

**PROTOCOL**  
**Drug Therapy Management**

**Title: Thrombosis**

Authority: Health Occupations Article, §§12-6A-01 – 12-6A-10, Annotated Code of Maryland.  
10.34.29 Drug Therapy Management

Section I (.02 A 2a) This protocol covers the following disease states and conditions:

- A. Prevention (primary or secondary) of embolic stroke secondary to atrial fibrillation, atrial flutter, prosthetic heart valves, myocardial infarction, dilated cardiomyopathy, patent foramen ovale, carotid artery disease, cerebrovascular disease, or any other condition or disease process that the physician(s) covered under the physician-pharmacist agreement determines places the patient at high risk for an embolic stroke.
- B. Treatment or prevention (primary or secondary) of venous thromboembolism including deep vein thrombosis and pulmonary embolism secondary to surgery, trauma, a disorder of hypercoagulability, pulmonary hypertension, pregnancy, estrogen replacement therapy, estrogen-containing oral contraception, or any condition or disease process that the physician(s) covered under the physician-pharmacist agreement determines places the patient at high risk for a venous thromboembolism.

Section II (.02 A 2b) The pharmacist(s) may modify, continue, or discontinue the following medications according to current standards of care for the conditions and diseases states listed in Section I of this protocol:

- A. Vitamin K antagonists
  - a. Warfarin
- B. Unfractionated heparin
- C. Low-molecular-weight heparins
  - a. Dalteparin
  - b. Enoxaparin
  - c. Tinzaparin
- D. Factor Xa inhibitors
  - a. Fondaparinux
- E. Antiplatelet drugs
  - a. Aspirin
  - b. Clopidogrel
  - c. Ticlopidine
- F. Vitamin K (phytonadione)

Section III (.02 A 2c) The pharmacist(s) is permitted to monitor the patient covered by this agreement using the following laboratory tests and evaluation procedures:

- A. Physical Examination
  - a. Visual inspection of the skin
  - b. Vital signs

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## Drug Therapy Management Protocol: Thrombosis

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- i. Blood pressure
    - ii. Heart rate
    - iii. Respiratory rate
    - iv. Height
    - v. Weight
    - vi. Temperature
  - c. Neurological examination
    - i. Sensory perception
    - ii. Muscle strength
    - iii. Deep tendon reflexes
    - iv. Gait and cerebellar function
  - d. Mental status
- B. Coagulation Tests
  - a. Prothrombin Time (PT) / International Normalized Ratio (INR)
  - b. Activated Partial Thromboplastin Time (aPTT)
  - c. Serum Anti-factor Xa activity
  - d. Serum Factor X Concentration
  - e. Prothrombin-Proconvertin Time
- C. Liver Function Tests (LFTs)
  - a. Serum Aspartate Aminotransferase (AST)
  - b. Serum Alanine Aminotransferase (ALT)
  - c. Alkaline Phosphatase
  - d. Serum Bilirubin (direct and indirect)
  - e. Serum Albumin
- D. Kidney Function Tests
  - a. Serum Creatinine
  - b. Blood Urea Nitrogen (BUN)
- E. Hematological Tests
  - a. Complete Blood Count (or its separate components)
  - b. d-Dimer
- F. Urinalysis (UA)
  - a. Semi-quantitative test for blood
- G. Fecal Occult Blood Test (FOBT)

Section IV (.02 A 2d) The pharmacist(s) shall contact the physician(s) according to the methods outlined in the Physician-Pharmacist Agreement under the following circumstances:

- A. A finding(s) indicates the patient's symptoms related to the initial thrombotic event have worsened from baseline or the patient has developed a new thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism, stroke, or TIA);
- B. A finding(s) suggests the patient may have developed a new medical condition requiring further medical evaluation; or
- C. A new finding(s) indicates the patient may be experiencing an adverse drug event that may preclude the continued use of an agent and may require an intervention beyond the scope of this protocol.

## **Drug Therapy Management Protocol: Thrombosis**

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- D. In anticipation of a known drug-drug or drug-food interaction that will likely result in the patient's coagulation test moving outside the therapeutic target range.
- E. When new clinical trials or other scientific information is published that changes the efficacy or safety record of the agents in Section II of this protocol.

Section V (.02 A 2e) The pharmacist(s) may not substitute among chemically dissimilar drug products prescribed by the physician unless such substitution is permitted in the drug therapy management contract.

Section VI (.02 A 2f) The pharmacist(s) may alter doses, modify the drug treatment regimen, switch among the agents in Section II of this protocol, or discontinue the drug treatment regimen prescribed for the patient according to the methods outlined in the Physician-Pharmacist Agreement under the following conditions:

- A. The coagulation status tests indicate that the patient is outside the target range.
- B. The patient will have an invasive procedure which precludes the continued use of the drug treatment regimen.
- C. When the patient is simultaneously using warfarin with an injected antithrombotic drug and the coagulation test(s) indicate that the patient has reached or exceeded the therapeutic target for warfarin therapy.

Section VII (.02 A 2g) The pharmacist(s) shall document each patient encounter utilizing a format that minimally includes pertinent subjective and objective information as well as an assessment and a drug therapy management plan according to the methods specified in the Physician-Pharmacist Agreement. Copies of this documentation shall be sent to the physician in a timely manner.

Section VIII (.02 A 2h) The following provisions may be customized within a drug therapy management contract:

- A. The physician(s) should specify the patient's target therapeutic range for a coagulation test used to monitor drug therapy,
- B. The physician(s) should specify which chemically dissimilar drug products the pharmacist(s) may substitute in section II of this protocol,
- C. The physician(s) may alter the list of circumstances that the pharmacist(s) may alter doses, or modify the treatment regimen of the patient as defined in Section IV and VI of this protocol.

Section IX (.02 A 2i) The pharmacist will implement the following action plan when a situation is encountered that is not addressed in this protocol:

- A. In the case of emergency, the pharmacist(s) will notify the physician(s) and contact the appropriate emergency services;
- B. In a situation of an urgent nature, the pharmacist(s) will contact the physician(s) according to the methods outlined in the Physician-Pharmacist Agreement; and
- C. In a situation of non-urgent nature, the pharmacist(s) will instruct the patient to contact his or her primary care physician.

## **Drug Therapy Management Protocol: Thrombosis**

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Section X (.02 A 2j) This protocol may be technically modified in writing by the physician(s) and pharmacist(s) listed in the Physician-Pharmacist agreement with notification at the time of renewal with the Board of Pharmacy without submitting a request for amendment to the Boards under the following circumstances:

- A. Changes in recognized standards of care or guidelines for the treatment or prevention of thromboembolism indicate that an agent should be added to or removed from Section II of this protocol; or
- B. Changes in recognized standards of care or guidelines for the monitoring of thromboembolism or the drug products in Section II of this protocol indicate that a laboratory test or evaluation procedure should be added to or removed from Section III of this protocol.