Practice Location: Duquesne University Center for Pharmacy Care, Muldoon Building

Background:
Pennsylvania Pharmacy Act 9.3 allows pharmacists to modify and administer drug therapy under a written agreement with physicians in the outpatient setting.

The written agreement refers to the practice where physicians refer patients to and authorize pharmacists to engage in specific activities involved in evaluating and managing drug therapy. The agreement, between a licensed physician and licensed pharmacist, may include the modification (adjust drug regimen, dosage strength, and route or frequency of administration) and administration of drug therapy, ordering and evaluating lab work, making physical assessments, and any other provision of drug therapy and patient care management within the scope of practice and practice skills of the parties involved. Verbal consent will no longer be required to perform the activities within the scope of practice authorization.

Protocols/Guidelines/References:
American College of CHEST Physicians 2012, Center for Pharmacy Care
Anticoagulation Management Services Protocol

Scope of Practice Authorization:
Full scope of practice may be conducted according to the established Anticoagulation Management Service Protocols/Policies and in accordance with all stipulations for the Anticoagulation Clinical Pharmacists named in this agreement. The Anticoagulation Clinical Pharmacists are the responsible providers for the Anticoagulation Management Service. The clinical pharmacy scope of practice includes the following authorized activities:

A. Assessment:
1. Indications for anticoagulation therapy
2. INR range and values
3. Concomitant medications and herbal/nutritional supplements
4. Recent alterations in diet or alcohol use
5. Medication compliance
6. Level of understanding or literacy
7. Other medical history and lab values pertinent to the patient’s anticoagulation status.
8. Identify signs and symptoms of thrombosis or serious bleeding and determine need for physician evaluation. Patients with adverse physical findings will be referred to the Emergency Department or their primary/referring physician.

B. Education: Provide education to patients and caregivers
   1. Review clinical indication for anticoagulation therapy
   2. Review necessary laboratory tests and terminology
   3. Importance of adherence with anticoagulation regimens
   4. Specified goals and length of anticoagulation therapy
   5. Adverse event monitoring and when to seek treatment
   6. Drug interactions and concurrent medications
   7. Dietary considerations (vitamin K)
   8. Cautions regarding alcohol use
   9. Role of the pharmacist in drug therapy management; the patient will be afforded the opportunity to refuse drug therapy management by the pharmacist.
   10. Provide dosing and follow-up instructions

C. Monitoring: Monitor and adjust anticoagulation regimens
   1. The pharmacist will provide recommendations for dosing of warfarin and other anticoagulant medications.
   2. The pharmacist will evaluate the current INR (International Normalized Ratio) value and assess the need for changes in the current regimen.
   3. The pharmacist determines the frequency of INR testing.
   4. The pharmacist will authorize refills of anticoagulant medications ordered by physicians.
   5. The pharmacist will make recommendations for discontinuation of anticoagulation and verify this with the referring physician.
   6. The pharmacist will alert the referring physician regarding patients who are noncompliant with anticoagulation regimens and clinic appointments.

D. Laboratory Tests: Order appropriate tests necessary to determine baseline levels or to monitor the efficacy or toxicity of anticoagulation regimens via the following:
   1. Venous PT/INRs.
   2. Point of care testing (POCT) using finger stick PT/INRs.
      a. If INR is above upper limits defined in the Anticoagulation Management Service, the result is to be verified by a venous sample.
   3. Based on the patient’s presentation and concurrent medication use, request orders be written for basic metabolic panel and CBC with platelet count and differential when necessary.
E. Documentation
   1. All pertinent information of each patient encounter will be documented in the patient’s medical record and will occur as soon as practicable, but no later than 72 hours after the intervention.

F. Physician Notification
   1. The authorizing physician and/or covering physician will be notified of any modifications to a patient’s anticoagulation regimen within 72 hours of the change.

G. Process Improvement
   1. A database will be used to generate quarterly reports on patient progress and clinic outcomes

H. Pharmacist or Physician Absence
   1. If the clinic pharmacist is absent, a covering pharmacist will be available.
   2. If an authorizing physician is not available at the time of the patient encounter, the physician covering his/her service will receive the notification progress notes within 72 hours of the intervention, with additional notification of the authorizing physician as needed upon their return.
   3. The Anticoagulation Service Medical Director will be available for staff consultation with regards to patient care in the event that an authorizing or covering physician cannot be reached.

I. Agreement Review and Duration
   This agreement shall be valid for a period not to exceed 2 years from the effective date. However, it may be reviewed and revised at any time at the request of any of the physicians or pharmacists. The physicians may list any exclusions or specific instructions in the area provided below:

   Special instructions/exceptions:

   ________________________________________________
   ________________________________________________
J. Record Retention
   1. A copy of a patient’s referral shall be maintained in the patient’s medical record and kept on file by the clinic pharmacists.
   2. This written protocol will be available at the practice site of any physician who is a party to the protocol; at the Center for Pharmacy Care; at the medical directors office; and to any patient who is subject to this protocol; and to the Pennsylvania Department of Health and Bureau of Professional and Occupational Affairs.

K. Withdrawal or Alteration of Agreement
   1. A physician may withdraw from the agreement at any time or may override this agreement whenever he or she deems such action is necessary or appropriate for a specific patient.
   2. Any patient affected by the withdrawal or alteration of the agreement will be notified by the clinic pharmacist.

Approvals:

Suzanne Higginbotham, Pharm.D.
Director, Center for Pharmacy Care
Signature __________________________ Date ____________

Michael Essig, MD
Medical Director Name
Signature __________________________ Date ____________
The Center for Pharmacy Care Anticoagulation Management Service Clinical Pharmacist Statement:

This protocol has been reviewed by all clinical pharmacists within the Anticoagulation Management Service and by signing, agrees to adhere to the responsibilities outlined within this Delegation of Duties Agreement.

CPC Pharmacists:

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<tr>
<th>Pharmacist</th>
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<tr>
<td>Brandon Herk</td>
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<td>Suzanne Higginbotham</td>
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<td>Bob Laux</td>
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<td>Monica Skomo</td>
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Please retain a copy of this form with the CPC AMS Protocol
The physicians of the _______________________________ physician group

below agrees with the terms of the Center for Pharmacy Care Anticoagulation Service Management Delegation of Duties Agreement. By signing, the physician understands their responsibilities as an authorizing and referring physician.

This Delegation of Duties Agreement is entered into this ________ day of the month__________________ in the year_______________ by and between:

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<tr>
<th>Physician</th>
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