



**Advancing Team-Based Care Through
Collaborative Practice Agreements
A Resource and Implementation Guide
for Adding Pharmacists to the Care Team**

Dear Pharmacists and Collaborating Prescribers:

Nearly one in every three deaths in the United States is caused by cardiovascular disease (CVD).¹ Sixty percent of preventable heart disease and stroke deaths happen to people under age 65.² With the burden of chronic disease in the US increasing, we need new ways to empower patients and improve care. Pharmacists have long been identified as an underutilized public health resource.³ Pharmacists are well positioned to help fill the chronic disease management gap and can make a difference when they are actively engaged as part of a team-based care approach.

Collaborative practice agreements increase the efficiencies of team-based care and formalize practice relationships between pharmacists and collaborating prescribers. For this reason, the **National Alliance of State Pharmacy Associations (NASPA), American Pharmacists Association (APhA), American Medical Association (AMA), the American Association of Nurse Practitioners (AANP), the Network for Public Health Law – Eastern Region, and University of Maryland Francis King Carey School of Law** have collaborated with the **Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention**, to develop this guide, **Advancing Team-Based Care through Collaborative Practice Agreements**.

The guide is a resource for pharmacists to use in developing and executing collaborative practice agreements in the spirit of advancing team-based care. It provides a customizable template that can be used as a starting point to developing a collaborative practice agreement.

The collaborating organizations recognize the value of pharmacists as a necessary member of the patient care team and endorse use of this guide to form collaborative practice agreements. Together, we can work to improve the quality of patient care, better prevent and treat chronic disease and improve population health.

National Alliance of State Pharmacy Associations (NASPA)

American Pharmacists Association (APhA)

American Medical Association (AMA)

American Association of Nurse Practitioners (AANP)

Network for Public Health Law – Eastern Region

University of Maryland Francis King Carey School of Law

1 Centers for Disease Control and Prevention. National Statistics Report: Deaths: Final Data for 2014. 2016(June);65(4). Chamblee, GA: CDC, U.S. Department of Health and Human Services; 2016. Accessed December 19, 2016.

2 Centers for Disease Control and Prevention. [Vital Signs: Preventable Deaths from Heart Disease & Stroke](#). Accessed December 19, 2016.

3 American Public Health Association. APHA policy 8024: The Role of the Pharmacist in Public Health. 1981; 71:213–6. American Journal of Public Health.



Executive Summary

Rationale

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths in this country. In 2014, one in every three deaths was due to cardiovascular disease (CVD). One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control. Team-based care results in personalized, timely, and empowered patient care—and it facilitates communication and coordination among team members. The evidence is strong that when pharmacists are members of the health care team, outcomes related to preventing or managing chronic disease (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and medication adherence improve. The purpose of this guide is to empower community pharmacists and collaborating prescribers to initiate collaborative practice agreements (CPAs) focused on caring for patients with chronic diseases, including CVD.

Collaborative Practice Agreements

CPAs create a formal practice relationship between a pharmacist and a prescriber, who is most often a physician, although a growing number of states are allowing for CPAs between pharmacists and other health professionals, such as nurse practitioners. The agreement specifies what functions (in addition to the pharmacist's typical scope of practice) can be delegated to the pharmacist by the collaborating prescriber. The terms used and the functions provided under a CPA vary from state to state based on the pharmacist's and prescriber's scope of practice and the state's collaborative practice laws. Most often, the functions delegated to pharmacists by prescribers include initiating, modifying, or discontinuing medication therapy. Ordering and

interpreting laboratory tests may also be included if those services are not already authorized in the pharmacist's regular scope of practice.

CPAs Support Team-Based Care

CPAs are built upon a foundation of trust between pharmacists and prescribers and serve as a useful mechanism for increasing efficiencies of team-based care. When designed correctly, CPAs are beneficial to the collaborative delivery of care through delegation by the physician or other prescriber of specific patient care services to pharmacists. This delegation can expand available services to patients and increase coordination of care. For example, the use of CPAs can decrease the number of requests to authorize refills, modify prescriptions, initiate therapeutic interchanges (in which the pharmacist can substitute another drug for the medication prescribed), and order and interpret laboratory tests, while keeping the prescriber apprised of the pharmacist's actions through established communication mechanisms. This allows each member of the health care team to complement the skills and knowledge of the other members and more effectively facilitate patient care, resulting in improved patient outcomes.

Scope of Service and Requirements

Many pharmacists' services do not require a CPA. For example, assessing medication therapy for drug-related problems, performing hypertension and cholesterol screenings, and educating patients are already within pharmacists' regular scope of practice. A CPA is not required for pharmacists or practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. While it is important to have shared goals,

clear roles, effective communication, and measurable processes and outcomes, the degree of trust within the relationship is often the deciding factor for turning collaborative relationships into contractual CPAs.

Building trust is often a progressive process. For example, a collaborative relationship may begin with a pharmacist dispensing a prescriber's prescription, followed by an exchange of medication information. This advances to a prescriber accepting a pharmacist's recommendations for medication therapy, and then to a prescriber delegating disease management responsibilities and granting authority for medication therapy management to a pharmacist under a formal CPA. Trustworthiness, role specification, and professional interactions are three critical factors to establishing trust within a collaborative relationship.

Components of a CPA and Applicable Laws

Pharmacists interested in pursuing CPAs with prescribers should seek to understand the laws on CPAs within their state, identify prescribers with whom a relationship already exists or build a relationship with prescribers with mutual interests, and consider offering basic services (e.g., refill authorizations, therapeutic interchange) as an initial step. Seeking to identify and understand the prescriber's unmet needs and demonstrating competency as it relates to

the prescriber's patient population and the services provided will help to facilitate the uptake of a CPA. Finally, pharmacists can anticipate prescribers' concerns related to delegating authority for care and be prepared to respond to those concerns in an effective manner.

Steps to Implementation

A CPA template and sample language for each component are included in this resource guide. The implementation of a CPA involves a series of steps that depend on state laws and pharmacist-prescriber preferences. The implementation steps may include registering the CPA with the board of pharmacy or some other governing body, developing data sharing and business associate agreements, obtaining a pharmacist National Provider Identifier number, and identifying a business model that sustains the agreed-upon scope of services.

CPAs offer a unique opportunity for pharmacists to collaborate with prescribers in the treatment and management of chronic conditions, including CVD and hypertension. This guide offers resources to develop and implement a CPA between pharmacists and prescribers for the purpose of advancing public health and improving patient outcomes, quality and process measures, efficacy, and patient and provider satisfaction.

A formal CPA can have many components including the following:

Scope of Agreement

- Parties to the agreement
- Patient inclusion criteria
- Patient care functions authorized

Legal Components

- Authority and purpose
- Liability insurance
- Informed consent of the patient
- Review of the agreement and maximum period of validity
- Rescindment or alteration of agreement
- Signatures of the parties to the agreement

Administrative Components

- Training and education
- Documentation
- Communication
- Quality assurance (or quality measurement)
- Retention of records

Acknowledgments

The Division for Heart Disease and Stroke Prevention within the Centers for Disease Control and Prevention in collaboration with ChangeLab Solutions, the National Alliance of State Pharmacy Associations, the American Pharmacists Association, the Network for Public Health Law – Eastern Region, and the University of Maryland Francis King Carey School of Law developed this guide.

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Suggested Citation

Centers for Disease Control and Prevention. *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017.

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Financial Disclosure/ Funding

This publication was supported by the Cooperative Agreement Number 5U38OT000141-03 awarded to ChangeLab Solutions from the Centers for Disease Control and Prevention.

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Overview

Impact of Chronic Disease

Chronic diseases are the leading causes of death and disability in the United States, accounting for seven of every ten deaths.¹ In 2012, 117 million Americans (about half of the adult population) had at least one chronic illness.² An estimated 25% of U.S. adults with chronic conditions have one or more limitations in daily activities.² In 2014, one in every three deaths was due to cardiovascular disease (CVD).^{3,4}

Hypertension, hyperlipidemia, and smoking are key risk factors for CVD, and 47% of Americans have at least one of these three risk factors.⁵ One in three U.S. adults has high blood pressure, and almost half of these individuals do not have this condition under control.⁵ Another 11.5 million of these adults are neither aware of their hypertension nor taking antihypertensive medications.^{3,5} In addition, only one third of people with high cholesterol have adequate control of their hyperlipidemia, and 17% of U.S. adults smoke cigarettes.^{6,7,8} Improved control of the risk factors for CVD requires an expanded effort from health care systems and health care professionals in the health system, including pharmacists.⁶

Value of Pharmacists' Patient Care Services

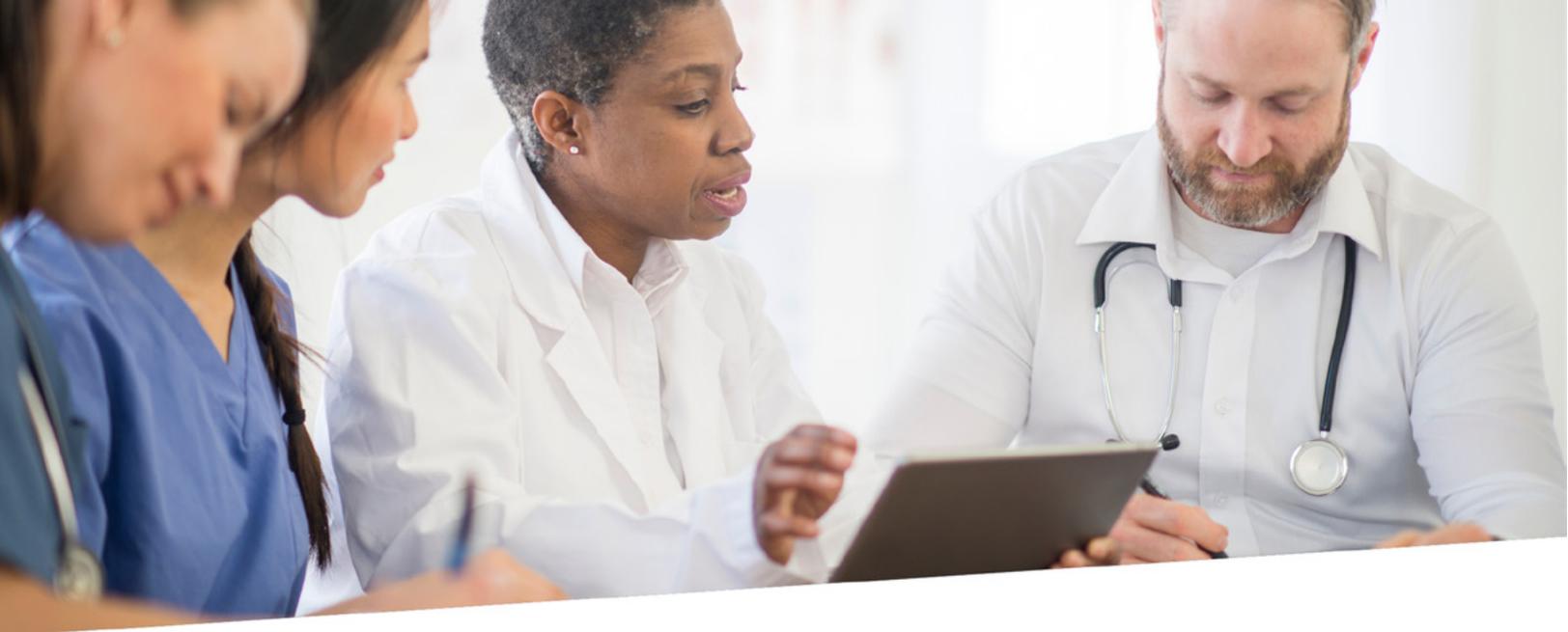
Interventions to manage and control hypertension and other risk factors for CVD can focus on removing health care professional- and patient-related barriers.^{9,10,11}

A team-based model organizes care around patient needs and commonly involves systems that support clinical decision making through collaborations between health care professionals or between these professionals and their patients. There is strong evidence that when pharmacists are part of the health care team, outcomes related to preventing or managing chronic diseases (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and adherence to medication improve.^{12,13} Team-based care results in

personalized, timely, and empowered patient care and facilitates communication and coordination among team members.

In 1981, the American Public Health Association declared that pharmacists were an underutilized resource in promoting public health. Since then, several public health needs—such as public access to immunizations—have been addressed by community pharmacists. One of the reasons that pharmacists can address emerging public health needs is that they are among the most accessible health care professionals in the United States. Notably, an estimated 86% of the U.S. population lives within 5 miles of a community pharmacy.¹⁴ While examples of pharmacists practicing in team-based environments exist, there remains an opportunity to increase and accelerate the inclusion of pharmacists as part of the patient care team.

In 2011, the chief pharmacist officer of the U.S. Public Health Service authored a report, titled *Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice*, to the U.S. surgeon general.¹⁵ This report highlighted the efficacy of pharmacists in advanced practice roles and advocated for intensified utilization of pharmacists in alleviating our nation's imminent primary care provider crisis. The findings of the report were promptly endorsed and supported by the 18th surgeon general, Vice Admiral Dr. Regina Benjamin, who recommended that health leadership and policy makers optimize the pharmacist's role.¹⁶ Vice Admiral Benjamin recommended that this be done through implementation of collaborative practice models; recognition of pharmacists as providers, clinicians, and essential members of the health care team; and exploration of additional compensation models to support pharmacists in these expanded roles.



Advancing Pharmacists in Team-Based Care

The Centers for Disease Control and Prevention (CDC) recognizes the role of pharmacists in team-based care for chronic disease management. The CDC Division for Heart Disease and Stroke Prevention has created resources to encourage pharmacists and prescribers (physicians and others who prescribe drugs) to work collaboratively and formalize those relationships through collaborative practice agreements (CPAs), when possible. These resources include:

- [A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases](#). This resource provides examples of how pharmacists can work within the four public health domains (i.e., environmental approaches, health systems, community-clinical linkages, and epidemiology and surveillance) to have a positive effect on patient health outcomes.¹⁷
- [How Pharmacists Can Improve Our Nation's Health](#). This resource (a CDC Public Health Grand Rounds presentation) provides examples of the roles that pharmacists can play in team-based care.¹⁸
- [Collaborative Practice Agreements and Pharmacists' Patient Care Services](#). This resource provides an overview of CPAs.¹⁹

- [Collaborative Drug Therapy Management: Case Studies of Three Community-Based Models of Care](#).²⁰ This resource illustrates how CPAs have been successfully implemented in three pharmacy practice settings.

Purpose and Development Process

The purpose of this resource guide is to empower community pharmacists and collaborating prescribers to initiate CPAs that are focused on caring for patients with chronic diseases. CVD and its risk factors are used as an example throughout the resource guide. The primary audience is pharmacists practicing in states where existing regulations permit them to engage in CPAs for the monitoring and management of chronic disease.

The information contained in this resource guide was collected in these four ways: (1) reviewing existing literature and resources; (2) analyzing laws and regulations on collaborative practice; (3) reviewing examples of CPAs currently in use; and (4) holding roundtable meetings with pharmacists, physicians, public health professionals, academicians, and payer representatives in five states (i.e., Kentucky, Minnesota, Tennessee, Washington, and Wisconsin).



CPA-related Terminology

Other terms for a CPA include:

- Collaborative pharmacy practice agreement.
- Collaborative care agreement.
- Consult agreement.
- Physician-pharmacist agreement.
- Standing order or protocol.
- Delegation of authority by physician.

Terms used to describe the services provided under a CPA include:

- Collaborative drug therapy management.
- Drug therapy management.
- Pharmaceutical care.
- Medication therapy services.
- Collaborative pharmacy practice.²²

About Collaborative Practice Agreements

Definition of a CPA

CPAs create a formal practice relationship between a pharmacist and a prescriber. The agreement specifies what functions—in addition to the pharmacist’s typical scope of practice—are delegated to the pharmacist by the collaborating prescriber. The collaborating prescriber is most often a physician, but a growing number of states are allowing for CPAs between pharmacists and nurse practitioners or other nonphysicians. This resource guide uses the term “prescriber” to reference the collaborating provider who is delegating patient care services to the pharmacist under the CPA.

The functions provided under the agreement vary from state to state based on the pharmacist’s scope of practice and the state’s collaborative practice laws.²¹

Most often, CPAs are used in the context of authorizing pharmacists to initiate, modify, or discontinue medication therapy. Functions performed under a CPA may also include ordering and interpreting laboratory tests if those services are not already authorized in the pharmacist’s scope of practice.

Using CPAs to Facilitate Team-Based Patient Care²²

When trust has been established, CPAs are a useful way to increase the efficiency of team-based care. When designed correctly, CPAs benefit the collaborative delivery of care by delegating specific patient care services to pharmacists. This delegation can expand available services to patients and increase the efficiency and coordination of care. For example, CPAs can decrease the number of phone calls required to authorize refills or modify prescriptions, thus allowing each member of the health care team to complement the skills and knowledge of the other member(s) and more effectively facilitate patient care, resulting in improved patient outcomes.

Terminology

This resource guide uses the term “collaborative practice agreement,” “collaborative agreement,” or “CPA” to describe a practice relationship in which a prescriber delegates selected patient care services to a pharmacist. The terminology used to describe this authority varies among states as do the terms used to describe the services provided under a CPA.

States Permitting CPAs

As of May 2016, 48 states permit some type of pharmacist-prescriber collaborative practice authority. However, some of these states' laws and regulations may not support the implementation of a CPA. For example, in Alabama and Delaware, prescribers cannot delegate authority to pharmacists via a CPA, and in Florida and Oklahoma, pharmacists are restricted to providing only limited services under a CPA.

State laws for CPAs vary widely; the key variables in these laws are below. Thus, the terms of the written CPA will need to be customized to the laws and regulations of a given state.

Finding the Applicable State Laws and Regulations

Before entering into a CPA, pharmacists and prescribers may benefit by reviewing their state's current laws and regulations pertaining to CPAs. Appendix A contains CPA laws for each state (as of December 31, 2015). State boards of pharmacy and medicine and state pharmacy and medical associations can serve as points of contact for the most up-to-date information on CPA authority. To obtain access to a specific state's current pharmacy laws and regulations, visit the [National Association of Boards of Pharmacy](#) website.

Pharmacy Services Under CPAs

A variety of pharmacist-provided services can be performed under a CPA. CVD-related services are used as examples below to illustrate how pharmacists may define pharmacy services within a CPA. Because of variations in state laws, some of the services may be permitted under a pharmacist's regular scope of practice in some states but represent an expansion of practice in others.

Authorization of refills. In this service, the prescriber authorizes the pharmacist to extend refills based on the pharmacist's assessment (e.g., using the [pharmacists' patient care process](#)) of the patient. For example, under the terms of a CPA, a pharmacist may be permitted to extend refills of a patient's medications for treating chronic hypertension and hypercholesterolemia, thereby removing delays in therapy and administrative barriers and potentially increasing medication adherence. Without a CPA, in most states, pharmacists would need to contact the prescriber to obtain authorization for a refill.



Variables in State CPA Laws and Regulations

CPA Participants

- Number of pharmacists.
- Number of prescribers.
- Number of patients.
- Types of prescribers.
- Relationship between patient and prescriber.
- Pharmacist-to-prescriber ratio.

Authorized Functions

- Modify medication therapy.
- Initiate medication therapy.
- Discontinue medication therapy.
- Conduct physical assessment.
- Order laboratory studies.
- Interpret laboratory studies.
- Perform laboratory tests.

Requirements and Restrictions

- Continuing education.
- Qualifications of pharmacist.
- Liability insurance.
- Disease state of patient.
- Practice setting.
- Medications to be managed.
- Involvement of patient.
- Agreements approved or reported, and to which entity.
- Length of time that agreement is valid.
- Documentation.
- Communications.
- Review by physician.

Therapeutic interchange. Here the prescriber authorizes the pharmacist, under a CPA, to substitute another drug in the same drug class (e.g., angiotensin-converting enzyme inhibitors to treat hypertension) for the medication originally prescribed. This usually happens because of the variability in a particular health plan's formulary of accepted drugs. The pharmacist's clinical knowledge of medications informs his or her choice of medication within a particular class of drugs.

Hypertension management. In this service, the prescriber authorizes the pharmacist to initiate, modify, or discontinue medications. For example, under the terms of a CPA, a pharmacist may be permitted to add therapies if the patient's hypertension is uncontrolled, adjust doses of medication, or discontinue medications that are not working or cause side effects. The medications or medication classes that pharmacists are permitted to initiate, modify, or discontinue may be indicated in the agreement. Without the CPA, the pharmacist would have to assess the patient and make a

recommendation to the prescriber. The prescriber would then have to act on the recommendation in order for the pharmacist to make a change in therapy. The CPA leverages the pharmacist's medication and health-related expertise to extend the care of the prescriber's patients while coordinating care with the prescriber.

Ordering laboratory tests.

Here the CPA may authorize the pharmacist to order and interpret laboratory tests that are essential for effectively monitoring medications or the status of chronic conditions. For example, as part of a hypertension CPA, the pharmacist could order urine and blood analyses to test for electrolyte levels, fluid balance, and kidney function.

Note that some pharmacists' CVD-related services, such as assessing medication therapy for medication-related problems, performing hypertension and cholesterol screenings, and educating the patient, are within pharmacists' regular scope of practice.

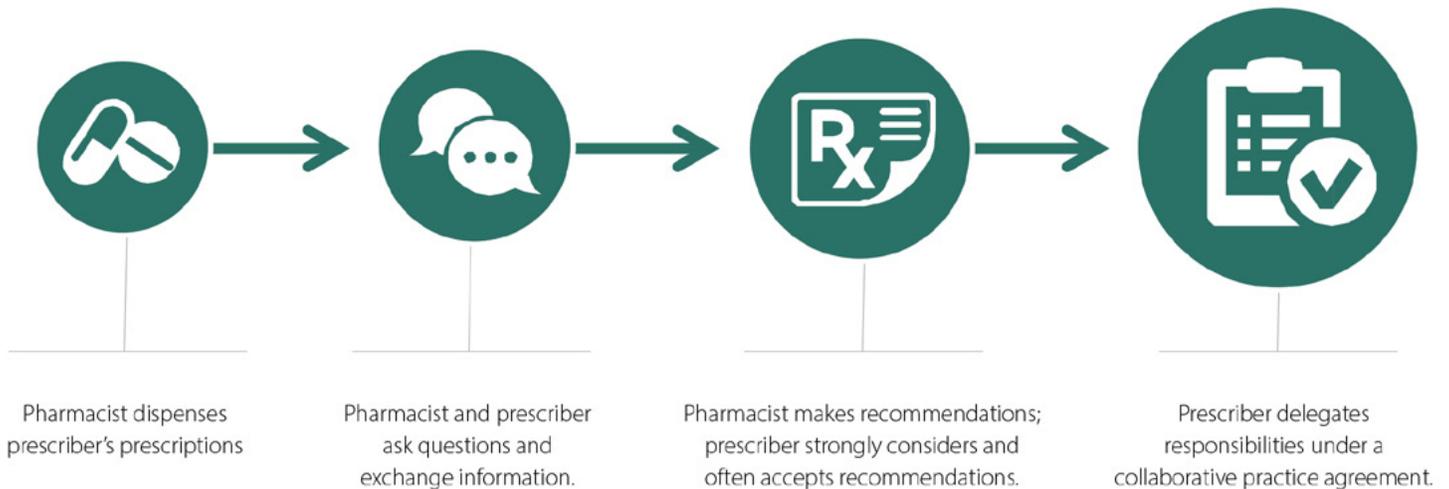


State Scope of Practice & CPAs

The patient care functions that pharmacists are authorized to perform with and without a CPA are highly variable from state to state. A function that a pharmacist can perform only if authorized under a CPA in one state may be a function that a pharmacist can perform autonomously in another state. This resource guide's primary focus is on developing a CPA to facilitate those patient care functions required by state law to be delegated to the pharmacist through a written CPA. However, it is important to note that pharmacists

and other health care professionals may still choose to formalize their collaboration with an agreement—to outline communications, documentation, and other pertinent subjects—even if the activities the parties agree to collaborate on can be performed autonomously by the pharmacist pursuant to the state pharmacy practice act. Pharmacists should consult with the state board of pharmacy or a licensed attorney when there is a question regarding whether an agreement must comply with a given state's CPA laws.

Figure 1: Level of Professional Interaction Reflects Degree of Trust Between the Pharmacist and the Prescriber



Collaborative Care as a Basis for CPAs

The World Health Organization has stated that “Collaborative care in health care occurs when multiple health providers from different professional backgrounds provide comprehensive services by working with patients, their families, care providers, and communities to deliver the highest quality of care across settings.”²³ Thus, a CPA is not required for practitioners to collaborate in providing care. The only requirement is cooperation toward achieving a common goal—providing optimal patient care. As part of collaboration, it is important to have shared goals, clear roles, effective communication, and measurable processes and outcomes. The degree of trust within the relationship is often the deciding factor for collaborative relationships becoming contractual CPAs.²⁴ Figure 1 illustrates the relationship between greater trust within a collaborative relationship and a higher degree of professional interactions.

Developing the Relationship and Building Trust

Once an initial relationship is established, the collaborating providers can work together to develop mutual trust. Three factors that may be important to the development of a working clinical relationship are trustworthiness, role specification, and professional interactions.^{24,25,26,27,28,29}

Trustworthiness. The development of trust requires time and the demonstration of competence.²⁹ Physicians may be more trusting when they know the amount of training, experience, and credentials that the pharmacist has.^{24,25,26,27,28,29} Pharmacists may recognize this tendency and be open to sharing this information about themselves.

Patients also benefit from developing trust with the members of their care team. One way to accomplish

this is for the prescriber and pharmacist to meet with the patient together. If a joint appointment is not possible, the prescriber can advise the patient of the benefits from seeing the pharmacist. Regardless, the expectation is that trust will be built gradually among pharmacists, providers, and patients.

Role specification. Defining which activities will be performed by pharmacists and which by the prescriber enables both parties to have shared expectations about how they will collaborate. When first establishing a collaborative relationship, health care professionals may choose to begin with focusing on basic services until trust can be established. As both health care professionals work together to understand each other's skills and competence, trust will grow, and more complex services can be introduced.³⁰ Many pharmacists have reported that as prescribers experience pharmacists' skills firsthand, the prescribers begin to offer ideas for more collaboration.

Professional interactions. Direct interactions between pharmacists, prescribers, and their patients are essential to growing trust and collaboration. Effective communication is key to building professional interactions and demonstrating trustworthiness. When pharmacists and physicians start their collaborative relationship, frequent in-person communication may be ideal.²⁵ For example, pharmacists may consider practicing in the prescriber's office for a specific time frame (e.g., a half day each week for 2 months) to learn the prescriber's approach to patient care and style of communication. When building the relationship, pharmacists can consider providing an example of the type of communication the prescriber can expect to receive after patient visits. This may serve as a conversation starter when developing the CPA.²⁵ Communication between providers can be initiated by either party; communication could include, for example, sharing relevant patient information, discussing drug-related problems, or requesting a pharmacist

consultation. Increasing professional interactions leads to increased collaboration.²⁸

Formalizing Collaborative Relationships Through CPAs

Once pharmacists and prescribers have established collaborative relationships built upon trust, they may choose to enter into a formalized CPA to facilitate the pharmacist's ability to care for the prescriber's patients in accordance with mutually established role specifications. In the beginning of the collaborative relationship, the pharmacist will likely initiate the conversation about the CPA; he or she should be prepared to make the case for the value of formalizing the relationship. Pharmacists should be aware that the collaborating prescriber would be increasing his or her own liability by entering into a CPA, and so it will be important to let the prescriber ask questions, voice concerns, and help to shape the scope of the CPA. When first establishing a formal collaborative arrangement, pharmacists and prescribers may choose to begin with focusing on basic services such as authorization for refills or therapeutic interchange.



Identifying Partners

Finding and approaching a potential collaborator without having a prior relationship with that person can seem daunting. One approach is for pharmacists to work with prescribers they already know. This familiarity might come from collaborating on initiatives, such as the delivery of immunizations, or through mutual involvement in community organizations or local coalitions.²⁵ In addition, pharmacists can approach prescribers in their community with whom they do not have a prior relationship but where common goals exist.



Pharmacists' ability to improve metrics of quality—both clinical and financial—can also create opportunities for collaboration. Hospitals are increasingly under pressure to reduce readmissions, and the services of pharmacists can help here. Pharmacists can meet with the medical director and pharmacy director from local hospitals to explore collaboration on transitions of care from the hospital to an outpatient/office or clinic setting. Clinics and physicians' offices, as well as hospitals, are held to quality measurements that pharmacists' services can often improve. Other potential collaborators include state and local public health agencies, accountable care organizations, and patient-centered medical homes. It can be helpful for pharmacists to understand the metrics for which potential collaborators are responsible and then think of ways to help them improve those scores.

When identifying providers for new collaborative relationships, pharmacists may consider those provisions in state CPA laws that limit which prescribers can enter into CPAs with pharmacists. In all states, pharmacists may partner with physicians in their community to deliver collaborative care. Additionally, in states where nurse practitioners and physician assistants can enter into CPAs with pharmacists, these prescribers may be familiar candidates for collaboration because they were previously required to have CPAs with physicians in order to prescribe. Table 1 in Appendix A describes state laws and regulations, including those governing which prescribers can authorize a CPA.

Initiating the Relationship

Pharmacists seeking to start a collaborative model of care delivery may benefit from taking the first step in initiating the relationship.^{25,26}

To initiate discussions, a face-to-face meeting should be held with the prospective collaborating prescriber.

The meeting can be scheduled in advance by the pharmacist, and might take place over lunch or dinner and include other staff members whose buy-in may be important.²⁵



During the initial meeting with a prospective collaborator, the pharmacist should be prepared to articulate specific goals and benefits of collaboration and discuss how the collaboration can lead to enhanced patient care. He or she should consider focusing on unmet patient needs in the prescriber's practice and in the community. Where are there gaps that the pharmacist could fill? If the pharmacist has worked with other prescribers in the past, using examples of how that collaboration worked can spark conversation. For example, a pharmacist can use the first collaborating prescriber as a reference for future potential collaborations. If this is a new endeavor, one place to start is for the pharmacist to assist with improving medication adherence for patients in the prescriber's practice. Improving medication adherence is a service that pharmacists can provide without a CPA. In brief, it is a way to engage in offering a basic service with the intent to demonstrate success, build trust, and work collaboratively before a CPA is started. In a study reported in 2011, physicians' belief that collaboration with pharmacists could result in increased patient adherence to medication regimens was a predictor of a positive attitude toward collaboration.²⁷ Regardless, pharmacists should expect that prescribers, especially those who have not previously worked in collaborative relationships, might have many questions. It is important to consider each of the questions set forth on the next page titled "Anticipating the Concerns of Prescribers" before meeting with a prescriber and to have a well-formulated response to each one.

Garnering the support of prescribers for entering into a CPA might require various approaches and timelines. Once the partners agree to formalize their collaboration, creating the legal agreement may require consideration of the components included in state CPA laws (Appendix A). Figure 2 presents a sample CPA and sample language that may be customized by pharmacists and prescribers using their specific state laws to create a CPA.

Anticipating the Concerns of Prescribers

1. What is the pharmacist's training, and what credentials does the pharmacist have?

Pharmacists can educate the prescriber on the pharmacist's training and focus on the skills and credentials of the particular pharmacist(s) who would be working in the practice.

2. What has been the pharmacist's experience in delivering various patient care services?

Pharmacists can explain how their experience aligns with the needs of the patient population cared for by the prescriber and elaborate on how that experience can benefit the patient and improve outcomes.

3. What is the pharmacist's scope of practice in the state?

Pharmacists can educate the prescriber about which patient care functions pharmacists can perform pursuant to the state's pharmacy practice act as well as the functions that can be authorized in a CPA. Providing specific examples can be very helpful.

4. How will the pharmacist communicate with the prescriber?

Pharmacists can discuss the prescriber's preferred method of communication and review opportunities for using health information technology to facilitate the exchange of information. In addition, they should provide examples of how pharmacists communicate (using health information technology and other means) with prescribers in collaborative care models.

5. Will the prescriber incur additional liability?

In a collaborative care relationship that is not governed by a CPA, the prescriber is not likely to incur additional liability for any actions of the pharmacist. This is because the prescriber must approve any recommendations made by the pharmacist before medication therapy is initiated or modified. In this scenario, the risk may be lower because care is likely to be better coordinated in a collaborative care relationship. When using a CPA, pharmacists should discuss terms of liability—which can be clearly described in the CPA—to mitigate risk and any concerns of either party to the agreement.

6. What costs will be incurred by the prescriber in collaborating with the pharmacist?

The prescriber is likely to bring up issues of cost and reimbursement. Costs may vary depending on where the pharmacist will practice (e.g., within the physician's office or remotely). Pharmacists should be prepared to discuss needs for resources and payment. During this discussion, it may be important to include the value that pharmacists can bring to the practice. Appendix B provides general information about payment for pharmacy services.²⁸





1 in 3 adults

has high blood pressure



1 in every 3 deaths

was from cardiovascular disease

Adapting a Template CPA for a Hypertension and Cardiovascular Disease Service*

This section provides examples of language that can be used to draft a CPA. Figure 2, the sample CPA, demonstrates how the language options presented in the following call-out boxes can be applied to create a customized CPA. (Note that Figure 2 uses Virginia's provisions as an example and thus would not meet the requirements in all states.)

The language in the call-out boxes was adapted from CPAs that are currently in use and from feedback received at the roundtable meetings. This language is provided solely for educational purposes and is only for use as an example. Pharmacists may benefit from consulting legal counsel when drafting a CPA based on the laws

and regulations in the jurisdiction where the CPA will be implemented. To get a better understanding of state laws and regulations—as of December 2015—those drafting a CPA should refer to the tables in Appendix A and be sure to check the current laws and regulations.

Not every state addresses every component that appears in these tables. The word “silent” indicates that the state has not addressed that particular issue in its laws and regulations. In these cases, pharmacists and prescribers should work within their scope of practice, use their judgment while developing a CPA, and keep the best interests of the patient in mind.

*Disclaimer: The information contained in this document does not constitute legal advice. Use of any provision herein should be contemplated only in conjunction with advice from legal counsel. The CPA language in the text boxes below was provided by attorneys at the University of Maryland Francis King Carey School of Law as example CPA language for educational purposes only and is adapted from CPA language from multiple states. Provisions may need to be modified, supplemented, or replaced to ensure appropriate citation of or compliance with relevant laws, to accurately reflect the intent of the parties to a particular agreement, or to otherwise address the needs or requirements of a specific jurisdiction.

Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease (Continued on next page)

COLLABORATIVE PRACTICE AGREEMENT <i>for authorization of therapy continuation and therapeutic interchange</i>	
A. AUTHORITY AND PURPOSE I, Dr. Susan Patel and Jessica Johnson authorize the pharmacist(s) named herein, who hold an active license to practice from the Commonwealth of Virginia, to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of the Commonwealth of Virginia. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.	
B. PARTIES TO THE AGREEMENT The following providers agree to the parameters outlined in this agreement:	
Pharmacists:	Prescribers:
James Lee, PharmD	Susan Patel, MD
Alexa Garcia, PharmD	Jessica Johnson, ANP
C. PATIENTS Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by a prescriber listed in Section B of this agreement.	
D. PATIENT CARE FUNCTIONS AUTHORIZED Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section. In managing and/or treating patients, the pharmacist(s) may authorize continuation of drug therapy and modification of drug therapy to a therapeutic alternative medication (defined as a medication in the same class with an equivalent dose), if appropriate, based on current literature and clinical judgment.	
D.1. Dyslipidemia¹ The pharmacist(s) will evaluate dyslipidemia as outlined by 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of lipids which may include, but are not limited to the following classes: HMG-CoA reductase inhibitors (statins), bile-acid sequestrants, cholesterol absorption inhibitors, fibrates, omega-3 fatty acids, niacin.	
D.2. Hypertension² The pharmacist(s) will evaluate hypertension therapy as outlined in 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) and other nationally recognized standards of care as supported by current literature. Pharmacist(s) will have authority to authorize continuation of therapy or therapeutic interchange for the treatment of hypertension which may include, but are not limited to the following classes: beta-blockers, calcium channel blockers, ACE inhibitors, angiotensin II receptor blockers, direct renin inhibitors, diuretics, alpha-blockers, α_1 -centrally active agents.	
E. TRAINING/EDUCATION All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.	
F. LIABILITY INSURANCE All parties to this agreement shall maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy.	
G. PATIENT INFORMED CONSENT The pharmacist shall obtain written informed consent from the patient upon first meeting with the patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.	

Figure 2: Sample Collaborative Practice Agreement for Hypertension/Cardiovascular Disease (Continued from previous page)

H. DOCUMENTATION

The pharmacist(s) shall document each continuation or modification of therapy authorization in the patient’s pharmacy record.

I. COMMUNICATION

The pharmacists shall provide the patient’s original prescriber with notification in the form of fax or secure email when their patient’s therapy is continued or therapeutically interchanged pursuant to this agreement. In this notification, the pharmacists will include any relevant information that was collected from the patient such as current blood pressure, adherence issues, or any socioeconomic challenges identified.

The pharmacist shall report any new patient complaints and/or deterioration in the patient’s condition to the patient’s primary care provider and/or other provider immediately after learning of the new condition or as soon as possible thereafter.

J. QUALITY ASSURANCE

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and satisfaction surveys of patients and providers as appropriate.

K. AGREEMENT REVIEW AND DURATION

This agreement shall be valid for a period not to exceed two years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

L. RECORD RETENTION

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at their primary place of practice. Record of each therapeutic interchange made for a specific patient shall be maintained in the patient’s pharmacy record.

M. RESCINDMENT OR ALTERATION OF AGREEMENT

A signatory may rescind from this agreement or a patient may withdraw from treatment under this agreement at any time. The prescriber(s) may override this agreement whenever he or she deems such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.

N. REFERENCES

1. Stone NJ, Robinson J, Lichtenstein AH, et al. "2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults." *Circulation* (2013) [Epub ahead of print: <http://www.ncbi.nlm.nih.gov/pubmed/24222016?dopt=Abstract>.
2. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. doi:10.1001/jama.2013.284427. Published online December 18, 2013

O. AGREEMENT SIGNATURES

This agreement includes patients under the care of the practitioner(s) and extends for a period of two (2) years from this date unless rescinded earlier in writing.

Signatures:

_____	_____	_____	_____
[Prescriber name and credentials]	[Prescriber Signature]	License #	Date
_____	_____	_____	_____
[Prescriber name and credentials]	[Prescriber Signature]	License #	Date
_____	_____	_____	_____
[Pharmacist name and credentials]	[Pharmacist Signature]	License #	Date
_____	_____	_____	_____
[Pharmacist name and credentials]	[Pharmacist Signature]	License #	Date

A. Authority and Purpose

This section is not required by law to be included in a CPA but may help the collaborating providers establish their vision for the purpose of the agreement.



AUTHORITY AND PURPOSE:

I, [INSERT PRESCRIBER NAMES], authorize the pharmacist(s) named herein, who hold an active license to practice issued by [STATE NAME], to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of [STATE NAME]. The purpose of this agreement is to facilitate consistent access to medications for the collaborating providers' mutual patients.

-OR-

PURPOSE:

In order to enhance collaborative patient care and optimize medication-related outcomes, patient care services will be provided by the pharmacists listed in Section B of this agreement in collaboration with the prescribers listed in Section B of this agreement. Services will include those listed in Section D of this agreement. The pharmacists will deliver these services in a manner consistent with the parameters outlined in this collaborative practice agreement and in compliance with the protocols included in the appendices to this agreement.

B. Parties to the Agreement

Both the pharmacists and the prescribers who are participating in the CPA are identified in this section. In some states, a medical director may be authorized to sign onto an agreement on behalf of the providers within a given practice. In this case, each practitioner may or may not have to individually sign the agreement, depending on state laws and regulations. Which prescribers may authorize a CPA and how many pharmacists and prescribers may be on an agreement varies from state to state.

See Table 1 in Appendix A for more information on the authority and restrictions in a particular state.



PARTIES TO THE AGREEMENT:

The following parties agree to the parameters outlined in this agreement:

Pharmacists:	Prescribers:

C. Patients

In this section, either the specific patient(s) or the defined population of patients that will receive care can be specified. Some state laws restrict eligibility to only those patients who are actively being treated by the collaborating provider. Others specify that each patient who will receive care under the parameters of the agreement be listed in the agreement. Still others may even require that the agreement be specific to a single patient and disease state. Drafters of a CPA should see Table 1 in Appendix A for more information on their state.



PATIENTS [PRESCRIBER'S PATIENT PANEL]:

Patients whose therapy may be managed pursuant to this agreement include those who are currently receiving hypertension or dyslipidemia therapy prescribed by one of the prescribers listed in Section B of this agreement.

-OR-

PATIENTS [SPECIFIC LIST OF PATIENTS]:

The pharmacists listed in Section B of this agreement are authorized to provide care to the following patients, pursuant to this agreement:

-OR-

PATIENTS [SPECIFIC TO A SINGLE PATIENT]:

Pursuant to this agreement, the pharmacist(s) listed in Section B of this agreement are authorized to provide care, in the manner outlined in this agreement, to [INSERT PATIENT], a patient of [AUTHORIZING PRESCRIBER].



D. Patient Care Functions Authorized

Role specification allows for mutual understanding of each provider's role in care delivery. As trust develops and the collaborative relationship grows, providers can become interdependent, and their roles can evolve over time.^{27,29} Setting expectations for each provider's role can help all parties to feel more comfortable with moving forward. Note that it may be helpful to set expectations for when the initial role specification will be assessed and adjusted. Setting such expectations allows for open communication and continual process improvement.

All CPAs define the scope of the patient care functions that pharmacists are authorized to provide pursuant to the agreement. In the sample agreement, pharmacists are authorized to continue prescription therapy for a medication that does not have refills remaining and make a therapeutic substitution for medications in the same drug class as that prescribed.

Not all states require that a treatment protocol be used as part of a CPA. For example, in Michigan and Wisconsin, physicians can delegate any patient care service to a pharmacist, and the pharmacist's authority does not require the use of a treatment protocol. Even in states where such a protocol is required, providing general guidance, such as referring to evidence-based guidelines, may be appropriate.

Additionally, some states require that the CPA specify which drugs the pharmacist may initiate and/or modify. If this is required, the list of drugs could be included in the "Patient Care Functions Authorized" or in an appendix to the agreement.

It may also be useful to include language covering the instances when the pharmacist refers the patient back to the prescriber. This language would discuss issues outside the scope of the agreement.

Those interested in drafting a CPA should look at Table 2 in Appendix A for more information on what patient care functions can be authorized under such an agreement.

PATIENT CARE FUNCTIONS AUTHORIZED:

Pharmacist(s) included in Section B of this agreement will have the authority to manage and/or treat patients in accordance with this section. In managing and/or treating patients, the pharmacist(s) may [INSERT PATIENT CARE FUNCTIONS AUTHORIZED, SUCH AS INITIATE, MODIFY, OR DISCONTINUE DRUG THERAPY], if appropriate, based on current literature and clinical judgment. The pharmacist(s) will refer the patient back to her/his prescriber for issues that are outside the scope of this agreement. [DEPENDING ON STATE LAW, IT MAY BE NECESSARY TO LIST THE DRUGS, DRUG CLASSES, AND/OR TREATMENT PROTOCOLS AS WELL. THESE ELEMENTS COULD BE INCLUDED IN AN APPENDIX TO THE AGREEMENT.]

E. Training/Education

Some states require that specific education and/or training be completed before a pharmacist is allowed to enter into a CPA. In other states, the education and training that is appropriate for each situation should be determined by the collaborating prescribers. In the example CPA in Figure 2, Virginia does not require any specific education or training. Thus, the collaborating prescribers wrote the agreement so that the responsibility rested with each provider to ensure that he or she actively maintained his or her clinical competencies. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

TRAINING/EDUCATION:

All parties to this agreement are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement.



F. Liability Insurance

State laws/regulations in some states require that providers maintain professional liability insurance in order to participate in a CPA. Regardless of whether it is required by law, health care professionals may want to maintain

liability insurance and may consider including that as a requirement in the CPA. Those interested in developing a CPA should see Table 3 in Appendix A for the requirements in their state.

LIABILITY INSURANCE:

All parties to this agreement shall maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement, which specifically covers drug therapy.



G. Informed Consent of the Patient

Although obtaining a written informed consent from the patient is not required in all states, it is beneficial for patients to have an understanding of how their care is delivered. Even in states where a specific form of patient consent is not mandated, health care professionals can discuss whether it needs to be obtained at the first meeting with the patient and the procedure that will be used. Those interested in creating a CPA should see Table 3 in Appendix A for the requirements in their state.

INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT REQUIRED]:

The pharmacist shall obtain written informed consent from the patient upon first meeting with that patient. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.

-OR-

INFORMED CONSENT OF THE PATIENT [WRITTEN CONSENT NOT REQUIRED]:

At the start of care provided by the pharmacist, each new patient will be provided with an explanation of the collaborative relationship between the pharmacist and the collaborating prescriber. Patients will be informed of their right to opt out of care.



H. Documentation

Several states have specific laws and regulations pertaining to the documentation of care delivered under a CPA (see Table 3 in Appendix A for more information). Regardless of whether it is required by law, thorough documentation of clinical activities is considered standard practice. Clinical documentation is a relatively new concept for the community pharmacy setting, however, especially beyond formal medication therapy management services. Documentation can be performed using electronic software systems or in a paper chart, although some states require that services provided pursuant to a CPA be documented in an electronic health record. It is sometimes required that the collaborating prescriber and pharmacist both have access to the patients' medical records. Documentation can be done in the traditional subjective, objective, assessment, plan (SOAP note) method or using forms that are more tailored to the specific service(s) the pharmacist is providing.³¹

It can be beneficial to include specifications on documentation and the maintenance of records in the CPA. Some states may require it and even have a minimum duration for retaining records.³² Table 3 in Appendix A lists state requirements for documentation and the maintenance of records associated with CPAs. Because provisions related to documentation are often complex, those interested in a CPA should refer to the actual legal language in their state to be sure that they are in compliance with the requirements.



DOCUMENTATION [SIMPLE]:

The pharmacist(s) shall document each continuation or modification of an authorization for therapy in the patient's pharmacy record.

-OR-

DOCUMENTATION [NO SHARED ACCESS TO AN ELECTRONIC RECORD]:

The pharmacist will complete a progress note for each patient encounter. For each visit, the pharmacist will record subjective/objective information, the assessment, and the plan. Following each visit, the pharmacist will communicate (e.g., fax) the visit note to the referring provider.

-OR-

DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD]:

The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued.

-OR-

DOCUMENTATION [SHARED ACCESS TO AN ELECTRONIC RECORD; PRESCRIBER REVIEW REQUIRED]:

The pharmacist shall document each scheduled visit with the patient in the patient's medical record. The documentation contained in the medical record shall include medical and medication history, assessment, recommendations, monitoring, educational interventions, and documentation of decisions made, including medications initiated, modified, or discontinued. The collaborating prescriber will review and cosign all notes in the patient chart and provide feedback to the pharmacist on a regular basis.

I. Communication

As discussed earlier, communication among providers can be helpful for building trust, and it is essential for providing high-quality care. Without efficient and consistent communications, care can become fragmented, duplicative, ineffective, or even harmful.²⁴ Communication can occur through a variety of media, such as mutually accessed patient records, telephonic and live conversations, email, and text messages or instant messaging.²⁴ Expectations for the methods used, their frequency, and the timing of communications can be discussed among providers and, when appropriate, outlined in the CPA. When initiating work under a CPA, there may need to be more collaboration on individual clinical decisions and, therefore, more regular communications. Once both parties are comfortable with the care plan and each other's communication needs, the communication procedures outlined in the CPA could be reexamined.

Some states do have specific requirements for communications between providers (see Table 3 in Appendix A and relevant state laws and regulations, as these provisions can be complex).



COMMUNICATION:

The pharmacist shall provide the patient's original prescriber with notification in the form of a fax or secure email when her/his patient's therapy is continued or there is a therapeutic interchange pursuant to this agreement. In this notification, the pharmacist will include any relevant information that was collected from the patient, such as current blood pressure, adherence issues, or any socioeconomic challenges identified.

The pharmacist shall report any new patient complaints and/or deterioration in the patient's condition to the patient's primary care provider and/or other provider/prescriber immediately after learning of the new condition or as soon as possible thereafter.

J. Quality Assurance [and/or Quality Measurement]

Although a specific plan for quality assurance is not required in most states, it may be best to implement a program for continuous quality improvement.

A few states specifically require that a section on quality assurance be included in the CPA (see Table 3 in Appendix A).

Additionally, practitioners may consider collecting and analyzing data related to outcomes. This information can be used to assess the effectiveness of interactions, to market services in the future, and to demonstrate value to payers, patients, and potential collaborating prescribers. It may be helpful to consider a variety of outcome measures, including those that are economic (e.g., reduction in overall health costs), clinical (e.g., adherence measures, reduction in blood pressure), and personal (e.g., patient satisfaction, quality of life). More information about quality measurements related to pharmacy and to health care in general can be found on the [Pharmacy Quality Alliance website](#) and the [Agency for Healthcare Research and Quality website](#).



QUALITY ASSURANCE [MORE GENERAL LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. Annual evaluation of pharmacist(s) may include clinical outcomes, number of patients treated, and surveys of patient and provider satisfaction, as appropriate.

-OR-

QUALITY ASSURANCE [MORE SPECIFIC LANGUAGE]:

Care provided as a result of this collaborative practice agreement will be routinely evaluated to assure delivery of high-quality patient care. For each visit with the patient, parties to this agreement will collect and share information, including the patient's blood pressure, recent hospital admissions, and days missed from work or school. Outcomes will be analyzed and discussed among the parties to the agreement at least once per year.

K. Review of the Agreement and Maximum Period of Validity

About half of the states have set a maximum length of time that agreements are valid — typically 1 to 2 years. Even in those states where it is not required, the parties to the agreement may find it beneficial to discuss and agree upon a period for review and renewal of the agreement.

Those interested in creating a CPA should review Table 3 in Appendix A for their state's requirements.



REVIEW OF THE AGREEMENT AND MAXIMUM PERIOD OF VALIDITY:

This agreement shall be valid for a period not to exceed 2 years from the effective date. However, it may be reviewed and revised at any time at the request of any signatories.

L. Retention of Records

Some states have provisions regarding how long and in what manner patient records should be maintained (see Table 3 in Appendix A). In addition to any state requirements, pharmacists should know that if any insurer contracts are in place, these contracts may include separate requirements for maintenance of records. Record retention methods should be compliant with federal laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA), state laws and regulations, and any payer contracts in place.

RETENTION OF RECORDS:

Each signatory to this agreement shall keep a signed copy, written or electronic, of this agreement on file at his/her primary place of practice. A record of each therapeutic interchange made for a specific patient shall be maintained in the patient's pharmacy record.



M. Rescindment or Amendment of Agreement

It may be beneficial to have a method for providers to withdraw their participation in the agreement and a procedure for altering the terms of that agreement.

RESCINDMENT OR AMENDMENT OF AGREEMENT:

A signatory may rescind this agreement or a patient may withdraw from treatment under this agreement at any time. Prescribers may override this agreement whenever they deem such action necessary or appropriate for a specific patient without affecting the agreement relative to other patients.



N. References

If any clinical guidelines are referred to within the text of the agreement, it may be advisable to include the sources so that providers can quickly reference them and ensure that the most up-to-date resources are being used.

O. Signatures of the Parties to the Agreement

The providers or designees of organizations (e.g., medical directors) who are listed as parties to the agreement must sign the agreement in this section. Note that there are some states that also require the patient(s) to sign the agreement. Because this requirement can make implementation of the agreement challenging in the community setting, providers may want to work together to create a procedure that allows for compliance with this requirement.

The parties should see Table 3 in Appendix A for their state's requirements regarding patient signatures on the CPA.



Facilitating the Use of CPAs: Other Considerations

While writing the agreement is the key step for entering into a CPA, other logistical steps may be considered. The list below outlines several of these steps, although there may be others, depending on the circumstances.

Registering With State Agencies

Some states require registration with the board of pharmacy or a similar body for the pharmacist to qualify for participation in a CPA. Others require that the CPA be submitted to or approved by such a body. Those interested in developing a CPA should see Table 3 in Appendix A for their state's requirements.

Data Sharing and Business Associate's Agreements

Per HIPAA, protected health information can be shared with a health care provider for treatment of an individual patient. Covered entities include health plans, health care clearinghouses, and certain health care providers.³³

According to the U.S. Department of Health & Human Services, "The Privacy Rule does not require you to obtain a signed consent form before sharing information for treatment purposes. Health care providers can freely share information for treatment purposes without a signed patient authorization."³⁴ However, if patient health information is used by or is accessible to an organization that is not a covered entity, such as legal counsel or a firm of certified public accountants, a business associate agreement may already be in place. Sample business associate agreements are available from the U.S. Department of Health & Human Services.³⁵

Sustainability of Pharmacists' Patient Care Services

The focus of this resource guide is to help pharmacists establish CPAs to facilitate the treatment and management of chronic conditions. For any services to be incorporated into a pharmacist's practice, it also can be beneficial to have a viable business model in place, regardless of whether there is a CPA. Appendix B of this resource guide provides an introduction to the topic as well as recommendations for other resources that are available.

Pharmacist's National Provider Identifier Number

If the pharmacist is the provider listed on a prescription, his or her National Provider Identifier (NPI) number may need to be updated to reflect the appropriate taxonomy code. Pharmacists should consult Appendix C for information on why and how to update their NPI number.

Conclusion

CPAs offer a unique opportunity for pharmacists and prescribers to collaborate in a formal way. Such collaboration increases the efficiency of team-based care in the treatment and management of chronic conditions, including CVD and hypertension. This resource guide provides pharmacists with information and resources to empower them to initiate CPAs with collaborating prescribers. Although the target audience is community pharmacists, CPAs can be used in all pharmacy practice settings, such as long-term care facilities, primary care offices or clinics, specialty clinics, and general and specialty hospitals. Each of these practice settings has its own nuances, challenges, and opportunities.

CVD and hypertension were used in this resource guide as examples of disease states that can be managed using a CPA, but the concepts presented here can be applied to many other chronic conditions, treatments for acute illness, and preventive health measures as well.

No two collaborative relationships look exactly the same, and the development process will vary.²⁸

The information in this resource guide is intended to provide ideas and spur innovation, but it is not intended to be rigid steps in a process. Pharmacists attempting to initiate collaborative relationships should have patience and be flexible. Both the collaborative relationship and the CPA are likely to change over time. By keeping patients and a continuous improvement in their outcomes the central goal of therapy, it is clear that collaborative care delivery, facilitated by CPAs, can result in improved health, efficiency, and patient and provider satisfaction.²⁸



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Appendix A: Collaborative Practice Agreement Authority Tables

Table 1: Participants

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
AK	Silent	Yes - H	Multiple	All prescribers	Multiple	Multiple - T	Silent
AL	CPAs not allowed under state law.						
AZ	Silent	Silent	Single	Physician + NP	Single	Single	Yes - LL
AR	Silent	Silent	Single	All prescribers - U	Single	Single - HH	Silent
CA	Silent	Yes - I	Single	All prescribers - V	Single	Single	Yes - MM
CO	Yes - A	Yes - I	Multiple	Physician + NP	Multiple	Multiple	Yes - NN
CT	Silent	Yes - J	Multiple	Physician	Multiple	Single - II	Yes - OO
DC	Silent – E3	Silent – E3	Single – E3	Physician, others – E3, F3	Single	Silent – E3	Silent – E3
DE	CPAs not allowed under state law.						
FL	Silent	Silent	Multiple	Physician	Single	Single	Yes - PP
GA	Silent	Yes - K	Single	Physician	Single	Multiple - T, JJ	Yes - QQ
HI	Silent	Silent	Multiple	Physician	Single	Single	Yes - RR
ID	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent
IL	Silent	Silent	Multiple	Physician	Single	Multiple	Silent
IN	Yes - A	Yes - L	Multiple	Physician, others - W	Multiple	Multiple	Yes - RR
IA	Yes - A	Yes - M	Multiple - S	Physician	Multiple	Single	Yes - MM
KS	Silent	Silent	Multiple	Physician	Multiple	Single	Yes - SS
KY	Silent	Silent	Multiple - T	All prescribers - X	Multiple	Multiple - T	Yes - TT
LA	Yes - B	Yes - N	Single	Physician	Single	Single	Yes - UU
ME	No - C	Yes - I	Multiple	All prescribers - Y	Single	Multiple - T	Yes - QQ
MD	Silent	Yes - I	Multiple - GG	Physician, others - Z	Multiple - GG	Single	Yes - VV
MA	Yes - A	Yes - J, O	Single	Physician - C3	Single	Single	Yes - WW
MI	Silent	Silent	Multiple	Physician	Single	Silent	Silent
MN	Silent	Silent	Multiple	Physician, others - AA	Multiple	Silent	Silent
MS	Silent	Yes - I	Multiple	All prescribers - BB	Multiple	Single - KK	Silent
MO	Yes - A, B	Yes - I	Multiple	Physician	Multiple	Single	Yes - QQ
MT	Yes - B	Silent	Multiple	Medical practitioner - CC	Multiple	Silent	Silent
NE	Silent	Silent	Single	Medical practitioner	Single	Silent	Silent
NV	No - D	Silent	Single	All prescribers	Single	Single	Silent
NH	Yes - E	Yes - J, O, P	Single	All prescribers	Single	Single	Yes - OO
NJ	Silent	Yes - I	Multiple - T	Physician	Multiple - T	Single	Yes - MM
NM	Silent	Yes - I	Multiple	Physician	Multiple	Multiple	Silent
NY	Yes - F	Yes - I	Single	Physician	Single	Single	Yes - MM
NC	Silent	Yes - I	Single - A3	Physician - DD, A3	Single	Single	Yes - XX
ND	Silent	Yes - M	Multiple - S, B3	Physician + NP - A3	Multiple - S	Silent	Silent
OH	Silent	Yes - D3	Multiple	Physician	Multiple	Multiple	Yes - SS
OK	Silent	Silent	Silent	Physicians	Silent	Silent	Silent
OR	Silent	Yes - Q	Multiple - S	Physician - EE	Multiple - S	Single	Silent
PA	Silent	Silent	Single	Physician	Single	Multiple	Yes - TT
RI	No - C	Yes - I	Single	All prescribers	Multiple	Single	Silent
SC	Silent	Silent	Silent	All prescribers	Multiple	Silent	Silent
SD	Silent	Silent	Silent	All prescribers	Single	Silent	Silent
TN	Silent	Silent	Multiple	All prescribers - C3	Multiple	Multiple	Silent
TX	Yes - E	Yes - R	Single	Physician	Single	Single	Yes - YY
UT	Silent	Silent	Multiple	All prescribers	Multiple	Multiple	Silent

State	Site restrictions	Pharmacist qualifications	Multiple or single pharmacist(s)	Which prescribers (MD, NP, PA?)	Multiple or single prescriber(s)?	Multiple or single patient(s)?	Prescriber–Patient Relationship defined?
VT	Silent	Silent	Single	All prescribers	Multiple	Multiple	Silent
VA	Yes - G	Silent	Multiple - S	All prescribers - FF	Multiple	Multiple - ZZ	Yes - TT, ZZ
WA	Silent	Silent	Multiple	All prescribers	Single	Multiple	Silent
WV	Yes - A	Yes - I	Multiple	Physician	Multiple	Single	Silent
WI	Silent	Silent	Multiple	Physician	Multiple	Silent	Silent
WY	Silent	Silent	Multiple	All prescribers	Multiple	Single	Yes - TT, XX

Key for Table 1: Participants

A	Allowed in most or all settings but with different rules for some
B	Physician must be nearby the collaborating pharmacist - see law/regulations for more details
C	Site must be specifically identified in the agreement
D	Nearly all locations allowed
E	Not allowed in community pharmacy settings
F	Limited to teaching hospitals
G	If multiple pharmacists are included in an agreement, all must be at a single physical location where patients receive services
H	Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol
I	Complicated requirements - see state law/regulations for details
J	Nearly all pharmacists would qualify - see state law/regulations for details
K	Application to board of pharmacy, additional continuing education, and a fee required - see state law/regulations for details
L	Physician responsible for ensuring pharmacist is properly trained to administer the protocol
M	Nearly all pharmacists would qualify, extra requirements for non-PharmD
N	Must register with the board and renew annually
O	Additional logistical requirements - see law/regulations for details
P	Must register with the board
Q	As specified in the agreement
R	Additional continuing education required
S	All must work within the same practice
T	All must be listed on the agreement
U	Practitioner authorized to prescribe drugs and responsible for the delegation of disease state management
V	Patient's treating prescriber
W	Physician, nurse practitioner, physician assistant
X	Medical/osteopathic physicians, dentists, chiropractors, veterinarians, optometrists when administering or prescribing pharmaceutical agents, advanced practice registered nurses, physician assistants when administering or prescribing pharmaceutical agents, and other health care professionals who are residents of and actively practicing in a state other than Kentucky and who are licensed and have prescriptive authority under the professional licensing laws of another state
Y	Any individual who is licensed, registered, or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice
Z	Licensed physician, licensed podiatrist, or certified advanced practice nurse with prescriptive authority
AA	Dentist, optometrists, physicians, podiatrists, veterinarians, nurse practitioners, physician assistants
BB	Physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs
CC	Any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty
DD	Must be approved by the board - see law/regulations for details
EE	Physician or group of physicians

FF	Any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in §32.1-276.3 (Virginia Law), provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900 (Virginia Law), involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners
GG	One plus a designated alternate
HH	A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient
II	Multiple patients under one agreement; protocol is patient specific
JJ	Multiple but each patient's diagnoses and current medication list must be listed in agreement
KK	Single in community setting, multiple in institutional setting
LL	Collaborating prescriber must be acting as a primary care provider
MM	Individual patient's treating prescriber
NN	All physicians who are actively involved in the management of the relevant conditions shall be parties to the agreement
OO	Physician-patient relationship narrowly defined - see law/regulations for details
PP	Individualized assessment
QQ	Patient specific information must be included in the protocol/agreement - see laws/regulations for details
RR	Agreement must be related to the condition(s) for which the patient has been seen by the collaborating prescriber/physician
SS	Established "physician-patient relationship"
TT	Referral from collaborating prescriber required
UU	Patient/ drug/disease or condition specific order set prepared by the physician must be based on a face-to-face visit with the patient
VV	Directly involved in patient care
WW	Referral required, must include a diagnosis from the supervising physician
XX	Diagnosis and initial drug therapy must be prescribed
YY	The delegation must follow a diagnosis, initial patient assessment, and drug therapy order by the physician. The physician must have an established a physician-patient relationship with each patient who is provided drug therapy management by a delegated pharmacist. Physician-patient relationship must be maintained.
ZZ	Pharmacist may only implement drug therapy post diagnosis by the prescriber
A3	Limited to one physician to three pharmacists
B3	A pharmacist may have an agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances
C3	Pharmacies can't hire physicians to maintain CPAs
D3	Training and experience related to the particular diagnosis for which drug therapy is prescribed
E3	For immunization or vaccination written protocols: multiple pharmacists may participate, pharmacists must be board certified and meet continuing education requirements; a written immunization or vaccination protocol may apply to individual or groups of patients; some setting limitations apply; patient informed consent required. Board of pharmacy and board of medicine are required to issue regulations jointly governing the implementation and use of CPAs between a pharmacist and physician; however, as of 11/2016, no new rules have been promulgated.
F3	Additional licensed health practitioners with independent prescriptive authority may participate in CPAs if authorized by rule (none authorized as of 11/2016)

Table 2: Functions Authorized

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
AK	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
AL	CPAs not allowed under state law.					
AZ	Yes - W, AA	Yes - A, W, AA	Silent	Yes	Silent	Silent
AR	Yes - V, AA	Yes - A, V, AA	Silent	Silent	Silent	Silent
CA	Yes - Z	Yes - A, Z	Yes	Yes	Yes	Silent
CO	Yes - A, V, AA	Yes - A, M, V, AA	Yes - G	Yes - I, M	Yes - I, M	Silent
CT	Yes - B, W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
DC	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
DE	CPAs not allowed under state law.					
FL	No	No - GG	Silent	Yes	Yes	Silent
GA	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
HI	Yes	Yes	Yes - H	Yes	Silent	Silent
ID	Yes - AA	Yes - AA	Yes - I	Silent	Silent	Yes
IL	Yes - A	Yes - A	Silent	Yes - I	Yes - I	Silent
IN	Yes	Yes	Silent	Silent	Silent	Silent
IA	Yes - BB	Yes - BB	Yes	Yes	Yes	Yes
KS	Silent	Silent	Silent	Silent	Silent	Silent
KY	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
LA	Yes - C, W, CC	No	Yes	Yes	Yes - P	Silent
ME	Yes - D, V, AA	Yes - D, V, AA	Yes	Yes	Yes - P, Q	Silent
MD	Yes - A, V, AA	Silent	Yes - J	Yes - I	Yes, I	Silent
MA	Yes - X, FF	Yes - X, FF	Yes - G	Yes - N	Yes - P	Silent
MI	Yes	Yes	Silent	Silent	Silent	Silent
MN	Yes	Yes	Silent	Silent	Silent	Yes
MS	Yes - AA	Yes - AA	Silent	Yes	Silent	Silent
MO	Yes - E, W, CC	Yes - E, W, CC	Yes	Yes	Yes	Yes
MT	Yes - W, AA	Yes - W, AA	Silent	Silent	Silent	Silent
NE	Yes - W	Yes - W	Silent	Silent	Silent	Silent
NV	Yes - AA	Yes - AA	Yes - K	Yes	Yes	Silent
NH	Yes - W, AA	Yes - W, AA	Silent	Yes	Silent	Silent
NJ	Yes - W, AA	No	Silent	Yes	Yes - Q	Yes
NM	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes	Silent
NY	Yes - F, W, AA	No - F	Yes - I	Yes	Yes - R	Silent
NC	Yes - U, AA	Yes - U, AA	Silent	Yes - I	Silent	Silent
ND	Yes - BB	Yes - BB	Silent	Silent	Silent	Silent
OH	Yes - W	Yes - W	Silent	Yes	Yes - P	Silent
OK	No	No - EE	Silent	Silent	Silent	Silent
OR	Yes - W, AA	Yes - W, AA	Silent	Yes - I	Yes - I	Silent
PA	Yes - AA	No	Yes	Yes	Silent	Yes
RI	Yes - W, AA	No	Yes - G	Yes	Yes - R	Yes
SC	Yes - DD	Yes - DD	Silent	Silent	Silent	Silent
SD	Yes	Yes	Silent	Silent	Silent	Silent
TN	Yes	Yes	Yes	No	Silent	Silent
TX	Yes - W, AA	Yes - A, W, AA	Yes - H	Yes	Silent	Silent
UT	Yes	Yes	Yes - G	Yes	Yes - S	Silent

State	Modify Existing Therapy	Initiate New Therapy	Perform a Physical Assessment	Order Laboratory Tests	Interpret Laboratory Tests	Perform Laboratory Tests
VT	Yes - W, AA	Yes - W, AA	Yes	Yes - I	Yes - I	Silent
VA	Yes - Y, AA	Yes - Y, AA	Silent	Yes	Silent	Silent
WA	Yes - W, AA	Yes - A, W, AA	Yes - G	Yes	Yes - R	Silent
WV	Yes - CC	No	Yes - L	Yes - O	Yes - T	Yes
WI	Yes	Yes	Silent	Silent	Silent	Silent
WY	Yes - W, AA	Yes - A, W, AA	Yes	Yes	Silent	Yes

Key for Table 2: Functions Authorized

A	Drugs limited to those in the protocol
B	Notify physician within 24 hours if therapy is discontinued
C	Therapeutic substitution not allowed without the physicians explicit consent
D	First 3 months limited to monitoring
E	State specific rules regarding initiation and modification of a prescription - refer to state laws/regulations for details
F	Therapeutic substitution allowed but not initiation of new therapy
G	Obtaining and checking vital signs
H	Ordering or performing routine drug therapy-related patient assessment procedures
I	As specified in the agreement/protocol
J	Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy
K	Examinations
L	The protocol may authorize the pharmacist to check only these findings: vital signs, oximetry, or peak flows that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred to the patient's physician for follow-up. Pharmacists shall not conduct any physical examination of the patient other than taking vital signs.
M	Protocol requirements outlined in the regulations are very prescriptive - see Colorado regulations before initiating a CPA
N	Under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component
O	Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician
P	Evaluate but not to be used for diagnosis

Q	In direct consultation with the physician
R	Evaluate
S	Ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed in accordance with approved protocols applicable to the practice setting
T	Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center. All laboratory results obtained are to be sent to the physician within 48 hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately.
U	Agreement is disease specific
V	Disease states limited to those defined in agreement for each individual patient
W	Disease states limited to those specified in protocol or agreement
X	Disease states limited to those specified in the protocol or agreement; restrictions for community pharmacists only
Y	Diseases states limited to those with a defined standard of care required or the protocol must be approved by the board of pharmacy
Z	Restricted to conditions for which the patient has first been seen by a physician
AA	Medications limited to those specified in agreement or protocol
BB	Does not include CIs
CC	Does not include any controlled substances
DD	Medications limited to those specified in the therapeutic plan
EE	Limited to administering immunizations and therapeutic injections
FF	Restrictions for community pharmacists only
GG	Therapy initiation is limited to a defined list of drugs but does not require a collaborative agreement

Table 3: Requirements

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
AK	Silent	Silent	Yes - I, O, AA	Silent	Yes - WW	Yes - ZZ
AL	CPAs not allowed under state law.					
AZ	Silent	Silent	Yes - Z	Silent	Silent	Silent
AR	Silent	Silent	Yes - O, P, Q, Z	Silent	Yes - UU	Yes - YY
CA	Silent	Silent	Yes - R, S	Silent	Silent	Silent
CO	Silent	Yes - L	Yes - T, U, Y	Yes - QQ	Yes - UU	Yes - YY
CT	No - A	Silent	Yes - V, W, X	Silent	Yes - UU	Silent
DC	Silent - E3	Silent	Yes - E3	Silent - E3	Silent - E3	Silent - E3
DE	CPAs not allowed under state law.					
FL	Silent	Silent	Yes - BB, Z	Silent	Silent	Silent
GA	Yes - B	Silent	Yes - H, Z, CC	Yes - RR	Silent	Yes - ZZ
HI	Silent	Silent	Yes - R	Silent	Silent	Silent
ID	Silent	Silent	Yes - S, Z	Silent	Yes - UU	Yes - YY
IL	Silent	Silent	Silent	Silent	Silent	Silent
IN	Silent	Silent	Yes - S, DD	Silent	Silent	Yes - YY
IA	Silent	Silent	Yes - I	Yes - SS	Yes - UU	Yes - ZZ
KS	Silent	Silent	Silent	Silent	Silent	Silent
KY	Silent	Silent	Yes - H, EE	Yes - SS	Yes - UU	Silent
LA	Silent	Silent	Yes - H	Yes - SS	Yes - UU	Yes - YY
ME	Yes - C	Yes - M	Yes	Silent	Yes - VV	Yes - I
MD	Silent - D3	Silent - D3	Yes - H, D3	Yes - SS, D3	Yes - VV, D3	Yes - YY, D3
MA	Yes - D	Yes - L	Yes - H	Yes - TT	Yes - UU	Yes - ZZ
MI	Silent	Silent	Silent	Silent	Silent	Silent
MN	Silent	Silent	Yes - FF	Silent	Silent	Silent
MS	Yes - E	Silent	Yes - I	Yes - RR	Yes - WW	Yes - YY
MO	Yes - F	Silent	Yes - H	Silent	Yes - VV	Yes - YY
MT	Silent	Silent	Yes - I, Y	Yes - SS	Yes - VV	Yes - YY
NE	Silent	Silent	Silent	Silent	Yes - VV	Yes - YY
NV	Silent	Silent	Yes - Z, GG	Silent	Yes - WW	Silent
NH	Yes - G	Yes - L	Yes - I, HH	Yes - SS	Yes - UU	Yes - ZZ
NJ	Yes - H	Silent	Yes - I, Y	Yes - TT	Yes - UU	Yes - YY
NM	Yes - H	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
NY	Silent	Silent	Yes - I, II	Yes - SS	Silent	Silent
NC	Yes - H	Silent	Yes - NN	Yes - RR	Yes - UU	Silent
ND	Silent	Silent	Yes - JJ, E3	Silent	Yes - WW	Yes - A3
OH	Silent	Silent	Yes - B3, F3	Yes - SS	Yes - UU	Yes - ZZ
OK	Silent	Silent	Silent	Silent	Yes - UU	Silent
OR	Yes - I	Silent	Yes - I	Silent	Yes - UU	Yes - ZZ
PA	Silent	Yes - L	Yes - I, KK, C3	Yes - RR	Yes - VV	Yes - ZZ
RI	Yes - J	Yes - M	Yes - I	Yes - TT	Yes - VV	Yes - ZZ
SC	Silent	Silent	Silent	Silent	Silent	Silent
SD	Silent	Silent	Silent	Silent	Yes - WW	Silent
TN	Silent	Silent	Yes - S, KK	Silent	Check	Yes - ZZ
TX	Yes - K	Silent	Yes - I, X, LL	Silent	Yes - VV	Yes - YY
UT	Silent	Silent	Silent	Silent	Silent	Silent
VT	Silent	Silent	Yes - OO	Silent	Silent	Yes - YY

State	Additional continuing education requirements	Requirement for liability insurance?	Documentation and/or notification requirements	Patient involvement in agreement – signature or opt out?	Must agreements be sent to or approved by a state agency?	Length of time agreement is valid defined?
VA	Silent	Silent	Yes - I	Yes - TT	Yes - XX	Silent
WA	Silent	Silent	Yes - I	Silent	Yes - VV	Yes - ZZ
WV	Silent	Yes - N	Yes - I, V, W, MM, PP	Yes - TT	Yes - WW	Yes - ZZ
WI	Silent	Silent	Silent	Silent	Silent	Silent
WY	Silent	Silent	Yes - I, O	Yes - SS	Yes - WW	Yes - YY

Key for Table 3: Requirements

A	Continuing education is mentioned in CPA language but the requirements are the same as for licensure
B	Annual completion of 0.3 CEUs regarding modification of drug therapy
C	Fifteen hours per year: 2 hours in drug administration, 5 hours in the areas of practice covered by agreement
D	Five additional contact hours of continuing education that addresses areas of practice generally related to collaborative practice agreements
E	Biennial basis: obtain recertification in each disease state by completing a continuing education program consisting of not less than 6 hours focusing on nationally recognized updates
F	Biennial recertification required (6 hours of continuing education in medication therapy management)
G	Complete at least 5 contact hours or 0.5 CEUs of board-approved continuing education each year; such continuing education shall address the area or areas of practice generally related to the collaborative pharmacy practice agreement or agreements
H	Complicated requirements - see law/regulations for details
I	As specified in the agreement
J	Five hours of continuing education each year that must be in the practice area covered by the agreement; documentation must be maintained and available for inspection at the practice site
K	Six hours of continuing education related to drug therapy
L	At least \$1,000,000 of professional liability insurance
M	Agreement must include proof that liability insurance is maintained by all parties to the agreement
N	Personally have or have employer coverage of at least \$1,000,000 of professional liability insurance coverage
O	Documentation/patient records maintained for 2 years
P	Documentation recorded within a reasonable time of each intervention
Q	Documentation may be on the patient medication record, patient medical chart, or in a separate logbook
R	Written notification to patient's treating prescriber or entry into electronic patient record shared by the prescriber of any drug initiation within 24 hours
S	Medical records of the patient must be available to both the patient's treating prescriber and the pharmacist
T	Notification to the physician within 24 hours of modification of therapy
U	Physician must review and document acceptance or rejection of the drug therapy modification within 72 hours
V	All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record
W	The pharmacist shall report at least every 30 days to the physician regarding the patient's drug therapy management
X	Protocol must include a plan for periodic review, feedback, and quality assurance
Y	Records maintained for 7 years
Z	Physician notification/review as specified in agreement
AA	Physician review of pharmacist's decisions at least every 3 months
BB	Transferrable patient record for orders and progress notes
CC	Patient records maintained for 10 years after protocol is terminated
DD	Document in patient record immediately after making a change to drug therapy
EE	Records maintained for 5 years

FF	Document change of therapy in medical record or report to patient's provider
GG	Specific requirements for protocols developed for use in care transitions - see laws/regulations for details
HH	All agreements must include provisions for documentation of any initiation, modification, or discontinuation of a patient's medications in the patient's permanent medical record; community pharmacists must maintain a written record of the individual patient referral and the patients' written informed consent
II	Must immediately enter into the patient record any change or changes made to the patient's drug therapy and notify the physician (and the patient's other physicians)
JJ	The practitioner and the pharmacist must have access to the patient's appropriate medical records; the care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner
KK	Document as soon as possible, no longer than 72 hours after a change is made, as specified in the agreement
LL	The delegating physician must receive, as appropriate, a periodic status report on each patient, including any problem or complication encountered as defined in the protocol. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book.
MM	Notify the treating physician of any discontinuation of drug therapy
NN	Agreement must include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP
OO	Annual quality assurance review by the collaborating practitioner
PP	All evaluation notes shall be in the physician's patient's chart within 1 week of the evaluation and drug management change
QQ	Patients must be informed of their right to refuse care under the agreement; patient's signature on the institution's general consent may be used
RR	Patient notification required
SS	Written consent required
TT	Informed consent required
UU	Maintained and available upon request
WV	Copy of agreement must be submitted to the relevant board(s)
WW	Agreement must be reported to and approved by the relevant board(s)
XX	Protocol only needs to be approved for conditions for which there is no accepted standard of care
YY	Agreement can only be valid for up to 1 year
ZZ	Agreement can only be valid for up to 2 years
A3	Agreement can only be valid for up to 4 years
B3	Records maintained for 3 years
C3	Records maintained in an electronic medical record
D3	Extensive requirements regarding components of the agreement - see regulations for details
E3	Pharmacist must notify the prescriber within 24 hours of initiating or modifying therapy; CPA may clarify some situations where notice within 72 hours is acceptable
F3	Communication must occur between providers on a regular basis - see laws/regulations for details

Appendix B: Sustainability of Pharmacists' Services Delivered Under Collaborative Practice Agreements

Sustainable business models are needed to support pharmacists' patient care services, including those services delivered under collaborative practice agreements (CPAs). While CPAs can be very helpful in providing expanded authority for pharmacists to provide care to patients, a viable business model is critical for supporting the time commitment of the pharmacist and the expertise that he or she brings as part of a health care team. CPAs can improve access to care as well as facilitate efficiencies in the delivery of coordinated team-based care and sufficient payment to sustain pharmacists' services over the long term.

If revenue sources are already available for the services that pharmacists will be delivering under a CPA, then development of the CPA may focus on the operational aspects of the agreement. If revenue sources are not available, the negotiation phase of the CPA can also include discussions about the business model for compensating the pharmacist. Focus areas to consider include potential sources of direct payment and the value-added benefits that the pharmacist can provide. This appendix covers three key areas: potential payment sources for pharmacists' services, development of a value proposition, and monitoring the return on investment.

Potential Payment Sources

The health care system is undergoing significant changes in payment models for health care. The long-standing fee-for-service (FFS) model is shifting toward value-based models that pay for services provided by health care providers based on the value of those services in meeting quality measures, improving outcomes, and containing costs. In addition, bundled payments to organizations to cover the medical management of a patient population are becoming more common. Many payment models are currently a mix of FFS and value-based incentives.

Traditional FFS Payment Opportunities for Pharmacists

- FFS is currently the predominant compensation mechanism for health care providers in the United States. Under this model, health care providers are reimbursed for the number and array of clinical services they provide, typically through the use of specific billing codes that correspond to the level and type of services provided.¹ Commercial, public, and private insurers, along with pharmacy benefits managers and managed care organizations, all have potential to be payers for pharmacists' services. FFS payment opportunities for pharmacists' patient care services have been sporadic to date, however. As of 2016, many payers view pharmacists as being eligible for compensation only for dispensing medications, not for the provision of collaborative patient care services.²

Among the list of services below that pharmacists can currently provide, direct payment opportunities are available only for medication therapy management (MTM) and, in some cases, training in diabetes self-management. The other listed services are Medicare Part B services, where physicians or other qualified providers bill for the pharmacist's service under specific billing requirements:

- MTM.
- Training in diabetes self-management.
- A service incident to physician services in a physician-based practice or hospital outpatient clinic.
- Transitional care management as part of a team-based bundled payment.
- Chronic care management.
- Annual wellness visit.¹

Potential payers for pharmacists' patient care services include those described below:

- **Centers for Medicare & Medicaid Services (CMS)**

Part B—Pharmacists' services are not currently recognized for payment through Medicare Part B (where outpatient health care professionals' services are covered). Under specific circumstances, physicians and qualified nonphysician practitioners (NPPs) can utilize their National Provider Identifier number to bill for pharmacists' services performed under the direct or general supervision of the physician or NPP (depending on the service). This process is often referred to as "incident to" billing, and the setting is either a physician-based practice or a hospital outpatient clinic.

- Because specific requirements for this type of billing must be met, and the requirements vary by the service, it is extremely important to consult applicable resources. Pharmacists must be in an employed, contracted, or leased arrangement in order for the physician to bill for the pharmacist's services.¹
- For services requiring direct supervision, the physician or NPP must be present in the office suite or in the building and immediately available to the pharmacist. In contrast, under general supervision, the physician

provides overall direction and control, but the physician's presence is not required. Community pharmacists under the general supervision of the physician or NPP could perform Medicare services with a general supervision requirement (e.g., chronic care management, transitional care management) in the pharmacy.

- **CMS Medicare Part D**—CMS contracts with Part D Prescription Drug Plans (PDPs) to provide MTM services for eligible beneficiaries. PDPs can then contract with pharmacies or pharmacists to provide MTM services. MTM service opportunities are variable but, where present, could be a revenue source to support the pharmacist working under a CPA with a prescriber. Pharmacists would bill directly for any MTM services provided to the patient.
- **State Medicaid programs**—Some state Medicaid programs provide payment to pharmacists for various services, which can include medication management, chronic condition management, and wellness services. There also may be opportunities in some state Medicaid programs for physicians to bill for pharmacists' services under an "incident to" arrangement. Pharmacists should check with state boards of pharmacy or state pharmacy associations to learn about available opportunities in a given state.



- **Commercial health plans and self-insured employers**—Commercial health plans may cover pharmacists’ services delivered in an “incident to” arrangement with a prescriber. It will be helpful for pharmacists to become familiar with the requirements for specific plans because commercial health plans often follow CMS’s guidelines but may have their own requirements. In addition, some commercial health plans are involved in pilot programs to pay pharmacists directly for certain services, such as diabetes management. Many state pharmacy associations are working to address payment barriers for pharmacists’ services. For example, the state of Washington recently implemented a law that requires commercial health plans in that state to cover pharmacists’ services if the service is within the pharmacist’s scope of practice and that same service is covered for other health care practitioners. Self-insured employers are another potential source of payment for services such as the management of chronic conditions and wellness services. Pharmacists interested in these opportunities may benefit from networking to learn about available programs.

Funding Opportunities in New Models for Delivering Care

In new care delivery models, such as accountable care organizations and patient-centered medical homes, various health care practitioners are compensated for delivering quality, affordable, and coordinated care to patients under new payment models. In these models, the focus is on “pay for value” instead of the “pay for volume” approach in FFS. Pharmacists may be able to contract directly with an organization for specific services or integrate directly into the organization as salaried employees. This will depend on the nature of the care provided and the interest of the collaborating providers or insurers.²

New care delivery models may include a mix of FFS payment, incentive payments for meeting quality metrics and cost targets, and payments for managing and coordinating the care of populations of patients. The incentive payments may be provided through payments for nontraditional services, higher rates for contracted services, lump sum payments, additional per-member per-month payments, shared savings when expected expenditures are below actual costs, or other pay-for-performance incentives.²

Payment models are not mutually exclusive. For example, a pharmacist may be contracted by a medical group to provide patient care services 3 days per week. Each time the pharmacist conducts services that are currently paid under the fee-for-service model, the medical group bills the insurer to recover reimbursement for the provided service. If the pharmacist improves the outcomes of patients who are part of an integrated care model, the medical group will earn an incentive payment. The reimbursement received by the medical group may be used to offset the cost of the pharmacist or may be shared with the pharmacist as a bonus payment, depending on the terms of the contract.

Pharmacists who plan to seek payment within integrated care models will benefit from being prepared to document, monitor, and improve specific quality measures that drive incentive payments. Because many care delivery organizations receive capitated payments to cover a patient population, there is a greater focus on keeping the population healthy and achieving better health outcomes. Pharmacists may want to focus on understanding the organization's relevant quality measures and how pharmacists' services can improve specific metrics and increase savings.

Assessing Payer Mix

If the source of payment for pharmacists' services will come from the physician's practice, it will be helpful to understand the types of payers (the payer mix) in the practice in order to build a business model. For example, in a practice that has a payer mix of 60% Medicare, 30% commercial health plans, and 10% Medicaid, a pharmacist working in the practice might want to collaborate with the physician to deliver annual wellness visits (incident to physician services) and chronic care management services to the practice's Medicare beneficiaries. A pharmacist might collaborate to deliver chronic care management services and transitional care management while assisting the practice with meeting selected quality metrics. Payment opportunities available through Medicaid or commercial health plans could be considered as well. The pharmacist's contributions to meeting quality metrics could be covered through incentive payments.

Formulating the Value Proposition^{3,4,5}

With an understanding of potential payment sources, pharmacists can begin building the business case for collaborating with physicians to deliver services under a CPA. The value proposition is composed of the most persuasive reasons why a physician should consider entering into a business agreement with the pharmacist to deliver services under a CPA. Value propositions can also be developed for approaching payers directly for coverage of pharmacists' services. Potential elements of the value proposition include the following:

- Specific patient care services that the pharmacist can provide.
- Unique benefits that the pharmacist can bring to the practice, such as assistance with meeting quality metrics, providing drug information, and assistance with meeting evidence-based guidelines.
- Revenue opportunities and potential ROI as well as other factors that help to justify the business case for making the decision.

The value proposition is often summarized in an executive summary of one or two pages that creates a compelling case to be used during negotiations. A pro forma that projects anticipated revenues for specific services over a specified timeline is a helpful addition to the executive summary.

Monitoring the Return on Investment (ROI)

A physician practice that is contemplating paying for the services of a pharmacist may be interested in the ROI, which is the ratio of the gains (revenue and other benefits) to the total costs of the collaborative services. An ROI greater than 1 indicates that the investment is beneficial, and the higher the ROI above 1, the better the investment.

$ROI = \text{Gains (revenues and other benefits)} / \text{Costs}$

Costs may include payment to the pharmacist, the physical space used by the pharmacist, health

information technology, and staff to support the pharmacist. Gains, which can be more difficult to quantify, can include direct revenues from pharmacists' services, cost savings to the practice, and indirect benefits such as physician efficiencies, patient and physician satisfaction, and meeting quality metrics. Published studies, previously collected data, and case studies can be used to help estimate these components to provide the overall "gains" in the ROI calculation. Pharmacists can anticipate that it may take time to reach a positive ROI, and tracking mechanisms should be in place to track the ROI over time.



Appendix B: References

1. U.S. Department of Health & Human Services. Health information privacy: business associate contracts website. <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>. Accessed September 1, 2016.
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Appendix C: Updating a National Provider Identifier Number

If the pharmacist will be the signatory on prescriptions that are initiated or modified under a collaborative practice agreement, it may be beneficial for him or her to obtain an updated National Provider Identifier (NPI). The updated NPI number will indicate to pharmacy benefit managers that the pharmacist has an expanded scope of practice that may include authority to write prescriptions. Although updating the NPI number will not ensure coverage of prescriptions written with that NPI number, it may increase the likelihood that the pharmacy benefit manager identifies the pharmacist as a valid prescriber. Having an NPI is also important for billing.

The instructions below outline how to update an existing NPI number. If the pharmacist is applying for an NPI for the first time, he or she should follow the instructions found on the NPI website (<https://nppes.cms.hhs.gov/NPPES/>), taking note of the instructions below to select the correct provider taxonomy.

Step 1: Pharmacists should log into their NPI account at <https://nppes.cms.hhs.gov/NPPES/>. Note: Because passwords expire every 60 days, the pharmacist may need to go through the “lost password” process available on this page.

Step 2: Select view/modify NPI data.

Step 3: *Most important step.* Update taxonomy. The pharmacist can add multiple taxonomies and should choose the taxonomy code for the primary taxonomy that most appropriately fits his or her position. Pharmacists in the community setting who are participating in medication initiation and/or modification should consider the pharmacist clinician (PhC)/clinical pharmacy specialist as their primary taxonomy. Note: More information about the provider taxonomies is available at <http://www.wpc-edi.com/reference/>.

Step 4: Update other information (e.g., password, profile, mailing address, practice location).

Step 5: Complete the certification statement.

Step 6: Submit and log off.



