



PHARMACIST COLLABORATIVE PRACTICE AGREEMENTS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY

A REPORT OF THE COLLABORATIVE PRACTICE WORKGROUP
CONVENED BY THE NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

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PROJECT OVERVIEW

Collaborative practice agreements (CPAs) create a formal practice relationship between pharmacists and other health care practitioners, whereby the pharmacist assumes responsibility for specific patient care functions that are otherwise beyond their typical “scope of practice,” but aligned with their education and training. These patient care services can include initiation and modification of drug therapy. The extent of the services authorized under the collaborative agreement depends on the state’s statutory and regulatory provisions for collaborative practice authority, as well as the terms of the specific agreement between the pharmacist and other health care practitioners.

State laws and regulations authorizing CPAs are highly variable. Some states specify the practitioners able to participate in CPAs, restrict the services that may be provided under a CPA, or include extensive logistical barriers that limit the utility of such agreements.

In their 2015 paper, *The Expanding Role of Pharmacists in a Transformed Health Care System*, the National Governors Association (NGA), presented the following state policy considerations in regards to collaborative practice provisions:

- Enact broad collaborative practice provisions that allow for specific provider functions to be determined at the provider level rather than set in state statute or through regulation.
- Evaluate practice setting and drug therapy restrictions to determine whether pharmacists and providers face disincentives that unnecessarily discourage collaborative arrangements.
- Examine whether CPAs unnecessarily dictate disease or patient specificity.¹

The National Alliance of State Pharmacy Associations’ (NASPA’s) Executive Committee directed staff to convene a workgroup to build upon the NGA recommendations with additional specificity. The workgroup was charged with examining existing state CPA laws and regulations. The workgroup was tasked with developing recommendations for what elements of collaborative practice authority should appropriately be defined under state law and/or regulation, and what elements are best left to be determined between pharmacists and other practitioners when developing their specific collaborative practice arrangement. Using a modified Delphi method, the Collaborative Practice Workgroup conducted this work with two key questions in mind:

- Is this recommendation in the best interest of the patient receiving care under a collaborative agreement?
- Is this recommendation aligned with pharmacists’ education and training?

The following is a report of the workgroup’s recommendations.

¹ National Governors Association. *The Expanding Role of Pharmacists in a Transformed Health Care System*. <http://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf>. Accessed 6.15.15

WORKGROUP RECOMMENDATIONS

The workgroup took the approach that rapid innovation in education, training, technology, and evidence-based guidelines necessitate a collaborative practice framework that is flexible and facilitates innovation in care delivery. Thus the following statements include two levels of recommendations:

1. Elements of collaborative practice authority that should be codified in state law and/or state regulations; and
2. Elements that are more appropriately determined by the parties at the practice level who voluntarily enter into a CPA, and thus for which the laws and regulations should be silent.

The workgroup views both levels of recommendations as needed and synergistic. State law and/or regulations, if too restrictive, can impede innovative team-based care models.

COLLABORATIVE PRACTICE AGREEMENT PARTICIPANTS

RECOMMENDED ELEMENTS FOR INCLUSION IN STATE LAWS AND/OR REGULATIONS

Collaborative practice laws and/or regulations should specify that:

- Any practitioner with prescriptive authority may collaborate with pharmacists using a CPA.
- CPAs may be between a single or multiple pharmacists and a single or multiple prescribers.
- CPAs may apply to a single patient, multiple patients, or patient populations as specified in the agreement.

ELEMENTS THAT MAY BE DETERMINED AT THE PRACTITIONER LEVEL

Individual CPAs may address the below elements but state laws and/or regulations should be silent.

- CPAs should specify which patient(s) and/or patient population(s) can receive services under the agreement.
- Depending on the complexity of the services being provided under a CPA, it may be appropriate for the pharmacist to have additional credentials or training, beyond what is required for licensure.
- CPAs should specify which pharmacist(s) may provide services under the CPA. A pharmacist's practice setting should not be a barrier to their ability to enter into a CPA.

COLLABORATIVE PRACTICE AGREEMENT AUTHORIZED SERVICES

RECOMMENDED ELEMENTS FOR INCLUSION IN STATE LAWS AND/OR REGULATIONS

Collaborative practice laws and/or regulations should specify that:

- The initiation and modification of drug therapy may be authorized under a CPA with a prescriber.

ELEMENTS THAT MAY BE DETERMINED AT THE PRACTITIONER LEVEL

Individual CPAs may address the below elements but state laws and/or regulations should be silent.

- In some situations, the use of an evidence-based protocol can ensure optimal care when pharmacists are initiating or modifying drug therapy and may be included in the CPA, though they may not be needed or appropriate in others.

- Performing physical assessments, as well as ordering, performing, or interpreting laboratory tests (e.g., CLIA-waived tests) may be included in a CPA to help identify or refer patients for services, however a pharmacist may also perform these services without a CPA as these activities should fall within pharmacists' standard scope of practice.
- Specific disease states may be included in a CPA at the participating practitioners' discretion.

COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS AND RESTRICTIONS

RECOMMENDED ELEMENTS FOR INCLUSION IN STATE LAWS AND/OR REGULATIONS

Collaborative practice laws and/or regulations should specify that:

- All prescription drugs, including controlled substances, may be included within pharmacists' collaborative practice authority.
- CPAs should be maintained by the pharmacist(s) and collaborating prescriber(s) and be available upon request or inspection.

ELEMENTS THAT MAY BE DETERMINED AT THE PRACTITIONER LEVEL

Individual CPAs may address the below elements but state laws and/or regulations should be silent.

- Pharmacist(s) and prescriber(s) may specify the level of patient involvement in the CPA. Depending on the level of service, elements such as informed consent, written consent or opt-out provisions may be appropriate, as determined by the parties to the agreement.
- Agreements should not be required to be sent to or approved by a state regulatory board or other agency; such requirements create unnecessary paperwork burden and slow the efficiency of care delivery.
- Collaborating practitioners are encouraged to review and/or renew their CPAs within a timeframe that is clinically appropriate.
- Collaborating practitioners should conform to evidence-based guidelines and the agreed upon process of care with regards to the documentation requirements, and the collaborating practitioner's responsibility for review of services provided under the agreement.
- Practitioners may consider liability insurance provisions, and the appropriateness of articulating these in their voluntary agreement.
- It is the professional duty of all healthcare professionals to stay current in the clinical areas in which they practice. If individual practitioners determine that continuing education requirements are appropriate for their clinical arrangement, they may be specified in the agreement.

APPENDIX A: WORKGROUP PARTICIPANTS

The individuals listed below were appointed to participate in the Collaborative Practice Workgroup by one of two methods. NASPA invited all Joint Commission of Pharmacy Practitioners (JCPP) member organizations' CEOs to appoint a representative from their organization to participate (an invitation for an appointment was also extended to the National Association of Chain Drug Stores, who currently is not a member of JCPP). It was recommended that professional affairs staff be considered for this work.

State representatives were nominated by state pharmacy associations and appointed by the NASPA Executive Committee. The selection process was intended to produce a group of participants who had experience with CPAs and practice in a variety of settings.

Of note, participants were only asked to represent their own opinions. Participants from the national pharmacy associations were not acting as representatives of their organizations but rather as individuals whose experiences with their various memberships provide them with an informed perspective.

Name	State/National	Organization/State
Alex Adams	National	NACDS
Jennifer Bacci	State	Pennsylvania
Lynette Bradley-Baker	National	AACP
Anne Burns	National	APhA
Carolyn Ha	National	NCPA
Julie Johnson	State	Minnesota
Sandra Leal	State	Arizona
Christine Lee-Wilson	State	Maryland
Dianne Miller	State	Michigan
Susan Oh	National	AMCP
Anthony Pudlo	State	Iowa
Kelly Ridgway	State	Arizona
Scotti Russell	National	NABP
Douglas Scheckelhoff	National	ASHP
L. Michelle Vaughn	State	Alaska
Pete Vlasses	National	ACPE
Ed Webb	National	ACCP
Bryan Ziegler	State	South Carolina

APPENDIX B: MODIFIED DELPHI METHOD

The goal of the workgroup was to reach consensus on each of the elements discussed. To do this, a modified Delphi method was used. A survey was sent to all participants to collect their initial thoughts on each of the elements identified in currently existing collaborative practice authority laws and/or regulations. Participants were given the current variations of each element as a multiple-choice selection with the opportunity to answer in free form text if the desired option was not listed. After completion of the survey, the workgroup discussed all questions where consensus was not already reached via conference call. The conference call discussions were structured to have a defined period of time for discussion, followed by a summary of the current options being discussed, and a roll call vote by each of the participants. The item was included on the next survey if consensus was not reached on the conference call. This process was repeated a total of three times before the group reached consensus on all items being considered. See below for a diagram of the process used.

