RBC Cardinal Health DENVER

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Collaborative Practice Agreements Made Easy: A Roadmap for Success

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

Pharmacist and Technician Learning Objectives

1. Summarize the laws governing Collaborative Practice Agreements.
2. Outline the most important provisions and best practices for successfully implementing a Collaborative Practice Agreement.
3. Identify pitfalls to avoid when engaging in a Collaborative Practice Agreement.
4. Discuss how one party to a Collaborative Practice Agreement can legally compensate the other party for services.

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Introduction

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Introduction

- Over half of Americans have a chronic health condition.[1]
- Americans spend over $300 billion per year on medications, and over 90% of these medications are used for the treatment of a chronic condition. Despite the high volume of prescription use in the United States, over $40 billion is spent annually on hospital readmissions and two out of three readmissions are medication-related.[2]

1. Centers for Disease Control and Prevention ("CDC")
2. National Institute for Health Care Management ("NIHCM") Foundation

Introduction

- **Collaborative Practice Agreements (CPAs)** are formal relationships between pharmacists and prescribers that specify the functions a pharmacist can perform in addition to his/her typical scope of practice.
- Nearly every state has a version of a law allowing for collaborative practice between a physician and pharmacist. Most states allow for collaborative practice in any setting a pharmacist practices.
- Initiation of a working relationship between pharmacists and physicians requires collaboration from both parties seeking to allow pharmacists to fill a need.

Trust

Trust

- To create a successful relationship, physicians must be confident in the pharmacist’s clinical skills and organizational abilities to properly train, document, and communicate utilization of a CPA.
- Credibility may be established by advanced credentialing, professional memberships, and patient-care experience.

Role Specification

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Role Specification

- A clearly defined scope of practice is essential to the development of a collaborative working relationship (CWR), allowing physicians and pharmacists to rely on each other to complete their negotiated responsibilities.
- The development of a CPA often begins with a pharmacist taking ownership of a specific patient-care function, such as tobacco cessation counseling or diabetes self-management education, with eventual expansion as the CWR matures.

Interaction Between Physician and Pharmacist

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Interaction Between Physician and Pharmacist

- Physicians entering into a CPA choose to expand limited prescriptive rights to community pharmacists in an effort to resolve the unmet needs of their patients.
- Under a CPA, the physician provides primary care during scheduled patient appointments, and the pharmacist provides secondary care between physician visits. The physician's role shifts from approving daily pharmacist-led interventions to receiving updates of resolved interventions.
- Physicians hold the right to override or withdraw approval from any action performed by a pharmacist under the CPA.

Interaction Between Physician and Pharmacist

- The role of the pharmacist operating under a CPA is to identify and resolve patient-care interventions in accordance with the policies and procedures delineated in the CPA.
- Under state licensure, pharmacists may perform many specific clinical functions without a CPA, including medication therapy management, patient counselling, and disease screening. However, CPAs allow an additional level of autonomy to pharmacists through the expansion of a physician's license.
- Following resolution of pharmacist-led interventions, pharmacists must communicate changes to their collaborating physician in a timely manner.

Interaction Between Physician and Pharmacist

- In most states, pursuant to a CPA, pharmacy interns may identify and resolve patient-care interventions when precepted by a licensed pharmacist. Though the pharmacy intern may assist in the process, the pharmacist preceptor assumes responsibility for the intern's actions.
- Pharmacy technicians may assist the pharmacist in organizational functions related to the communication and documentation of CPA activities. The technician may relay therapy changes to collaborating physicians following approval by a pharmacist. Prescription processing and record keeping of communication are functions for which pharmacy technicians are well suited.

Compensation Between the Parties

Federal Laws

- The federal anti-kickback statute (“AKS”) prohibits one party from paying money to another party for
  - referring a patient covered by a federal health care program (“FHCP”),
  - arranging for the referral of FHCP patients, or
  - recommending the purchase of a good or service reimbursable by an FHCP.

Federal Laws

- The Office of Inspector General ("OIG") has published a number of "safe harbors" to the AKS.
- If an arrangement meets all of the elements of a safe harbor, then as a matter of law the arrangement does not violate the AKS.
- If an arrangement does not meet all of the elements of a safe harbor, it does not mean that the arrangement violates the AKS.
- Rather, it means that the parties must carefully scrutinize the arrangement in light of the language of the AKS, court decisions and published OIG guidance.

Federal Laws

- The federal physician self-referral statute ("Stark") prohibits a physician from referring a Medicare/Medicaid patient to a person/entity (for a "designated health service" as defined by Stark) with whom/which the physician has a compensation or ownership interest.
  - Stark has a number of exceptions, some of which are similar to the safe harbors to the AKS.

Calculation of Compensation

- If the physician refers FHCP patients to the pharmacy, and if the pharmacy pays compensation to the physician for his/her services, then the arrangement needs to comply with
  - the Personal Services and Management Contracts (“PSMC”) safe harbor to the AKS and
  - the Personal Services (“PS”) exception to Stark.
- Among other requirements,
  - the methodology for calculating the compensation must be set one year in advance,
  - the compensation must be the fair market value (“FMV”) equivalent of the services rendered, and
  - the compensation cannot take into account the anticipated business generated by the parties to each other.

Calculation of Compensation

- Conversely, if the pharmacy refers FHCP patients to the physician, and if the physician pays compensation to the pharmacy for its services, then the arrangement needs to comply with
  - the PSMC safe harbor to the AKS and
  - the PS exception to Stark.

Goals of a CPA

General Goals

- The goals of the CPA include:
  - To optimize drug therapy.
  - To reach clinical health targets and quality metrics.
  - To improve patient adherence and medication access.
  - To increase access and efficiency of primary care physician.
  - To decrease preventable emergency room visits and hospital readmissions.
  - To improve the health of patients and their quality of life.

Introduction

- Most CPAs in institutional health systems provide very broad definitions of pharmacist-led interventions (i.e., warfarin management). However, CPAs in non-institutional settings must be composed of specific interventions that can be implemented within the medication-use process.
- Foundationally, a CPA must describe methods by which the physician and pharmacist collaborate to manage specified disease states.
- By including organizational features (i.e., policies and procedures) in the CPA, the health care team can ensure reasonable expectations are documented and accepted by all members of the team.
- Listing targeted interventions improves feasibility for pharmacies and including an appendix of clinical guidelines enhances the credibility of the rationale for intervention resolution.

Authority

The physician must expressly authorize the pharmacist to manage/treat patients in accordance with the CPA.

Purpose

Creation of multi-disciplinary teams that can function as physician extenders are one way to achieve the goal of providing excellent patient care. The purpose of the CPA is to enhance collaborative patient care and optimize medication-related outcomes for mutual patients of the physician and pharmacy.

Patient Care Functions

- Within the parameters of state law defining the scope of functions allowed under a CPA, physicians and pharmacists may collaborate to determine what disease states and interventions would best help their mutual patient population.
- A list of targeted interventions stratified by disease state is important.
- Pharmacists are ideally positioned to recommend medication interchanges that will benefit the patient, but physician response-time imposes a barrier to immediate access. Through a CPA, pharmacists may utilize a guideline-based drug optimization and initiation of therapy strategy to manage disease states monitored by point-of-care laboratory testing.

Quantity Adjustments

- Inaccurate prescriber calculations on prescriptions lead to delays of patients accessing a full course of therapy.
- By adjusting the approved quantity of prescriptions under a CPA, pharmacists may help a patient receive the full course of therapy while optimizing the patient's insurance benefits without waiting for a physician response.

Therapeutic Interchange

- Therapeutic interchange is the practice of replacing a medication with a chemically different medication in the same drug class.
- Therapeutic interchange may be the most efficient response to an insurance-mandated prior authorization.

Formulation Interchange

- Through a CPA-targeted intervention, pharmacists may interchange formulations of prescribed medication, allowing the pharmacists to adapt a drug regimen to find a formulation that meets the patient's needs and reduces costs.
- Many chronic medications are available as combination products, and pharmacists can advocate for their patients to reduce pill burden and extra co-pays by utilizing combination therapies. Interchanging dosage forms (tablets, capsules, liquid, etc.) may improve the patient's ability to comfortably take the medication. Time release formulations may improve adherence or reduce side effects.

Drug Optimization

- Dose adjustments for drug optimization are commonly supported by clinical guidelines for patients with uncontrolled disease states.
- As point-of-care laboratory testing becomes more common, pharmacists have the opportunity to identify uncontrolled disease states and optimize therapy between a patient's visits with his/her physician.

Drug Initiation

- While some medications require laboratory testing and a physician diagnosis to warrant initiation, many medications provide symptomatic relief solely based on the patient's description of symptoms. Often, OTC medications impose an additional financial burden on patients when their insurance would cover the product following a prescription by a physician.
- On a daily basis, pharmacists recommend self-treatment with OTC therapies. Under a CPA, a pharmacist can recommend a therapy for symptomatic relief and write the prescription to ensure insurance coverage.
- This practice will reduce a patient's out-of-pocket expenses with an added benefit of allowing the pharmacy to maintain an accurate list of medications, both prescription and OTC, a patient is taking.

Provider Eligibility

- The type of prescriber eligible for inclusion in a CPA varies from state-to-state.
- In some states, medical directors may include all physicians in the practice under a CPA while other states require an individual CPA per patient, pharmacist and physician.

Training/Education

- Professionals interacting under a CPA must maintain up-to-date clinical competencies and knowledge of current guidelines for the disease managed by a CPA.
- State laws may mandate the completion of additional continuing education to utilize a CPA.

Liability

- Statements regarding the liability of collaborators are necessary for legal protection in the event of unintended consequences arising from the use of a CPA.
- Pharmacists and physicians providing care through a CPA are not liable for each other's clinical decisions.
- Some states require physicians and pharmacies to maintain a specific level of liability insurance.

Informed Consent

While state laws vary in detail pertaining to informed consent, most states require some level of informed consent prior to initiating care by a pharmacist through a CPA.

Documentation

- Policies regarding the documentation of CPA activities are essential to maintaining accurate patient records and assessing outcomes. Each party to a CPA must document all patient-care activities and communications among team members.
- Appropriate documentation ensures that data may be collected for quality assurance and quality improvement.

Period of Validity

- As dictated by state law, CPAs must be reviewed regularly by all responsible parties.
- Ideally, the CPA renewal will follow the annual quality improvement meeting, given that the policies and procedures are often adapted based on initiatives identified during this meeting.

Retention of Record

All records, whether physical or electronic, must be retained and readily retrievable for a period of time specified by state law.

Rescission and Amendment

- It is the right of each participant in a CPA, whether a health care professional or patient, to withdraw consent. Rescission should be written and disseminated to each member of the team.
- Because the goal of the CPA is to facilitate team-based care, amending the CPA should avoid rescission when possible.
- CPAs may be amended within the accepted period of validity of the whole agreement without affecting all other aspects of the agreement.

Data Collection

- A data collection plan should be designed prior to initiation of a CPA.
- Innovative practices must be measured so that quality can be assured and facets of the program can be improved when needed.

Key Provisions of a CPA

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Background

- “Physician is a medical doctor who treats patients suffering from chronic health conditions.”
- “Physician desires to collaboratively manage the chronic health conditions of certain patients with a certified pharmacist.”
- “Pharmacist is a pharmacist certified to provide patient care services under a collaborative practice agreement.”
- “Pharmacist desires to collaboratively manage the chronic health conditions of certain patients with a physician.”

Terms

- “Pharmacist represents that (s)he has received his/her collaborative practice certification from the _____ Board of Pharmacy, and a copy of Pharmacist’s certification is included as the **Certification Attachment** to this Agreement.”
- “Physician represents that the patient care services delegated to Pharmacist under this Agreement are within Physician’s scope of practice.”
- “The term of this Agreement is two years from the Effective Date. This Agreement will automatically terminate unless Physician and Pharmacist enter into a written agreement to renew this Agreement. Either Physician or Pharmacist may terminate this Agreement in writing at any time.”

Terms

- “If this Agreement ever expires or is terminated:
  - Physician will notify each patient receiving patient care services from Pharmacist by phone and in writing within five days of the expiration or termination.
  - Pharmacist will transfer a copy of each patient’s medical records related to this Agreement to Physician within 30 days of the expiration or termination.”

Terms

- “Physician and Pharmacist each must maintain on file a copy of this Agreement at his/her respective practice location and must make a copy of this Agreement available to the _____ Board of Medicine and the _____ Board of Pharmacy upon request or inspection.”
- “Pharmacist must submit a signed copy of this Agreement to the _____ Board of Pharmacy through Pharmacist’s online licensure account or via U.S. Mail before this Agreement may be implemented.”

Terms

- “Physician and Pharmacist understand and agree that Physician may not delegate to Pharmacist the authority to initiate or prescribe a controlled substance.”
- “For each patient that Physician delegates to Pharmacist the authority to collaboratively manage one or more chronic health conditions, Physician will prepare, sign, and date a copy of the **Patient Attachment**.”

Representations and Warranties

- “Physician represents and warrants that s/he has and will maintain a valid medical license without limitations and such other qualifications, as required by federal, state or local law or third-party payor or rule to perform his/her services hereunder.”
- “Pharmacist represents and warrants that s/he has and will maintain a valid pharmacy license without limitation and such other qualifications, as required by federal, state or local law or third-party payor or rule to perform his/her services hereunder.”

Patient Attachment to CPA

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Patient Attachment

- This Patient Attachment relates to the Collaborative Practice Agreement between me, Dr. _____, and pharmacist _____.
- Date: _____
- Patient name: _____
- Patient's chronic health condition(s) to be collaboratively managed by _____ (initial all that apply):
  - Arthritis _____
  - Asthma _____
  - COPD _____
  - Type 2 diabetes _____
  - HIV or AIDS _____
  - Obesity _____
  - Hyperlipidemia _____
  - Hypertension _____
  - Anti-coagulation management _____
  - Smoking cessation _____
  - Opioid use disorder _____
- Specific medicinal drug(s) to be managed for patient _____ by _____:
  - _____
  - _____
  - _____
  - _____
  - _____
- Under the following circumstances, _____ may order or perform and evaluate laboratory or clinical tests for patient _____:
  _____
  _____
  _____
  _____
  _____
- Upon occurrence of the following conditions and events, _____ must notify patient in the manner and timeframe specified below:
  _____
  _____
  _____
  _____
  _____

Related Issues

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Site Restriction/Presence of Pharmacist

- Is the collaborating pharmacist site restricted?
- Does the CPA require the pharmacist to be in a pharmacy?

Definition of Patient to be Served

- The definition can be simple. For example, “All patients of legal age in this state who present to the pharmacist and request an influenza vaccine, except for those who report a serious or anaphylactic reaction to a previous influenza vaccine.”
- Conversely, the definition can be detailed, with specific considerations for age, gender, pregnancy, health status and immunosuppression, etc.
- The more descriptions about the patient, the less likelihood of confusion or concern as the CPA is implemented.

Definition of Patient to be Served

Items to consider should include:

Specific Questions About Patient

- Is there a patient age restriction?
- Is there a restriction if the patient is pregnant?
- Is there a restriction if the patient is immunosuppressed?
- Is there a gender restriction?
- Are there other factors or health conditions that may restrict the patient?
- Are there patients or groups of patients who are being specifically targeted for the defined service?
- Are there physical assessments required to determine therapy?

Specific v. General Patient

- In some instances the CPA will apply only to a patient who is a patient of the collaborating physician.
- In other instances the patient may be any appropriate candidate for care or treatment with a direct impact on public health, (e.g., vaccines).

Definition of Services Under the CPA

- Defining the services is the most time consuming and professionally challenging component of a CPA.
- When standards of care exist, they should be used and cited.

Time/Drug Therapy

- Is there a time issue to be addressed? For example, can the service be delivered only if the collaborating physician is unavailable or is this service to be offered only during influenza season?
- Will drug therapy be dispensed pursuant to the CPA?

Communication Between Physician and Pharmacist

- Communication is essential to maintaining the trust that allows the collaboration to exist. Considering what information is to be shared between the physician and pharmacist, the timing of that communication, and the format of the communication are important for the successful implementation of the CPA.
- Considerations include:
  - Does the collaborating physician want to be notified of every service provided?
  - Is it appropriate to notify the patient's primary care provider? If this is done, does the collaborating physician want to be notified also?

Communication Between Physician and Pharmacist

- Define a clear communication method between the pharmacist and the physician, including actions to be taken if communication is necessary after regular office hours, or if one of both parties is unavailable.
- What are the arrangements made in the event of an emergency during care and treatment?

Hold Harmless

The CPA needs to spell out that each party to the CPA is a health care professional with a duty to provide appropriate care, but neither is liable for the practice of the other.

Discussion Points When Presenting a Collaborative Practice Proposal to a Physician or Health System

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Introduction

- Most physicians and many hospital systems do not have a clear understanding of how collaborative practice arrangements work. Because of this lack of understanding, there may be hesitation on the part of physicians/hospital systems to enter into CPAs.
- The challenge for the pharmacy, as it proposes a collaborative practice arrangement, is to quickly (and clearly) dispel doubts/uncertainties regarding such arrangements. The following are discussion points that a pharmacy can use when proposing a collaborative practice arrangement:

Discussion Points

“CPAs have been used for many years. They are an accepted arrangement designed to (i) allow physicians to delegate certain decisions, regarding treatment of patients, to pharmacists, (ii) free up physicians’ time, and (iii) facilitate a team approach to provide proactive (rather than reactive) health care to patients.”

“CPAs are governed by state law, including regulations by the State Board of Pharmacy and State Medical Board.”

“I have hired a health care attorney who specializes in structuring collaborative practice arrangements. S/he has provided clear guidance on how a CPA between us can be properly drafted and implemented. My attorney will be happy to visit with your attorney about structuring the arrangement.”

Discussion Points

"If you would like, I can provide to you a draft CPA that complies with state law. We can use the draft as the basis for our discussions. Our attorneys can take the draft and customize it for our needs."

"In addition to the draft CPA, I can provide to you a White Paper, prepared by my attorney, that (i) summarizes the law in our state regarding collaborative practice arrangements and (ii) discusses how such an arrangement can be properly structured."

Questions?

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