

Collaborative Practice Agreements for Independent Pharmacies

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By Michael H. Cohen

Healthcare providers regularly write prescriptions for all types of healthcare conditions. These prescriptions are then filled out by a pharmacist of the patient's choosing – not the physician's choosing. While many doctors and pharmacists work independently, there are suggestions by both doctors and pharmacists that coordinating all types of pharmaceutical care with healthcare may be beneficial to patients. These suggestions have been placed into practice through the use of collaborative practice agreements (CPAs) between pharmacists and healthcare providers.

Why collaborative practice agreements are being encouraged

The [National Community Pharmacists Association](#) (NCPA) states that as more patients seek medical care, the administrative requirements increase, and payment is tied to quality; prescribers are finding the ability to meet their patients' needs more challenging. Some patients can wait months for an appointment. The NCPA emphasizes that pharmacists can *"increase patient access to care, decrease the overall number of hospitalizations, improve patient outcomes, and reduce total net healthcare spend."*

A CPA is a contract between a pharmacist and a prescriber that defines what patient care functions – *"like prescribing or modifying drug therapy"* can be delegated to the pharmacist and when and how the pharmacist can provide those functions. The CPA *"delegates patient care functions to pharmacists beyond the pharmacist's typical scope of practice."* *"This collaboration improves the efficiency and reduces the fragmentation of patient care."*

"When used to their full potential, collaborative practice agreements have the ability to increase access to care, expand available services to patients and increase the efficiency and coordination of care," said Jeff Durthaler, pharmacist consultant in the Division for Heart Disease and Stroke Prevention with the U.S. Centers for Disease Control and Prevention (CDC).

What are collaborative practice agreements?

The NCPA defines collaborative practice agreements as voluntary, formal relationships between the pharmacist and physician or other healthcare provider that allows for certain patient care functions, including but not limited to:

- Modification or initiation of drug therapy
- Performing, interpreting, or ordering laboratory tests
- Conducting physical assessments, as authorized by the practitioner under specified situations and conditions.

“Expanding enhanced services opens the door for community pharmacists to embed themselves within a provider’s practice or provide additional patient care services directly in the pharmacy.”

Pharmacists may be able to help patient outcomes (and be compensated) through chronic care management.

“Chronic Care Management is a monthly management program for Medicare patients with two or more chronic conditions. Community pharmacists can provide just about every CCM activity under a physician’s supervision, and can assist prescribers obtain a more complete picture of their patients. Pharmacists are in a prime position to manage patients with complex medication regimens and improve a physician’s quality measures.”

How do collaborative practice agreements improve patient health?

According to the US Centers for Disease Control and Prevention (CDC), a CPA between healthcare providers and pharmacists can help improve a patient’s health by:

- Reducing “fragmentation of care,” lowering healthcare costs, and improving health outcomes.
- Recognizing that team-based care can improve blood pressure control when a pharmacist is included on the team.

According to PBA Health, “Collaborative partnerships between pharmacists and physicians empower team-based care, which has been proven to result in better quality care and health outcomes for patients,” said Anne Burns, R.Ph., vice president, professional affairs at the American Pharmacists Association (APhA).

Collaborative practice agreements, as mentioned above, are very useful for patients who have chronic disease management problems.

CPAs and compliance issues

While there are many benefits to collaborative practice agreements, there are some major compliance issue concerns. The CPA arrangements cannot violate Stark Law and the Anti-Kickback Statute which govern referral arrangements between healthcare providers and companies. There are also state laws that govern the scope of practice of medicine that must be reviewed if a pharmacist’s medical duties are expanded by a CPA. CPAs also need to comply with any other relevant state laws and the rules and regulations of the state pharmacy and medical practice boards.

PBA Health states that federal and state laws place limits on the ability of pharmacists to improve patient healthcare. A CPA, PBA Health asserts, is a way to help solve those limitations. Before entering into a CPA, pharmacists and physicians should review these limitations and the terms of any CPA with experienced healthcare compliance lawyers.

A CPA provides the way for a pharmacist, if certain conditions are met, to “*directly adjust patients’ medication regimens to optimize outcomes without constantly consulting the physician for approval.*” Without a CPA, a pharmacist would normally need permission for the doctor to modify a patient’s drug therapy. A CPA can reduce a lot of fax, email, and phone call communications so that the pharmacist can authorize drug therapy modifications without having to wait for a doctor’s permission each time.

What are the terms of a collaborative practice agreement?

PBA Health states that the CPA can specify the patients, the disease states, and the medications that the CPA covers. CPAs can be adjusted, depending on state law, to meet the needs of the community. Each CPA is different.

Common CPA services, depending on the state’s laws and regulations include:

- **Authorizing refills.** The physician/prescriber grants the pharmacist the ability to “*extend refills based on the pharmacist’s*

assessment of the patient.”

- **Chronic disease management.** *“The prescriber authorizes the pharmacist to initiate, modify or discontinue medications.”*
- **Laboratory tests.** *“The CPA may authorize the pharmacist to order and interpret laboratory tests essential to effectively monitor medications or the status of chronic conditions.”*
- **Therapeutic Interchange.** *“The prescriber authorizes the pharmacist to substitute another drug in the same drug class for the medication originally prescribed.”*

A few examples of CPAs

PBA Health discusses how a pharmacy in Rhode Island was able to enter into a CPA to help the community by enabling the pharmacy to provide emergency prophylactics to patients with Lyme Disease. The pharmacy is still required to evaluate patients according to detailed criteria outlined in the agreement such as requiring that the patient *“bring in the tick or a photograph of the tick for the pharmacist to identify as a deer tick.”* Another criterion is that the tick bite must have occurred within the prior 72 hours.

The CDC examples include:

- The El Rio Community Health Center at Arizona’s El Rio Community Health Center switched to an electronic health record system that helped healthcare providers
 - *“Set up CPAs with local pharmacists for the center’s 800 patients who are receiving diabetes management services. Doctors and nurse practitioners refer patients to the pharmacist through the EHR. The pharmacist care plan is then documented in the EHR, along with a copy of the CPA.”*
 - *“Changes to patients’ medications—such as the introduction of a new medication or a change to a current prescription—are tracked in the system, and this information is accessible to the provider and pharmacist.”*
- In Asheville, North Carolina:

The Asheville Project, the Patient Self-Management Program for Diabetes (PSMP), and the Diabetes Ten City Challenge (DTCC) were efforts by self-insured employers to provide education and mentoring for employees with chronic health problems such as diabetes, high blood pressure, and high cholesterol.

Patients were enrolled in collaborative care programs that included a community pharmacist on their health care team.

Health spending savings included:

- - - The Asheville Project. Average net savings of \$1,622–\$3,356 per person per year.
 - PSMP. Average net savings of \$918 per person per year.
 - DTCC: Average net savings of \$1,079 per person per year.

Patient care improved as follows”

- - - Asheville: 50% average reduction in number of sick days.

- PSMP:
 - 100% of study participants had their glycosylated hemoglobin (A1C) level tested;
 - 94% of patients met the Health Plan Employer Data Information Set (HEDIS) goal of 7% or less for A1C.
- DTCC: A1C and screening rates improved to 97%; 91% of patients achieved an A1C level that met the HEDIS goal.

What are the business benefits of a CPA for pharmacists?

Some of the factors that should be reviewed with an experienced healthcare lawyer when considering a CPA include:

- Whether the service is reimbursable
- How much more efficient is the CPA?
- Does more efficiency mean more business and more retention of patients?
- Does the CPA mean more patients for the pharmacy or the physician?
- What conditions may limit the ability of the pharmacist to provide a service to the patient?

Another benefit may be obtaining more referrals – provided that the referral arrangement does not violate Stark Law or the AKS.

PBA Health states that *“Collaborative practice agreements also help pharmacy businesses adapt to evolving payer preferences because they position pharmacists as providers.”*

There are also a lot of practical issues involved with determining which physicians pharmacists may want to work with, developing a working relationship with that physician, preparing and negotiating the CPA, and ensuring that the arrangement complies with federal and state laws and regulations.

State limitations of collaborative practice agreements

Some of the state limitations that may govern a pharmacist/physician CPA include:

- Limiting which kinds of practitioners can participate
- What terms must be included in the CPA
- That length of time the CPA is valid
- The functions that the pharmacist can legally perform

How can a seasoned healthcare lawyer help pharmacists and physicians prepare collaborative practice agreements?

Some of the issues experienced healthcare lawyers will review include:

- Whether the CPA needs to be registered with a pharmacy board or any other medical boards.
- Negotiating the terms of the agreement.
- Reviewing any business associate agreements and data sharing arrangements – to comply with HIPAA and for other reasons.
- Addressing the scope of service issues.
- Other formalities such as obtaining a pharmacist National Provider Identifier number.

The lawyer will also review any referral arrangements, Stark Law and AKS compliance, and whether any Stark Law exceptions or AKS safe harbors apply.

- **Stark Law.** Stark Law is a federal law that prohibits physicians from making referrals to any business entity where the physician or an immediate family member has a financial interest in the business entity. Possible Stark Law exceptions include “*physician services*” if the pharmacist is a member of the group practice and other conditions apply, “preventive services” covered by Medicare, a “*personal service arrangement*” that meets specific criteria, and the arrangement qualifies as “*fair market value compensation*.”
- **The AKS.** The Anti-Kickback Statute prohibits either the pharmacist or physician from paying anything of value to the other healthcare provider in order to receive referrals.
- **Scope of practice laws.** The scope of practice laws govern the type of services healthcare providers can provide and when and how one healthcare provider may be able to provide healthcare services if that healthcare provider is properly supervised and monitored by another healthcare provider who is providing care clearly within the scope of his/her practice.

Exceptions to the Stark Law Prohibition of Medical Referrals

The Stark Law governs what types of referrals doctors can make if they bill for Medicare and Medicaid. The presumption is that that referrals made by a doctor to a designated health service are [...]

Anti-Kickback vs. Stark: When do these laws apply?

In today’s video, we give a brief refresher on the difference between Stark and anti-kickback laws.

California’s New Scope of Practice Law for Nurse Practitioners – Part One

California passed a new law, effective January 1, 2023, that permits nurse practitioners in specific settings to provide care (under certain conditions) that does not meet “standardized procedures.”

Pharmacists, physicians, and patients may all benefit from collaborative practice agreements. These agreements expand the opportunities for pharmacists to provide essential health care subject to the conditions set by the physician. Collaborative practice agreements may be profitable for the healthcare providers while providing more efficient and timely care for patients. There are compliance issues though. The agreements should be reviewed with legal counsel to help ensure the agreements comply with Stark Law, the AKS, scope of practice laws, and any other federal or state regulations – as well as medical board requirements.

Pharmacists and physicians should contact Cohen Healthcare Law Group to discuss the pros and cons of collective practice agreements and the relevant compliance concerns. Our experienced healthcare attorneys advise pharmacists and medical practices about healthcare compliance laws and regulations.

[Schedule a Legal Strategy Session Today](#)

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.