



COLLABORATIVE PRACTICE AGREEMENTS

An Implementation Guide for Community Pharmacies



St. Vincent de Paul charitable pharmacy

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ABOUT US

St. Vincent de Paul Charitable Pharmacy is the only organization in southwest Ohio dedicated to the unique mission of improving the health and welfare of community residents by providing free, pharmaceutical care to individuals living in poverty. When the poor and vulnerable of our community have no other place to turn, the Society of St. Vincent de Paul provides spiritual and material assistance, regardless of race or creed. People in financial crisis often make choices that sacrifice their health, forgoing prescriptions to pay for other necessities. The Charitable Pharmacy serves as a last resort for people who have no other way of accessing their prescription medications. Since opening in 2006, the pharmacy has dispensed more than 370,000 prescriptions valued over \$42 million.



ACKNOWLEDGEMENTS

St. Vincent de Paul (SVDP) Charitable Pharmacy in collaboration with Good Samaritan Free Health Center (GSFHC), University of Cincinnati James L. Winkle College of Pharmacy (UC), and Ohio Northern University Raabe College of Pharmacy (ONU) developed this guide for the implementation of collaborative practice agreements in community pharmacies. Funding for this guide was provided by the Community Pharmacy Foundation.

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PURPOSE

The purpose of this toolkit is to guide community pharmacists and primary care providers in a step-wise approach toward the implementation of collaboration practice agreements. This guide intends to promote the role of community pharmacists in team-based care, particularly for the management chronic diseases.

While collaborative practice has been routinely used in health system and ambulatory care settings, few models exist for practical approaches to implementation in community pharmacy settings. Strategies recommended in this guide were tested in a pilot program between St. Vincent de Paul Charitable Pharmacy and Good Samaritan Free Health Center. The recommendations and tools provided in this document demonstrate the lessons learned through this pilot program.

The information in this document should not be considered legal advice. Use of this guide may complement an organization's development of policies and procedures with advice from legal counsel specific to state law jurisdiction.

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COMMUNITY PHARMACISTS AND TEAM-BASED CARE

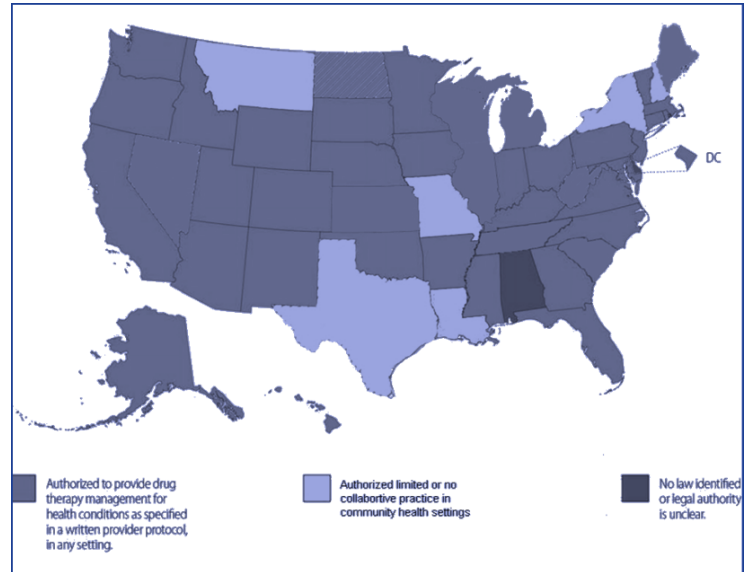
Chronic diseases are the most common and most expensive of all health problems. By 2020, over 157 million Americans will have a chronic health condition. Of the top ten causes of death in 2014, seven were chronic diseases.¹ Americans spend over \$300 billion per year on medications, and 91% of these medications are used for the treatment of a chronic condition. Despite the high volume of prescription use in the U.S., \$41 billion is spent annually on hospital readmissions and two out of three readmissions are medication-related.²

While chronic conditions continue to rise, medically underserved areas persist. An estimated 86% of Americans live within 5 miles of a community pharmacy. With further inclusion of community pharmacists into team-based care, medically underserved areas may find an improvement in access to health care specifically for chronic conditions.²

Collaborative Practice Agreements (CPAs) are formal relationships between pharmacists and prescribers that specify the functions a pharmacist can perform in addition to the typical scope of practice. The delegation of responsibilities from a prescriber to a pharmacist has been utilized in institutional and ambulatory care settings for various services (i.e. anticoagulation, diabetes management), but few models exist for the use of CPAs in community pharmacies.

Nearly every state in the U. S. has some version of law allowing for collaborative practice between a prescriber

and pharmacist. Currently, 42 states allow for collaborative practice in any setting a pharmacist practices, including the community pharmacy.³ However, the busy workflow of the typical community pharmacy is one of



the biggest barriers to the effectively integrating CPAs into mainstream pharmacy practice. Additionally, few business plans exist to financially justify the augmentation of clinical services with a CPA in a community pharmacy. Innovative models for overcoming these barriers can be useful to implement CPAs, thereby integrating the community pharmacist into a team-based approach to health care.

Steps to Implement a CPA

- 1 Establishing Collaboration and Trust**
- 2 Developing the Business Plan**
- 3 Building a Collaborative Infrastructure**
- 4 Designing a Collaborative Practice Agreement**

ESTABLISHING COLLABORATION AND TRUST

Initiation

Initiation of a working relationship between pharmacists and physicians requires collaboration from both parties seeking to allow pharmacists to fill a need at the medical practice site.^{4,7} Frequent, face-to-face communication is important in the development of a professional and collaborative relationship. Pharmacists physically providing care within the physician practice is an ideal way to initiate this working relationship. By establishing on-site clinical pharmacy services with limited but scheduled availability, the pharmacist is able to establish rapport with physicians and medical support staff as a member in team-based care. Large time commitments for pharmacists are typically not feasible for most community pharmacies, but scheduling a half day every other week is a reasonable first step to initiating the relationship.

Trust

Trust can be the most difficult resource to gain in the development of a CWR, but CPAs are dependent on garnering physician trust of not only the pharmacist, personally, but also the profession of pharmacy, generally. To create a successful relationship, physicians must be confident in the pharmacist's clinical skills as well as organizational abilities to properly train, document, and communicate utilization of the CPA. Credibility may be established by advanced credentialing, professional memberships, and patient-care experience, but trust often begins by the shared testimony of collaborators within the profession, such as a college of pharmacy, and outside the profession, such as a physician who champions pharmacists' inclusion in team-based care.^{6,7}



The development of CPAs between physicians and pharmacists requires a collaborative working relationship (CWR) with interpersonal, business, and patient-care facets. In team-based care, the CWR is dictated by the context of the practice sites and dynamics of the exchanges between the providers. Initiating the relationship, defining the interactions, building trust, and specifying provider roles are the most dominant drivers in the implementation of these relationships.^{4,5}

Interactions

Pharmacist-led services, such as tobacco cessation counseling and diabetes self-management education, are programs that typically offer added patient-care value as an adjunct to primary care. The initiation of clinical pharmacy services on a routine basis establishes the pharmacist's role in team-based care and lays the groundwork for the sharing of information between a community pharmacy and a physician practice for mutual patients. As the pharmacist builds credibility through repeated face-to-face interactions, discussions of CPA may naturally ensue for disease states managed by the pharmacist in the clinic. As the relationship develops, expansion of the CPA may broaden the pharmacist's potential to impact patient care and further develop the business model.

Role Specification

A clearly defined scope of practice is essential to the development of a CWR, allowing physicians and pharmacists to rely on each other to complete their negotiated responsibilities.⁴ 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.⁸ All members of the healthcare team must recognize each other's specific roles within a physician practice before further patient engagement within the community pharmacy can be realized. With the roles clearly specified, a pharmacist may design a strategy for scaling in-clinic services to the community pharmacy through specific interventions outlined in a CPA.

DEVELOPING A BUSINESS PLAN

The goal of the business plan is to provide a guide for the successful implementation of a CPA that is not only beneficial to all parties involved but also sustainable. A full version of a business plan (see Appendix A3) is designed as a template for community pharmacists to adapt to their organization's needs. By understanding the potential revenue a community pharmacy may gain through a CPA, pharmacists may be inclined to seek innovative collaboration that will integrate the use of CPAs in mainstream community pharmacies and physician practices.

Enhanced Billing of MTM Services

Through Medication Therapy Management (MTM) services, community pharmacists may be reimbursed for services. The comprehensive medication review is usually the highest dollar value for reimbursement, but this service generally leads to the identification of further reimbursable interventions.

Physician response is often a barrier to reimbursement. For many community pharmacies, a pharmacist will attempt to contact the physician three times before closing an intervention as unsuccessful due to lack of response. In most billing strategies, the reimbursement of

an unsuccessful intervention is 10% the reimbursement of a successful intervention.

By incorporating a CPA into MTM workflow, a pharmacist is provided the opportunity to initiate a therapeutic intervention and resolve this intervention without directly contacting the physician each time. Through this reimbursement strategy, pharmacist-led MTM interventions will achieve a 100% success rate through the use of a CPA. This change in workflow will decrease unsuccessful interventions for lack of timely physician communication.

Initiation of OTC Prescribing

For decades, pharmacists have been providing free clinical consultations to patients who are purchasing over-the-counter (OTC) products for self-treatment. While the pharmacist's organization may benefit from the sale of the OTC product, the pharmacist still acquires a significant liability for the professional advice that led to the purchase of the OTC treatment. The process of billing for consultation services is common practice in most healthcare settings, but community pharmacists provide consultations for free every day due to the lack of a reimbursement strategy for these services.

By purchasing products OTC, patients pay out-of-pocket foregoing their prescription insurance benefits.

Furthermore, patients add OTC products to their prescription regimen without a pharmacist's review of their full regimen. Through a CPA, a pharmacist could provide consultation for an OTC treatment as well as prescribe the product to the patient.

For instance, a patient may request a consultation by a pharmacist for nicotine patches. Under a CPA, a pharmacist may prescribe the OTC product, bill the insurance for the product and consultation, and perform a full drug utilization review for the patient. As a result, patient safety is improved and the potential for a successful quit attempt is increased. In addition, the community pharmacist has been compensated for dispensing and consultation.

BUILDING A COLLABORATIVE INFRASTRUCTURE

The feasibility of maintaining a CPA relies on the infrastructure to support it. Resources, both personnel and technology, are vital to efficient and effective team-based care. As opposed to many institutional-based pharmacies, community pharmacies support the expansion of physician authorities to off-site pharmacist collaborators. While community pharmacists are typically more accessible to the public than institutional pharmacists, they must overcome barriers to efficient communication to the initial site of care. Clearly defined personnel roles, policies and procedures for communication, and technology to support reliable communication and documentation are the essential framework for CPA development.

Team Members



MANAGEMENT

The management team of a CPA consists of the pharmacy manager and the medical director, collaborating for CPA development, quality assurance, and quality improvement. Collaboration within this management team will define the disease states and interventions managed by community pharmacists as well as the policies and procedures for resolving pharmacist-led interventions. Truly, the management team is the vector of the CPA, providing directional guidance and a timeline to achieving clinical goals. The management team will conduct regular reviews of data collected to investigate the outcomes of utilizing the CPA. At regularly scheduled intervals, the management team will meet to assure compliance to policies and procedures (at least quarterly) and ensure quality improvement (at least annually).



PHYSICIANS

Physicians entering in a CPA choose to expand limited prescriptive rights to community pharmacists in an effort to resolve the unmet needs of their patients. While CPAs have been proven to increase adherence and improve patient outcomes, few models exist for implementation in community pharmacies. For this reason, physicians must work with community pharmacists to identify gaps in patient care, delegating certain services that a pharmacist can provide through the CPA. In this relationship, the physician provides primary care during scheduled patient appointments, and the pharmacist provides secondary care between physician visits. By approving a CPA, the physician's role shifts from approving daily pharmacist-led interventions to receiving updates of resolved interventions. Without the approval delay, pharmacists are able to provide more efficient care while the patient is present in the community pharmacy. Physicians hold the right to override or withdraw approval from any action performed by a pharmacist under the CPA while working cooperatively in the best interest of the patient.



PHARMACISTS

The role of the community pharmacist operating under a CPA is to identify and resolve patient-care interventions in accordance to 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 community pharmacists through the expansion of a physician's license. Pharmacists may facilitate experiential learning by serving as a preceptor for residents and interns to assist in the delivery of patient-care services related to the CPA. Following resolution of pharmacist-led interventions, pharmacists must communicate changes to their collaborating physician in a timely manner.



PHARMACY INTERNS AND TECHNICIANS

Certain functions of a pharmacist may be facilitated by designees under a pharmacist's supervision. For pharmacists to operate sustainably at the top of their licensure, the use of designees in a community pharmacy is vital to efficiency. In 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.



MEDICAL SUPPORT STAFF

The role of medical support staff is to ensure communication from the community pharmacy is documented in the patient's electronic medical record and stored appropriately for immediate retrieval, if necessary. Physicians may assign medical support staff to facilitate this communication and subsequent documentation in the electronic medical record. When medication therapy changes are made, nurses or medical assistants may update the patient's medication list based on the pharmacist's use of the CPA. In some settings, pharmacy interns completing ambulatory care experiential learning may function as medical support staff.

Technology

Despite the growth in collaboration between primary care and community pharmacy, barriers to shared technology persist. Community pharmacies house valuable adherence data necessary for medication reconciliation in ambulatory care settings, and primary care practices store valuable diagnostic and laboratory data necessary for assurance of medication safety and patient education in community pharmacies. While shared technology between non-affiliated healthcare settings is ideal for patient care, many legal and business policies prohibit this level of data sharing. Innovative solutions, like software that collects and reports community pharmacy activity, have developed accessible databases for physicians, but they impose a financial burden to the entity offering this service. A breakthrough in team-based care may be recognized by investigating methods to share community pharmacy and physician practice data in one accessible, cost-effective database. Current practice often relies on telephone and fax for communication and an institution-specific electronic medical record for documentation.


ELECTRONIC MEDICAL RECORD

Among physician practices, a variety of electronic medical record (EMR) databases are used, but most contain similar features for intervention documentation. Because fax is still the most common method of communication between community pharmacies and physician practices, scanned imaging of pharmacy faxes is an ideal way to document all information communicated by a community pharmacist. Following a drug therapy change by CPA, a patient's medication list should be updated in the EMR. Additionally, a patient's follow-up visit with the physician should be scheduled to assess response due to the therapy change.



CPA FAX FORM

In most community pharmacies, fax is still the most convenient way to communicate with physician practices. A “Prescription Medication Update” fax form (Appendix A4) communicates to the physician any changes made by a community pharmacist. Along with pertinent patient and pharmacist information, the pharmacists will use this form to document a medication discontinuation or initiation along with a rationale for the drug therapy change. The pharmacist should consider recommending a time frame to schedule a follow-up with the physician following this therapy change. After the form is faxed to the physician, the CPA fax form serves as the hard-copy prescription to be processed in the pharmacy’s database.



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Phone: (513)347-0743
Fax: (513)347-0720

Prescription Medication Update

TO: Good Samaritan Free Health Center
3727 St. Lawrence Avenue, Cincinnati, OH 45239
Phone: (513)246-6888 Fax: (513)246-6887



FROM: _____, RPh

DATE: _____

RE: Changes to our mutual patient's drug therapy

Patient Name: _____ DOB: _____

As a physician extender under the consult agreement signed by Dr. R. Stephen Eby on 8/30/2017 in accordance with ORC 4729.39 and OAC 4729-29-02, a pharmacist made the following changes to a mutual patient's drug therapy:

DISCONTINUED PRESCRIPTION	INITIATED PRESCRIPTION
<div>  </div> <div>REFILL _____ TIMES</div> <div> Dr. R. Stephen Eby Prescriber </div>	<div>  </div> <div>REFILL _____ TIMES</div> <div> Dr. R. Stephen Eby Prescriber </div>

Rationale: _____

☐ Recommend physician follow-up in _____ weeks.

As a mutual patient of Good Samaritan Free Health Center and St. Vincent de Paul Charitable Pharmacy, I understand my physician has approved my pharmacist to make clinical decisions. I understand my right to opt out of prescription changes made by a pharmacist. By signing below, I provide consent for the pharmacist to intervene:

Patient Signature: _____ DOB: _____

Page _____ of _____



PRESCRIPTION PROCESSING DATABASE

Community pharmacies vary greatly in databases used for prescription processing. Most community pharmacies have a scanned imaging feature that allows for hard-copy prescriptions to be entered into the patient’s record. This function is ideally suited for the documentation of drug therapy changes by CPA. After the “Prescription Medication Update” fax form is sent to the physician, it may serve as the hard-copy prescription to be processed in the pharmacy’s database. By filing the fax as a prescription, records of all CPA interventions are readily retrievable through processes already utilized by community pharmacy.



► About the MTM Service

► New or Recommended Prescription

► Additional Notes (optional)

Additional notes regarding this claim (optional)

Resolved by CPA

MTM SOFTWARE

Medication Therapy Management (MTM) software is readily available to community pharmacies, and this software can serve to track CPA interventions as well as bill for services. Currently, reimbursement for clinical services provided by a community pharmacist is limited to MTM, but a CPA ensures 100% approval rates of pharmacist-led interventions permitted by CPA. In addition, interventions resolved by CPA and documented in MTM software makes this data readily retrievable for reporting. By indicating “resolved by CPA” in the notes of the MTM claim, pharmacists can pull data from this software to summarize outcomes and project implications of the CPA program.

DESIGNING A COLLABORATIVE PRACTICE AGREEMENT

CPA Policy Checklist

- | | |
|---|---|
| <input checked="" type="checkbox"/> Background | <input checked="" type="checkbox"/> Informed Consent |
| <input checked="" type="checkbox"/> Authority & Purpose | <input checked="" type="checkbox"/> Documentation |
| <input checked="" type="checkbox"/> Collaborating Professionals | <input checked="" type="checkbox"/> Communication |
| <input checked="" type="checkbox"/> Patients | <input checked="" type="checkbox"/> Quality Assurance/Improvement |
| <input checked="" type="checkbox"/> Goals | <input checked="" type="checkbox"/> Period of Validity |
| <input checked="" type="checkbox"/> Patient-Care Functions | <input checked="" type="checkbox"/> Retention of Records |
| <input checked="" type="checkbox"/> Provider Eligibility | <input checked="" type="checkbox"/> Rescindment & Amendment |
| <input checked="" type="checkbox"/> Training/Education | <input checked="" type="checkbox"/> Signatures of Approval |
| <input checked="" type="checkbox"/> Liability | <input checked="" type="checkbox"/> Appendix |

See Appendix A5 for CPA Template

On a daily basis, community pharmacists encounter opportunities for the management of a broad range of disease states, but time for the management of various diseases is a commodity not often afforded in most traditional community pharmacies. Community pharmacists are one of the most accessible healthcare professionals, practicing patient care in busy community settings to meet the immediate needs of the public often outside of typical business hours. To accommodate this pace of community care, pharmacists rely on well-tuned processes to guide the split-second-decision-making skills required to operate an efficient pharmacy.

Most CPAs in institutional health systems provide very broad definitions of pharmacist-led interventions (i.e. warfarin management). However, CPAs in a community pharmacy must be composed of specific interventions which can be implemented within the medication-use process. The specificity of prescriptive rights expanded to community pharmacists

may be the key to maintaining the efficiency required to provide effective patient care. With this in mind, the design of the CPA in a community pharmacy should be composed of feasible expectations that support effective clinical decision making balanced by efficient patient-care delivery.

Foundationally, a CPA must describe methods by which healthcare professionals collaborate to manage specified disease states. By including organizational features (i.e. policies and procedures) in the CPA, the healthcare team can ensure reasonable expectations are documented and accepted by all members of the team. Listing targeted interventions improves feasibility for community pharmacies, and including an appendix of clinical guidelines enhances the credibility of the rationale for intervention resolution. The CPA's design is fundamental to an organized expansion of physician authority to pharmacist collaborators.

1

Background

Though not required by law, this section provides the context by which the physician practice and pharmacy began collaborating. Citing references to state-specific laws and regulations informs all collaborators of the legal expectations and consequences of the agreement.

2

Authority & Purpose

As directed by state law, a physician may extend limited prescriptive rights to a pharmacist. Some states allow for agreements between organizations encompassing all physicians and pharmacists. The purpose helps to define the vision for this agreement.

3

Collaborating Professionals

Physicians and pharmacists included in this agreement will be stated with their contact information. Depending on the state, a medical director may encompass all physicians in a group or the number of collaborators may be limited.

Authority

I, Dr. Eby, authorize the pharmacists named herein, who hold an active license to practice, issued by the state of Ohio, to manage and/or treat patients pursuant to the parameters outlined in this agreement. This authority follows the laws and regulations of Ohio.

Purpose

St. Vincent de Paul (SVDP) Charitable Pharmacy and Good Samaritan Free Health Center (GSFHC) are committed to providing high quality care in the most affordable, efficient way. Creation of multi-disciplinary teams who can function as physician extenders are 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 SVDP and GSFHC.

4

Patients

The definition of the patients included in the CPA will be stated. Requirements for specific patient information vary from state to state. Some states allow for a CPA to cover all mutual patients receiving care at both collaborating practices.

5

Goals

Quality improvement is a critical element to CPAs, and it is dependent on the development of realistic goals. While stating the goals of the CPA may not be required by law, assuring quality and promoting improvement will begin by establishing these goals.

Goals

- 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

When determining disease states that will be managed by the community pharmacist, a close analysis of state law, population needs, and clinical goals is necessary. While state laws defines 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.

For CPAs in a community pharmacy, a list of **targeted** interventions stratified by disease state will ensure feasibility in a fast-paced workflow. Prescribing errors, insurance

prior authorizations, and unaffordable medications often delay a patient’s access to a necessary medication. As experts in the pharmaceutical industry, 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. Through a CPA with targeted interventions, community pharmacists may resolve interventions that improve patient access and reduce adherence barriers to increase the potential for patients to reach their clinical goals.

Errors & Delays⁸

5%

Prescriptions with a prescribing error

25%

Errors resolved in greater than 1 day

“...but my insurance covers a 30-day supply.”

Mrs. Jones drops off a prescription to her community pharmacy for 1 vial of Lantus insulin to be injected 60 units every night at bedtime. Because the prescriber approved a quantity of 10mL, Mrs. Jones will have to pay her co-pay twice monthly to obtain enough insulin to manage her diabetes. Through a CPA, the pharmacist is able to adjust the quantity without delaying access to her insulin.

1. Quantity Adjustments

Inaccurate prescriber calculations on prescriptions lead to delays of patients accessing a full course of therapy for acute and chronic conditions. In these cases, pharmacists must contact physicians to adjust quantities and await a reply. Additionally, prescription insurance dictates the allowable days’ supply per patient co-pay. By adjusting the approved quantity of prescriptions under a CPA, pharmacists may help a patient receive the full course of therapy while optimizing their insurance benefits without waiting for a prescriber response.

ORIGINAL PRESCRIPTION

Rx

Lantus 100 units/mL

Sig: Inject 60 units QHS

10 mL

REFILL 5 TIMES

Dr. Diana Beatties

Prescriber

PRESCRIPTION RESOLVED BY CPA

Rx

Lantus 100 units/mL

Sig: Inject 60 units QHS

20 mL

REFILL 5 TIMES

Dr. Diana Beatties

Prescriber

Dr. Rex Farmer

Pharmacist

2. Formulation Interchange

Physicians often rely on pharmacists' expertise of the pharmaceutical industry and available drug formulations to determine best prescribing practices. Through a CPA targeted intervention, pharmacists may interchange formulations of prescribed medication, allowing the pharmacist 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. Additionally, time release formulations may improve adherence or reduce side effects.

"I already take too many pills to add another one."




Mr. Bartlett presents to the pharmacy to pick up his monthly metformin. In response to his recent elevated hemoglobin A1c, Mr. Bartlett's physician called in a new prescription for Januvia. However, the patient refuses to pick it up stating that he already takes too many pills to add another one. The pharmacist discusses Mr. Bartlett's concerns and uses a CPA to combine his metformin and Januvia into a different formulation — Janumet. Without the increased pill burden and number of co-pays, Mr. Bartlett agrees to initiate therapy.


ORIGINAL PRESCRIPTION

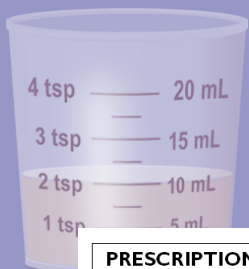
 Januvia 100mg
Sig: Take 1 tablet PO Q day
30 tablets
REFILL 5 TIMES

ORIGINAL PRESCRIPTION


 Metformin 1,000mg
Sig: Take 1 tablet PO BID
60 tablets
REFILL 5 TIMES
Dr. Diana Beatties
Prescriber

PRESCRIPTION RESOLVED BY CPA


 Janumet 50/1000mg
Sig: Take 1 tablet PO BID
60 tablets
REFILL 5 TIMES
Dr. Diana Beatties
Prescriber
Dr. Rex Farmer
Pharmacist



ORIGINAL PRESCRIPTION

 Amox/Clav 875mg/125mg
Sig: Take 1 tablet PO BID x 7 days
14 tablets
REFILL 5 TIMES
Dr. Diana Beatties
Prescriber

PRESCRIPTION RESOLVED BY CPA

 Amox/Clav 400mg/5mL
Sig: Take 11mL PO BID x 7 days
100mL
REFILL 5 TIMES
Dr. Diana Beatties
Prescriber
Dr. Rex Farmer
Pharmacist



"I'm having trouble swallowing a pill this big."



Ms. Sanchez was treated for a respiratory tract infection with Augmentin 875/125mg for a respiratory tract infection. Due to her sore throat, she is having trouble swallowing a large tablet. Through a CPA, the pharmacist is able to interchange the tablet to a liquid formulation to improve adherence.

93%

Physicians state that prior authorizations negatively impact their ability to treat a patient.⁹

3. Therapeutic Interchange

Therapeutic interchange is the practice of replacing a medication with a chemically different medication in the same drug class. Due to competition in the pharmaceutical industry, multiple manufacturers may design similar medications that compete for market share. With authority by a CPA, pharmacists are ideally positioned to perform therapeutic interchange when it benefits the patient's adherence, improves access, or reduces financial burden.

Interchanges are a common practice among safety-net organizations that rely on drug sample donations to care for underserved patients. In traditional community pharmacies, therapeutic interchange may be the most efficient response to an insurance-mandated prior authorization. Prescription insurance often drives prescribing practices when choosing among therapeutically similar medications.

Patients experience delays from days to weeks awaiting a physician to complete prior authorization paperwork and subsequent processing by an insurance company. This process results in a delay of treatment for the patient's health condition, potentially worsening the condition. Therapeutic interchange by a pharmacist through a CPA may eliminate delays imposed by insurance companies by allowing community pharmacists to select formulary medications from therapeutically similar agents.

“Is there anything my insurance will cover?”

Mr. Lansing has recently changed employers and presents his new prescription insurance at the pharmacy. Though he has been using a Symbicort inhaler for years to control his asthma, his new insurance requires a prior authorization. His current inhaler is empty and his next physician appointment is 2 months away.

He asks if there is another option that his insurance will cover. Using the CPA, the pharmacist interchanges the prescription to Dulera, a formulary inhaler similar to Symbicort.

ORIGINAL PRESCRIPTION



Symbicort 160/4.5

Sig: Take 1 puff into the lungs BID

1 inhaler

REFILL 5 TIMES

Dr. Diana
Pres

PRESCRIPTION RESOLVED BY CPA



Dulera 200/5

Sig: Take 1 puff into the lungs BID

1 inhaler

REFILL 5 TIMES

Dr. Diana Beatties
Prescriber

Dr. Rex Farmer
Pharmacist

4. Drug Optimization



“My doctor can’t see me again for 3 months.”

Mr. Washington was diagnosed with diabetes type 2 two weeks ago with fasting blood glucose greater than 500 mg/dL. He was started on metformin 500mg twice daily and Lantus 10 units at bedtime. Despite taking his medications as prescribed without significant side effects, he continues to experience symptoms of hyperglycemia and fasting blood glucose readings in the 400s.

Upon discussing the lack of control of his diabetes with his pharmacist, Mr. Washington expresses frustration that his doctor is not available to see him again for 3 months. To improve his diabetes control and prevent a potential hospital admission, the pharmacist utilizes the CPA to increase his metformin dose.

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 in community pharmacies, pharmacists have the opportunity to identify uncontrolled disease states and optimize therapy between a patient’s visits with their physician.

For instance, titrations for anti-diabetic medications are often recommended over a few weeks, but patients are often only able to visit their physicians every 3-6 months. This delay in follow-up results in prolonged periods without diabetes control.

Through a CPA based on clinical guidelines, pharmacists can perform drug optimization interventions to ensure more efficient disease state control for chronic conditions, like diabetes, hypertension, or hyperlipidemia.



	Pre Post	Carbs Insulin	Pre Post	Carbs Insulin	Pre Post	Carbs Insulin	Pre Post	Carbs Insulin	Pre Post	Carbs Insulin	Diet, exercise, ketones, illness, stress
Mon											
Tue											
Wed											
Thu											
Fri											

ORIGINAL PRESCRIPTION



Metformin 500mg
Sig: Take 1 tablet po BID
60 tablets

REFILL 5 TIMES

Dr. Diana Beatties
Prescriber

PRESCRIPTION RESOLVED BY CPA



Metformin 1,000mg
Sig: Take 1 tablet po BID
60 tablets

REFILL 5 TIMES

Dr. Diana Beatties
Prescriber

Dr. Rex Farmer
Pharmacist


5. 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, over-the-counter (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, community pharmacists recommend self-treatment with OTC therapies. Under a CPA, a pharmacist could recommend a therapy for symptomatic relief and write the prescription to ensure insurance coverage. This practice may provide a breakthrough in accessibility for tobacco cessation aids, acute care products, diabetes testing/injection supplies, and cardiovascular disease risk reduction with OTC aspirin 81mg.


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 all medications, both prescription and OTC, a patient is taking. By processing OTC medications as prescriptions, pharmacists are able to perform a more formal drug interaction check to ensure safety within a patient's full medication regimen.

PRESCRIPTION RESOLVED BY CPA



Fluticasone NS
Sig: use 1 spray 1EN daily
1 inhaler

PRESCRIPTION RESOLVED BY CPA




Nicotine 21mg Patch
Sig: Apply 1 patch daily
30 patches

REFILL 5 TIMES

Dr. Rex Farmer
Pharmacist

PRESCRIPTION RESOLVED BY CPA



Aspirin 81mg
Sig: Take 1 tablet po daily
30 tablets

REFILL 5 TIMES

Dr. Diana Beatties
Prescriber

Dr. Rex Farmer
Pharmacist



“Can you recommend something I can afford?”

Mrs. Steely approaches her community pharmacist to request an affordable recommendation for a nasal corticosteroid for her allergies. During the conversation about her allergies, the patient mentions her repeated attempts to stop smoking have always been cut short because of the cost of nicotine replacement.

The pharmacist recommends fluticasone nasal spray for her allergies and nicotine patches to help her quit smoking. Also, the pharmacist discusses her risk for a heart attack and stroke in relation to her smoking, age, and other health conditions. Given her ASCVD risk, the pharmacist recommends aspirin 81mg.

Upon reviewing the cost of these products, the patient informs the pharmacist that she is living on a fixed income and she cannot afford these recommendations. Under a CPA, the pharmacist can prescribe these items for symptomatic relief, tobacco cessation, and ASCVD risk management. Because these OTC products were prescribed, the pharmacist can submit reimbursement through Mrs. Steely's insurance which significantly reduce her out-of-pocket costs.

7

Provider Eligibility

The type of prescriber (i.e. MD, PA, CNP) eligible for inclusion in a CPA is vary 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. Universally, all providers partnered in a CPA must maintain good standing of their licensure and an ongoing relationship with the patient managed by a pharmacist.

8

Training/Education

Team-based care relies on each member understanding their unique roles in the delivery of effective, efficient care. Team members must be trained in state law to ensure compliance. Healthcare professionals interacting under a CPA must maintain up-to-date clinical competencies and knowledge of current guidelines for the disease states managed by a CPA. State laws may mandate the completion of additional continuing education to utilize a CPA. The management team is responsible to ensure that team members receive training sufficient for the logistics necessary for service delivery, documentation, communication, and adherence to all policies and procedures. Following scheduled quality assurance checks and quality improvement initiatives, the pharmacy manager and medical director must provide team training to ensure refinement of the CPA over time.

9

Liability

Statements regarding the liability of collaborators are necessary for legal protection in the event of unintended consequences to the use of a CPA. Pharmacists and physicians providing care through a CPA are not liable for each other's clinical decisions. While liability insurance is highly recommended for all providers, some states require providers to maintain a specific level of liability insurance.

10

Informed Consent

While state laws vary in details pertaining to informed consent, most states require some level of informed consent prior to initiating care by a pharmacist through a CPA. Typically, CPAs are used for the longitudinal management of chronic disease states, but the aim for CPAs in a community pharmacy is to provide more effective, efficient patient care delivery. The majority of CPA-resolved interventions in a community pharmacy find their utility as a means to remove barriers to efficient care, resulting in interventions for specific disease states without a longitudinal follow-up plan.

Because CPAs in a community pharmacy serve as a troubleshooting aid, patients may experience interventions from a pharmacist inconsistently. For this reason, community pharmacies should document informed consent with each intervention resolved by a CPA to remind patients of the pharmacist's expanded rights and their right to opt out of this level of this care.



Informed Consent

As a mutual patient of Good Samaritan Free Health Center and St. Vincent de Paul Charitable Pharmacy, I understand my physician has approved my pharmacist to make clinical decisions. I understand my right to opt out of prescription changes made by a pharmacist. By signing below, I provide consent for the pharmacist to intervene:

Patient Signature: _____ Date: _____

11

Documentation

Policies regarding the documentation of CPA activities are essential to maintaining accurate patient records and assessing outcomes. Whether physical or electronic, each organization joined by a CPA must document all patient-care activities and communications among team members. Additionally, appropriate documentation ensures data may be collected for quality assurance and quality improvement. Documentation that is readily retrievable facilitates good communication among team members and, thus, a cohesive patient-centered message to the patient.



12 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. The maximum period of validity allowed by law should be the goal for CPA renewal.

13 Retention of Record

All records, whether physical or electronic, must be retained and readily retrievable for a period of time specified by state law. To maintain compliance to respective federal and state laws, community pharmacies and physician practices must retain separate records for the activities of a CPA.

14 Rescindment & Amendment

A collaborative working relationship among pharmacists, physicians, and patients often necessitates compromise with respect to the needs and rights of each other. It is the right of each participant in a CPA, whether healthcare professional or patient, to withdraw consent if the need arises. Rescindment 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 be investigated to avoid rescindment when possible. Negotiation and compromise often matures relationships, and CPA amendments are the by-product of these compromises. CPAs may be amended within the accepted period of validity of the whole agreement without affecting all other aspects of the agreement. Written documentation with signatures of responsible parties is necessary for the formal approval of CPA amendments.

15 Signatures of Approval

The providers responsible for the agreement must sign to formally approve the CPA. State laws vary in allowing a designee from an organization to sign for all providers of that organization. The period of validity starts on the day when all signatures have been collected.

16 Appendix

Clinical guidelines and research may be referenced through the CPA to provide insight into rationales for interventions and unify team-based care when multiple approaches to care may be justifiable. Online references ensure automatic updates when new guidelines become available, but many providers prefer a hard-copy appendix of these documents. Either way, easily accessible references are important to ensure consistency among the care delivered by all members of the team.



Signatures of Approval

As a licensed healthcare provider authorized to prescribe medication in the State of Ohio, delegate prescriptive authority to the pharmacists listed below to initiate, modify, refill, and discontinue drug therapy for patients shared by the Good Samaritan Free Health Center (GSFHC) and St. Vincent de Paul Charitable Pharmacy (SVDP). This authority pertains to the protocol established in this agreement in accordance with the laws and regulations (ORC 4729.39) of the State of Ohio.

SVDP pharmacists shall document all drug therapy adjusted under this protocol and communicate with the healthcare team at GSFHC. As the authorizing prescriber, I or authorized staff under my supervision, will be available to review drug therapy adjustments by SVDP pharmacists.

This protocol will be in effect for two years unless rescinded earlier in writing by either party. Any modification of the protocol shall be treated as a new protocol, requiring signed approval from responsible parties.

Signatures of Responsible Parties:

Physician: _____ Date: _____

Pharmacist: _____ Date: _____

DATA COLLECTION PLAN

A data collection plan must 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. Designing the data collection plan prior to implementing the CPA is necessary to the long-term survival of the collaboration between healthcare professionals. Quality data provides the management team with goals to move the program forward and open the doors for funding opportunities to further solidify the partnership of collaborating organizations. While data collections strategies will vary depending on technology available and disease states managed, the following are suggestions of non-clinical data points that can be used to determine the value of using a CPA in a community pharmacy.

INTERVENTIONS RESOLVED BY CPA

The documentation process, discussed previously in this implementation guide, is designed to extract the number and type of interventions that are resolved by CPA. The fax form used to communicate changes to the physician becomes the physical prescription stored in the pharmacy database and scanned in the clinic's electronic medical record. While retrieval of this paper trail is possible, it is not feasible for an efficient data collection strategy. However, most MTM software platforms have reporting functions designed to export to a spreadsheet. All MTM interventions resolved by CPA should be documented as "resolved by CPA" in the notes of the submitted interventions. By exporting the data from the MTM software to a spreadsheet, the find option can be used to search for interventions "resolved by CPA." This process isolates the targeted interventions to yield data including the number and type of interventions resolved by CPA.

ESTIMATED COST AVOIDANCE

The value of a CPA ensure that patients receive help when and where it is needed. Each intervention resolved by CPA can be associated with a healthcare cost that would have taken place if the CPA had not been in effect. For example, a patient who cannot access a specific brand of insulin due to a prior authorization may need to visit an emergency room to access treatment during the time it takes for the physician to collaborate with the insurance company. An intervention resolved by CPA could have interchanged the patient's insulin prescription to an option that was accessible. Thus, the insulin interchange resolved by CPA prevented an emergency room visit for which the average cost of an emergency room visits would be associated. Most MTM software platforms have a method to rationalize the severity level of each intervention to attribute the estimated cost avoidance.

Healthcare Costs¹⁰

The national averages of healthcare services are ever changing, but current research has considered the following values:

Physician Visit:	366.73
Additional Medication:	424.33
Emergency Room Visit:	845.25
Hospital Admission:	\$26,205.40

CPAs can be utilized to prevent these healthcare costs, equating the value of an MTM program with the estimation of costs that were avoided.

Calculating MPR¹¹

Medication Possession Ratio (MPR) is the most accessible way to calculate medication adherence.

Total Days' Supply in a Period

$$\frac{\text{Last Fill Date} - \text{First Fill Date} + \text{Last Fill Date}}{\text{Days' Supply}}$$

MEDICATION ADHERENCE RATES

While clinical markers will vary with the type of CPA that is approved, medication adherence rates will likely be impacted by any disease state that is being managed by a pharmacist. CPAs are designed to ensure a patient does not experience a delay in obtaining a medication used for a chronic condition. This innately improves medication adherence. While several strategies exist for determining medication adherence, medication possession ratio (MPR) is a value pharmacists can calculate in a time efficient way without expensive statistical software. This provides a surrogate marker to understand the impact a CPA has on medication adherence. The American Pharmacists Association has made available strategies for the gathering a MPR for high volume prescription data.¹²

CPA IMPLEMENTATION TIMELINE

Planning for Follow Up

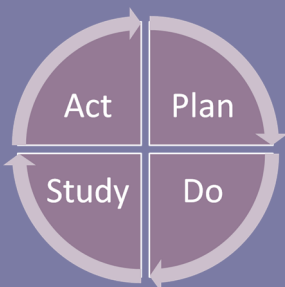
Upon signing the CPA document, the medical director and pharmacy manager are ready to pilot the expansion of prescriptive rights to pharmacists. When finalizing the document, it is important that the management team schedule routine face-to-face meetings to discuss outcomes of the change and plan for cycles of quality improvement. Metrics of success should be set prior to unveiling the program to the full healthcare team. While clinical metrics will largely depend upon the disease state that is being managed, process metrics will apply to each CPA. Number/type of interventions resolved and medication adherence rates are mainstay metrics that should be gathered routinely

First Quarter Pilot

An initial pilot of 3 months is recommended to ensure processes reflect best practices and assure staff member are abiding by all processes. During the first quarter pilot phase, it is best to focus on only one disease state managed by CPA. For most primary care practices, tobacco cessation is an ideal condition to be managed by a community pharmacist in an early CPA relationship. Because the pharmacist is more accessible in the community pharmacy, patients may have more opportunity to discuss a tobacco quit attempts. Furthermore, a pharmacist physically gives the patient cessation aids making patient education more practical with the product in hand.

Quality Improvement

Most state laws require that the management team meet regularly to discuss the CPA and assure quality. Data should drive these meetings to direct management to make changes when needed. Plan, do, study, act (PDSA) is a typical cycle used to facilitate the quality improvement process. Data is used to understand progress toward goals while processes should be critiqued to ensure efficiency and patient safety.



Staff Training

The pharmacy manager and medical director should make a plan to train their respective staff members prior to initiation. Depending on the workflow of each organization, a process flow diagram should be designed to ensure each team member understands their unique responsibilities. Training materials should include:

- State Law Allowing for CPA
- CPA Implementation Guide
- Signed Collaborative Practice Agreement
- CPA Fax Form
- Description of Roles/Responsibilities
- Goals of Initiative
- Documentation and Data Collection Strategies
- Quality Improvement Processes

Data Collection

As with each facet of utilizing a CPA, data collection is a team effort. The community pharmacist should lead data collection efforts for non-clinical markers. The pharmacist can report number/type of interventions resolved by CPA, estimate cost avoidance, and medication adherence rates. Physicians can report clinical values associated with the specific disease state the is managed by the CPA.

The data collected should be summarized in a report to be given to the pharmacy manager and medical director. This report will provide insight into quality improvement initiatives to ensure clinical and process goals are being met.

Amendment

Following the first quality improvement meeting of the management team, amendments are likely to be made in response to the analysis of the process. Process changes may be necessary and should be documented in the CPA. Amendments should be signed by the management team and training should be provided to staff.

As the CPA further evolves, additional disease states should be added to increase the breadth of services which can be offered by a pharmacist.

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APPENDIX

A1

Full Business Plan

A2

CPA Fax Form

A3

CPA Template

22

44

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