The Role of Pharmacy Through Collaborative Practice in an Ambulatory Care Clinic

Abstract: *Pharmacists have been practicing in ambulatory care environments managing patients with chronic illnesses since the 1970s. The US Surgeon General and the Centers for Disease Control and Prevention support pharmacists working in collaboration with physicians to optimize medication outcomes, improve patient satisfaction, and lower health care costs. Through collaborative practice agreements, pharmacists are able to work as part of a health care team with access to electronic health records, and they assist busy physicians manage patients with chronic diseases such as diabetes. This article will review the different types of ambulatory care practice settings, what is included in a collaborative practice agreement, the credentialing and privileging of pharmacists working in such environments, the qualifications of pharmacists, the scope of practice, and some challenges for reimbursement.*

Keywords: collaborative practice agreement; ambulatory care clinic; disease state management; comprehensive medication management

Clinical pharmacy services, pharmaceutical care, disease state management, collaborative drug therapy management, or comprehensive medication management (CMM) are different names of clinical pharmacy services, which have been provided by pharmacists in ambulatory care settings for decades, with

Prevention (CDC) states how patient care services provided by pharmacists can reduce fragmentation of care, lower health care costs, and improve health outcomes.^{3,4} Furthermore, another study found that patient health improves significantly when pharmacists work with doctors and other providers to manage patient care.⁵

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documented improvement in health care quality, safety, cost, and satisfaction.¹ However, this role of pharmacists remains unfamiliar to many physicians, health care professionals, and the general public. Pharmacists are often characterized as the most underutilized health care practitioners in the health care system.² A report by the Centers for Disease Control and

The US Surgeon General, CDC, and the Institute of Medicine have noted that pharmacists are essential members of the health care team. The CDC has recognized pharmacists' medication expertise and the potential for expanded access to care through collaborative practice agreements (CPAs) for chronic condition management and prevention services.³

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History of Pharmacists' Engagement in Ambulatory Care and Defining Ambulatory Care

Since 1974, pharmacists in the Indian Health Service have had postdiagnostic prescriptive authority under CPAs with physicians, primarily to manage chronic conditions treated with medications.^{2,4,6} The Department of Veterans Affairs has had similar practices for pharmacists since 1995 with independent prescribing privileges.^{2,4,6,7} These types of settings are referred to as ambulatory care clinics where medical care can be provided to patients in an outpatient basis including consultation, intervention, and treatment. Certain conditions are more common in ambulatory care such as diabetes, hypertension, or chronic obstructive pulmonary diseases.

A definition of ambulatory care pharmacy practice provided by the Board of Pharmacy Specialties (BPS) and developed by a joint task force of the American Pharmacists Association, the American Society of Health-System Pharmacists, and the American College of Clinical Pharmacy states that it is

the provision of integrated, accessible health care services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management. The ambulatory care pharmacists may work in both an institutional and community-based clinic involved in direct care of a diverse patient population.⁸

Different Models of Ambulatory Care

A variety of ambulatory care settings exist in health care, including

pharmacists practicing in physician's offices, physician residency programs, community pharmacies, and institutional ambulatory environments.⁹ Institutional ambulatory environments can include clinics in hospitals, specialty clinics (eg, transplant, cardiology), emergency departments, urgent care centers, outpatient treatment centers (eg, cancer chemotherapy, dialysis), correctional institutions, managed care clinics, and government programs (eg, Indian Health Services, federally qualified health centers, Veterans Affairs hospitals).⁹

To describe 2 of these models in more detail, an ambulatory care clinic can be a primary care group practice with clinical pharmacists embedded in its practice and a hospital-based ambulatory care clinic can provide outpatient services for patients that are discharged. In the primary care group practice, clinical pharmacists have access to the electronic health records (EHRs) used by the practice and see patients by appointment to help manage the patient's disease and provide additional education. El Rio Community Health Center in Arizona is an example whereby clinical pharmacists based at the health center have a CPA with physicians to help manage diabetes patients.¹⁰ Referrals are made by physicians and nurse practitioners through the EHR directly to the pharmacist.¹⁰ The pharmacist can document the care plan in the EHR and the provider can access it.

The hospital-based ambulatory care clinic provides outpatient services for patients recently discharged to provide continuity of care, and tries to minimize 30-day readmission rates, and acts as a bridge until patients can see their primary care provider. In this setting, the pharmacists also have access to the inpatient health records. An example of a hospital-based ambulatory care clinic is in Ohio, where a comprehensive anticoagulation management service has been created by the Health Alliance of Greater Cincinnati at a university hospital and a community hospital.¹¹ The crucial element for practicing in these environments is the CPA.

Definition and Types of CPA

The CDC defines a CPA as a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.³ It is also described as an agreement between one or more prescribers and one or more qualified pharmacists that expand pharmacists' scope of practice to assume professional responsibility to perform patient assessments, counsel, and make referrals; order laboratory tests; administer drugs; and select, initiate, monitor, continue, discontinue, and adjust drug therapy regimens.^{2,12,13}

Adams and Weaver described 2 types of CPAs. First is a patient-specific one where a relationship exists between the patient, provider, and the pharmacist and the services are limited to only those patients. This tends to be more restrictive. The second is a population-specific CPA where a relationship exists between the provider and the pharmacist and services may be provided for broad patient populations regardless of whether they were previously a patient of the collaborating provider.¹³ Population-specific CPAs are the less restrictive of the 2 types and can be used in management of chronic diseases.¹³

Although 48 states and the District of Columbia enable pharmacist prescriptive authority under CPAs, standing order, or statewide protocols,¹⁴ only 36 states allow the initiation of medications in outpatient settings,¹⁵ and 12 other states limit the CPAs to inpatient settings only or allow only the modification of medication regimens, and not the initiation of a medication.¹³ Furthermore, only 17 states permit population-specific CPAs.¹³ Hence, depending on the state in which the pharmacist practices, there are differences in the scope of practice that is allowed in the management of patients.

Elements of a CPA

Disease state management, collaborative drug therapy management,

or CMM requires a CPA with a physician; thus, the physician remains in the leadership role on the health care team.¹⁶ Group or individual physicians can decide what range of clinical privileges can be comfortably granted to pharmacists through CPAs. In addition to clarifying clinical privileges, CPAs outline how and when pharmacists will communicate patient care issues with physicians and other health care team members.¹⁶

The National Association of Boards of Pharmacy¹⁷ identified 8 elements that are required of a CPA:

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

CPAs often contain evidence-based treatment protocols, or reference to established treatment guidelines that the pharmacist can follow in making decisions about prescribing new medications postdiagnosis or modifying existing therapies.² It is expected that there is care coordination of the patient and that the pharmacist needs to communicate actions and decisions to the prescriber, including alerting the

prescriber when patients need care that extends beyond the pharmacist's expertise.²

A well-designed CPA should outline when the terms of agreement can be dissolved so that there is an exit strategy for both parties. One of the limitations of a CPA is making the requirements of the clinical pharmacists too stringent that not many in the institution are able to qualify to sign nor work under the CPA. When creating CPAs and evaluating the qualifications for pharmacists, there needs to be trust and rapport between the 2 parties to negotiate what appropriate levels of training should be required of clinical pharmacists to work under the CPA. Mutual trust and respect is essential in CPAs. Trust is built via rapport building and purposeful communication between the physician and the pharmacist. Respect comes from knowing that pharmacists have professional competence, appropriate qualifications, and experience to care for patients. Confirming the academic pedigree and clinical expertise of pharmacists may reassure others through the credentialing process.

Credentialing and Privileging

The definition of credentialing and privileging from the Council on Credentialing in Pharmacy states that a *credential* is documented evidence of professional qualifications, such as academic degrees, state licensure, residency certificates, and certification.¹⁸ Credentialing is the process of granting a credential (a designation that indicates qualifications in a subject or area), and the process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services.¹⁸ The purpose of a "credentialing process" is to document and demonstrate that the health care professional being evaluated has attained the credentials and qualifications to provide the scope of care expected for patient care services in a particular setting.¹⁹

Privileging, on the other hand, is the process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that person to perform a specific scope of patient care services within that organization.¹⁸ The purpose of a "privileging process" is to assure stakeholders that the health care professional being considered for certain privileges has the specific competencies and experience for specific services that the organization provides and/or supports.¹⁹

Credentialing and privileging is commonly instituted for physicians in any setting. However, this is not a standard of practice in all pharmacy settings and still remains voluntary.²⁰ In ambulatory care settings, it is becoming more common and recommended to ensure optimum qualifications that a pharmacist has the knowledge, skills, and experience to perform the functions granted under the CPA.

All US-educated pharmacists attain a fundamental set of credentials to qualify to enter practice—an accredited professional pharmacy degree and a license awarded upon successful completion of a national postgraduation examination administered by the National Association of Boards of Pharmacy on behalf of state boards of pharmacy.¹⁹ However, residencies, board certification, and certificate programs are voluntary. The Doctor of Pharmacy (PharmD) standards in the United States require graduates to have knowledge, skills, and abilities in delivering patient-centered care as the medication expert, managing medication use systems, managing chronic disease and improving health and wellness, and understanding how population-based care relates to patient-centered care.^{2,21}

Qualifications for Pharmacists to Work in an Ambulatory Care Setting

Although post-graduate residency training is optional for pharmacists, it is a

desirable next step that provides accelerated growth beyond entry-level professional competence.²² Graduates of residency programs are better positioned to enter into practice settings such as academia and advanced clinical practices in acute care hospitals in specialty areas and ambulatory care clinics.²² In most cases, a post-graduate year 1 (PGY1) residency produces a generalist pharmacist and a post-graduate year 2 (PGY2) residency produces pharmacy specialists.²³

Since 1978, pharmacists have been certified as specialists through examination processes developed and administered by the BPS.²⁴ Initially, there were 5 specialty examinations including nuclear pharmacy (1978), nutrition support (1988), pharmacotherapy (1988), oncology (1996), and psychiatric pharmacy (1996).^{24,25} The ambulatory care board certification exam became available in 2011 and received accreditation in 2014.^{25,26} An estimated 295 620 pharmacists were employed in the United States in May 2015.²⁷ Although it is unknown how many pharmacists are currently practicing under a CPA, what is known is the number of pharmacists who are board certified in ambulatory care pharmacy (BCACP) or pharmacotherapy specialists (BCPS) to practice in these types of settings. The BPS, who administers the board certification exams, lists certificants by specialty and location.²⁸ In 2006, only about 2.4% of the overall pharmacist population held a specialty board certification credential.²⁵ By 2016, 24 532 or 8.3% of working pharmacists were board certified in the United States in any area including ambulatory care (2438), oncology (1793), psychiatry (856), and pharmacotherapy (16963).²⁸

In order to become board certified, the pharmacist has to meet minimum criteria. To become BCPS, for example, the pharmacist must have graduated from an accredited pharmacy program, have an active license, have 3 years of practice experience, or have completed a PGY1 pharmacy residency, and pass the certification exam.²⁹ To become a BCACP, the pharmacist must have graduated

from an accredited pharmacy program, have an active license, have 4 years of practice experience, or have completed a PGY1 pharmacy residency plus an additional year, or completed a PGY2, or second year specialized pharmacy residency, and pass the certification exam.⁸

Board certification is also a voluntary process and optional. However, newly developing ambulatory care CPAs are requiring board certification for their pharmacists through the credentialing and privileging process. For example, at a federally qualified health center primary care clinic in San Bernardino, California, pharmacists were credentialed and privileged to manage ambulatory care patients with chronic illnesses under a CPA but they were required to have board certification and meet the requirements of an Advanced Practice Pharmacist (APP).

In California, senate bill 493, known as SB493, was signed on October 1, 2013, and recognized pharmacists as health care providers and created a new category of pharmacists called the APP. The requirements to become an APP states that the pharmacist must meet 2 of the 3 following criteria: complete an accredited PGY1 residency following the doctorate in pharmacy degree, or obtain board certification in any area, or have worked under a CPA for at least 1 year.³⁰ Hence, the executive committee developing the CPA for this new practice in 2014 adapted the requirements of the APP and verified that the pharmacists were board certified and had a residency before signing the CPA. Furthermore, pharmacists specializing in psychiatry also were required to have residency training and board certification in psychiatric pharmacy to work under a CPA managing psychiatric patients.³¹ APP licensure applications have been made available for pharmacists in California since December 2016.

Scope of Practice for Pharmacists

Some of the most common services provided by pharmacists in ambulatory care settings include managing patients

with diabetes, hypertension, anticoagulation, asthma, chronic obstructive pulmonary disease, and heart failure.²⁶ Other clinics or services include anemia, depression, chronic kidney disease, oncology, human immunodeficiency virus, and hepatitis C virus clinics.²⁶ Additionally, pharmacists can also assist in drug therapy management of complex acute conditions (eg, complicated urinary tract infections, seizures, pain management) and acute exacerbations of chronic diseases.²⁶ According to a report in 2015 from the California Department of Public Health on Comprehensive Medication Management,¹⁶ specific functions may include the following:

- Recruiting high-risk and/or high-cost patients who would likely benefit the most from disease state management or comprehensive medication management
- During scheduled visits, evaluating patients for baseline knowledge, attitudes, beliefs and behaviors regarding medical conditions, medications, and medication use
- Performing basic assessments including vital signs, point-of-care testing, administration of screening/monitoring tools
- Ordering tests related to monitoring the safety and/or efficacy of drug therapy
- Identifying medication-related barriers to attaining treatment goals and formulating individualized plans to resolve these barriers through shared decision making with patients
- Consulting with other members of the health care team and referring patients per referral criteria
- Initiating, adjusting, and discontinuing therapy based on recommended guidelines
- Communicating urgent matters immediately to the primary care provider, which are defined by the CPA and/or specific protocols (eg, critical blood pressures, pulse rates, plasma glucose levels)
- Following up with patients, either by phone or in person, as frequently and

long as necessary to ensure treatment goals are met

The corpus of literature is replete with examples of how pharmacist care, delivered collaboratively, has achieved improved goals for patients with diabetes, hypertension, and coagulation disorders.⁴ Ambulatory care pharmacists are optimally equipped and positioned to provide CMM for patients in a variety of ambulatory care settings, which is supported by published evidence of improved clinical and economic outcomes.³² A meta-analysis completed by Chisholm-Burns and colleagues showed statistically significant improvements in clinical outcomes for hemoglobin A1C reduction, low-density lipoprotein reduction, and systolic blood pressure reduction.⁵ In addition, improvements in humanistic outcomes were observed in medication adherence, patient knowledge, and patient-reported quality of life (ie, general health).⁵ Perez and colleagues included 93 articles, out of which 40% described services at ambulatory care clinics or community settings and the most frequently provided services were pharmacotherapeutic monitoring, target drug programs, or disease state management.³³ The return on investment for clinical pharmacy services was \$4.81 of savings to every \$1.00 invested into employing pharmacists.³³ A recent systematic review of 65 patient populations in 63 settings of pharmacist-led chronic disease management found that “pharmacist-led care increased the number or dose of medications received and improved study-selected glycemic, blood pressure, and lipid goal attainment (moderate-strength evidence).”³⁴ (p. 30) However, the authors concluded that “further research is needed to determine whether increased medication utilization and goal attainment improve clinical outcomes.”³⁴ (p. 30)

In the words of Butler and colleagues of the Comprehensive Medication Management Programs,

Physicians who wish to collaborate with a pharmacist to offer CMM are

able to determine the range of clinical services that pharmacists can provide, within the scope of practice laws for each state. Generally speaking, pharmacist-provided CMM offers maximum value to physicians and patients when the targeted population for enrollment consist of high-risk and/or high-cost patients that struggle to reach provider and patient defined medication treatment goals. By having pharmacist provide CMM to these patients and carry forth evidence-based medication treatment plans, physicians have more time and capacity to see other patients and access to healthcare services improves.¹⁶ (p. 22)

Legislative Changes

Changes have been occurring in health care legislation in California and across the country over the past decade. Outside of ambulatory care settings, more community pharmacists started working with providers through the passage of the Medicare Modernization Act of 2003, which established Medicare Part D, a voluntary prescription drug benefit where patients had to opt-in in order to receive medication therapy management (MTM).³⁵ Then, in 2006, Medicare Part D prescription drug plans were required to offer MTM and patients could opt-out if they did not want those services.³⁵ Additionally, with the passage of the Affordable Care Act in 2010 with the triple aim of improving care for individuals, improving overall health for populations, and decreasing health care costs,² more pharmacists were starting to be incorporated into a health care team on a wider scale. However, MTM is a distinct service or group of services that optimizes therapeutic outcomes for individual patients with Medicare Part D, and is not provided for all patients. MTM includes 5 core elements: medication therapy review, personal medication record, medication-related action plan, intervention and/or referral, and documentation and follow-up.³⁶ Pharmacists typically provide MTM services in the community setting or are contracted with the health plan to

complete these services. Because of this, most pharmacists who provide MTM services do not have access to the patient's EHRs nor have direct access to the provider. They only have knowledge of the medications prescribed rather than the clinical status of the patient; thus, the impact of the MTM program has been limited.¹⁶ Hence, in an MTM encounter only drug interactions, duplicative therapy, potentially inappropriate drugs for elderly, or opportunities for generic substitution and education about the drug can be addressed.¹⁶ However, without access to the patient's full health records, or knowledge of the clinical goals, the patient may still not have reached any therapeutic goals to control, for example, diabetes or hypertension.¹⁶ The 2016 Status Report on Part D states that Centers for Medicare & Medicaid Services (CMS) has been “concerned with the effectiveness of Part D's MTM programs due to the fact that plans are unable to contact many eligible beneficiaries, and many beneficiaries refuse the service.”³⁷ Moreover, physicians are reluctant to accept recommendations from drug plans when they do not have a direct relationship with them.³⁷ However, CMS plans to implement a new program called Part D Enhanced Medication Therapy Management Model in 2017 and plans to offer incentives and provide claims data to the enrollees to see if it improves coordination and engagement.³⁷

Challenges: Reimbursement

The main challenge for pharmacists practicing in ambulatory care settings is reimbursement. Billing for pharmacist services have been successful in some physician offices as “incident to” billing where the patient is billed under the physician and expanded if the patient is also seen by the pharmacist. Specifically, pharmacists can indirectly bill third-party payers for CMM services provided on behalf of the physician when the pharmacist has a CPA in place or is an employee of a physician practice and the payment is made to the physician.⁶

In hospital-based clinics, billing for CMM services falls under a “technical/facility fee” using Ambulatory Payment Classification codes based on the duration and complexity of the visit.⁶ The clinic receives payment. At a hospital-based anticoagulation clinic, a standardized billing model was created using facility charge codes where it facilitated appropriate channeling of revenue to pharmacy cost centers.¹¹ MTM can be billed by pharmacists without a CPA with Current Procedural Terminology codes, which are characterized as “initial” (15 minutes), “follow-up,” and “additional” (in 15-minute increments).⁶ In this case, the pharmacy receives payment. However, challenges remain for consistent billing in these ambulatory settings and the process needs to be worked out with the compliance officer and the billing department of the institution. Other models to consider for primary care groups interested in having a pharmacist provide ambulatory care services is to consider working with a local school of pharmacy and having a faculty member provide the service in exchange for allowing students pharmacists to rotate through the clinic.³¹

Payers will require proof that pharmacists have the qualifications to provide services. Establishing benchmarks for pharmacy training and credentialing will be a necessary component in the future of pharmacist-provided direct patient care services.²⁵ A sound and progressive specialty board certification process could help fulfill this credentialing need and might provide further support for pharmacists to be recognized by payers as direct patient care providers.²⁵

Example of a CPA

Sample CPAs can be found in the following publications for those who are interested in establishing a CPA in a new practice environment. The first example CPA outlines an open protocol that references the most up-to-date clinical practice guidelines.¹⁶ Furthermore, an example of a professional service agreement, which is a legal agreement

between a school of pharmacy and a health care service provider, is also included and covers the responsibilities of the respective organizations, scope of practice, and liability insurance. These documents may be required if a school of pharmacy places a faculty member in a health care practice environment. Another sample CPA can be found in the book by Kliethermes and Brown, *Building a Successful Ambulatory Care Practice: A Complete Guide for Pharmacists*.³⁸ This reference contains not only a CPA that can easily be adapted to any environment but also a business plan, marketing tools, quality assurance tools, and billing and coding tools to help start a new ambulatory care practice.

Conclusion

Pharmacists in ambulatory care settings have been practicing under CPAs with physicians and have had expanded scope of practice to initiate, adjust, and discontinue medication therapy in primary care clinics or hospital-based clinics for some time. The construct of CPAs between physicians and pharmacists are mutually agreed upon, voluntary in nature, and contain appropriate communication mechanisms between the physician and pharmacist to coordinate care.³⁹ Initiation and monitoring of therapy occurs per protocol postdiagnosis and uses the expertise of the pharmacist in managing multiple medication regimens, including chronic disease management.³⁹ As underutilized health care professionals, more pharmacists and physicians can form CPAs to work together to implement the triple aim of improved health outcomes, decreased costs, and improved patient satisfaction.

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