

Collaborative Practice Agreements Between Physicians and Pharmacists

Section 1 - Definitions

For purposes of this regulation, unless the context clearly indicates otherwise:

A. “Collaborating pharmacist” means a pharmacist licensed and in good standing in South Carolina who enters into a collaborative practice agreement (CPA) with a physician and provides medication management services or related patient care services pursuant to the CPA.

B. “Collaborating physician” means a physician licensed and in good standing in South Carolina who enters into a CPA with a pharmacist and who is the physician treating and is responsible for establishing the patient’s diagnosis, treatment goals, and overall plan of care.

C. “HIPAA compliant method of written record sharing” means a secure written communication process used when access to the same electronic medical record is not practicable and that allows the physician and pharmacist to document regular, secure, and timely communication to ensure coordinated patient care.

D. “Medication management services” means evidence-based patient care services authorized by a CPA that support the treatment goals established by the collaborating physician, including medication assessment, initiation, ordering, continuation, modification, or discontinuation on behalf of the collaborating physician pursuant to disease-specific CPA protocol(s), monitoring, therapeutic interchange, laboratory management, patient education, adherence interventions, preventive care services, and other related patient care services authorized by the CPA and applicable law.

E. “Related patient care services” means patient care activities that support safe and effective medication use and are within the pharmacist’s education, training, and experience, including monitoring, education, assessment, care coordination, medication adherence support, laboratory monitoring related to drug therapy, and referral back to the collaborating physician.

F. “Shared electronic medical record” means an electronic health record or electronic medical record system through which the collaborating physician and collaborating pharmacist have access to documentation necessary to coordinate care under the CPA.

G. “Specifically identified patients” means:

A defined population of patients who meet objective criteria established by the physician in the CPA, whose care is under the responsibility of the physician, and the patient who is receiving care pursuant to the CPA has provided informed consent obtained by the physician.

H. “Treatment protocol” means the written clinical protocol contained within or incorporated by reference into a CPA that describes the disease state, condition, medication or medication category, patient care service, decision criteria, monitoring plan, documentation standards, communication requirements, and referral criteria applicable to the pharmacist’s delegated activities.

Section 2 - Eligibility to Enter into a Collaborative Practice Agreement

A. Physician eligibility.

1. A physician may enter into a CPA pursuant to 40-47-20 if the physician:
2. Has established or accepted responsibility for the applicable patient’s diagnosis, treatment goals, and overall plan of care; and
3. Delegates only services consistent with the physician’s regular course of professional practice.

B. Pharmacist eligibility.

1. A pharmacist may enter into a CPA pursuant to 40-43-30 if the pharmacist:
2. Has education, training, or experience appropriate to the delegated services; and

3. Practices only within the scope authorized by the CPA;
- C. Multiple physicians or pharmacists.
 1. A CPA may include more than one physician and more than one pharmacist, provided the CPA identifies the participating individuals covered by the agreement.

Section 3- Required Elements of a Collaborative Practice Agreement

A CPA shall be in writing and shall include, at minimum:

- A. Identification of collaborating parties, to include at a minimum the Name, license number, practice location, and contact information for each collaborating physician and pharmacist.
- B. Specifically identified patients covered by the CPA
- C. Physician established treatment goals, including a description of the disease states, conditions, medication therapies, or care needs covered by the CPA;
- D. Delegated pharmacist activities pursuant to 40-43-30, et. seq. including medication management services and patient care services that are consistent with the CPA, applicable treatment protocol, and applicable law.
- E. Treatment protocol.

The CPA shall include evidence-based guidelines, clinical standards, institutional protocols, or other documentation that support the delegated services and the physician's established treatment goals. These may include but are not limited to one or more treatment protocols identifying applicable disease states, medications, authorized pharmacist activities, clinical decision criteria, monitoring requirements, communication requirements, referral criteria, and any circumstances requiring physician notification or approval.
- F. Documentation and communication.

The CPA shall establish documentation requirements, communication requirements, timeframes, and methods for access to relevant patient records. Patient records must be maintained for no less than ten years pursuant to 44-115-160.
- G. Quality assurance.

The CPA shall include a description of the quality assurance process appropriate to the scope and complexity of the services provided. This process must contain at a minimum a review of elements, review frequency, and patient outcomes.
- H. Override and consultation.

The CPA shall state the conditions that require consultation with and/or return of care to the collaborating physician.
- I. Duration, review, amendment, and termination.

The CPA shall include the effective date, expiration date, review interval no less than every 3 years, and mechanisms for amendment, termination of the agreement by any party, and patient or collaborating party withdrawal when applicable. All participants must sign the agreement.
- J. Records of the CPA.

A copy of the executed CPA must be maintained onsite by all parties and be readily available for review upon Board request within 72 hours. The Board is authorized to conduct audits to ensure compliance with these regulations and applicable state and federal law.

Section 4 - Orders and Prescriptions Generated Under a CPA

- A. Orders and/or prescriptions generated pursuant to a CPA shall:
 1. Identify the pharmacist responsible for the action and collaborating physician; and
 2. Be traceable to the applicable CPA.

Section 5 - Patient Notice, Participation, and Withdrawal

- A. Patient notice.
 - 1. The CPA shall ensure that each patient and/or caregiver is informed that care may be provided pursuant to a CPA. This informed consent, obtained by the physician, must be documented in the patient record.
- B. Patient refusal or withdrawal.
 - 1. A patient may decline participation under a CPA. A patient may withdraw from a CPA by providing written notice to the physician.
- C. Financial relationships between parties
 - 1. Any financial relationship or conflicts of interest between collaborating parties shall be disclosed in accordance with applicable state or federal law.

Section 6 - Institutional and Health System Agreements

CPAs approved by an institutional committee such as the pharmacy and therapeutics committee in an institutional facility, as defined in S.C. Code 40-43-30(27) with an institutional pharmacy, as defined in S.C. Code 40-43-30(28), that will be used solely for patients while receiving care in the institutional facility, must be developed through policies and procedures within the institution to govern collaborative practice and must be consistent with these regulations.

Section 7 - Prohibited Activities and Limitations

- A. A pharmacist acting under a CPA shall not:
 - 1. Diagnose.
 - 2. Provide services outside the scope of the CPA or treatment protocol.
 - 3. Initiate, modify, or discontinue controlled substances.
 - 4. Provide services that exceed the pharmacist's education, training, experience, or competency.
- B. A CPA shall not:
 - 1. be construed to establish a physician-patient relationship. Patients receiving services under a CPA must be under the care of the collaborating physician who has responsibility for the patient's care under applicable laws.
 - 2. be used to replace necessary physician evaluation, referral, or medical decision making.
 - 3. limit other services otherwise authorized under the South Carolina Pharmacy Practice Act, Board of Pharmacy regulations, statewide protocols, or federal or other applicable law.