

COLLABORATIVE PRACTICE AGREEMENT

CARDIOVASCULAR DISEASE

TEMPLATE

[Community Pharmacy Name]

[address]

[phone number]

[Physician Practice]

[address]

[phone number]

Effective: [date]

Expiration: [date]

TEMPLATE

TABLE OF CONTENTS

I.	Introduction	1
II.	Collaborative Practice Agreement for Cardiovascular Disease	2
	i. Purpose and Goal	2
	ii. Physician and Pharmacist Eligibility	2
	iii. Liability	2
	iv. Documentation and Record Keeping	3
	v. Communication and Supervision	3
	vi. Quality Assurance and Improvement	4
	vii. Delegated Authority	4
II.	Protocol 1: Diabetes Management	6
	i. Quantity Adjustments	6
	ii. Refill Authorization	6
	iii. Formulation Interchange	6
	iv. Therapeutic Interchange	6
	v. Drug Optimization	7
	vi. Therapeutic Monitoring and Follow-up	8
	vii. Medication Management	8
	viii. Over-the-Counter (OTC) Product	8
III.	Protocol 2: Hypertension Management	9
	i. Quantity Adjustments	9
	ii. Refill Authorization	9
	iii. Formulation Interchange	9
	iv. Therapeutic Interchange	9
	v. Drug Optimization	10
	vi. Therapeutic Monitoring and Follow-up	10
	vii. Medication Management	10
	viii. Over-the-Counter (OTC) Product	10

IV.	Protocol 3: Hyperlipidemia Management	11
i.	Quantity Adjustments	11
ii.	Refill Authorization	11
iii.	Formulation Interchange	11
iv.	Therapeutic Interchange	11
v.	Drug Optimization	12
vi.	Therapeutic Monitoring and Follow-up	12
vii.	Medication Management	12
viii.	Over-the-Counter (OTC) Product	12
V.	Appendix A: Prescription Medication Update Form	13

Introduction

A collaborative practice agreement (CPA) is a written document that represents a formal relationship between qualified pharmacists and prescribers. CPAs expands the professional responsibility of pharmacists in the delivery of patient care by authorizing pharmacists to perform additional services within the context of a defined disease or patient specific protocol. CPA authorizes the delegation of tasks on behalf of a prescriber, such as initiating, monitoring or adjusting patient medications, ordering laboratory testing and administering specified medications. It is a partnership utilized to expand team-based health care.

The following is a template that was developed to provide a step-wise approach to create any CPA. It is customizable to meet the needs of unique relationships between healthcare providers, as well as different practices. Actions authorized under this CPA must be agreed upon by both prescribers and pharmacists entering this agreement. Additional information of CPAs can be found in the Centers for Disease Control's (CDC's) CPA toolkits: [A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases](#) and [Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team](#).

Note that the boxed texts throughout the CPA are intended to provide additional information and guidance. The boxes should be removed from the final CPA.

As part of a grant funding issued by the Michigan Department of Health and Human Services' (MDHHS) Heart Disease and Stroke Prevention Unit and the Diabetes and Kidney Unit, the Michigan Pharmacists Association (MPA) convened a CPA stakeholder workgroup. The following individuals were appointed to participate in the Collaborative Practice Stakeholder Workgroup based on their background and involvement in CPA efforts:

Jodie Elder, Pharm.D., BCPS

Nada Farhat, Pharm.D., BCPS, BCACP

Candice Garwood, Pharm.D., FCCP, BCPS, BCACP

Tiffany Jenkins, Pharm.D., BCACP

Rachel Kollmeyer, Pharm.D., BCACP

Phil Levy, M.D., MPH, FAHA, FACC

Melissa Lipari, Pharm.D., BCACP

Brittany Stewart, RD, Pharm.D.

Pragnesh Patel, M.D.

The workgroup was facilitated by MPA Director of Professional Development, Farah Jalloul, Pharm.D., MBA, and MPA/PSI Executive Fellow, Carol Bugdalski-Stutrud, B.S.Pharm. The workgroup was charged with creating a CPA template for hypertension, diabetes and hyperlipidemia. The template is intended to serve as a blueprint utilized by pharmacists and physicians to promote the adoption of the customized CPA into practice. The template was independently reviewed by the Michigan State Medical Society (MSMS) for additional review and input.

COLLABORATIVE PRACTICE AGREEMENT FOR CARDIOVASCULAR DISEASE

PURPOSE AND GOAL

This section defines the purpose and goal of the agreement; both should be agreed on by the delegating prescriber and pharmacists operating under the CPA.

Acting in good faith, [Community pharmacy] and [physician practice or delegating physician] are committed to providing high quality care, in the most affordable, efficient way. The creation of multi-disciplinary teams who can function as care extenders is one way to achieve these goals and provide excellent patient care. The purpose of this agreement is to enhance collaborative patient care and optimize medication-related outcomes for mutual patients of [community pharmacy] and [physician practice]. The goal of the CPA is to:

- Optimize drug therapy for cardiovascular risk factor(s) named under this CPA.
- Reach clinical health targets and quality metrics set by standard guidelines, as agreed upon by the delegating physician.
- Improve patient adherence and medication access.
- Increase access to healthcare providers.
- Improve the health of patients and their quality of life.

PHYSICIAN AND PHARMACIST ELIGIBILITY

The following section identifies who is eligible to operate under the CPA. It could include criteria such as specified educational requirements, licensure and certifications.

Physicians of [physician practice] and pharmacists of [community pharmacy] are considered qualified providers to participate in patient-care activities related to this agreement. All qualified personnel are expected to maintain up-to-date competencies and knowledge of current guidelines for disease states covered under this agreement

[List educational requirements agreed upon for the pharmacist, i.e., residency training, board certification or one-hour of continuing education training pertaining to a specific disease state]

All providers must be licensed in good standing with their respective board and follow established standards for entering and managing a collaborative practice agreement. Student pharmacists may participate in patient-care activities related to this agreement, under the supervision of a pharmacist.

LIABILITY

A liability clause defines the legal responsibility of the delegating physician and pharmacist.

In accordance with the requirements of the Michigan Public Health Code §16215(1)¹ and subject to the terms of this agreement, the delegating physician has determined that the delegated pharmacist is qualified by education, training or experience to perform the services in accordance with the accepted medical standard of care. The delegating physician acknowledges responsibility for supervising the delegated pharmacist's performance of the services and accepts legal and ethical responsibility for any services undertaken by the delegated pharmacist pursuant to this agreement. Delegating physician(s) and pharmacists are not required to but are highly recommended to maintain liability insurance that covers the actions identified.

DOCUMENTATION AND RECORD KEEPING

Proper documentation of any CPA activity is essential to maintain accurate patient records. Documentation in the patient's electronic medical record (EMR) is recommended; therefore, bi-directional access to the EMR is strongly encouraged. If EMR access cannot be established or maintained, another form of documentation should be utilized. This section outlines the documentation and record keeping requirements.

Patient-care encounters with a pharmacist must be documented *[include process for documentation; i.e., in the patient's EMR or on a standardized facsimile signed by the pharmacist]*. If faxed, physician practice support staff shall document all patient-care encounters taken under this agreement in the patient's EMR.

The pharmacy must also retain a copy of the form utilized either electronically (scanned into the pharmacy's prescription processing database) or as a hard copy. All records in the pharmacy must be readily retrievable and shall be retained in accordance with Michigan laws, rules and regulations (R 338.3153; R 338.479b; 42 CFR § 422.504). Refer to Appendix A for a template of a Prescription Medication Update fax form.

COMMUNICATION AND SUPERVISION

The following section describes the communication method to be utilized by the delegating prescriber and pharmacist. It also outlines the level of supervision requested by the delegating prescriber.

Routine communication shall be conducted through telephone, fax, electronic communication or secure email as deemed appropriate by the two parties. Interventions resolved by a pharmacist shall be communicated to the physician practice in a timely manner via *[include method agreed up by both parties]*. The communication will include the rationale for each intervention and a recommendation for a timeline for physician follow-up. The physician must review the actions of the pharmacist within a timely manner. In the event a physician disagrees with a decision made by the pharmacist under this agreement, the referring physician is permitted to override that pharmacist's decision by communicating the overridden action via fax or electronically.

¹ A licensee who holds a license other than a health profession subfield license may delegate to a licensed or unlicensed individual who is otherwise qualified by education, training, or experience the performance of selected acts, tasks or functions where the acts, tasks or functions fall within the scope of practice of the licensee's profession and will be performed under the licensee's supervision. An act, task or function shall not be delegated under this section which, under standards of acceptable and prevailing practice, requires the level of education, skill and judgment required of a licensee under this article. MPHC article §16215(1).

Physician agrees to be continuously available in person or by telecommunications for consultation and support when Pharmacist is providing Services under this Collaboration Agreement. On a regular basis, Physician shall review any Services provided by the Pharmacist and provide Pharmacist with appropriate feedback and education.

QUALITY ASSURANCE AND IMPROVEMENT

This section describes the activities utilized to assure improvement in quality of care. It may involve assessing the quality of care provided, identifying problems with the delivery of care and designing quality improvement activities to overcome.

Physician and Pharmacist shall conduct meetings on a regular basis, no less than [desired time frame; i.e., annually], to review and update this Collaboration Agreement, and to establish mutual written goals, parameters, protocols and clinical standards for providing care under this Collaboration Agreement. Both parties agree to ongoing development of this relationship and evaluation on regular intervals, both formally and informally.

DELEGATED AUTHORITY

This section establishes the authority in which delegation through CPA can occur. A list of physician(s) and pharmacist(s) identified under the CPA may be listed under this section. An appendix can also be attached if several practitioners are involved. Note: medical directors may be authorized to sign an agreement on behalf of the practice.

According to, and in compliance with, the Michigan Public Health Code, MCL 333.16215 sets forth the requirements for delegation, stating that: "a licensee who holds a license other than a health profession subfield license may delegate to a licensed or unlicensed individual who is otherwise qualified by education, training, or experience the performance of selected acts, tasks, or functions where the acts, tasks, or functions fall within the scope of practice of the licensee's profession and will be performed under the licensee's supervision. A licensee shall not delegate an act, task, or function under this section if the act, task, or function, under standards of acceptable and prevailing practice, requires the level of education, skill, and judgment required of the licensee under this article." The article referred to under this Statute is Article 15, Occupations. Pharmacists are licensed under Part 177 of Article 15 of the Michigan Public Health Code, Public Act 368 of 1978.

I, [medical director name or delegating physician's name], a licensed healthcare provider authorized to prescribe medication in the state of [state], authorize the pharmacists named under [Section XXX or Appendix XXX], who hold an active license to practice issued by the state of [state], to manage and/or treat patients pursuant to the parameters outlines in this agreement under [Protocol XXX or this agreement]. As the authorizing prescriber, I authorize staff under my supervision and will be available to review drug therapy adjustments by pharmacists.

This authority pertains to the protocol established in this agreement in accordance with all state laws and regulations. This agreement is valid for up to XXX years following signatures of all

parties, unless rescinded earlier in writing by either party, with or without cause. Any modification of the protocol shall be treated as a new protocol, requiring signed approval from responsible parties. The patient, at any time, may withdraw from the agreement with a written notice of termination. A record of provision of care by a pharmacist shall be maintained in the patient's pharmacy record, which is available to the pharmacist.

Prescribers may exempt a specific patient intervention from this agreement whenever they deem such action necessary or appropriate. This will not affect the agreement relative to other patients.

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

[Name of delegating physician] or Physicians of [physician practice]

[address]

[phone]

[fax]

[E-mail]

[Medical license number]

[NPI]

[Name of authorized pharmacist] or Pharmacists of [community pharmacy]

[address]

[phone]

[fax]

[E-mail]

[Pharmacy/pharmacist license number]

[NPI]

Signatures of Responsible Parties:

[medical director or delegating physician's name]

Medical Director

[physician practice]

License Number

Date

[pharmacy manager name]

Pharmacy Manager

[community pharmacy]

License Number

Date

Protocol 1: Diabetes Management

The following section will provide additional guidance on the patient care services authorized under this CPA for diabetes management. Note that not all sections are required. It is important to customize patient care functions to fit the need of the pharmacy, physician and patient population. Protocols should be developed using current evidence based guidelines and in collaboration with the delegating prescriber.² Evidence based guidelines change routinely and it is advised that these are reviewed on an annual basis.

Pharmacists authorized under this CPA may carry out the following patient care services in accordance with this section. The pharmacist shall exercise his or her professional judgment prior to engaging in any of the following patient care functions.

QUANTITY ADJUSTMENTS

Pharmacists may adjust drug quantities on prescriptions to optimize the treatment of diabetes to dispense additional refills.

REFILL AUTHORIZATION

Pharmacists may dispense additional refills on a medication [insert number of authorized refills]. Once the maximum number of additional refills are dispensed or for any reason the pharmacist believes it is in the patient's best interest to follow up with their prescriber, the pharmacist shall refer the patient back to their back to their provider.

FORMULATION INTERCHANGE

After consulting with a patient, a pharmacist may change the formulation of a prescribed drug when appropriate to improve adherence and increase affordability for the patient. Acceptable formulation interchange includes:

[List approved formulation interchange, as agreed upon by both parties. This may include switching to or from combination products or switching to a different time release formulation].

THERAPEUTIC INTERCHANGE

Note that therapeutic interchange is the modification of drug therapy to dispense a drug different from the drug prescribed. The CPA may include a list of acceptable drugs to interchange. It is suggested that both parties review the drug classes and appropriate algorithms to determine what best fits the need of the population being served.

² Evidence based guidelines and information can be gathered from the following organizations: the American Diabetes Association (ADA): www.Professional.Diabetes.org and the American Association of Clinical Endocrinologists (AACE): www.AACE.com.

The following are examples of what the suggested therapeutic interchange language might look like for the CPA that is created for your practice:

Insulin-

Pharmacists may interchange between the following short-acting and rapid-acting insulin products at an equivalent one to one dosing ratio.

- [List approved insulins authorized for interchange]

Pharmacists may interchange between the following mixed insulin products at an equivalent one to one dosing ratio:

- [List approved insulins authorized for interchange]

Pharmacists may interchange between the following basal insulin products at an equivalent one to one dosing ratio:

- [List approved insulins authorized for interchange]

Oral agents

Pharmacists may interchange between the following sulfonylureas at equivalent dosing:

- [List approved agents authorized for interchange]

Pharmacists may interchange between the following dipeptidyl peptidase-4 (DPP-4) inhibitors at equivalent dosing:

- [List approved agents authorized for interchange]

Pharmacists may interchange between the following selective sodium-glucose transporter-2 (SGLT-2) at equivalent dosing:

- [List approved agents authorized for interchange]

Pharmacists may interchange between the following glucagon-like peptide 1 (GLP-1) at equivalent dosing:

- [List approved agents authorized for interchange]

DRUG OPTIMIZATION

There are many instances where titration, de-escalation or discontinuation of antidiabetic medications may occur. Both parties must agree upon the therapeutic algorithm.

The following are examples of what the suggested drug optimization language might look like for the CPA that is created for your practice:

Metformin Titration

- Pharmacists may authorize metformin titration to achieve target hemoglobin A1c of less than seven percent.
- For patients currently using metformin, metformin dose may be adjusted up to 2,550mg/day in divided doses based on blood sugar response and patient tolerability.
- Pharmacists may convert metformin to an extended-release formulation to improve patient tolerability.

THERAPEUTIC MONITORING AND FOLLOW-UP

Follow-up visits with patients will be scheduled and charts will be reviewed at [insert agreed upon interval] depending on patient's response and adherence to treatment. Delegated pharmacist shall follow-up with the patient after modifying/discontinuing therapy. This can take place over the phone or face-to-face, as required, until patient reaches A1C goal. When at goal for at [insert agreed upon interval], follow-up can occur every [insert agreed upon interval].

MEDICATION MANAGEMENT

Pertinent laboratory testing is authorized under this protocol to monitor therapy and outcomes, including A1C and [insert other approved lab testing as agreed upon].

OVER-THE-COUNTER (OTC) PRODUCT

In compliance with federal and state laws and regulations, pharmacists may authorize up to one-year refills of the following OTC products. Below are examples of OTC supplies that might be necessary in order to appropriately monitor. Each list is customizable to the agreed upon protocol.

The dispensing of following OCT products via a prescription is authorized under this protocol:

- Blood glucose testing supplies, including: blood glucose monitors, test strips, lancets, alcohol swabs and lancing devices
- Injection supplies, including: pen needles, needles and syringes
- OTC oral hypoglycemic medications, including: glucose products (tablets, gel, etc.)
- Aspirin
- [List additional OTCs authorized]

Protocol 2: Hypertension Management

The following section will provide additional guidance on the patient care services authorized under this CPA for hypertension management. Note that not all sections are required. It is important to customize patient care services to fit the need of the pharmacy, physician and patient population. Protocols should be developed using current evidenced based guidelines and in collaboration with the delegating prescriber³. Evidenced based guidelines change routinely and it is advised that these are reviewed on an annual basis.

Pharmacists included under this CPA may carry out the following patient care services in accordance with this section. The pharmacist must exercise of his or her professional judgment prior to engaging in any of the following patient care functions.

QUANTITY ADJUSTMENTS

Pharmacist may adjust drug quantities on prescriptions to optimize treatment of hypertension to dispense additional refills.

REFILL AUTHORIZATION

Pharmacists may dispense additional refills on a medication [insert number of authorized refills]. Once the maximum number of additional refills are dispensed or for any reason the pharmacist believes it is in the patient's best interest to follow up with their prescriber, the pharmacist shall refer the patient back to their provider.

FORMULATION INTERCHANGE

After consulting with a patient, a pharmacist may change the formulation of a prescribed drug as appropriate to improve adherence and increase affordability for the patient. Acceptable formulation interchange includes:

[List approved formulation interchange, as agreed upon by both parties. This may include switching to or from combination products or switching to a different time release formulation.]

THERAPEUTIC INTERCHANGE

Note that therapeutic interchange is the modification of drug therapy to dispense a drug different from the drug prescribed. The CPA should include a list of acceptable drugs to interchange. It is suggested that both parties review the drug classes and appropriate algorithms to determine what best fits the need of the population being served.

The following are examples of what the suggested therapeutic interchange language might look like for the CPA that is created for your practice:

³ Evidence based guidelines and information can be gathered from the following organizations: the Joint National Committee, the American Academy of Family Physicians: www.AAFP.org, the American Heart Association: www.Heart.org, and the American College of Cardiology (ACC): www.ACC.org.

Pharmacists may interchange between the following angiotensin converting enzyme inhibitors (ACEI):

- [List approved ACEI authorized for interchange]

Pharmacists may interchange between the following calcium channel blockers (CCB):

- [List approved CCB authorized for interchange]

Pharmacists may interchange between the following angiotensin receptor blocker (ARB):

- [List approved ARB authorized for interchange]

DRUG OPTIMIZATION

There are many instances where titration, de-escalation or discontinuation of antihypertensive medications may occur. Both parties must agree upon the therapeutic algorithm.

The following are examples of what the suggested drug optimization language might look like for the CPA that is created for your practice:

Amlodipine Titration

- Pharmacists may authorize amlodipine titration to achieve target blood pressure goal.

THERAPEUTIC MONITORING AND FOLLOW-UP

Follow-up visits with patients will be scheduled and charts will be reviewed at [insert agreed upon interval] depending on patient's response and adherence to treatment. Delegated pharmacist shall follow-up with the patient after modifying/discontinuing therapy. This can take place over the phone or face-to-face, as required, until blood pressure goal is established. When at goal for at [insert agreed upon interval], follow-up can occur every [insert agreed upon interval].

MEDICATION MANAGEMENT

Pertinent laboratory testing is authorized under this protocol to monitor therapy and outcomes, including urinalysis, basic metabolic panel and [insert other approved lab testing as agreed upon].

OVER-THE-COUNTER (OTC) PRODUCTS

In compliance with federal and state laws and regulations, pharmacists may authorize up to one-year refills on OTC products. Each list is customizable to the agreed upon protocol.

Protocol 3: Hyperlipidemia Management

The following section will provide additional guidance on the patient care services authorized under this CPA for the management of hyperlipidemia. Note that not all sections are required. It is important to customize patient care functions to fit the need of the pharmacy, physician and patient population. Protocols should be developed using current evidenced based guidelines and in collaboration with the delegating prescriber.⁴ Evidenced based guidelines change routinely and it is advised that these are reviewed on an annual basis.

Pharmacists authorized under this CPA may carry out the following patient care services in accordance with this section. The pharmacist shall exercise his or her professional judgment prior to engaging in any of the following patient care functions.

QUANTITY ADJUSTMENTS

Pharmacists may adjust drug quantities on prescriptions for the treatment of diabetes to dispense quantities to optimize treatment

REFILL AUTHORIZATION

Pharmacists may dispense additional refills on a medication [insert number of authorized refills]. Once the maximum number of additional refills are dispensed or for any reason the pharmacist believes it is in the patient's best interest to follow up with their prescriber, the pharmacist shall refer the patient back to their provider.

FORMULATION INTERCHANGE

After consulting with a patient, a pharmacist may change the formulation of a prescribed drug only to improve adherence and increase affordability on the patient. Acceptable formulation interchange includes:

[List approved formulation interchange, as agreed upon by both parties. This may include switching to or from combination products or switching to a different time release formulation]

THERAPEUTIC INTERCHANGE

Note that therapeutic interchange is the modification of drug therapy to include the dispensing of a drug different from the drug prescribed. The CPA may include a list of acceptable drugs to interchange. It is suggested that both parties review the drug classes and appropriate algorithms to determine what best fits the need of the population being served.

The following are examples of what the suggested therapeutic interchange language might look like for the CPA that is created for your practice:

⁴ Evidence based guidelines and information can be gathered from the following organizations: the American College of Cardiology (ACC): www.ACC.org and the American Heart Association: www.Heart.org.

Pharmacists may interchange between the following HMG-CoA reductase inhibitors (statins) at the following equivalency:

- [List approved statins authorized for interchange]

DRUG OPTIMIZATION

There are many instances where titration, de-escalation or discontinuation of antihyperlipidemic medications may occur. Both parties must agree upon the therapeutic algorithm.

The following are examples of what the suggested drug optimization language might look like for the CPA that is created for your practice:

Atorvastatin titration

- Pharmacist may titrate up a patient's atorvastatin dose to achieve target blood cholesterol levels.

THERAPEUTIC MONITORING AND FOLLOW-UP

Follow-up visits with patients will be scheduled and charts will be reviewed at [insert agreed upon interval] depending on patient's response and adherence to treatment. Delegated pharmacist shall follow-up with the patient after modifying/discontinuing therapy. This can take place over the phone or face-to-face, as required, until patient reaches blood cholesterol (total cholesterol, LDL, HDL and/or triglyceride) goal. When at goal [insert agreed upon interval], follow-up can occur every [insert agreed upon interval].

MEDICATION MANAGEMENT

Pertinent laboratory testing is authorized under this protocol to monitor therapy and outcomes, including total cholesterol, LDL, HDL, triglycerides and [insert other approved lab testing as agreed upon].

OVER-THE-COUNTER (OTC) PRODUCTS

In compliance with federal and state laws and regulations, pharmacists may authorize up to one-year refills on OTC products. Each list is customizable to the agreed upon protocol.

Appendix A: Prescription Medication Update Form

TO:

[Insert Dr. name]

[Insert practice]

[Insert contact number]

FROM:

[Insert pharmacist name]

[Insert pharmacy name]


[Insert contact number]

RE: Changes to our mutual patient's drug therapy


Patient Name: _____ DOB: _____

Under the CPA signed by Dr. [insert Dr. name here] on [date of CPA signed agreement] a pharmacist made the following changes to a mutual patient's drug therapy:

DISCONTINUED PRESCRIPTION

	Encounter Date: <u>mm/dd/yy</u>
	REFILL _____ TIMES
	Dr. _____ Prescriber
Pharmacist Signature _____	

INITIATED PRESCRIPTION

	Encounter Date: <u>mm/dd/yy</u>
	REFILL _____ TIMES
	Dr. _____ Prescriber
Pharmacist Signature _____	

Rationale:

☐ Recommend physician follow-up in ____ weeks.