State of New Hampshire
Board of Pharmacy
7 Eagle Square
Concord, NH 03301
603-271-2152
Website: www.oplc.nh.gov/pharmacy/

COLLABORATIVE PHARMACY PRACTICE APPLICATION

PLEASE PRINT CLEARLY - ILLEGIBLE, INCOMPLETE OR APPLICATIONS WITHOUT THE REQUIRED ATTACHMENTS AS NOTED ON PAGE 2 CANNOT BE ACCEPTED.

1. GENERAL INFORMATION

Applicant's Name	First	Middle	Last
	Themio	J.V.C.	Papadopoulos

Mailing Address: 5082 Washington Street, Unit 1, Boston, MA 02132

NH Pharmacist License Number	Home or Cell Phone #	Work Phone #	E-mail Address
PHCY-01338	508-245-5770	857-304-5930	Tpapadopoulos@bwh.harvard.edu

2. CURRENT PHARMACY EMPLOYMENT ASSOCIATED WITH THIS COLLABORATIVE AGREEMENT

Name of NH Pharmacy: Mass General Brigham Integrated Care

Complete Mailing and Physical Address of NH Pharmacy: 30 Tuscan Boulevard Salem, NH 03079

3. PROFESSIONAL LIABILITY INSURANCE AND CARDIOPULMONARY RESUSCITATION (CPR) CERTIFICATION

I have at least $1,000,000 of professional liability insurance with the following insurance provider Controlled Risk Insurance Company of Vermont INC. (A Risk Retention Group).

* You must attach a copy of your certificate of insurance to this application.

I have current CPR certification, which includes the required 'hands-on' training which must be completed every 2 years, from (check one):

☑ American Heart Association ☐ American Red Cross.

* You must attach a copy of your certificate of completion of CPR training or a copy of the back & front of your signed CPR Card to this application.

4. PRACTICE SETTING LOCATIONS (LIST ALL PRACTICE SETTINGS YOU INTEND TO ENGAGE A COLLABORATIVE PRACTICE AT):

Location Name: Mass General Brigham Integrated Care

Location Address: 30 Tuscan Boulevard Salem, NH 03079

Location Name: _____

Location Address: _____

Location Name: _____

Location Address: _____

(If more than 3 locations, attach the information on a separate sheet)

APPLICATION CONTINUED ON NEXT PAGE

5. SUMMARY OF EDUCATION, TRAINING, AND EXPERIENCE RELATED TO RESPONSIBILITIES TO PERFORM VIA THE COLLABORATIVE PRACTICE AGREEMENT:

Northeastern University BS in Pharmacy Studies and PHARMD

Post Graduate Year 1 Pharmacy Practice Residency: Northeastern University/HHSI

Employment at Brigham & Women's Hospital Since 7/2017 as Advanced Practice Clinical Pharmacist

Working with Mass General Brigham Integrated Care in Massachusetts utilizing CPA to manage patients'

chronic disease states

6. APPLICANT ATTESTATION STATEMENT:

My signature below affirms that the answers and statements made on this application are true and correct to the best of my knowledge and belief. I also understand that pursuant to RSA 318:26-a, the Board must be notified within 15 days of any changes in the information contained on this form. Failure to notify the Board could result in disciplinary action or sanctions.

Signature: _____ Date: 9/6/2022

7. EMPLOYER ATTESTATION STATEMENT:

As owner / chief administrative officer of Mass General Brigham Integrated Care, Inc. (Name of Facility / Pharmacy) I certify that my Company agrees to be in compliance with all federal, state, and local laws related to this agreement. I have read this application and all of the statements made on it, reviewed all submitted supporting documents, attest that to the best of my knowledge, all provided information is true and accurate. As the owner/corporate representative of this organization, my signature below acknowledges my/the corporation's responsibilities as the permit holder, including all of the corporate/permit holder duties and responsibilities noted in NH RSA 318:38 and Ph 704.11(d).

Signature Of Organization Representative: _____ Title: President, Mass General Brigham Integrated Care, Inc. Date: 9/14/22

*** LIST OF SUPPORTING DOCUMENTS TO INCLUDE WITH THE APPLICATION:**

1. Copy of signed Collaborative Agreement
2. Copy of Insurance Certificate
3. Copy of Policy and Procedures governing the practice
4. Copy of Policy and Procedures for QA/CSI program
5. Copy of Patient Consent Form
6. List of all Providers Whom Are Party to the Agreement – Full Name, Address and NH License

Mass General Brigham

Integrated Care

Department of Pharmacy Services

COLLABORATIVE PHARMACY PRACTICE AGREEMENT

Chronic Disease State Management

Ambulatory Care Pharmacy

Please note that this guideline may not be appropriate for all patients and does not replace clinical judgment

Contents

Introduction

1. This Collaborative Pharmacy Practice Agreement (called the "CPA") follows the New Hampshire Board of Pharmacy Administrative Rules Chapter Ph 1100 titled *Collaborative Pharmacy Practice* and NH RSA 318:16-a titled *Standards for Collaborative Pharmacy Practice*. A copy of the current version of the law and rules will be provided to each pharmacist and attending practitioner (the "practitioner"), signing this CPA.
    a. The practitioner and medical director collaboratively engaged within this CPA is Dr. Devon Quasha, MD, JD.
2. By entering into this CPA, each Mass General Brigham Integrated Care pharmacist signing below (the "pharmacist") is authorized to provide drug therapy management services as described in this CPA to the patient signing below (the "patient") for the specified disease state identified on the cover page ("Disease State").

Purpose

To enhance healthcare access and the quality of patient care, the pharmacist will complement the care provided by the practitioner(s) for chronic disease state management. Upon receipt of a patient and disease-state specific referral order, the pharmacist will order appropriate and necessary labs, authorize appropriate medication refills, implement, modify, or discontinue medications, facilitate referrals, and provide education as appropriate for the referred patient.

Goals

1. To improve the patient's overall health and, specifically, chronic disease state management, by providing evidence-based, patient-centered care that results in optimal drug therapy and improved patient outcomes.
2. To expand healthcare access.
3. To provide cost-effective care to the patient.
4. To improve patient/caregiver self-management skills and adherence to drug therapy related to chronic disease state therapy.
5. To improve safety outcomes that may or may not lead to hospital admissions associated with the chronic disease states managed.

Term

Collaborative agreements shall be renewed at least every 2 years and signed by all practitioners who are a party to the agreement. When a collaborative agreement is terminated, the patient shall be provided written notification within 15 days. Such written notification shall include detailed information on how the patient may continue any medication therapy provided by the pharmacist without interruption.

Disease States to be Co-managed and Scope of Practice

The Clinical Pharmacist may practice CDTM for the following disease states only as set forth below (*check only those that apply)*:

Disease State	Scope of Practice/Collaborate Practice Agreement
Chronic disease states to be managed (Diabetes Type II, Dyslipidemia, Hypertension, Venous and arterial thrombosis (prevention and treatment), Smoking cessation)	• Collect and review patient histories • Perform physical assessments • Order and evaluate laboratory tests listed in **Appendix A, table 2** • Initiate, modify or discontinue medications listed in **Appendix A, table 4** • Order or modify orders for related devices listed in **Appendix A, table 5** • Order vaccines listed in **Appendix A, table 6** • Administer vaccines in accordance with NH RSA 318:16-b and NH RSA 318:16-d

*Upon referral, the Clinical Pharmacist can treat any disease which is checked above as 'co-morbid' regardless of the listed reason for referral, unless limits are specifically noted in the referral.

Procedures

Referral

- Patients will be referred for the management of their chronic disease state by their primary care provider (PCP), specialist provider or as appropriate per practice site
- The referring provider will communicate the official diagnosis and associated patient-specific therapeutic goals to the pharmacist upon referral
- The patient and the referring provider may 'opt out' at any time

Informed Consent

- The pharmacist (or designee) will discuss the collaborative relationship between the pharmacist and the referring provider for management of the primary and/or co-morbid disease states and will document this discussion in the medical record

Treatment Goals

- Treatment goals to be determined based on current treatment guidelines with input from the referring provider

Management

- Management will be based on current treatment guidelines and affiliate MGB-approved guidelines (see Appendix B) as applicable in conjunction with clinical judgement.
- Decisions regarding modifications of the patient's drug therapy and selection of drug therapy will be consistent with the metrics based on nationally recognized disease state guidelines detailed in **Appendix A, table 3**.
- The pharmacist may modify the drug therapy per the nationally recognized guidelines as well and use clinical judgment in providing the services under this CPA. The specific drugs to be managed by the pharmacist are detailed in **Appendix A table 4.**

- The pharmacist may order or modify an order for medication-related supplies and devices medically appropriate for the patient's disease state detailed in **Appendix A table 5**.
- The pharmacist may order laboratory tests listed in **Appendix A table 2** as they pertain to the patient's disease state management.
- The pharmacist may initiate, modify, discontinue, or refill drugs listed in **Appendix A table 4.**
- The pharmacist may (a) administer diphenhydramine or epinephrine in the event of an anaphylactic reaction, or (b) in a life-threatening event, perform cardiopulmonary resuscitation (CPR) or use a medical device such as an Automated External Defibrillator (AED).
- The practitioner reserves the right to override a collaborative practice decision made by the pharmacist where deemed appropriate and shall discuss the rationale for the decision with the pharmacist when possible.

Monitoring

- Patients will be followed for adjustment of medications at regular intervals deemed appropriate by the pharmacist-provider team
- Monitor laboratory markers and/or self-monitored blood pressure and heart rate readings to assess for clinical improvement, toxicity, cardiovascular risk, and for selection of appropriate therapy
- Assess patient for signs and symptoms of adverse drug events

Communication, Documentation and Supervision

Communication between the Supervising Physician and Clinical Pharmacist will occur via the shared electronic medical record. For more urgent matters, the Clinical Pharmacist and Supervising Physician shall communicate in person or by telephone. If the applicable Supervising Physician is unavailable or absent, the Clinical Pharmacist shall consult and communicate with the covering provider or applicable specialist at the practice location or specialty listed below.

The Clinical Pharmacist shall document all CDTM activities in electronic health record, including but not limited to, initiation, modification or discontinuation of a patient's medications, and tests ordered.

Outcome Measures

- Outcome measurements will be generated at least annually and reported regularly. Key clinical and operational metrics found in **Appendix A Table 1** will be monitored and reported at least annually to practitioner(s) and to the NH Board of Pharmacy. in accordance with Brigham and Women's Collaborative Drug Therapy Management Policy 8.1.24.

Risk Management and Quality Assurance

- At least once per year, the pharmacist shall review the collaborative practice agreement and each protocol developed pursuant thereto so as to determine whether changes should be made to reflect the standard of care. If such a review reveals that a change should be made, the pharmacist shall inform the attending practitioner and the patient or the patient's authorized representative. The pharmacist will provide written or electronic notification in accordance with applicable law and rules to the NH Board of Pharmacy ("NH BOP") within 15 days of changes made to the CPA, documentation and or the original CPA application.
- The CPA will be renewed if agreed upon by all parties that have signed the CPA at a minimum of every 2 years.
- The quality metrics of this CPA will be reported to the NH BOP annually.
- The pharmacist will maintain the qualifications to participate in the CPA, as required under applicable law and rules and will perform peer or self-review of documentation notes in the patients' EMR at least annually.
- The pharmacist will maintain basic life support (BLS) certification from a nationally recognized organization and documentation of this certification.
- Neither the practitioner nor the pharmacist shall seek to gain personal financial benefit by participating in any incentive-based program or accept any inducement that influences or encourages therapeutic or product changes or the ordering of tests or services.
- The pharmacist will provide services to the patient under this CPA in a private exam room, remotely (via telephone and or video), in-office or in a secluded area in accordance with the Health Information Portability and Accountability Act of 1996 (HIPAA) and associated regulations.
- The pharmacist will have dedicated time scheduled to perform the duties outlined in this CPA. The expected amount of time the pharmacist will devote to this CPA service will depend on the needs of the clinic, size of the patient population, the patient, and the availability of HIPAA compliant space in which to provide services.

The Clinical Pharmacist and the Supervising Physician will immediately provide written notice to each other and to the Clinical Pharmacy Credentialing Committee and to the Provider Enrollment Department if disciplined by their respective licensing Boards (whether by agreement or Board order), or if otherwise subject to any practice restrictions.

In the event of a serious patient concern or adverse occurrence, the pharmacist will:

- Make every effort to address and correct the event immediately
- Communicate the event to the referring provider (or designee) as soon as possible to address the urgent need
- Review case with referring provider or supervising physician to evaluate any preventable cause(s) and possible future improvements

Delegation

The Clinical Pharmacist may delegate CDTM administrative work to medication support coordinators in accordance with applicable law and Mass General Brigham Integrated Care policies.

Collaborative Pharmacy Practice Agreement Pharmacist and Practitioner Signatures

By signing this CPA, the pharmacist named below agrees to all the terms and conditions of this CPA with the named practitioner and patient who are also signing.

1. **Clinical Pharmacist's Signature, date, and address:**

Printed Name of Clinical Pharmacist: Themio Papadopoulos

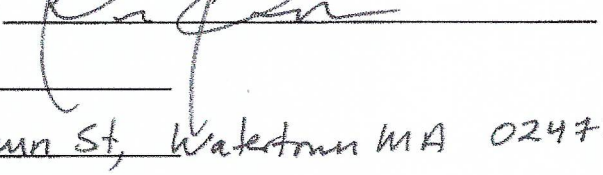
Signature of Clinical Pharmacist: 

Date: 9/6/2022

Address: 30 Tuscan Boulevard Salem, NH 03079

2. **Supervising Physician (s)**
   By signing this CPA, the practitioner named below agrees to all the terms and conditions of this CPA with the named pharmacist and patient. If the practitioner named below is a Medical Director or Lead Practitioner with supervisory responsibility for other practitioners, his/her signature commits all practitioners working under the Medical Director's or Lead Practitioner's supervision.

Printed Name of Supervising Physician: Devon Evasha MD

Signature of Supervising Physician: 

Date: 9/7/2022

Address: 1 Mount Auburn St, Watertown MA 02472

Patient Summary, Benefits and Signature

As discussed in the previous sections of this CPA, you and your practitioner have decided to seek additional healthcare support with the use of a Collaborative Pharmacy Practice Agreement. This CPA allows the pharmacist named on the previous page to assist in improving your treatment outcomes for your specified disease state through a combination of medical, educational and follow-up interventions as described in this CPA. The pharmacist will work closely with your practitioner to ensure your goals and health care needs are met.

The pharmacist's responsibilities to you (and your caretaker) for your disease state are, in conjunction with your practitioner, as follows:

- Help you recognize the importance and purpose of your medications by teaching you about how your medications work as well as educate you on your disease state and the risks and benefits of specific treatments plans that will be developed together with you;
- Demonstrate and teach you how to use your medical devices related to your disease state;
- Help you understand, establish, and reach lifestyle and dietary goals to the extent within the scope of practice of the practitioner under the law;
- Compile a complete list of your current medications along with discontinuing medication related to your disease state you will no longer be taking;
- Help identify and resolve medication related problems, for example drug-related side effects;
- Monitor relevant laboratory test results for medication therapy, and adjust medication doses as applicable;
- Adjust medications as necessary (for example discontinue, start, change a dose or add a new medication) to optimize your outcomes;
- Answer any questions you may have concerning your medication therapy for the specified disease state.

As a Mass General Brigham Integrated Care patient, we want you to be a part of the decisions made in your care. By signing this CPA, the named patient consents to being in this Collaborative Pharmacy Practice Agreement with the named pharmacist and practitioner and signifies agreement with the following statements:

- A copy of the CPA and supporting guidelines have been given to me and sufficient time has been provided to me to review the documents;
- The benefits and risks of the CPA have been explained to me;
- I understand I have the right to terminate this CPA at any time;
- I have been given all the information I asked for about the CPA;
- I was given time to ask questions about the CPA and all of my questions were answered satisfactorily; and
- I have read and understand this CPA and consent to be part of the CPA.

Patient's signature:
Patient's Full Name (printed):
Patient's Address:
Patient DOB:
Date signed:

If the patient is not able to consent for her/himself complete the following:

Legally responsible person's name:
Relationship to patient (State whether Legal Guardian, Agent under Durable Power of Attorney for Healthcare):
Date signed:

If an interpreter was used:

Interpreter's name:
Interpreter's signature:
Commercial service name:
Date signed:

Provider Name	**Pharmacist Name**
Address	Address

This Agreement is effective for two (2) years from the last signature date above and must be reviewed and renewed (re-signed) by the Clinical Pharmacist and Named Supervising Physician at least every two (2) years. The Clinical Pharmacist and Named Supervising Physician shall each retain copies of this Agreement and the Clinical Pharmacist shall send a copy to the Pharmacy Credentialing Committee for filing.

Appendix A: Tables

Table 1: Disease State and Quality Performance Metrics

Disease State	Quality Performance Metrics
Diabetes Type II Hypertension Dyslipidemia Venous and arterial thrombosis (prevention and treatment) Smoking cessation	Hospitalizations Achievement of guideline directed medical therapy Goal blood pressure achieved Goal LDL achieved Goal A1C Time in therapeutic range Thromboembolic/bleeding events

Table 2: Laboratory Tests*

Timeframe	Lab test
• As needed	• INR/PT • PTT • Aldosterone • Renin • Anti-Xa • Basic metabolic panel • Chest X-ray • Complete blood count +/- differential • Creatine kinase • Digoxin level • Electrocardiogram • Eye exam • Hemoglobin A1c • Microalbuminuria • Liver function tests • Lipid panel • Direct LDL • Aldosterone • Renin • Thyroid stimulating hormone • Thyroid function test

Abbreviations: INR/PT: international normalized ratio/prothrombin time**: PTT:** partial thromboplastin time; **Anti-Xa**: anti-factor XA

*Individual tests within each lab panel listed above and any other labs relevant to the medication and or specific disease state may be ordered.

Table 3: Practice guidelines:

Disease State	National Guidelines	Link
Diabetes Type II	ADA Standards of Medical Care in Diabetes	https://diabetesjournals.org/clinical/search-results?f_AllAuthors=American+Diabetes+Association https://professional.diabetes.org/content-page/practice-guidelines-resources
Hypertension and Dyslipidemia	American College of Cardiology / American Heart Association: Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults and Guideline on the Management of Blood Cholesterol ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults ESC Guidelines on Dyslipidaemias	https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Guidelines/2017/Guidelines_Made_Simple_2017_HBP.pdf https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Guidelines/2018/Guidelines-Made-Simple-Tool-2018-Cholesterol.pdf https://www.jacc.org/doi/pdf/10.1016/j.jacc.2019.03.010?_ga=2.88895067.1780582717.1608581136-2074456741.1585574152 https://www.jacc.org/doi/pdf/10.1016/j.jacc.2013.11.003?_ga=2.9396469.1780582717.1608581136-2074456741.1585574152 https://www.jacc.org/doi/pdf/10.1016/j.jacc.2018.11.003?_ga=2.115117767.1780582717.1608581136-2074456741.1585574152 https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.11.006?_ga=2.115117767.1780582717.1608581136-2074456741.1585574152 https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Dyslipidaemias-Management-of
Venous and arterial thromboembolism	Chest Guidelines: Antithrombotic Therapy for VTE Disease American Society of Hematology (ASH) 2018 guidelines for management of venous thromboembolism: optimal management of anticoagulation therapy	https://journal.chestnet.org/article/S0012-3692(15)00335-9/fulltext https://www.hematology.org/Clinicians/Guidelines-Quality/Guidelines.aspx https://www.acc.org/education-and-meetings/products-and-resources/guideline-education/valvular-heart-disease https://journal.chestnet.org/article/S0012-3692(12)60132-9/fulltext

	AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease CHEST Guidelines: Antithrombotic and Thrombolytic Therapy for Valvular Disease	https://journal.chestnet.org/guidelines
Smoking Cessation	ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment	https://www.jacc.org/doi/pdf/10.1016/j.jacc.2018.10.027

Table 4:

Medications

ANTICOAGULANTS	
Generic name	Brand name
Warfarin	Coumadin, Jantoven
Phytonadione	Vitamin K
Enoxaparin	Lovenox
Fondaparinux	Arixtra
Rivaroxaban	Xarelto
Apixaban	Eliquis
Edoxaban	Savaysa
Dabigatran	Pradaxa

ANTIHYPERTENSIVES	
Generic name	Brand name
Angiotensin Converting Enzyme (ACE) Inhibitors	
Benazepril	Lotensin
Captopril	Capoten
Enalapril	Vasotec
Fosinopril	Monopril
Lisinopril	Prinivil, Zestril
Moexipril	Univasc
Perindopril	Aceon
Quinapril	Accupril
Ramipril	Altace
Trandolapril	Mavik
Angiotensin Receptor Blockers (ARB)	
Azilsartan	Edarbi
Candesartan	Atacand
Eprosartan	Teveten
Irbesartan	Avapro
Losartan	Cozaar

Olmesartan	Benicar
Telmisartan	Micardis
Valsartan	Diovan
Diuretics	
Acetazolamide	Diamox
Amiloride	Midamor
Bumetanide	Bumex
Chlorothiazide	Diuril
Chlorthalidone	Hygroton
Ethacrynic acid	Edecrin
Eplerenone	Inspra
Furosemide	Lasix
Hydrochlorothiazide	Esidrix, Hydrodiuril
Indapamide	Lozol
Metalozone	Zaroxolyn
Spironolactone	Aldactone
Torsemide	Demadex
Triamterene	Dyrenium
Beta-Blockers	
Acebutolol	Sectral
Atenolol	Tenormin
Betaxolol	Kerlone
Bisoprolol/hydrochlorothiazide	Ziac
Bisoprolol	Zebeta
Carvedilol	Coreg
Labetalol	Normodyne, Trandate
Metoprolol	Lopressor, Toprol XL
Nadolol	Corgard
Nebivolol	Bystolic
Pindolol	Visken
Propranolol	Inderal
Timolol	Blocadren
Calcium Channel Blockers	
Amlodipine	Norvasc
Diltiazem	Cardizem, Tiazac
Felodipine	Plendil
Nifedipine	Adalat, Procardia
Nimodipine	Nimotop
Nisoldipine	Sular
Verapamil	Calan, Verelan, Isoptin
Alpha-Adrenergic Acting Agents	
Clonidine	Catapres
Doxazosin	Cardura

Methyldopa	Aldomet
Prazosin	Minipress
Terazosin	Hytrin
Other Vasodilators	
Hydralazine	Apresoline
Isosorbide mononitrate	Imdur
Isosorbide dinitrate	Isordil
Nitroglycerin	NitroBid, NitroStat
Minoxidil	Loniten

LIPID LOWERING AGENTS	
Generic name	Brand name
Statins	
Atorvastatin	Lipitor
Fluvastatin	Lescol
Lovastatin	Mevacor
Pitavastatin	Livalo
Pravastatin	Pravachol
Rosuvastatin	Crestor
Simvastatin (+/-ezetimibe)	Zocor/Vytorin
Fibrates	
Fenofibrate	Tricor
Gemfibrozil	Lopid
Bile Acid Sequestrants	
Colesevelam	Welchol
Cholestyramine	Questran
Colestipol	Colestid
PCSK-9 Inhibitors	
Alirocumab	Praluent
Evolocumab	Repatha
Nicotinic Acids	
Niacin	Niacor, Niaspan
Cholesterol absorption inhibitor	
Ezetimibe	Zetia
Omega-3 Fatty Acids	
Omega-3-acid ethl esters	Lovaza
Icosapent ethyl	Vascepa

ANTIPLATELETS	
Generic name	Brand name
Aspirin	Bayer, Ecotrin, Entercote
Clopidogrel	Plavix
Ticagrelor	Brilinta
Prasugrel	Effient
Dipyridamole	Persantine
Cilostazol	Pletal

Diabetes Type II	
Generic name	Brand name
Biguanides	
Metformin	Glucophage
Sulfonylureas	
Chlorpropamide	Diabinese
Glimepiride	Amaryl
Glipizide	Glucotrol/Glucotrol XL
Glyburide/Glibenclamide	Micronase/Glynase/Diabeta
Meglitinides	
Nateglinide	Starlix
Repaglinide	Prandin
Thiazolidinediones	
Pioglitazone	Actos
Rosiglitazone	Avandia
Alpha-Glucosidase Inhibitors	
Acarbose	Precose
Meglitol	Glyset
DPP-4 Inhibitors	
Alogliptin	Nesina
Linagliptin	Tradjenta
Saxagliptin	Onglyza
Sitagliptin	Januvia
SGLT-2 Inhibitors	
Empagliflozin	Jardiance
Dapagliflozin	Farxiga
Canagliflozin	Invokana
Glucagon-like Peptide-1 Receptor Agonists	
Dulaglutide	Trulicity
Exenatide, Exenetide extended release	Byetta, Bydureon
Liraglutide	Victoza

Lixisenatide Semaglutide	Adlyxin Ozempic, Wegovy, Rybelsus
Bile Acid Sequestrants Colesevelam	 Welchol
Dopamine-2 Agonists Bromocriptine	 Cycloset, Parlodel
Insulin Rapid-acting: Aspart, Glulisine, Lispro Regular-Acting: Human Regular Intermediate-Acting: Human NPH Long-Acting: Degludec, Detemir, Glargine Ultra-Long Acting: Glargine U-300 Inhaled Insulin: Technosphere insulin-inhalation system Insulin Combinations: 75% Insulin Lispro Protamine + 25% Insulin Lispro 50% Insulin Lispro Protamine + 50% Insulin Lispro 70% NPH + 30% Regular Insulin 70% Insulin Aspart Protamine + 30% Insulin Aspart 70% Insulin Degludec + 30% Insulin Aspart Insulin Glargine and Lixisenatide Insulin Degludec and Liraglutide	 NovoLog, Apidra, Humalog Humulin R/Novolin R Humulin N/Novolin N Tresiba, Levemir, Lantus/Basaglar/Semglee Toujeo Afrezza Humalog Mix 75/25 Humalog Mix 50/50 Humulin 70/30, Novolin 70/30 Novolog Mix 70/30 Ryzodeg 70/30 Soliqua Xultophy

MISCELLANEOUS	
Generic name	Brand name
Nicotine replacement therapy	

Table 5: Devices

MEDICAL DEVICES
Blood pressure monitor
Point of Care PT/INR home machines
Glucometer and supplies
Continuous Glucose Monitor and supplies

Table 6: Vaccines

VACCINES	
Generic name	Age Requirement (per RSA 318:16-b and RSA 318:16-d)
Influenza	None
Pneumococcal	18 years or older
Varicella Zoster	
Hepatitis A	
Hepatitis B	
Tdap (Tetanus, Diphtheria, Pertussis)	
MMR (Measles, Mumps, Rubella)	
Meningococcal	
COVID-19	

Appendix B: Policies

Mass General Brigham Policies

a. Ellucid Policy Manager

CONTROLLED RISK INSURANCE COMPANY OF VERMONT INC. (A Risk Retention Group)
Burlington, Vermont

Evidence of Insurance

BRIGHAM & WOMEN'S HOSPITAL
75 FRANCIS STREET
BOSTON, MA 02115

Named Insured: THE BRIGHAM AND WOMEN'S HOSPITAL, INC. **Date:** 11/18/2021

Coverage	**Limits of Liability:**	
Medical Professional Liability:	$5,000,000.00	each “Claim”
	$10,000,000.00	annual aggregate each insured person for all claims made and reported during the "Policy Period".
General Liability:	$5,000,000.00	each “Claim”
Policy Number:	BWH-CRICO-C-GLPL-1710-2022	
Policy Period:	01/01/2022 to 12/31/2022	

Special Provisions:

The insured named above is insured under the policy referenced. Coverage is subject to all the terms, conditions and exclusions of the CRICO policy.

Should the above described policy be canceled before the expiration date thereof, the “Company” will endeavor to mail 30 days written notice to the certificate holder, but failure to mail such notice shall impose no obligation or liability of any kind upon the “Company” or the Risk Management Foundation.

This Evidence of Insurance does not extend any rights to persons or entities who are not “Insured’s” under the policy and neither affirmatively nor negatively amends, extends or alters the coverage afforded by the policy. It is furnished as a matter of information only, and is issued with the understanding that the rights and liabilities of the parties will be governed by the original policy.

* CLAIMS MADE AND REPORTED POLICY: This is a claims made and reported policy. Please review the policy carefully.

NOTICE

“The policy pursuant to which this Evidence of Insurance is provided is issued by the “Insured’s” risk retention group. The “Insured’s” risk retention group may not be subject to all the insurance laws and regulations of your State. State insurance insolvency funds are not available for the “Insured’s” risk retention group.”

Terms appearing in quotation marks in the Evidence of Insurance shall have the same meaning as the definition of that term in the policy.

Controlled Risk Insurance Company of Vermont, Inc.
(A Risk Retention Group)

Duly Authorized Representative

Rev. 10-2019

Policy Name:	BWH Pharmacy Credentialing Policy
Policy #	Pharmacy 1.12
Contact:	Katelyn Sylvester, PharmD, BCPS, CACP Paul M. Szumita, PharmD, BCPS
Sponsor:	John Fanikos, RPH, MBA Executive Director of Pharmacy Tom Cooley, RPh, MBA
Effective Date:	03/2021
Approved By:	Department of Pharmacy, 6/11, 1/15, 11/16, 12/16, 01/2021, 03/2021

Purpose

The purpose of this policy is to establish guidelines for the creation and operation of Collaborative Drug Therapy Management agreements within the department of pharmacy. To this end, this policy will outline the requirements of and limits to a scope of practice for an authorized pharmacist who has entered into a Collaborative Drug Therapy Management agreement with a supervising physician, as well as the responsibilities of the supervising physician at Brigham and Women's Hospital ("BWH") as provided by state and federal law.

In addition, the purpose of this policy is to outline the minimum administrative requirements necessary to allow a pharmacist to prescribe medications at BWH under Collaborative Drug Therapy Management agreements as provided by state and federal law. Nothing in this policy is intended to exempt a pharmacist from his/her obligation to have knowledge of and familiarity with all state and federal laws and regulations regarding prescribing medications.

Policy

Refer to BWH Hospital Policy 8.1.24 - Collaborative Drug Therapy Management (CDTM): Pharmacist Prescription Writing

Procedures

1.) The pharmacist will apply for credentialing using the processes outlined in the following document - **CDTM Credentialing Steps for Pharmacists**

2.) The pharmacist applicant, a member of the BWH Pharmacy Credentialing Committee and BWH Provider Services will use the processes outlined in the following document to complete the credentialing Process – BWH Pharmacy Credentialing Procedure

3.) The pharmacist will complete the BWH Department of Pharmacy Privileging Form for both their initial and reappointment application

References

- The Board of Registration in Pharmacy has promulgated 247 CMR 16.00 in accordance with G.L.c.112, ss. 24B1/2 and 24B3/4. Available at: http://www.mass.gov/courts/docs/lawlib/230-249cmr/247cmr16.pdf
- The Board of Registration in Medicine has promulgated 243 CMR 2.12 to include additional definitions and requirements applicable to pharmacists and physicians entering collaborative

practice agreements to practice CDTM in the Commonwealth. Available at: http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-2.pdf

- The Department of Public Health also has regulations around CDTM, CMR 105, available at: http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr700.pdf

Title:	**Collaborative Drug Therapy Management (CDTM): Pharmacist Prescription Writing**
Number:	8.1.24
Contact:	Lina Matta, PharmD
Sponsor:	Sunil Eappen, MD, John Fanikos, RPh, MBA
Effective Date:	3/2022
Approved By:	Pharmacy and Therapeutics Committee, 10/27/16, 10/22/20, 2/22 Medical Staff Executive Committee, 3/18, 11/20, 3/22

PURPOSE:

The purpose of this policy is to establish guidelines for the creation and operation of Collaborative Drug Therapy Management agreements. To this end, this policy will outline the requirements of and limits to a scope of practice for an authorized pharmacist who has entered into a Collaborative Drug Therapy Management agreement with a supervising physician, as well as the responsibilities of the supervising physician at Brigham and Women's Hospital ("BWH") as provided by state and federal law.

In addition, the purpose of this policy is to outline the minimum administrative requirements necessary to allow a pharmacist to prescribe medications at BWH under Collaborative Drug Therapy Management agreements as provided by state and federal law. Nothing in this policy is intended to exempt a pharmacist from his/her obligation to have knowledge of and familiarity with all state and federal laws and regulations regarding prescribing medications.

POLICY:

Pharmacists may prescribe medications at BWH pursuant to a written Collaborative Drug Therapy Management agreement that has been approved by the BWH Pharmacy and Therapeutics Committee, provided they are credentialed to do so. Pharmacists may not diagnose. Pharmacists may not prescribe any medications outside of the scope of the written agreement.

APPLICABILITY:

This policy applies to pharmacists who are employed by or provide services at BWH.

DEFINITIONS:

a. Collaborative Drug Therapy Management or CDTM, as defined in 243 CMR 2.12(1), is the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by an authorized pharmacist under the supervision of a physician in accordance with a Collaborative Practice Agreement.
b. Collaborative Practice Agreement or CDTM Agreement, as defined in 243 CMR 2.12(1), is a written and signed agreement between an authorized pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the authorized pharmacist and supervising physician propose to practice. The collaborative practice must be within the scope of the supervising physician's practice.

c. CDTM Protocol, "Protocol", is a written, evidence based practice agreement authorizing pharmacists to perform pharmacotherapy services. This protocol will have a supervising physician and will be approved by the BWH Pharmacy & Therapeutics Committee (hereinafter "BWH P&T Committee").
d. Authorized Pharmacist, shall be a pharmacist registered by the Massachusetts Board of Pharmacy ("BORP") and in good standing; meet the requirements of 247 CMR 16.02; and is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.
e. Supervising Physician, is a physician with a full license issued by the Massachusetts Board of Registration in Medicine ("BORM"). A supervising physician is a subject matter expert working in collaboration with the pharmacist and BWH P&T Committee. Pursuant to 243 CMR 2.12(3), to qualify to enter into a CDTM Agreement, a physician must:
    i. Be actively engaged in the clinical practice of medicine and provision of patient care in the particular field of medicine the CDTM agreement governs
f. Physician designee, is a physician with a full license issued by the BORM, and to whom a supervising physician may delegate duties under a CDTM agreement.

REQUIRED TERMS AND PROVISIONS FOR CDTM AGREEMENTS

a. Specific disease state(s) being co-managed. Each disease state must be identified as "primary" or "co-morbid"
b. Specific pharmacist prescribing authority pursuant to the agreement
c. Detailed practice protocols
d. Description of risk management activities
e. Documentation of any initiation, modification or discontinuation of a patient's medication in the patient's medical record in the custody of the supervising physician
f. Description of outcome measurements
g. Detailed informed consent procedures that are appropriate to the practice setting for treatment at Brigham and Women's Hospital per Informed Consent Policy 1.6.1.
h. Detailed procedures and periods by which time any test results, copies of initial prescriptions, modifications or discontinuances, copies of patient consent and the CDTM agreement, and other patient information will be available to the supervising physician in the electronic medical record
i. Specific procedure for the pharmacist to identify and transmit urgent communications with the supervising physician
j. Description of the nature and form of the supervision of the pharmacist by the supervising physician
k. Description of the procedure to be followed when either the pharmacist or the supervising physician is unavailable or absent
l. Any specific requirements based on the particular CDTM agreement to be entered into
m. Attestation of satisfaction by the supervising physician of the qualifications listed in 243 CMR 2.12 and by the pharmacist of the qualifications listed in 247 CMR 16.02(1) for participating in CDTM

SPECIFIC PRACTICE SITE REQUIREMENTS

a. Ambulatory care clinics require on-site supervision by an attending physician affiliated with the ambulatory clinic. During an emergency period, virtual care may be provided. The physician must be available by telephonic or electronic communication means to respond to immediate patient care concerns.

SUPERVISING PHYSICIAN'S RESPONSIBILITIES

a. Oversee pharmacist compliance with all required state and federal licenses for each approved CDTM Protocol.

b. Develop the practice guidelines for the CDTM Protocol based upon most current medical evidence. The supervising physician will develop quality criteria to review protocol compliance, outcome assessment and report this data to the BWH Rx Credentialing Committee annually. These criteria will be specified in each protocol.
c. Sign the Application for Massachusetts Controlled Substances Registration for Pharmacists. See application: http://www.mass.gov/Eeohhs2/docs/dph/quality/drugcontrol/app_pharmacist.pdf
d. The supervising physician is the supervisor and retains the ultimate responsibility for the care of the patient.
e. A supervising physician may delegate duties under the agreement; however, the CDTM agreement must clearly specify when and how these duties may be delegated and the duration and scope of such delegation.
f. The supervising physician or physician designee shall assess the patient and consult with the pharmacist regarding referral of the patient to receive CDTM services. The referral should include a primary diagnosis and any co-morbid conditions covered by the CDTM agreement.
h. The supervising physician or physician designee will monitor and evaluate the implementation of the CDTM agreement and will verify pharmacist credentialing for each agreement.

AUTHORIZED PHARMACIST'S RESPONSIBILITIES

a. The pharmacist shall hold a current unrestricted license in good standing to practice pharmacy in the Commonwealth and currently be engaged in pharmacy practice in the Commonwealth.
b. The pharmacist shall wear a nametag, which identifies him/her as a pharmacist.
c. The pharmacist shall have completed 5 years of experience as a licensed pharmacist or have satisfied one of the requirements in 247 CMR 16.02(1)(c)
    1. Have earned a doctor or pharmacy degree and have entered into a collaborative practice agreement on or before 2017; or
    2. Have completed such other education or residency criteria that the Board of pharmacy determine to be the equivalent of five years experience as a licensed pharmacist
d. The pharmacist shall devote a portion of practice to the defined drug therapy area that the pharmacist shall co-manage.
e. For each year of a CDTM agreement, pharmacists MUST complete at least 5 additional contact hours (i.e., total of 25 contact hours yearly) that address areas of practice generally related to the specific collaborative practice agreement. If there is more than one specific area of practice, it is recommended to obtain additional contact hours in each area, however only 25 total contact hours per calendar year are required. f. If prescriptive practices are included in the collaborative practice agreement:
    1. Maintain a current controlled substance registration issued by the Department during the term of the agreement, pursuant to M.G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.000: Implementation of M.G.L. c. 94C.
    2. Complete pain management training required pursuant to M.G.L. c. 94C, § 18(e) prior to initially obtaining a controlled substance registration and at least biennially thereafter as a condition precedent to renewing his or her pharmacist license
    3. Submit an attestation, signed under the pains and penalties of perjury, that the pharmacist participates in, or had applied to participate in, MassHealth as either a provider of services or for the limited purpose of ordering and referring services covered by MassHealth, in accordance with M.G.L. c. 112, § 24B½.

g The pharmacist must notify the Board of Registration of Pharmacists of change of employment, supervising physician or departure from the state within 30 days. Whenever an authorized pharmacist participating in CDTM is disciplined by the Board, whether by agreement or Board order, or otherwise subject to any practice restrictions, the authorized pharmacist must provide written notification of such discipline or practice restriction to each supervising physician.

SUPERVISORY RESPONSIBILITIES

a. A pharmacist may provide CDTM services only when such services are rendered under the supervision of a supervising physician or physician designee.
b. Such supervision must be ongoing, but does not require the physical presence of the supervising physician.
c. The supervising physician is responsible for determining the scope of services which may be performed by a pharmacist and providing appropriate supervision within the defined scope of services. The specific scope of services to be provided will be described in individual CDTM Protocols. Scope for a pharmacist is defined by considering:
    i. Competence of the pharmacist
    ii. Scope of service of supervising physician.
    iii. Each collaborative practice protocol shall be approved by the BWH P&T Committee.
d. On follow-up care, hospital visits, and in similar circumstances in which the supervising physician has established a therapeutic regime or other written protocol, the pharmacist shall check and record the patient's progress and report the patient's progress to the supervising physician or physician designee. Supervision is adequate if it permits a pharmacist who encounters new problems not covered by a written protocol or which exceed the established parameters to initiate a new patient plan in consultation with the supervising physician or physician designee.
e. The supervising physician or physician designee shall review all historical and physical data obtained by a pharmacist in a timely manner. (For inpatients, timely shall mean within 24 hours of admission).
f. The supervising physician or physician designee and the authorized pharmacist will work together in accordance with the prescribing guidelines described below. Each pharmacist who prescribes controlled substances must have:
    i. A current MCSR (Massachusetts Controlled Substances Registration) and DEA (Drug Enforcement Administration) registration.
    ii. Full, not temporary nor provisionary, licenses, along with both Massachusetts & Federal DEA licenses, and a Massachusetts Controlled Substances Registration.
g. When the supervising physician is absent, a physician designee shall assume temporary supervisory responsibilities for the pharmacist.
h. The supervising physician, and/or Director of Pharmacy Services, in accordance with BWH process, shall notify Provider Services upon termination or change of employment of a pharmacist.

APPOINTMENT PROCESS FOR AUTHORIZED PHARMACIST

a. Privileges and credentials are approved through the Allied Health Practitioner Credentialing Process, which grants privileges as described in the Policy VIII-21 Credentialing Allied Health Practitioners.
b. No pharmacist may prescribe or order medications under a CDTM agreement (neither inpatient nor ambulatory) until the pharmacist's duties and credentials have been approved as described in Policy VIII-21.

AUTHORIZATION OF SPECIFIC CDTM SERVICES TO A CREDENTIALED AUTHORIZED PHARMACIST

a. A supervising physician or physician designee may permit a pharmacist to approach patients of all ages and with all types of conditions, to perform the following tasks pursuant to a written CDTM agreement including, but not limited to:
    i. Collect and review patient history, including a medication history and relevant disease state history to manage CDTM services as appropriate per protocol.
    ii. In the ambulatory setting, monitor vital signs as appropriate per protocol and record pertinent data.
    iii. Assist the supervising physician or physician designee in an inpatient setting as follows:
        1. Record patient progress notes
        2. Order and interpret select laboratory test as outlined in the specific CDTM protocols
        3. Order medications as outlined in the specific CDTM Protocols
        4. Instruct and counsel patients on the use of prescribed drug therapy.

PROHIBITED SERVICES BY AN AUTHORIZED PHARMACIST SPECIFIC TO CDTM

a. Pharmacists may not diagnose
b. Pharmacists may not order anything outside of the written protocol
c. Pharmacists may not provide anesthesia, procedural sedation or perform procedures involving ionizing radiation
d. Pharmacists shall not be utilized as sole medical personnel in charge of emergency services, outpatient services, or any other clinical service where licensed physicians are not readily available.
e. Pharmacists may not order radiology tests

RECORD KEEPING AND WRITTEN ORDERS

a. Pharmacists with prescription privileges may write medication orders in accordance with written protocols developed by the pharmacist and supervising physician, and approved by the BWH P&T Committee.
b. Pharmacists with prescription privileges may write prescriptions and medication orders. For those pharmacists without prescription privileges, no prescription or medication orders will be accepted.
c. Pharmacists may write and sign progress notes.
d. Pharmacists may order laboratory tests in accordance with written protocols developed by the pharmacist and the supervising physician, and approved by the BWH P&T Committee.
e. Pharmacists may write other non-prescription based treatment orders, in accordance with written protocols developed by the pharmacist and supervising physician, and approved by the BWH P&T Committee.
g. The supervising physician must maintain the original of the current collaborative practice agreement.
h. To the extent required and/or permitted by law, the supervising physician or physician designee shall make the patient's medical record available upon request during a BORM investigation (243 CMR 2.12(5)(e)).
i. A pharmacist must maintain a copy of the current collaborative practice agreement in the primary practice setting, which is readily retrievable at the request of the BORM and BORP.

PROCEDURE:

A. Registration Requirements

In order to issue, modify or discontinue a written prescription, oral prescription or medication order in accordance with requirements for collaborative drug therapy management for Schedule II through VI drugs, pharmacists must register with the Massachusetts Department of Public Health, Division of Food and Drugs, and the United States Drug Enforcement Administration.

In order to register, pharmacists must meet all licensure requirements set by their respective boards of registration and must also have completed the requisite continuing education requirement of 5 hours of pharmaco-therapeutics in addition to their annual 20 hour CME requirement which must include one hour of pain management training.

The registration requirements are set out in detail in 105 Code of Massachusetts Regulations 700.003 (C), 700.003(I), and 700.004 and in 21 Code of Federal Regulations 1300. These regulations are available through the Partners Office of General Counsel.

B. Supervisory Requirements

Each pharmacist who prescribes controlled substances must do so pursuant to a written CDTM agreement. The pharmacist must meet all applicable requirements of the BORP. The supervising physician or physician designee for a pharmacist must hold an unrestricted, full license from the BORM; must have completed an ACGME-accredited or accredited Canadian post-graduate medical training in a specialty area appropriately related to the pharmacist's area of practice; and be board-certified or board eligible, in a specialty area appropriately related to the pharmacist's area of practice, or have hospital admitting privileges in a specialty area appropriately related to the pharmacist's area of practice. The supervising physician or physician designee and the pharmacist will work together in accordance with the prescribing guidelines described below. Only pharmacists with a full (not temporary or provisional) Massachusetts license, a current Federal DEA registration (for prescribing schedule II-V only), and a current Massachusetts Controlled Substances Registration may prescribe.

C. Prescribing Guidelines

Written guidelines for prescribing must exist in the practice setting representing the relationship between the supervising physician or physician designee and the pharmacist. CDTM agreements and specific CDTM protocols for pharmacists must be reviewed every 2 years.

The content of a CDTM agreement/protocol for a pharmacist must include but is not limited to:

a. The identification of the supervising physician for that setting;
b. A description of the nature and scope of the pharmacist practice;
c. The types and classes of and limitations on medications to be prescribed by pharmacists;

D. Prescription Form

All outpatient prescriptions by an authorized pharmacist must contain the following information:

a. The DEA number of the prescribing pharmacist must be recorded on all prescriptions issued for drugs in Schedule II-V. Prescriber may use either their DEA number or Massachusetts Controlled Substances Registration number on Schedule VI prescriptions.
b. The name of the supervising physician or physician designee must appear on the prescription form. A co-signature is not required.
c. The prescription form may be any color, but must conform to the requirements of 105 CMR 721.000 "Standards for Approved Prescription Forms in Massachusetts."

ROLE OF PHARMACY ORDER APPROVAL

Inpatient medication orders and outpatient prescriptions written by an authorized pharmacist pursuant to the written CDTM Protocol must be evaluated and approved by a second licensed pharmacist pursuant to the normal protocol for ordering and administering prescriptions. An outpatient prescription issued by an authorized pharmacist can be distinguished by the name of the supervising physician or physician designee which must appear on the prescription blank.

ROLE OF NURSING

The nurse's responsibility remains in accordance with the implementation of any written or verbal order from any provider who under law is permitted to prescribe. (See Clinical Practice Manual CPM-MED 01 and MGL Chpt. 94C, Sect. 9(b)). If the nurse has any questions regarding a provider's order he/she will continue to call the assigned responding clinician for the patient in question.

Reference	M.G.L. c. 112, § 24B½. M.G.L. c. 94C, §§ 7 and 9 M.G.L. c. 94C, § 18(e) 243 CMR 2.00 247 CMR 16.00 105 CMR 700.00

Policy Name:	Medication Error and Adverse Drug Event Reporting
Policy #	Pharmacy 5.3.2
Author:	Heather Dell'Orfano PharmD, CACP, CPPS, BCPS (AQ-C)
Sponsor:	John Fanikos, RPh, MS, Executive Director of Pharmacy Services
Effective Date:	9/21
Approved By:	Department of Pharmacy, Drug Safety Committee Reviewed and revised: 7/05, 12/06, 7/11, 12/12, 11/13, 7/14, 1/15, 11/16, 4/17, 9/18, 7/19, 9/20, 9/21

Purpose

To outline the medication error and adverse drug event reporting process at Brigham and Women's Hospital.

Policy

A. All healthcare providers have an obligation to report any situation that is not consistent with the routine delivery of patient care or routine operation of the hospital through the appropriate channels, including the BWH Safety Reporting System (RL Solutions) and the BWH Risk Management Department.
B. Timely reporting of all medication errors, adverse drug events (ADEs), adverse drug reactions (ADRs), and drug incompatibilities provides the institution with an opportunity to identify trends in both patient, visitor and employee safety issues in order to implement appropriate corrective measures.

Procedure

A. Definitions:
    1. Medication Incidents are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
    2. Medication Errors are defined as any preventable event that may cause or lead to inappropriate medication use and result in patient temporary, minor or permanent harm or death as determined by the event reviewer while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order

communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

3. Adverse Drug Events (ADEs) are defined as preventable medication errors that result in injury or have the potential to result in injury to a patient.
4. Adverse Drug Reactions (ADRs) are defined as any unexpected, unintended, undesired, excessive response to a drug (those not due to error and are non-preventable).

a. An example of a non-preventable ADR would be a rash due to an antibiotic

5. Drug Incompatibilities are defined as an occurrence when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.

B. Procedure

1. Refer to Hospital Administrative Policy 5.4.1 Adverse Event Reporting
2. Complete information and open discussion of process improvement opportunities in the interest of patient safety require that all staff report medication errors.
   a. Briefly describe the event and the patient's untoward reaction and any continued assessment, if any in the electronic health record. Document that the covering team has been made aware of the event.
3. The person detecting the medication error will enter a description of the event into the BWH Safety Reporting System (RL Solutions). This information will be electronically sent to key process holders for the Medication Use System. The covering provider will be notified, and they will notify the attending provider when available.
4. The appropriate manager or supervising physician will conduct follow-up with the persons involved to determine causes, other related factors that may have played a role in the event, and a possible solution and will ensure prescriber notification for adverse drug events.
5. The manager will provide the follow-up in the BWH Safety Reporting System and as necessary to the Drug Safety Committee, a sub-committee of the Pharmacy & Therapeutics Committee.

C. QAPI (Quality Assessment and Performance Improvement) Process

1. All information collected on medication events will be recorded and tracked in a database with reports sent to the Drug Safety Committee on a routine basis.
2. The Committee will further review the event for trends, commonality with other events, and determine if a system-wide prevention or intervention may be implemented.
3. Medication events will also be classified as to the severity of the event.

a. The Drug Safety Committee uses the CRICO system as the guide for determining the critical level of follow-up indicated.

4. The goal of follow-up is to track and prevent further events from occurring and to determine effectiveness of prior interventions.
5. Full discussion of serious medication event reports occurs at the Pharmacy and Therapeutics Committee when recommended by the Drug Safety Committee.
6. Quarterly QAPI Reports Track & Trend:
   a. Top 5 Medications involved in medication event reports
   b. Outcome Severity
   c. Process Involved (ordering, approval, dispensing, administration, etc.)

D. The Medication Event Report Review Committee, a sub-committee of the Drug Safety Committee, meets on a routine basis to review specific medication event reports to determine potential system-wide prevention and improvement initiatives and tracking of medication event report statistics including: total number of ADEs/ADRs, process involved, and actual severity.

E. Mechanisms for Identification of ADRs/ADEs
   1. Spontaneous Reporting
   2. On-line BWH Safety Reporting System
   3. The Pharmacy Department has pharmacists dedicated to the oversight of a Pharmacy Clinical Surveillance and Adverse Drug Event Monitoring System.
   4. These pharmacists are responsible for maintaining system administrative and clinical oversight of the application.
   5. These pharmacists, along with the Rx Acuity Scoring CCBO are responsible for updating the rules contained within the application.
   6. Clinical pharmacist staff follow up on potential alert based adverse drug events and document interventions within Epic iVents.
   7. The Rx Acuity Scoring Tool illicits alerts based on an electronic set of rules created in the application that monitors approved medication orders and lab information results.
   8. Pharmacists receive alerts for the assigned patient care areas continuously in real-time. They investigate the alerts and make interventions where appropriate. These results are reviewed on a monthly basis.
   9. The goal is to identify possible ADEs and prevent them from occurring both during each patient episode through follow-up and contact with the medical and nursing staff as well as long-term system intervention, if possible.

References:	Standard MM.07.01.03

Title:	**Adverse Event Reporting**
Number:	5.4.1
Contact:	Risk Management
Sponsor:	Chief Medical Officer
Effective Date:	2/2022
Approved By:	MSEC, **3/19, 2/22**

Keywords: safety reporting; medical error; near miss; harm; injury; preventable

I. Policy

In order to improve the quality of care we deliver to our patients and maximize patient safety, BWH strives to identify and analyze in a timely manner adverse events that are a result of known or unknown causes. An adverse event is an occurrence that results in injury to the patient or has the potential for causing injury. Certain adverse events may be identified as sentinel events and as a result, require review through the collaborative case review process. Other events may not be sentinel events but by their very nature identify system issues that require full review. This includes "near miss" events that are adverse events that do not reach the patient and cause injury. Adverse event reporting provides an opportunity for the institution to promote a culture that values safety, and actively seeks staff participation in systems review and corrective action development.

II. Definitions

Adverse Event: a patient care event in which a patient has experienced a treatment-related injury or death, or in which there is a risk of such injury, or death. Adverse events may or may not have been preventable. (See BWH Policy 5.4.7 on External Regulatory Reporting of Adverse Events for further information.)

Medical Device Related (MDR) Reportable Event: An event that a device likely has or may have caused or contributed to a serious injury or death of a patient or user. (See BWH Policy 5.4.7 on External Regulatory Reporting of Adverse Events for further information.)

Medical Error: Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

Sentinel Event: an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. (See BWH Policy 5.4.7 on External Regulatory Reporting of Adverse Events for further information.)

Serious Reportable Event: Serious reportable events are errors in medical care that are clearly identifiable, preventable, and serious in consequence for patients. (See BWH Policy 5.4.7 on External Regulatory Reporting of Adverse Events for further information.)

Adverse Medication Event: A drug administration error, adverse drug reaction or drug incompatibility that may or may not be preventable and causes harm or has the potential to cause harm to a patient.

Preventable Adverse Events: An injury (or complication) that results from an error or systems

failure.

Examples:

- technical error during the performance of a procedure;
- nurse administers wrong medication to patient;
- IV pump program error that results in wrong dose administered;
- resident enters order in CPOE on the wrong patient;
- medication error related to failure to perform medication reconciliation; or
- failure of system to communicate abnormal test results to ordering physician.

Non-preventable Adverse Events: An injury or complication that was not due to an error or systems failure and is non preventable at the current state of scientific knowledge. For complications related to treatment and/or procedures, the complication was communicated to and accepted by the patient as part of the informed consent process.

Examples:

- Complications of chemotherapy;
- Side effects of medications;
- Certain wound infections; or
- Known risk of use of medical device.

III. BWH Principles of Patient Safety

A significant number of adverse events are the result of complex system-based problems and not individual error. However, many adverse events are not reported because of healthcare providers' misperceptions of the consequences for reporting. As a result, opportunity for review and improvement of systems issues is lost. In order to improve the care we deliver, BWH is committed to:

- Promoting and supporting open reporting and discussion of adverse events and harm.
- Protecting reporters from retaliation or reprisals.
- Distinguishing between adverse events or patient harm caused by reasonable human limitation and/or system constraint from those resulting from substandard performance or misconduct.
- Protecting those individuals whose participation in adverse events is a result of reasonable human limitation and/or system constraint and using their insights to identify actions to improve care.
- Evaluating our success in promoting a culture of safety by measuring willingness to openly communicate adverse events.
- Developing effective communication methods to inform clinicians, employees and patients about corrective measures taken as a result of certain adverse events that have been reported.

SAFETY REPORTING SYSTEM AND PROCEDURE:

All healthcare providers have an obligation to report any situation that is not consistent with the routine delivery of patient care or routine operation of the hospital through the appropriate channels, including the BWH safety reporting system. Timely reporting of all adverse events, including near misses, provides the institution with an opportunity to identify trends in both patient, visitor and employee safety issues in order to implement appropriate corrective

measures.

All adverse events must be reported using the BWH Safety Reporting System. (See BWH Policy 5.4.7 on External Regulatory Reporting of Adverse Events for further information about how events should be reported) and provide the information as the prompts suggest. A safety report should be completed for any unusual occurrence involving persons or property, including, but not limited to the following categories of events:

1. Airway Management
2. Blood Product/Transfusion
3. Coordination of Care
4. Diagnosis/Treatment
5. Employee Event
6. Facility/Environment
7. Fall
8. Healthcare IT
9. ID/Documentation/Consent
10. Imaging
11. Lab Specimen
12. Line/Tube/Drain
13. Maternal/Childbirth
14. Medication/IV Fluid
15. Skin/Tissue
16. Surgery/Procedure
17. Radiation Oncology
18. Covid-19
19. Professional Conduct
20. Safety/Security

Reference:	**BWH Policies**
5.4.1.1	Safety Reporting and Follow Up Guidelines
5.4.4	Case Review Process
5.4.7	External Regulatory Reporting of Adverse Outcomes
5.4.6	Disclosure of Adverse Patient Events
5.4.12	Serious Reportable Events
	Pharmacy & Therapeutics Committee Policy 16.0: Medication Error and Adverse Drug Event Reporting

Title:	**Safety Reporting and Follow-up Guidelines**
Number:	5.4.1.1
Contact:	Risk Management
Sponsor:	Chief Medical Officer
Effective Date:	6/19
Approved By:	Medical Staff Executive Committee, 6/19 Nurse Executive Board, 6/11/19 Executive Patient Safety Committee

Keywords: Safety, incident, adverse, injury

I. Purpose

These guidelines describe the rationale for, requirements for and process of reporting patient and visitor safety events and follow-up within the Brigham & Women's Hospital and its facilities.

II. Rationale for Reporting

Safety Reports serve as an early warning system for the institution, identifying problems in clinical and operational processes that may result in injury. Safety reports identify patients with whom the BWH staff may work more closely to provide care and follow-up, to minimize potential complications and to prevent future litigation. Safety Reports flag adverse events for which additional documentation may be appropriate and identify "near miss" events which did not reach the patient. Cumulatively, safety reports reveal patterns of care and process problems / system issues that may require intervention or change

III. Reporting Requirements

In accordance with the Risk Management policy and the Patient Care Assessment Plan of the Brigham & Women's Hospital, the following patient and visitor events MUST BE REPORTED to the Risk Management Department:

- All Patient and Visitor Incidents and Unusual Events;
- An INCIDENT OR UNUSUAL EVENT IS DEFINED AS:
  - Any accident, injury, or discovery of a hazardous condition, or any occurrence that is not consistent with routine operation of the hospital or routine patient care.
  - Near miss events that were caught before impacting a patient or visitor.

Reporting using the online Safety Reporting System:

All incidents should be reported through the online Safety Reporting System by choosing the "Safety Reporting - BWHC" icon under the Start Menu/Partners Utilities.

Reporting by Telephone

Call Risk Management @ 617-264-3005 when any of the following occur:

- Any serious injury to patient or visitor - A safety report must also be completed.
- Any threat of legal action or demand for compensation
- Any service of formal suit papers or subpoena

THE ON LINE (ELECTRONIC) SAFETY REPORTING SYSTEM

Safety Reporting Categories

Within the Safety Reporting System, events are reported as related to:

- Patients: In-Patient and Ambulatory Service Units
- Visitors
- Person or Location Not Applicable (for events that do not fall into above categories)

In the Safety Reporting System, there are 17 general event types. These include:

1. Airway Management
2. Blood Product/Transfusion
3. Coordination of Care
4. Diagnosis/Treatment
5. Employee Event (used for employee injuries and reported to Occupational Health)
6. Facilities/Environment
7. Fall
8. Healthcare IT
9. ID/Documentation/Consent
10. Imaging
11. Lab/Specimen
12. Line/Tube/Drain (LTD)
13. Maternal/Childbirth
14. Medication/IV Fluid
15. Professional Conduct
16. Skin/Tissue
17. Surgery/Procedure
18. Radiation Oncology (Department use only)

The specific event type is then selected by the reporter to further define the event. For any event, only one general event type and one specific event type can be selected using drop down menus, but, if several processes are involved, each involved process should be described in the brief factual description of the safety report.

Functions of the Safety Reporting System

The Safety Reporting System serves distinct but related organizational functions: Risk Management and Quality Measurement and Improvement.

Safety Reporting is historically linked to Risk Management and serves to identify incidents and trends that may put patients/visitors/staff or the institution at risk. Safety reporting also supports Quality Measurement and Improvement. Safety Reports including near miss events provide a rich source of data related to the major processes in-patient care, which, when analyzed, provide information that can lead to process improvements and prevention of future incidents.

The Safety Reporting System provides:

- Initial **identification and reporting** of adverse events and near misses.

- **Individual Notification**.
- Centralized **follow-up documentation**.
- A mechanism for identifying process problems/systems suitable for **improvement** initiatives.

Initial Safety Reporting

Responsibility for REPORTING of individual safety events:

The individual who discovers a safety event is personally responsible for completing a safety report. The report is to be completed as soon as possible after the event has been identified, ideally before the identifier leaves work for the shift.

- If significant patient injury has occurred or may be a consequence of the event, the individual who discovers the event is also responsible for notifying Risk Management by phone at: 617-264-3005.
- Events occurring off-shift or after business hours should be brought to the immediate attention of the off-shift administrator or nursing supervisor
- When an event requires immediate action by another department, such as engineering or security, the reporter should telephone that department immediately.

Event Notification by Email

Each submitted safety report generates an automatic E-Mail alert to the Supervisor/Manager/Director responsible the "location where the event occurred" as identified by the reporter.

All safety reports are reviewed by the Risk Management Department. Additional leadership may be alerted to an event based on the severity of an event or event type.

Please note that use of the "Notification" section of the safety report system does not trigger an automatic notification. This field is intended for the reporter to document those individuals who have been notified at the time of an event.

Event Follow-up

The supervisor/manager/director responsible for the location in which the event occurred is automatically notified of safety events reporting within that location. The supervisor/manger/director who is accountable for the event, may be the location manger or may be responsible for a service or process that occurs in the patient care space. The location supervisor/manger/director is expected to review and sign off all events that are reported. Supervisors/mangers/directors who are responsible for the event should document appropriate follow up and sign off on the report.

In the event of a manager's extended absence (beyond 3 weeks), the name of the covering manager should be communicated to Patient Safety (BWHSafetyReporting@partners.org) so appropriate safety report access can be given to the covering manger. Any changes in management personnel should also be communicated to Patient Safety.

Location Managers/Directors are responsible for reviewing event reports filed, and based on the event and after speaking with involved staff, determining the necessary level of follow up.

- Interview staff and identify of the factors that might have contributed to the event: i.e. deviation from established standard, policy, or procedure.

- Communicate with other hospital staff who might have been directly involved with the event: i.e. notify the patient's MD, or follow-up on the outcome of X-Rays obtained after a patient fall.
- Document actions initiated as a result of the event i.e. counseling of staff, necessary changes to policy, interventions with patient or family, involvement of Patient Relations, etc.
- Notify Risk Management at 617-264-3005 for any event in which a serious patient injury has occurred. Directors, managers and supervisors of local department managers will be notified of events that managers have not resolved (signed off) at three weeks.

Access

Access to safety reports is restricted to those responsible for event investigation and follow up and to those responsible for the oversight of a process/system as a whole. Managers and administrators have access to the reports within their scope of responsibility. Risk Management, Quality and Patient Safety have access to all safety reports.

Access to safety reports is controlled through the security system within the Safety Reporting System. Access levels are maintained by Risk Management and Patient Safety.

Reports

The Quality Management/ The Quality Improvement Function

Data is available in the Safety Reporting System. Custom reports are available by request.

Manager Analytical Reports

Standing analytical reports for managers are available through the Safety Reporting System. These report templates are developed through Patient Safety. Reports are also available via the Brigham Health BRIDGE (Brigham Interactive Data Gateway).

The Risk Management Function

The Risk Management function is described in the BWH Adverse Event Reporting policy. The Risk Management Department reviews all reported events, including near misses and those resulting in injury or the risk of injury.

Peer Review Protection

Safety reports of the patient and visitor events that are entered in the Safety Reporting System are part of the Patient Care Assessment Plan of the Brigham and Women's Hospital and as such are peer review activities. These reports are confidential/privileged documents, and are not subject to discovery, nor will copies of safety reports be provided to anyone.

Safety reports do not become part of the medical record, and the safety report should not be referred to in documentation within the medical record.

Relevant details of patient events should always be disclosed to the patient and/or family member by the responsible healthcare provider and details of the actual event should be documented in the medical record in an "event note":

- Describe the event,
- Detail any necessary treatment and the patient response,

- Document that disclosure occurred.

Patient Summary, Benefits and Signature

As discussed in the previous sections of this CPA, you and your practitioner have decided to seek additional healthcare support with the use of a Collaborative Pharmacy Practice Agreement. This CPA allows the pharmacist named on the previous page to assist in improving your treatment outcomes for your specified disease state through a combination of medical, educational and follow-up interventions as described in this CPA. The pharmacist will work closely with your practitioner to ensure your goals and health care needs are met.

The pharmacist's responsibilities to you (and your caretaker) for your disease state are, in conjunction with your practitioner, as follows:

- Help you recognize the importance and purpose of your medications by teaching you about how your medications work as well as educate you on your disease state and the risks and benefits of specific treatments plans that will be developed together with you;
- Demonstrate and teach you how to use your medical devices related to your disease state;
- Help you understand, establish, and reach lifestyle and dietary goals to the extent within the scope of practice of the practitioner under the law;
- Compile a complete list of your current medications along with discontinuing medication related to your disease state you will no longer be taking;
- Help identify and resolve medication related problems, for example drug-related side effects;
- Monitor relevant laboratory test results for medication therapy, and adjust medication doses as applicable;
- Adjust medications as necessary (for example discontinue, start, change a dose or add a new medication) to optimize your outcomes;
- Answer any questions you may have concerning your medication therapy for the specified disease state.

As a Mass General Brigham Integrated Care patient, we want you to be a part of the decisions made in your care. By signing this CPA, the named patient consents to being in this Collaborative Pharmacy Practice Agreement with the named pharmacist and practitioner and signifies agreement with the following statements:

- A copy of the CPA and supporting guidelines have been given to me and sufficient time has been provided to me to review the documents;
- The benefits and risks of the CPA have been explained to me;
- I understand I have the right to terminate this CPA at any time;
- I have been given all the information I asked for about the CPA;
- I was given time to ask questions about the CPA and all of my questions were answered satisfactorily; and
- I have read and understand this CPA and consent to be part of the CPA.

Patient's signature:
Patient's Full Name (printed):
Patient's Address:
Patient DOB:
Date signed:

If the patient is not able to consent for her/himself complete the following:

Legally responsible person's name:
Relationship to patient (State whether Legal Guardian, Agent under Durable Power of Attorney for Healthcare):
Date signed:

If an interpreter was used:

Interpreter's name:
Interpreter's signature:
Commercial service name:
Date signed:

Provider Name
Address

Pharmacist Name
Address

This Agreement is effective for two (2) years from the last signature date above and must be reviewed and renewed (re-signed) by the Clinical Pharmacist and Named Supervising Physician at least every two (2) years. The Clinical Pharmacist and Named Supervising Physician shall each retain copies of this Agreement and the Clinical Pharmacist shall send a copy to the Pharmacy Credentialing Committee for filing.

BASIC LIFE SUPPORT

BLS Provider

American Heart Association.

Themio Papadopoulos

has successfully completed the cognitive and skills evaluations in accordance with the curriculum of the American Heart Association Basic Life Support (CPR and AED) Program.

Issue Date

9/24/2022

Training Center Name

Allied 100, LLC

Training Center ID

WI20877

Training Center City, State

Woodruff, WI

Training Center Phone Number

(800) 544-0048

Renew By

09/2024

Instructor Name

Jon Anzoni

Instructor ID

04150321375

eCard Code

225418799726

QR Code

To view or verify authenticity, students and employers should scan this QR code with their mobile device or go to www.heart.org/cpr/mycards.

Last Start Dt	ID	Last	First Name	Address	NH License #
8/15/2022	100623944	Knight	Esperanza	30 Tuscan Boule	087930-23
9/6/2022	100624113	Hassan	Ghinwa	30 Tuscan Boule	18175
1/3/2022	100288103	Marques	Maria	30 Tuscan Boule	087424-23
3/7/2022	100325414	Fulling	Nadine	30 Tuscan Boule	087732-23
9/6/2022	100624106	Lungulescu	Ovidiu	30 Tuscan Boule	14766
8/15/2022	100624269	Loosigian	Sarah	30 Tuscan Boule	948
8/15/2022	100624092	Ozaroff	Steve	30 Tuscan Boule	1910
9/6/2022	100624105	Zdrnja	Vlasta	30 Tuscan Boule	12446
9/6/2022	100624108	Wilson	Yvonne	30 Tuscan Boule	14365

Start Date	Unit	Dept ID	Job Code	Location	Job Title
8/15/2022	0400	ACC039	000512	SALEM SITE	Nurse Practitioner
9/6/2022	0400	ACC032	000521	SALEM SITE	Physician – Family Medicine
1/3/2022	0400	ACC032	000512	SALEM SITE	Nurse Practitioner
3/7/2022	0400	ACC039	000512	SALEM SITE	Nurse Practitioner
9/6/2022	0400	ACC032	000520	SALEM SITE	Physician – Internal Medicine
8/15/2022	0400	ACC039	000512	SALEM SITE	Nurse Practitioner
8/15/2022	0400	ACC039	000513	SALEM SITE	Physician Assistant
9/6/2022	0400	ACC032	000520	SALEM SITE	Physician – Internal Medicine
9/6/2022	0400	ACC032	000520	SALEM SITE	Physician – Internal Medicine

Dept	Manager Name
MGBIC Salem APP	Taylor,Kolleen M
MGBIC Salem Providers	Taylor,Kolleen M
MGBIC Salem Providers	Taylor,Kolleen M
MGBIC Salem APP	Taylor,Kolleen M
MGBIC Salem Providers	Taylor,Kolleen M
MGBIC Salem APP	Taylor,Kolleen M
MGBIC Salem APP	Taylor,Kolleen M
MGBIC Salem Providers	Taylor,Kolleen M
MGBIC Salem Providers	Taylor,Kolleen M