

PHARMACIST-PHYSICIAN COLLABORATIVE PRACTICE AGREEMENT (CPA) for Diabetes, Hepatitis C, and Medication-Assisted Treatment

INSTRUCTIONS:

- Complete this form and submit it to the BOP Chief Pharmacist, or designee, for review and final approval. The BOP Chief Pharmacist has designated CPA review and approval to the BOP Chief, Clinical Pharmacy Program.

GENERAL INFORMATION/SCOPE OF PRACTICE:

- A **CPA** refers to a written document that reflects a joint agreement between the collaborating professionals. The CPA describes a specific plan or arrangement—or a specific sequence of orders, steps, or procedures to be followed—for providing pharmacist-delivered patient care services.
- **PATIENT CARE DECISIONS** will normally follow the BOP Clinical Guidance documents¹ (**CGD**) and/or other nationally recognized treatment guidelines, when appropriate or when a BOP CGD is not available.
- **PHARMACIST-DELIVERED PATIENT CARE SERVICES**, under the auspices of a CPA, are defined as the pharmacist's evaluation of a patient's drug therapy needs for the purpose of rendering proper medication use decisions and prescribing therapy intended to optimize patient outcomes. These decisions should help patients meet treatment goals commensurate with the Primary Care Provider's (**PCP**) diagnosis and desired patient outcomes.

Pharmacist-delivered patient care services include:

- Collecting and reviewing a patient's medical record, including medication history;
 - Measuring and reviewing routine patient vital signs, including a limited physical assessment;
 - Ordering, interpreting, and monitoring the results of laboratory tests relating to drug therapy, e.g., blood chemistries and cell counts, drug levels, culture and sensitivity tests, and organ function tests;
 - Developing therapeutic plans and initiating, adjusting, and discontinuing medication regimens;
 - Providing appropriate preventative health services that are necessary to care for patients enrolled in pharmacist-run clinics;
 - Providing patient counseling/education and developing partnerships with patients in regard to drug therapy decisions/concerns, and providing care coordination and other healthcare services for wellness and prevention;
 - Documenting clinical encounters in the Bureau's Electronic Medical Record (**BEMR**). Medical documentation will include subjective data, objective data, assessment, medication treatment plan, referral to the PCP, patient education, and/or follow-up as appropriate.
- To go into effect, the CPA must be approved by the BOP Chief Pharmacist or designee, after review and recommendation by the BOP Chief, Clinical Pharmacy Program and/or National BOP Clinical Pharmacist Oversight Working Group, in cooperation with the collaborating physician, Institution Health Services Administrator (HSA), and Institution Governing Body Chairperson.
 - The pharmacist in consultation with the collaborating physician will regularly review and update the CPA.
 - Any modification of the CPA will require a new CPA, approved by the collaborating physician and the BOP Chief Pharmacist or designee.

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- When a CPA has been approved (both locally and by the BOP Chief Pharmacist or designee), the BEMR Team will activate approved prescribing rights and request laboratory ordering rights.
- This CPA may be terminated upon written notice from the collaborating physician or pharmacist, or the BOP Chief Pharmacist or designee. The pharmacist must notify the BOP Chief Pharmacist or designee, within 30 days of local-level termination.
- The physician with collaborative responsibilities will conduct clinical competency assessments.

INFORMATION FOR THIS CPA:

Institution:		Date:	<input type="checkbox"/> New CPA <input type="checkbox"/> Renewal
Title of CPA (Area(s) of Care):	Diabetes, Hypertension, Hyperlipidemia, Anticoagulation, Hepatitis C, and Medication-Assisted Treatment		
Pharmacist:			
Clinical Director (CD):			
Collaborating Physician*:			
Time period during which the approved CPA will be in effect (not to exceed 2 years):			
<i>* If CD has delegated collaborative responsibilities.</i>			

STATEMENT OF NEED:

Optimal patient care is best accomplished through a team management process involving all health care disciplines. Advanced pharmacy practices have been shown to improve patient and health system outcomes³, and collaborative practices have been encouraged by BOP health services leadership² and should be considered as an integral part of the team management delivery model³.

Diabetes mellitus:

Diabetes is a multi-faceted disease that is best managed in a collaborative effort of an interdisciplinary team to manage the co-morbid complications (most frequently hypertension and hyperlipidemia, but may also include additional comorbidities as discussed below), and prevent the progression of the disease. There is an array of oral agents and insulin utilized in the treatment of diabetes to manage and minimize the morbidity and mortality of the disease. (Institution) is a male correctional facility that presents challenges to diabetes management including non-compliance and a population resistant to lifestyle modifications. There are currently x inmates with diabetes housed at (Institution). The average hemoglobin A1c of the diabetic population is x%. The Bureau’s National Performance Measure (NPM) for diabetes looks at the percentage of inmates with an A1c of >9% (this population should be <15%). Currently, this goal is/is not being met. Continued focus of the pharmacist-run clinic will remain on the diabetics not meeting this NPM goal of having an A1c of <9%.

(Institution) has x inmates with hypertension. Of this number, x are not meeting the goal of having a blood pressure <140/90. The NPM standard for hypertension looks for >80% of inmates with hypertension to be

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meeting that goal. (Institution) has room for improvement, as only x% of diagnosed hypertensive patients are meeting that goal.

(Institution) didn't meet the standard of having > 80% of patients with a history of cardiovascular disease (any age) or diabetes (between 40-75) on moderate to high intensity statin therapy (x%).

Furthermore, additional justifications for the need of a pharmacist to provide clinical management services are centered around the narrow therapeutic index of insulin. Excessive or insufficient doses can have serious and potentially life-threatening consequences. Routine clinical evaluation of the patient, in addition to laboratory monitoring, is essential; therefore, a pharmacist-run Diabetes/Hypertension/Hyperlipidemia clinic is needed to more fully manage these patients efficiently.

Hepatitis C:

The Bureau of Prisons is trending towards universal hepatitis C treatment in alignment with AASLD (American Association for the Study of Liver Diseases) guidance. Hepatitis C is disproportionately represented in the incarcerated population, which also comprises high-risk patient populations, such as injection drug users. Expediting hepatitis C treatment will prevent disease progression, prevent development of hepatitis C-related morbidity and mortality and the associated healthcare costs, prevent transmission to other inmates and staff, prevent transmission to others upon release (about 90% of incarcerated inmates will release back to society), and reduce litigation. (Institution) has x hepatitis C-diagnosed inmates. A pharmacist-run hepatitis C clinic is needed to more fully identify, treat, and manage these patients more efficiently.

Medication-Assisted Treatment (MAT):

Approximately 8,000 offenders within the BOP are estimated to have a history of opioid use disorder. To address the potential of increased risk for those with opioid use concerns the Bureau has implemented a Medication-Assisted Treatment initiative. The medications selected for this program include methadone, buprenorphine, oral naltrexone, and naltrexone extended release injection (Vivitrol®). Methadone is a full agonist that works to eliminate withdrawal symptoms and reduce cravings by binding to opioid receptors in the brain with a high affinity, keeping other opioids (heroin, morphine, and prescription opioids) from binding. Buprenorphine is a partial opioid agonist that binds to opioid receptors in the brain but to a lesser degree than methadone. Buprenorphine has similar effectiveness to methadone for treating opioid use disorder. Naltrexone is an opioid antagonist works by blocking opioid receptors in the brain without activating them, thereby interfering with the pleasurable feelings associated with taking opioids and can thereby significantly enhance the ability of individuals to resist opioid-seeking behaviors. Providing offenders with tools to re-enter society as productive citizens is a central mission of the BOP. By providing MAT to individuals at risk for opioid use, especially during the known high-risk re-entry period, this initiative seeks to provide a tool to increase successful transition.⁴

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This CPA is intended to effectively integrate clinical pharmacy services into the BOP team medicine approach and to help patients reach their outcome goals, e.g., blood pressure, hemoglobin A1C, LDL cholesterol, viral load, and abstinence from opioids.

CLINIC INFORMATION:

Under the auspices of this CPA, the pharmacist will follow and treat a select patient population, based on patient needs and available pharmacy resources. The pharmacist will organize a pharmacist-run clinic to address specific patient care needs, according to the pharmacist's competency in the management of the respective medications and related disease state(s). Per local preference, patients with applicable pharmacist-delivered patient care services needs will be:

- (1) Referred to the pharmacist-run clinic by a BOP provider in consultation with the pharmacist and via BEMR administrative note,
- (2) Automatically enrolled, based on pharmacist's scope of practice and local patient care needs,
- (3) Referred to the pharmacist by the institution's MAT Point of Contact, or
- (4) Self-referred based on opioid use/addiction history

A PCP will provide diagnoses and targeted clinical/outcomes goals. The pharmacist will provide patient care functions necessary to help the patient achieve these goals.

Following are the health maintenance/preventive care process this clinic will provide as part of a comprehensive practice:

- For patients enrolled in the pharmacy Diabetes/Hypertension/Hyperlipidemia Management Clinic, the pharmacist will perform the following:
 - Initial Evaluation to gather data such as:
 - Self-blood glucose monitoring habits/values, signs/symptoms of hypoglycemia/hyperglycemia, smoking/ethanol history, signs/symptoms of hypotension, medication review, compliance review, nutrition history and practices, 10-year Atherosclerotic Disease risk, Vision exams, Feet exams, Dental exams, allergies, and immunization history, relevant comorbidities, relevant family history, OTC medications, social support, cultural values/emotions surrounding diagnosis, factors influencing learning, special needs or limitations requiring accommodation
 - Baseline Laboratory tests: Hemoglobin A1C (HgbA1C), Complete Metabolic Profile (CMP), Complete Blood Count (CBC), Thyroid Stimulating Hormone (TSH), microalbumin, lipid profile, and urinalysis.
 - Review blood glucose levels
 - Perform limited physical assessment, which may include blood pressure, temperature, point-of-care lab tests, and weight

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- Review medication compliance (including OTCs)
 - Initiate, change, or adjust medication therapy as needed
 - Patient education as needed
 - Order, review, and interpret labs as needed
 - Immunizations: hepatitis B, pneumococcal, influenza
 - Schedule patient follow-up
- For patients enrolled in the Hepatitis C Management Clinic, the pharmacist will perform the following:
 - Hepatitis C antibody screening
 - Hepatitis C viral load with reflex to genotype to confirm positive antibody
 - Baseline HIV screening and hepatitis B serology (sAb, sAg, cAb-total)
 - CMP, CBC, INR annually if no cirrhosis, every 6 months if cirrhosis
 - Work-up for treatment as indicated: NS5A resistance testing, FibroSURE, chronic hepatitis B labs (cAb-IgM, eAb, eAg, DNA), HIV labs (CD4, viral load)
 - Immunizations: hepatitis B, pneumococcal, influenza
 - Vital signs: Blood pressure, pulse, respiratory rate, and temperature (if necessary) will be documented
 - Assessment: On treatment monitoring to review the patient side effects, drug-interactions with new medication orders, compliance etc., and this information will be documented in a clinical encounter.
 - For patients enrolled in the Medication-Assisted Treatment Program, the pharmacist will perform the following:
 - Coordinate with outside OTP clinics and X-waivered BOP providers for initiation and/or maintenance of MAT
 - Ensure monthly counseling requirement is accomplished and proof of counseling is sent to the OTP clinic
 - Perform a limited medical screening to determine appropriateness of MAT:
 - Ordering initial labs: CBC, CMP, UA, LFTs, GFR, creatinine
 - Obtaining vital signs: Blood pressure, pulse, respiratory rate, weight, and temp

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- Conducting a medical interview (Data collection of pertinent family medical history, drug abuse/alcohol history, medical complications from drug abuse, triggers, coping strategies)
 - Reviewing medical conditions (History of liver failure, psychiatric disorders, current pain conditions)
 - Reviewing medication profile and compliance history
 - Ordering labs to assess health and compliance
- Consulting with addiction specialists to determine best course of therapy
 - Ordering medication if Vivitrol or oral naltrexone is the MAT therapy of choice
 - Providing follow-up and monitoring in between OTP clinic visits or Vivitrol doses
 - Entering consultation requests in BEMR and coordinating appointments with outside clinic if Buprenorphine or Methadone is the MAT therapy of choice
 - Developing detoxification treatment plan in the case of an inmate testing positive for opiates but volunteers to continue in the MAT program
 - Providing Naloxone exit counseling

Following is the process for addressing and treating comorbidities associated with the disease states covered by this CPA:

- a. Comorbidities commonly associated with the disease states covered in this CPA will be addressed and managed using the most up-to-date guidelines from major medical associations as well as the BOP clinical guidance documents.
- b. Common comorbidities associated with the disease states addressed are as follows:
 - a. Diabetes Comorbidities
 - i. Hypertension: Assess possible causes of increased BP and treat as appropriate (i.e. Ace Inhibitor or Angiotensin Receptor Blocker). Will enforce lifestyle modifications, may order additional labs, or blood pressure checks. Will refer hard to treat cases to CD.
 - ii. Hyperlipidemia: Assess possible causes of increased cholesterol labs and treat as appropriate (i.e. statin medications). Will enforce lifestyle modifications, and may order additional labs. Will refer hard to treat cases to CD.
 - iii. Hypo/Hyperthyroidism: Monitor TSH and recommend treatment if clinically indicated
 - iv. Diabetic Neuropathy: Conduct pain assessment, foot exam, and treat with agents for diabetic neuropathic pain if indicated (i.e. tricyclic antidepressants)
 - b. Comorbidities associated with Hepatitis C
 - i. Cirrhosis surveillance: imaging, EGD, medications to treat clinical manifestations of cirrhosis (propranolol/nadolol for varices; sodium restriction, diuretics, and antibiotics for ascites; etc.)

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- ii. Chronic hepatitis B and/or hepatitis D: Determine whether treatment is indicated or not, (i.e. nucleoside analogs, interferon), lab monitoring schedule, whether HCC screening is indicated
- iii. HIV: lab schedule, potential drug interactions, compliance/adherence issues, etc.
- c. Comorbidities that patients may have that are awaiting Medication-Assisted Treatment
 - i. Since MAT is a program that inmates can enroll into, they may present with a number of different disease states. Those disease states (or medications used to treat those disease states) may have characteristics associated with them that may preclude the use of naltrexone (hepatotoxicity...etc.). Examples include: Hepatitis, Cirrhosis, Renal disease, Diabetes, Hypertension, Asthma, and COPD.
 - ii. Will address each comorbidity as already indicated above
- c. For complicated patients who have extensive co-morbidities and are outside the scope of this CPA, the pharmacist will refer individuals to their primary care provider or the clinical director.

Patients can be discharged from the clinic as deemed appropriate by the pharmacist for legitimate reasons, e.g., refusal of treatment, end of treatment, or reached outcome goals. Patients being discharged when reaching outcome goals will continue to be followed in the appropriate chronic care clinic by the PCP and may be referred back to this clinic as needed. Patients will be discharged in consultation with the PCP, and the discharge will be documented in BEMR.

The pharmacist will refer patients to the PCP for treatment challenges or complications outside the pharmacist’s scope of expertise. The PCP will be notified by the pharmacist via verbal notification, BEMR note, or email, based on the urgency of the situation.

TRAINING AND LOCAL CERTIFICATION:

The level of training obtained inherently as a pharmacist should justify competency for basic pharmacist-delivered patient care services functions for a variety of disease states. If needed, the pharmacist will acquire additional training or experience commensurate with the level of prescribing authority granted by the collaborating physician. The pharmacist will review and be familiar with the respective BOP CGDs and other nationally recognized treatment guidelines. The pharmacist will continue to receive education based on the latest advancements in care, respective to the clinics being provided.

Any advanced training/experience or certifications should be documented below:

Date:	Training/certification:
Date:	Training/certification:
Date:	Training/certification:
Date:	Training/certification:
Date:	Training/certification:
Experience, including previous practice agreements:	

ROLE OF THE COLLABORATING PHYSICIAN: The collaborating physician will conduct peer review by sampling the decisions made by the pharmacist at least quarterly and will be available for ongoing collaboration with

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the pharmacist either in person or electronically as needed to discuss specific cases. The collaborating physician will perform biennial competencies (annually if National Clinical Pharmacy Specialist [NCPS] certified), and this documentation will be placed in the pharmacist's credential file.

PERFORMANCE IMPROVEMENT (PI):

A PI program for the pharmacist will be developed in conjunction with the institution's current PI program. This program will include a plan to continually monitor outcomes and identify problems in patient care processes with the intent of implementing measures to improve these processes on an on-going basis. The pharmacist will follow-up on implemented improvement measures to assure outcomes continue to improve and desired outcomes are maintained. Outcomes data will be collected by the pharmacist using the DUEs provided by BOP Clinical Pharmacy Working Group, including baseline data for new CPAs. This data will be collated and submitted to the local P&T Committee on a regular basis, and annually to the BOP Chief, Clinical Pharmacy Program. Data will also be submitted to the NCPS committee (using the NCPS approved DUE) annually if NCPS-certified.

PHARMACIST CPA PRESCRIBING AUTHORITY:

Indicate below the drug classes for which the pharmacist, in accordance with this CPA, has prescribing rights. Medications should be designated by the following Generic Product Identifier (GPI) codes. Click on the appropriate checkboxes so that an "x" shows in the box.

AMINOGLYCOSIDES: 07-Aminoglycosides, 1600006-Vancomycin

ANTICOAGULATION: 83-Anticoagulants, 772040-Vitamin K

DIABETES: 27-Antidiabetics, 6410-Salicylates (aspirin)

HEPATITIS: 1235-Hepatitis Agents, 1210857010-TDF, 1210990230-FTC/TDF,
 1210990229-FTC/TAF

HIV: 1210-Antiretrovirals, 1699000230-SMX-TMP, 16400020-Atovoquone,
 034-Azithromycin, 16300010-Dapsone

HYPERLIPIDEMIA: 39-Antihyperlipidemics

HYPERTENSION: 36-Antihypertensives, 33-Beta-Blockers, 34-Calcium Channel Blockers,
 37-Diuretics, 797-Potassium

Pain MANAGEMENT: 64-Analgesics-Non-Narcotic, 66-Analgesics-Anti-Inflammatory,
 72-Anticonvulsants, 58-Antidepressants, 7510-Central Muscle Relaxants,
 9085-Local Anesthetics-Topical, 46-Laxatives, 772020-Vitamin D,
 4927-Proton Pump Inhibitors

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PSYCHIATRIC: 59- Antipsychotic/Antimanic Agents, 72-Anticonvulsants, 57-Antianxiety Agents, 33-Beta-Blockers, 58-Antidepressants, 7310001010-Benztropine, 7310007010-Trihexyphenidyl, 3620203010-Prazosin

MAT: 6280-Agents for Chemical Dependency, 9340-Opioid Antagonists, 6520-Opioid Partial Agonists, 6510005010-Methadone Note: buprenorphine prescriber must have a DEA DATA-waiver or prescribed under a certified Opioid Treatment Program (OTP). Methadone must also be prescribed under an OTP.

IV SOLUTIONS: 7975-Sodium Chloride, 8010-Dextrose

Diabetic Supplies:

Other (list specific medications not covered under above GPI codes):

The following DUEs will be utilized to track and submit outcome measures corresponding with above prescribing rights:

- | | | |
|---|--|--|
| <input type="checkbox"/> Anticoagulation | <input checked="" type="checkbox"/> Diabetes | <input checked="" type="checkbox"/> HCV |
| <input type="checkbox"/> HIV | <input checked="" type="checkbox"/> Hyperlipidemia | <input checked="" type="checkbox"/> Hypertension |
| <input type="checkbox"/> Psychiatric Care | <input type="checkbox"/> Pain Management | <input checked="" type="checkbox"/> Other: MAT |

By signing this document, the above-named physician(s) and pharmacist enter into a Collaborative Practice Agreement (CPA) for their patients; as such, these patients may participate in the pharmacist-delivered patient care services described above, and the pharmacist is authorized to prescribe the above-listed medications.

CPA Approved by:

CLINICAL PHARMACIST: *

Signature Date

INSTITUTION CHIEF PHARMACIST (if other than CLINICAL PHARMACIST):

Signature Date

CLINICAL DIRECTOR (CD): *

Signature Date

COLLABORATING PHYSICIAN (if other than CD):

Signature Date

CPA Acknowledged by:

HEALTH SERVICES ADMINISTRATOR:

Signature Date

GOVERNING BODY CHAIRPERSON (WARDEN):

Signature Date

BOP CHIEF PHARMACIST or designee: *

Signature Date

* Signatures required for CPA modification.

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REFERENCES AND RESOURCES

1. BOP Clinical Guidance, available at: http://www.bop.gov/resources/health_care_mngmt.jsp
2. Memorandum: BOP Clinical Pharmacy Initiative Technical Guidance Document, RADM Newton E. Kendig, Assistant Director, BOP Health Services Division, Sep 2012
3. Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011.
4. BOP Medication Assisted Treatment (MAT) Program Resource Guide, http://sallyport.bop.gov/co/hsd/health_info/docs/Misc%20reference%20documents/MAT%20Resource%20Guide%203-26-19-%20final%20jlr.pdf

ANNUAL CPA REVIEWS

Date of original CPA approval (month/year): _____

CPA REVIEWS

	Date	Pharmacist Signature	Comments/Updates
1			
2			
3			
4			