This reformed health care paradigm calls for new interprofessional, collaborative practice models that provide high-quality, affordable patient-centered care. Examples of these models include accountable care organizations (ACOs) and patient-centered medical homes (PCMHs). U.S. residents without employer-provided plans can also choose a health care plan through health insurance exchanges, designed to be a marketplace where consumers can compare the benefits and prices of different health care plans so they may choose the plan that is best for them.⁴

Clinical pharmacists are well positioned to be integral members of the interprofessional teams that will seek to provide high-quality, low-cost care. By virtue of their knowledge and skills in managing drug therapy and their ability to identify and resolve complex drug-related problems, clinical pharmacists can help achieve optimal drug therapy outcomes. Growing recognition of the clinical pharmacist's role has contributed to considerable expansion of CDTM legislation across the United States since publication of the first ACCP Position Statement on CDTM in 1997 (Figure 1). Furthermore, the U.S. surgeon general,^{5,6} Centers for Disease Control and Prevention,⁷ and Institute of Medicine⁸ have each noted that pharmacists are essential members of the health care team.

The aims of this paper are to provide an overview of how CDTM legislation has advanced during the past decade; its role in enabling the provision of comprehensive medication management (CMM), the standard for direct patient care

provided by clinical pharmacists⁹; the potential impact of new models of care on CDTM and CMM; and the implications of the foregoing for future clinical pharmacist participation in patient-centered health care. Relevant trends in the health care environment, credentialing and privileging of clinical pharmacists, national and state health care regulations, and payment reform are also discussed.

Definitions

The term *MTM* was adopted by the Centers for Medicare & Medicaid Services (CMS) and incorporated into the 2003 Medicare Part D legislation. A consensus definition of MTM was developed and endorsed by national pharmacy organizations in 2005.¹⁰ Strictly speaking, MTM delivered under the Medicare Part D prescription drug benefit does not require a formal collaborative practice agreement between a pharmacist and a prescriber. MTM can be provided in any setting where a patient receives medications and often coincides with the dispensing of a medication. However, MTM may also be provided without dispensing a medication or product. An example of MTM might include assessing a medication profile to ensure that a patient with coronary artery disease is receiving β -blocker therapy. Essentially, MTM aims to ensure that patients receive the best medication therapy to achieve their respective pharmacotherapeutic goals.

The Patient-Centered Primary Care Collaborative (PCPCC), a partnership of stakeholders ranging from patient advocacy groups to medical professional organizations, charged a Medication Management Task Force to propose a well-defined process for the delivery of medication management. That process, CMM, ensures that individual patients are assessed to determine whether the patient's medications are appropriate, effective, and safe. CMM involves the development of a patient-centered care plan that the patient understands and with which the patient agrees and in which he or she actively participates. A key difference between MTM and CMM is that CMM includes an assessment of the patient's clinical status (e.g., evaluating blood pressure in patients on antihypertensive therapy) for each of the patient's medications and health problems. Another essential element of CMM incorporates a clinically appropriate follow-up evaluation to assess the patient's progress toward treatment goals. Finally, CMM requires collaboration among members of the health care team,

This document was prepared by the 2013 ACCP Publications Committee: Sarah E. McBane, Pharm.D., FCCP, BCPS, CDE (Chair); Anna Legreid Dopp, Pharm.D. (Vice Chair); Andrew Abe, Pharm.D.; Sandra Benavides, Pharm.D.; Elizabeth A. Chester, Pharm.D., MPH, FCCP, BCPS; Dave L. Dixon, Pharm.D., BCPS, CDE, CLS; Michaelia Dunn, Pharm.D., BCPS; Melissa D. Johnson, Pharm.D., MHS, AAHIVP; Sarah Jane Nigro, Pharm.D.; Tracie Rothrock-Christian, Pharm.D., BCPS; Amy H. Schwartz, Pharm.D., BCPS; Kim Thrasher, Pharm.D., FCCP, BCPS, CPP; and Scot Walker, Pharm.D., M.S., BCPS, BCACP. Approved by the ACCP Board of Regents on July 23, 2013. Final version received January 15, 2015.

Address reprint requests to the American College of Clinical Pharmacy, 13000 W. 87th Street Parkway, Suite 100, Lenexa, KS 66215; e-mail: accp@accp.com; or download from <http://www.accp.com>.

*Address for correspondence: Sarah McBane, UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, 9500 Gilman Drive, MC 0675, La Jolla, CA 92093-0675; e-mail: smcbane@mail.ucsd.edu.

© 2015 Pharmacotherapy Publications, Inc.

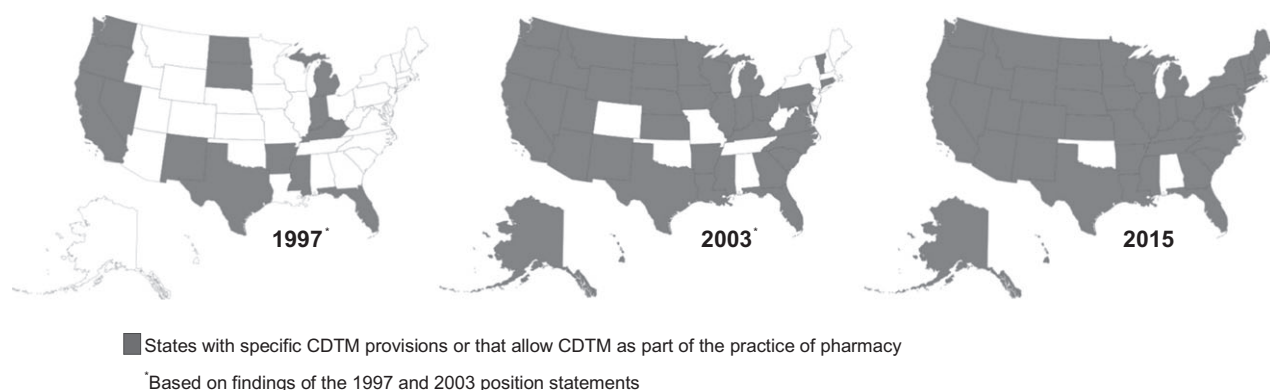


Figure 1. Expansion of CDTM legislation across the United States. CDTM = collaborative drug therapy management.

an element not necessarily included in MTM.¹¹ ACCP recently described in its clinical pharmacist practice standards the detailed processes involved in providing and documenting CMM.⁹

ACCP defines CDTM as involving a collaborative practice agreement between one or more physicians and qualified clinical pharmacists who work within the context of a defined protocol that permits the clinical pharmacist to assume responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.² Therefore, this paper uses CMM, as defined by ACCP, to describe the process of care provided by qualified clinical pharmacists and CDTM as the basis for collaboration between the clinical pharmacist and the provider.^{9, 11}

Perspectives on CDTM and CMM

ACCP has stated that qualified clinical pharmacists should provide CMM in all practice settings where a relationship exists between a patient, his or her provider(s), and the clinical pharmacist. A collaborative practice agreement (to provide CDTM), in accordance with state regulations, should serve as the regulatory framework for the clinical pharmacist's delivery of CMM. Clinical pharmacists practicing with physician and nonphysician health care professionals should do so in a collaborative, interprofessional environment that aims to improve health care value and efficiency using a patient-centered approach.⁹

The focus of the 1997 ACCP Position Statement on CDTM was on providing a historical account of how CDTM evolved over time including the documented outcomes (clinical, humanistic, and economic) associated with

CDTM, existing barriers, and recommendations for future collaborative practice. The historical overview presented in that paper is included in Figure 2.¹

The 2003 ACCP Position Statement on CDTM served to reaffirm the principles set forth in the 1997 paper and to provide updated information including a review of published literature addressing economic, clinical, and humanistic outcomes (ECHO); changes in state legislation; and the health care environment.² The paper described changes in health care costs and provided future estimates of medication-related expenditures, pointing out that rising drug costs and medication safety concerns provide a convincing rationale for increased clinical pharmacist involvement in collaborative care. Additional reports from the Pew Charitable Trust (1998) and the Institute of Medicine (1999 and 2001) were cited in the paper to further support the potential value of involving clinical pharmacists as members of the collaborative care team.^{12–14} Finally, the authors emphasized the growing impact of technology as a facilitator of collaborative practice.²

The founding of PCPCC in 2006 and the subsequent recommendations of its Medication Management Task Force provided additional impetus for the involvement of clinical pharmacists in patient-centered, team-based care. The PCPCC outlined a process to be followed in the provision of CMM that includes assessing patients' medication-related needs; identifying patients' medication-related problems; developing a care plan with individualized therapy goals and personalized interventions; and determining patient outcomes through patient follow-up.¹¹

Despite these recommendations, clinical pharmacist involvement in CDTM did not change dramatically. Attention shifted away from phar-

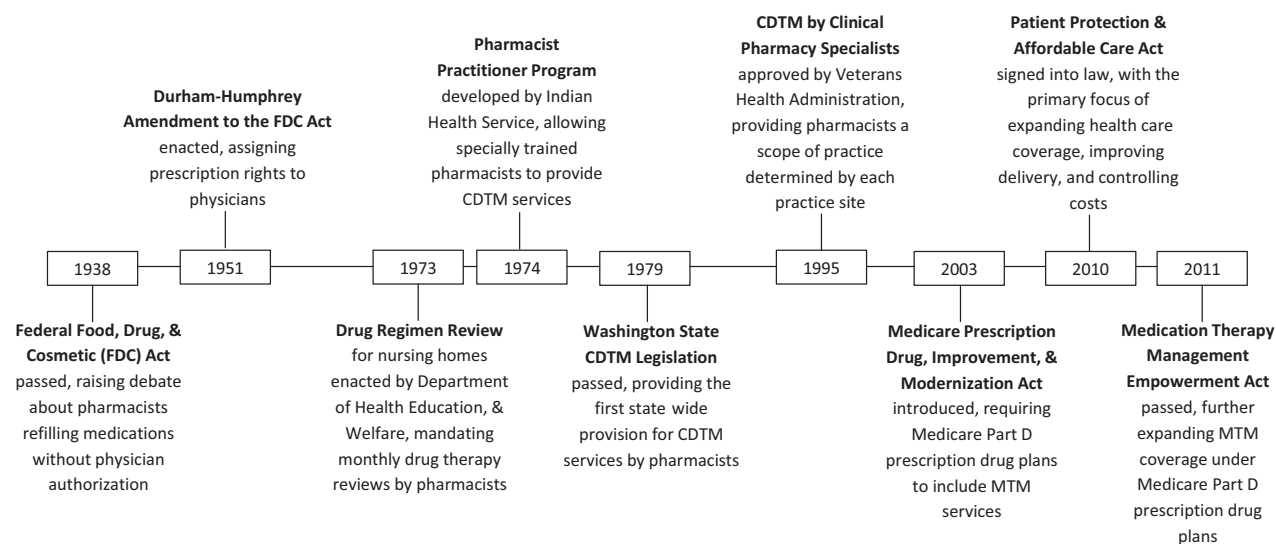


Figure 2. Historical overview of CDTM. CDTM = collaborative drug therapy management; MTM = medication therapy management.

maciſt provider ſtatus after paſſage of the MMA in 2003 and again after paſſage of the ACA in 2009 as Congress focused its energies on implementing theſe new laws. Nonetheless, work published in the ECHO literature continued to ſupport the clinical pharmacist’s involvement in team-based care after publication of the firſt evidence of the poſitive impact of the clinical pharmacist on mortality in patients with heart failure.¹⁵ Subſequentlſ, ACCP’s 2003 paper called for a more robuſt approach to reſearch on the value of the clinical pharmacist in collaborative care environments including more rigorous ſtudies (randomized, controlled, multicenter) with enhanced power, incorporating all ECHO parameters.² Finally, the 2003 paper noted that two iſſues continued to remain largely unad-dreſſed: the reſuiſite (vs minimum) education, poſtgraduate training, and/or certification requirements for clinical pharmacists engaged in CDTM; and models for financial compensation for the direct patient care provided by clinical pharmacists in collaborative practice ſettings.²

ſince publication of ACCP’s initial poſition ſtatement in 1997, CDTM legiſlation has expanded within the United States (Figure 1). States with CDTM legiſlation had increased from 14 (28%) to 38 (75%) by the time the 2003 ACCP paper was published. Currently, 48 ſtates (94%) have legiſlative provisions for CDTM. Of note, ſpecific CDTM provisions vary by ſtate, and even in ſtates without ſpecific CDTM legiſlation, pharmacists may collaborate with phyſicians to provide CMM. Several ſtates have

implemented new provisions related to the deliv-ery of CMM, with or without ſpecific CDTM language, and other ſtates with existing CDTM provisions have paſſed updated legiſlation ſince 2003 (Table 1).

Evolving View of Health Care

The health care landscape has experienced many changes during the paſt decade. Moſt notably, there has been a continued increase in health care ſpending without an appreciable improvement in health outcomes. According to 2011 ſtatistics from the World Health Organi-zation, the United States continues to ſpend more on health care per capita (\$8467) than any other country.¹⁶ Total health care coſts roſe 3.6% in 2013 and accounted for 17.4% of the groſs domeſtic product (GDP), or \$2.9 trillion. Health care coſts are projected to reach a fifth of the GDP by 2021, propelled by an aging population, new technology, an improving economy, and impending changes mandated by the health care reform law.¹⁷ Furthermore, the ACA potentially provides insurance coverage to millions of Americans, eſtimated by the Congressional Bud-get Office (CBO) to be 12 million in 2014 and riſing to 26 more million Americans from 2017–2024; CBO eſtimates provision of health care coverage is expected to add more than \$1,383 billion in coſts from 2015–2024.¹⁸

Implementation of the imminent changes in health care insurance coverage and their impact on chronic diſeaſe management is uncertain.

Table 1. Summary of Collaborative Drug Therapy Management Legislative Changes Since 2003: Position Statement

State	Year	Practice setting	Description
New Jersey	2004	All	Implementation of CDTM allowing pharmacists to collect, analyze, and monitor patient data; initiate, modify, continue, or discontinue drug therapy; order or perform laboratory tests; order clinical tests; perform therapeutic drug monitoring
New Hampshire	2006	Hospitals, long-term care and hospice facilities, ambulatory care clinics	Implementation of CDTM allowing pharmacists to implement, modify, and manage drug therapy; collect and review patient histories; obtain and check vital signs; order drug therapy-related laboratory tests
West Virginia	2008	All	Implementation of CDTM allowing pharmacists to implement, modify, and manage drug therapy; collect and review patient histories; obtain and check vital signs; order drug therapy-related laboratory tests
Massachusetts	2009	All	Implementation of CDTM allowing pharmacists to initiate, monitor, modify, and discontinue drug therapy; collect and review patient histories; obtain and check vital signs; order and evaluate the results of drug therapy-related laboratory tests
Indiana	2011	Acute care settings, private mental health institutions, outpatient clinics	Expansion of existing CDTM provisions to permit outpatient pharmacy drug therapy protocols
New York	2011	Teaching hospital, including any diagnostic center, treatment center, or hospital-based outpatient department	Implementation of CDTM allowing pharmacists to adjust or manage a drug regimen, including adjustment of drug strength, frequency of administration, or route of administration
Missouri	2012	All	Implementation of CDTM allowing pharmacists to design, initiate, implement, and monitor medication therapeutic plans
Virginia	2013	All	Update to existing CDTM statute to include postdiagnostic implementation of drug therapy pursuant to written <i>or electronic</i> protocol
Maine	2013	All	Implementation of CDTM allowing pharmacists to initiate, monitor, modify, and discontinue drug therapy; collect and review a patient's history; obtain and check vital signs; order and evaluate the results of laboratory tests
Wisconsin	2014	All	Expansion of existing CDTM provisions to permit pharmacists to perform any patient care service delegated to a pharmacist by a physician

(continued)

Table 1. (continued)

State	Year	Practice setting	Description
Kansas	2014	All	Implementation of CTDM, defined as a practice of pharmacy where a pharmacist provides care to a specific patient that has been delegated to the pharmacist by a physician through a collaborative practice agreement. Specifies that the pharmacist is not permitted to alter a physician's orders or directions, diagnose or treat any disease, independently prescribe drugs, or independently practice medicine and surgery
Tennessee	2014	All	Implementation of CDTM to permit pharmacists to interpret, evaluate, and implement medical orders and prescription orders; participate in drug, dietary supplement, and device selection; perform drug evaluation, utilization, or regimen review

CDTM = collaborative drug therapy management.

Cost has been shown to be a factor in health care utilization. The percentage of adults 18–64 years of age who reported not receiving or delaying needed medical care because of cost during a 12-month period increased from 11% in 1997 to 15% in 2010, during which time the percentage of adults not receiving prescription drugs because of cost almost doubled from 6–11%. In 2010, 35% of uninsured adults 18–64 years of age avoided, or delayed, seeking medical attention because of cost, compared with 13% of adults with Medicaid and 8% of privately insured adults. Data on obtaining prescriptions were similarly affected during this 12-month period of evaluation. Compared with 14% of adults with Medicaid and 6% of privately insured patients who did not have prescriptions filled because of cost, 26% of uninsured adults did not obtain prescription drugs because of cost.¹⁹

Dollars spent on medications had been decreasing in the years approaching 2012, yet in that year, sales of prescription drugs dropped for the first time by 1% to \$325.7 billion, ostensibly due to the greater use of generic drugs. Experts were quick to caution that the greater use of less expensive generic drugs might be overtaken by the use of more expensive and complex specialty medications, an observation that is unfolding.²⁰ In 2013, retail prescription drug spending increased 2.5% to over \$271 billion, with the growth attributed to increased use of the foregoing costly medications and increased utilization

of all medications.²¹ In addition, it is difficult to predict the impact of patent loss for current medications and the emergence of new drug approvals over the next several years. Given the expanding market and the extensive use of drugs in inpatient and outpatient settings, innovative team-based models designed to deliver safe and effective patient care to help contain medication costs and overall health care spending are long overdue.

New Models of Care

Health care in the United States is undergoing fundamental changes in care delivery and financing. This is providing increased opportunities to integrate clinical pharmacists as team members accountable for medication therapy outcomes. Health care complexity, information technology, and legislation have all contributed to the evolution of a team-based approach to patient care.²² Pharmacists' contributions to patient care teams and positive patient outcomes are well documented in the literature.^{6, 7, 11, 23} Government- and market-driven models of care are emerging as a means to simultaneously reduce the country's excessive health care costs and improve the quality of patient care.

Two models of health care delivery and financing established by the ACA are particularly relevant to the advancement and positioning of clinical pharmacists as providers of CMM—ACOs

and PCMHs.⁴ ACOs are defined by the ACA as a network of health care providers working together to improve the quality of health care services and reduce health care costs for a defined patient population. Similar to ACOs, the PCMH model is based on comprehensive coordination of primary care and communication among multiple providers. The value of team-based care models documented in the literature is gaining increased recognition among regulators and payers.²⁴ Available evidence shows that integrating clinical pharmacists into ACOs can decrease emergency department visits, hospitalizations, and cost of care.²⁵ In the PCMH, clinical pharmacists contribute to improved outcomes including the metrics of diabetes control, hospital readmissions, and overall health care cost savings.^{26–29} Clinical pharmacists are well positioned to contribute to the success of PCMHs and ACOs by providing CMM across virtually any patient care setting.^{30–32}

Credentialing and Privileging of Clinical Pharmacists to Provide CMM

Clinical pharmacists should possess the qualifications necessary to provide CMM in team-based, direct patient care settings. ACCP defines clinical pharmacists who provide direct patient care as “those who engage in the direct observation and evaluation of the patient and his/her medication-related needs; the initiation, modification, or discontinuation of patient-specific pharmacotherapy; and the ongoing pharmacotherapeutic monitoring and follow-up of patients in collaboration with other health care professionals.”³³ Clinical pharmacists who provide direct patient care should have completed accredited residency training or have equivalent postlicensure clinical experience. They should also hold board certification once they meet the eligibility criteria established by the Board of Pharmacy Specialties.³³

Clinical pharmacists should also be appropriately privileged to provide CMM in collaborative practice environments. Privileging is the method by which health care organizations authorize an individual to perform a particular clinical activity within a defined scope of practice. All patient care providers should be appropriately privileged to carry out the activities for which they are responsible within their respective practice settings.³⁴ In 2012, CMS released a final rule that amended the conditions of participation for hospitals and critical access hospitals to allow these organizations to grant privileges to pharmacists.³⁵ The CMS

directive broadened the concept of “medical staff” to allow hospitals the flexibility to include other practitioners, including pharmacists, as eligible candidates for the medical staff privileged to practice in the hospital in accordance with state law. The Veterans Health Administration has had a standardized system for privileging pharmacists’ scope of practice that can be found in VHA Directive 2008-043.³⁶ This directive includes an important facet of privileging: ongoing assessment and peer review. As more pharmacists enter into CDTM agreements that require specific privileges, health care institutions and organizations must understand and apply appropriate privileging processes.

Payer and Regulator Perspectives

Health care reform emphasizes the evaluation of health care quality.³⁷ Payers can evaluate quality measures of health systems, and employers and consumers can evaluate quality measures of health plans.^{38, 39} Currently, these metrics are often used as an indication of quality and may determine or influence reimbursement from both private and governmental payers. Clinical pharmacist involvement in patient care can improve quality and safety measures that are increasingly tied to reimbursement.⁴⁰ These quality measures include factors such as appropriateness of treatment, timeliness of treatment, and communication with patients about their medications.^{39, 41} Involving clinical pharmacists in medication management contributes to improved medication-related quality scores and reduced medication errors.^{42, 43} Clinical pharmacists have been shown to contribute to a reduction in the unintentional discontinuation of maintenance medications, fewer repeat emergency department admissions for medication-related adverse events, and less frequent prescribing of inappropriate medications for high-risk patients.^{44–46} Further research in this area is needed to demonstrate the impact of pharmacists on quality scores and consequent quality of patient care.

State regulations defining CDTM are widely varied. This may be due in part to the National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules that outline the process for and the required elements of a collaborative practice agreement but do not define the clinical activities for which pharmacists should have delegated authority (Table 2).⁴⁷ At present, 36 of the 48 states with legislative provisions for CDTM meet the basic minimum of

Table 2. National Association of Boards of Pharmacy: Elements of a Collaborative Practice Agreement/Collaborative Drug Therapy Monitoring Agreement⁴⁷

1. Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement
2. Types of decisions the Pharmacist is allowed to make
3. A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede when necessary
4. A description of the Continuous Quality Improvement Program used to evaluate the effectiveness of patient care and ensure positive patient outcomes
5. A provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate
6. A provision that allows either party to cancel the Agreement by written notification
7. An effective date
8. Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing

allowing pharmacists to initiate, modify, and discontinue medication therapies. Many states have provisions for agreements with providers that allow pharmacists to render various types of pharmacotherapeutic management. Although these provisions allow pharmacists to modify and monitor pharmacotherapy, they do not generally permit pharmacists to initiate or discontinue drug therapy.

Some states have created within their state pharmacy practice acts specific designations for pharmacists with specific training and/or credentials that empower them to perform additional activities including the ability to initiate, modify, and discontinue drug therapy, order laboratory tests, or refer patients to other providers.⁴⁸

Documented Value of Clinical Pharmacist Services

Economic studies have documented the benefits of clinical pharmacy services in a variety of patient care settings. The most recent ACCP economic evaluation of clinical pharmacy services found that the benefit-cost ratio ranged from 1.05:1 to 25.95.⁴⁹ Previous reviews of the economic value of clinical pharmacy services, dating back to 1988, have consistently documented positive benefit-to-cost ratios.⁵⁰⁻⁵²

Several clinical pharmacy-based services have not only led to improved clinical outcomes, but have increased overall savings and avoidance of health care services as well. Examples of these services include MTM provided by clinical phar-

macists at Fairview Healthcare Partners in Minnesota, resulting in an overall health care savings of \$2,814,307 for 7347 patients from September 1998 through December 2006.⁵³ The specific savings included avoidance of health care services such as outpatient clinic visits (\$1,700,505), specialty office visits (\$336,832), laboratory services (\$4488), urgent care visits (\$9266), long-term care stays (\$168,000), emergency department visits (\$70,512), and hospital admissions (\$466,639).⁵³ Savings were also associated with the number of employee workdays saved (\$58,065). Missouri's Pharmacy-Assisted Collaborative Disease Management Program resulted in 12% fewer hospitalizations, a 25% reduction in emergency department visits, and fewer drug-related problems. This program also had a 2.5-to-1 return on investment.⁵³ The Asheville Project on pharmaceutical care showed multiple economic benefits including decreased total direct medical costs, decreased days of sick time per year, and increased productivity.⁵³ The clinical pharmacy services in Harris County Hospital District in Texas documented \$1.5 million in cost savings in 2005 alone, consisting of reductions in emergency department and hospital visits.⁵³

Teaching hospitals have employed clinical pharmacists as members of their inpatient medical and surgical teams for more than 40 years. Pharmacist participation on patient care rounds as a member of the interprofessional team has been shown to decrease the number of adverse drug events and generate cost savings for the health care system.^{54, 55} In outpatient team-based care models such as the PCMH, the clinical pharmacist's unique knowledge and skills are complementary to the expertise of physicians and other team members.⁵⁶ Clinical pharmacists can contribute to these teams as integrated clinicians practicing in the primary care medical office, in the ambulatory clinic, or virtually from another location, using health information technology. Although optimal staffing ratios have not yet been clearly defined, integrated care delivery systems have published ratios suggesting that about 1 clinical pharmacist for every 10 primary care physicians is an effective ratio.⁵⁷⁻⁵⁹

Influence of Current and Future Payment Models

To facilitate access to clinical pharmacists' delivery of CMM, this service must be recognized by payers. Various billing models have

been proposed including fee-for-service, pay-for-performance, and capitated payment. Fee-for-service billing has been the most common model used.⁶⁰ Billing for services in the fee-for-service model is generally based on the type and complexity of the service provided. Some sources suggest that fee-for-service billing structures will be replaced by other reimbursement models,^{61, 62} especially as health care transitions to models such as PCMHs or ACOs.

Pay-for-performance models, encouraged through various mechanisms by the ACA, provide potentially higher rates of payment when patients meet predefined health outcomes.⁶² Although less common than fee-for-service practices, pay-for-performance models offer an alternative that may be attractive to payers of the future. Current data on pay-for-performance impact on overall health care quality are mixed, but most publications acknowledge that these models will require more time to fully assess their effect.^{63–67}

Other payment models include capitated and shared-risk shared-reward systems. Capitation payment models provide compensation on a per-patient-per-unit-of-time (commonly per-member per-month) basis. Clinical pharmacists providing CMM under a capitation payment system would receive their payment from the same funds for patient care that support a practice's other health care professionals. Historical concerns with capitation payment systems point to the financial incentive to provide only the minimum level of care because additional services may not receive any added compensation. Shared-risk shared-reward payment models reimburse health care organizations, such as ACOs or PCMHs, providing increased compensation when outcomes are met and applying penalties when outcomes are not achieved. Blended payment structures typically combine capitation payment systems with fee-for-service and/or pay-for-performance models.⁶⁸ Blended payment models often compensate health care providers for care coordination efforts that are commonly not recognized in the fee-for-service model. Blended payment models can support CMM by recognizing and providing compensation for improved outcomes, coordination among multiple prescribers, and other medication-related misadventures that can occur during transitions of care.¹¹

Current Medicare payment policies recognize pharmacists' medication management services in the Medicare Part D program. Part D drug plans determine how the MTM benefit will be struc-

tured and what will be reimbursed, often contracting with certain entities (that may include pharmacies but may also include nonpharmacist health professionals) to satisfy MTM requirements. Pharmacists providing MTM can use three Current Procedural Terminology codes. These characterize visits as "initial" (15 min), "follow-up," and "additional" (in 15-min increments). Each payer then defines the payment amounts for each visit type. In contrast to CDTM, a practice agreement with a physician is not required when billing for MTM services under Medicare Part D.

Pharmacists can indirectly bill third-party payers for CMM services provided on behalf of the physician when the pharmacist has a collaborative practice agreement in place or is an employee of a physician practice. In this case, payment is made to the physician. In hospital-based clinics, billing for CMM services usually falls under the "technical/facility fee" using Ambulatory Payment Classification codes based on the duration and complexity of the visit. Payment is made from third-party payers to the clinic. Some clinics have billed using relative value units, but this has generally not been a successful method for obtaining reimbursement.⁶⁹

Developing and implementing documentation and billing processes for CMM services can be challenging. Payers may establish their own criteria for coverage of an individual patient, and payers outside Medicare Part D may be unfamiliar with either MTM or the more inclusive CMM services. When billing indirectly, it can also be difficult to establish and track specific revenue from CMM services alone. This may also be a challenge in pay-for-performance or shared-risk shared-reward models where reimbursement is based on outcomes that are due to interventions from many different health care professionals.

As clinical pharmacists implement CMM services in various collaborative practice environments, it is essential that these activities be understood and recognized by payers. Currently, clinical pharmacists' services are excluded under Medicare Part B and only narrowly covered by the MTM provisions in Part D. Establishing coverage for CMM under Medicare Part B, and achieving CMM recognition among other payers, will increase opportunities for clinical pharmacists to provide these services to more patients. In pursuing this end, clinical pharmacists must possess a working knowledge of how practices

bill for clinical services and must have sufficient resources to facilitate that practice's billing for CMM services. The billing process can be difficult to navigate. Therefore, it is important that clinical pharmacists network with billing experts to establish best practices that minimize errors, avoid fraud, and secure appropriate levels of reimbursement for the services provided.

The Future of Clinical Pharmacist Participation in Team-Based Health Care

Notwithstanding the payment and regulatory barriers just described, defining the clinical pharmacist's process of care in collaborative practice environments and his or her qualifications to provide this care will be central to establishing CMM as a standard of care in the future. As set forth in the ACCP standards, clinical pharmacists must possess the requisite qualifications (i.e., board certification or other validated documentation of equivalent competence and experience) and privileges conferred by a CDTM agreement or other recognized formal privileging process.⁹ This is essential to ensure that the clinical pharmacist is afforded the opportunity to fully contribute to achieving desired medication-related outcomes, and assumes appropriate responsibility for achieving these outcomes. Collaborative approaches to practice, and the avoidance of compartmentalized care, are essential to the successful implementation of CMM.

Although some have advocated for "provider status" for pharmacists, the provision of CMM does not require recognition as an independent provider. Instead, it rests on an overall collaborative process of care and the existence of an agreement or policy that confers to the clinical pharmacist the appropriate authorities and responsibilities within a team-based practice. Indeed, achieving provider status may be viewed by some as primarily a vehicle for securing reimbursement for the services of pharmacists. However, in an outcomes-driven health care system, compensation is best tied not only to the benefits or services provided to patients (in this case, the provision of CMM by qualified clinical pharmacists), but also—and more importantly—to the outcomes achieved through the provision of these benefits and services. Achieving provider status per se is probably irrelevant if the clinical pharmacist is able to improve patients' medication-related outcomes meaningfully in a collaborative practice environment. In this scenario,

outcomes-driven payment flows to the practice, and the clinical pharmacist benefits as a member of the broader health care team.

Conclusion

Significant advances in the growth and scope of CDTM have ensued since publication of the 1997 and 2003 ACCP CDTM statements. In addition, stakeholders today acknowledge the positive impact of CMM on patients' medication-related outcomes. Enabling legislation at both the federal and state levels will increase the number of patients who have access to CMM in the future. Because ACOs and PCMHs will likely form the basis for much of tomorrow's health care delivery, clinical pharmacists must focus on adapting to these and other evolving team-based health care models. Clinical pharmacy practice has always been inherently team oriented and collaborative. Therefore, the clinical pharmacy discipline must continue to use CDTM agreements and other collaborative privileging mechanisms to facilitate clinical practice activities. Continued growth in the provision of CMM by qualified clinical pharmacists in collaborative practice settings will enhance recognition of their positive impact on patients' medication-related outcomes.

Acknowledgments

The authors thank Edith Nutescu, Pharm.D., M.S., FCCP; C. Edwin Webb, Pharm.D., MPH; and John McGlew for their assistance in the development and review of this paper.

References

1. Carmichael JM, O'Connell MB, Devine B, et al. Collaborative drug therapy management by pharmacists. *Pharmacotherapy* 1997;17:1050–61.
2. Hammond RW, Schwartz AH, Campbell MJ, et al. Collaborative drug therapy management by pharmacists—2003. *Pharmacotherapy* 2003;23:1210–25.
3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Available from www.govtrack.us/congress/bills/108/hr1. Accessed January 6, 2015.
4. Patient Protection and Affordable Care Act. Available from www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf. Accessed January 6, 2015.
5. Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report to the U.S. Surgeon General. Washington, DC: U.S. Public Health Service, Office of the Chief Pharmacist, December 2011. Available from www.usphs.gov/corpslinks/pharmacy/documents/2011advancedpharmacypracticereporttotheussg.pdf. Accessed January 6, 2015.
6. Benjamin R. Support letter from the United States Surgeon General. Available from <http://www.usphs.gov/corpslinks/pharmacy/documents/2011SupportLetterFromUSSG.pdf>. Accessed January 19, 2015.

7. Morrison CM, Glover D, Gilchrist SM, et al. A program guide for public health: partnering with pharmacists in the prevention and control of chronic diseases. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, August 2012. Available from www.cdc.gov/dhbsp/programs/nhdsp_program/docs/pharmacist_guide.pdf. Accessed January 6, 2015.
8. Institute of Medicine (IOM). Preventing medication errors: Quality Chasm Series. Washington, DC: National Academies Press, 2007.
9. American College of Clinical Pharmacy (ACCP). Standards of practice for clinical pharmacists. *Pharmacotherapy* 2014;34:794–7.
10. Bluml BM. Definition of medication therapy management: development of professionwide consensus. *J Am Pharm Assoc* 2005;45:566–72.
11. McInnis T, Strand LM, Webb CE. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes, 2nd ed. Patient-Centered Primary Care Collaborative, 2012. Available from <https://www.accp.com/docs/positions/misc/CMM%20Resource%20Guide.pdf>. Accessed January 6, 2015.
12. Pew Health Professions Commission. Recreating health professional practice for a new century. San Francisco, CA: Pew Charitable Trust, 1998.
13. Kohn LT, Corrigan JM, Donaldson MS, eds. *Institute of Medicine (IOM). To err is human: building a safer health system*. Washington, DC: National Academy Press, 2000.
14. Institute of Medicine (IOM). Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academies Press, 2001.
15. Gattis WA, Hasselblad V, Whellan DJ, O'Connor CM. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team: results of the Pharmacist in Heart Failure Assessment Recommendation and Monitoring (PHARM) study. *Arch Intern Med* 1999;159:1939–45.
16. World Health Organization. World health statistics 2014. Available from http://apps.who.int/iris/bitstream/10665/112738/1/9789240692671_eng.pdf. Accessed January 9, 2015.
17. Centers for Medicare and Medicaid Services. National Health Expenditure Data: NHE Fact Sheet. Available from <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html>. Accessed January 7, 2015.
18. Congressional Budget Office. Congress of the United States. Updated Estimates of the Effects of the Insurance Coverage Provisions of the Affordable Care Act, April 2014. Available from http://www.cbo.gov/sites/default/files/45231-ACA_Estimates.pdf. Accessed January 7, 2015.
19. U.S. Department of Health and Human Services (DHHS), National Center for Health Statistics. Health, United States, 2011: with special feature on socioeconomic status and health. Hyattsville, MD: DHHS, 2012.
20. Thomas K. U.S. drug costs dropped in 2012, but rises loom. *New York Times*. Available from www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?pagewanted=all&r=0. Accessed January 6, 2015.
21. Centers for Medicare and Medicaid Services. National Health Expenditure 2013 Highlights. Available from www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf. Accessed January 9, 2015.
22. American Society of Health-System Pharmacists (ASHP). Pharmacy Practice Model Initiative. Available from www.ashp-media.org/ppmi/. Accessed January 6, 2015.
23. Odum L, Whaley-Connell A. The role of team-based care involving pharmacists to improve cardiovascular and renal outcomes. *Cardiorenal Med* 2012;2:243–50.
24. Mitchell P, Wynia M, Golden R, et al. Core principles & values of effective team-based health care. Washington, DC: IOM, 2012.
25. Blank C. Minn. ACO uses MTM to reduce hospital readmissions. *Drug Topics*. Available from <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/minn-aco-uses-mtm-reduce-hospital-readmissions>. Accessed January 6, 2015.
26. Fillmore H, Dubard CA, Ritter GA, Jackson CT. Health care savings with the patient-centered medical home: Community Care of North Carolina's experience. *Popul Health Manag* 2014;17:141–8.
27. Edwards HD, Webb RD, Scheid DC, Britton ML, Armor BL. A pharmacist visit improves diabetes standards in a patient-centered medical home (PCMH). *Am J Med Qual* 2012;27:529–34.
28. Berdine HJ, Skomo ML. Development and integration of pharmacist clinical services into the patient-centered medical home. *J Am Pharm Assoc* 2012;52:661–7.
29. Anderson SL, Marrs JC, Vande Griend JP, Hanratty R. Implementation of a clinical pharmacy specialist-managed telephonic hospital discharge follow-up program in a patient-centered medical home. *Popul Health Manag* 2013;16:235–41.
30. Bates DW. Role of pharmacists in the medical home. *Am J Health Syst Pharm* 2009;66:1116–8.
31. Berdine H, Dougherty T, Ference J, et al. The pharmacists' role in the Patient-Centered Medical Home (PCMH): a white paper created by the Health Policy Committee of the Pennsylvania Pharmacists Association (PPA). *Ann Pharmacother* 2012;46:723–50.
32. Lipton HL. Pharmacists and health reform: go for it! *Pharmacotherapy* 2010;30:967–72.
33. American College of Clinical Pharmacy (ACCP). Board of Regents commentary. Qualifications of pharmacists who provide direct patient care: perspectives on the need for residency training and board certification. *Pharmacotherapy* 2013;33:888–91.
34. Philip B, Weber RJ. Enhancing pharmacy practice models through pharmacists' privileging. *Hosp Pharm* 2013;48:160–5.
35. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (DHHS). Medicare and Medicaid programs; reform of hospital and critical access hospital conditions of participation. Final rule. *Fed Regist* 2012;77:29034–76.
36. U.S. Department of Veterans Affairs. Scope of practice for pharmacists with direct patient care, 119: Pharmacy Service. Available from www.va.gov/vhapublications/publications.cfm?pub=1. Accessed January 6, 2015.
37. Centers for Medicare & Medicaid Services (CMS). Lower costs, better care: reforming our health care delivery system. Available from www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-02-28.html. Accessed January 6, 2015.
38. Centers for Medicare & Medicaid Services (CMS). Hospital Compare. Available from www.medicare.gov/hospitalcompare. Accessed January 6, 2015.
39. HCAHPSOnline.org [home page on the Internet]. Hospital Consumer Assessment of Healthcare Providers and Systems survey. Available from www.hcahpsonline.org. Accessed January 6, 2015.
40. CMS.gov [home page on the Internet]. Atlanta, GA: Centers for Medicare & Medicaid Services (CMS). Available from www.cms.gov. Accessed January 6, 2015.
41. National Committee for Quality Assurance (NCQA). HEDIS measures. Available from www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx. Accessed January 6, 2015.
42. Buckley B. Tales of success in boosting HCAHPS scores. *Pharmacy Practice News* 2012;39. Available from www.pharmacy-practicenews.com/ViewArticle.aspx?d=Operations%2B%26%2BManagement&d_id=53&ri=August+2012&ri_id=872&a_id=21375 [requires Web site registration]. Accessed January 6, 2015.
43. Avery AJ, Rodgers S, Cantrill JA, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet* 2012;379:1310–9.

44. Bell CM, Brener SS, Gunraj N, et al. Association of ICU or hospital admission with unintentional discontinuation of medications for chronic diseases. *JAMA* 2011;306:840–7.
45. Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med* 2011;365:2002–12.
46. Guthrie B, McCowan C, Davey P, Simpson CR, Dreischulte T, Barnett K. High risk prescribing in primary care patients particularly vulnerable to adverse drug events: cross sectional population database analysis in Scottish general practice. *BMJ* 2011;342:d3514.
47. National Association of Boards of Pharmacy (NABP). Model State pharmacy act and model rules of the National Association of Boards of Pharmacy. Mount Prospect, IL: NABP, 2012.
48. Hernandez E. California Senate Bill 493. An act to amend Sections 733, 4040, 4050, 4051, 4052, 4052.3, 4060, 4076, 4111, and 4174 of, and to add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210, and 4233 to, the Business and Professions Code, relating to pharmacy. Available from www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.htm. Accessed January 6, 2015.
49. Touchette DR, Doloresco F, Suda KJ, et al. Economic evaluation of clinical pharmacy services: 2006–2010. *Pharmacotherapy* 2014;34:771–93.
50. Perez A, Doloresco F, Hoffman JM, et al. ACCP: economic evaluations of clinical pharmacy services: 2001–2005. *Pharmacotherapy* 2009;29:128.
51. Schumock GT, Meek PD, Ploetz PA, Vermeulen LC. Economic evaluations of clinical pharmacy services—1988–1995. The Publications Committee of the American College of Clinical Pharmacy. *Pharmacotherapy* 1996;16:1188–208.
52. Schumock GT, Butler MG, Meek PD, Vermeulen LC, Arondekar BV, Bauman JL. Evidence of the economic benefit of clinical pharmacy services: 1996–2000. *Pharmacotherapy* 2003;23:113–32.
53. U.S. Department of Health and Human Services. Special report to the Senate Appropriations Committee on advancing clinical pharmacy services in programs funded by the Health Resources and Services Administration and its Safety-Net Partners. Senate Report 110-107. 2008. Available from https://docs.340bvpv.com/documents/public/resourcecenter/HRSA_ACPS_report.pdf. Accessed January 6, 2015.
54. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999;282:267–70.
55. Hamblin S, Rumbaugh K, Miller R. Prevention of adverse drug events and cost savings associated with PharmD interventions in an academic Level I trauma center: an evidence-based approach. *J Trauma Acute Care Surg* 2012;73:1484–90.
56. Smith M, Bates DW, Bodenheimer T, Cleary PD. Why pharmacists belong in the medical home. *Health Aff* 2010;29:906–13.
57. Reid RJ, Fishman PA, Yu O, et al. Patient-centered medical home demonstration: a prospective, quasi-experimental, before and after evaluation. *Am J Manag Care* 2009;15:e71–87.
58. Heilmann RM, Campbell SM, Kroner BA, et al. Evolution, current structure, and role of a primary care clinical pharmacy service in an integrated managed care organization. *Ann Pharmacother* 2013;47:124–31.
59. DaVanzo J, Dobson A, Koenig L, Book R. Medication therapy management services: a critical review. *J Am Pharm Assoc* 2005;45:580–7.
60. Steinbrook R. The end of fee-for-service medicine? Proposals for payment reform in Massachusetts. *N Engl J Med* 2009;361:1036–8.
61. National Commission on Physician Payment Reform. Available from <http://physicianpaymentcommission.org/>. Accessed January 6, 2015.
62. Lenz TL, Monaghan MS. Pay-for-performance model of medication therapy management in pharmacy practice. *J Am Pharm Assoc* 2011;51:425–31.
63. Lindenaer PK, Remus D, Roman S, et al. Public reporting and pay for performance in hospital quality improvement. *N Engl J Med* 2007;356:486–96.
64. Van Herck P, De Smedt D, Annemans L, Remmen R, Rosenthal MB, Sermeus W. Systematic review: effects, design choices, and context of pay-for-performance in health care. *BMC Health Serv Res* 2010;10:247.
65. Cutler TW, Palmieri J, Khalsa M, Stebbins M. Evaluation of the relationship between a chronic disease care management program and California pay-for-performance diabetes care cholesterol measures in one medical group. *J Manag Care Pharm* 2007;13:578–88.
66. Scott A, Sivey P, Ait Ouakrim D, et al. The effect of financial incentives on the quality of health care provided by primary care physicians. *Cochrane Database Syst Rev* 2011;9:CD008451.
67. Bardach NS, Wang JJ, De Leon SF, et al. Effect of pay-for-performance incentives on quality of care in small practices with electronic health records: a randomized trial. *JAMA* 2013;310:1051–9.
68. Robinson JC. Blended payment methods in physician organizations under managed care. *JAMA* 1999;282:1258–63.
69. Stump AL. Creating a fee schedule for the pharmacist CPT codes based on revenue value units (online presentation). American Society of Health-System Pharmacists. Available from www.ashp.org/DocLibrary/MemberCenter/Webinars/Fee_Schedule_Revenue_Value_Units.aspx. Accessed January 6, 2015.