Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Amended April 23, 2021

VHA DIRECTIVE 1108.16(1)
Transmittal Sheet
January 29, 2021

ANTICOAGULATION THERAPY MANAGEMENT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for effective management of Veterans receiving anticoagulation therapy.

2. SUMMARY OF MAJOR CHANGES:

Amendment dated April 23, 2021 updates the title of a VHA policy and changes the following: “critical, non-life-threatening international normalized ratio (INR)” to a “critical INR.” The descriptor “non-life-threatening” has been removed.

This directive:

a. Revises the responsibilities associated with the Anticoagulation Program Manager and Anticoagulation Program Champion, who must be either a physician, a nurse practitioner or a clinical nurse specialist, with credentials that include advance training and expertise in anticoagulation management. (see paragraph 5).

b. Updates Anticoagulation Therapy Management program staffing model recommendations to be individualized at the Department of Veterans Affairs (VA) medical facility level and must include adequate anticoagulation ancillary team members (e.g. clinical and administrative staff), to achieve optimal efficiency (see Appendix A).

c. Updates elements for the Anticoagulation Management Program quality assessment to include the requirement for VA medical facilities to develop action plans based on established thresholds identified within their quality monitoring programs for both warfarin and direct oral anticoagulants (DOACs) (see paragraph 5).

d. Revises the VA medical facility laboratory software package designates a critical international normalized ratio (INR) value of 4.5 or greater (see paragraph 5).

e. Adds a requirement to adopt evidence-based protocols for the use of reversal agents that is consistent across the VA medical facility with recommendations for medication order sets and quality monitoring for Veterans administered reversal agents (see paragraph 6).

f. Revised training requirements to be VA medical facility-specific and individualized to the staff and VA medical facility needs (see paragraph 7).

3. RELATED ISSUES: VHA Handbook 1106.01, Pathology And Laboratory Medicine Service (P&LMS) Procedures, dated January 29, 2016; VHA Directive 1138.01, Patient Self-Testing For Monitoring Of Prothrombin Time International Normalized Ratio In Veterans On Warfarin Anticoagulation Therapy, dated May 12, 2017; VHA Handbook

1101.11(3), Coordinated Care For Traveling Veterans, dated April 22, 2015, VHA Handbook 1108.11, Clinical Pharmacy Services, dated July 1, 2015.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Service (12PBM) in the Office of Patient Care Services, is responsible for the content of this directive. Questions may be addressed to 202-461-7326.

5. RECISSIONS: VHA Directive 1033, Anticoagulation Therapy Management, dated July 29, 2015, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of January 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Beth Taylor, DHA
Assistant Under Secretary for Health
for Patient Care Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publication Distribution List on February 1, 2021.

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ANTICOAGULATION THERAPY MANAGEMENT

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for optimal management of Veterans receiving anticoagulation therapy. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b).

2. BACKGROUND

a. Anticoagulants are commonly prescribed across numerous indications but remain in a high-risk medication class due to their adverse event profile. Improving anticoagulation care continues to be a National Patient Safety Goal (NPSG) for The Joint Commission. The National Center for Patient Safety (NCPS) evaluates root cause analysis reports involving anticoagulant adverse events and identifies repeated vulnerabilities associated with communication between providers. While warfarin remains a highly utilized therapy, the prescribing trends of direct oral anticoagulants (DOACs) continue to increase given their ease of use, efficacy and safety profiles and as additional indications for use are recognized in evidence-based literature. Direct oral anticoagulant (DOAC) adherence is important for treatment success, as effectiveness is directly related to patient compliance. Unlike warfarin therapy where adherence is objectively correlated with routine international normalized ratio (INR) monitoring, poor patient compliance is an emerging concern due to increased risks associated with DOAC nonadherence. Population management tools are increasingly effective in the monitoring and management of this patient population, with the goal of reducing the risk for adverse effects and improving adherence.

b. Anticoagulation services provided in a centralized fashion improve the quality outcomes and safety of warfarin therapy. Centralized anticoagulation programs allow improved consistency of care, standardization of practice and staffing. Utilizing a designated group of clinical pharmacy specialists (CPS) as anticoagulation providers, who are particularly skilled at anticoagulant monitoring (e.g., drug interactions, lab timing, problem solving, drug-food interactions, etc.) alongside pharmacy technicians, medical support assistant (MSA) and licensed practical nurses as anticoagulation ancillary team members offers a tremendous potential for improving operational efficiency, increasing patient access and unburdening physicians and nurses. An essential component to success is the assurance that the centralized anticoagulation programs have a sufficient staff-to-patient ratio to provide safe and appropriate care. Adequate staffing quantity and mix has been shown to be a strong predictor of patient outcomes. Staffing must include clinical and administrative support staff, as outlined in Appendix A.

c. In 2018, VA Pharmacy Benefits Management (PBM) services performed an assessment and analysis of anticoagulation programs at fifty-two Department of Veterans Affairs (VA) medical facilities. This assessment was focused to evaluate current practice models to determine practice standards for staffing and operational efficiencies to deploy system-wide. Results of this assessment demonstrated that 98 %

of anticoagulation management programs at the 52 VA medical facilities evaluated were fully or partially centralized, 37% and 61% respectively. Over 79% of anticoagulation programs at VA medical facilities included primary management by CPS as anticoagulation providers providing long-term management of Veterans on warfarin and low molecular heparin (LMWH). Over 86% of VA medical facilities utilized population management tools to monitor DOAC treated Veterans. Optimizing the use of population management tools vastly improves operation efficiency (i.e., target Veterans in need of an assessment and possible intervention) and avoids the requirement for recurring scheduled appointments. Universally, anticoagulation management programs optimized the use of alternative modalities of care, with the majority of care being provided by telephone to improve efficiency and patient access. A full description of the assessment and analysis is outlined in the PBM Guidance Staffing Recommendations for Centralized Anticoagulation Management Programs on the PBM Clinical Pharmacy Practice Office (CPPO) Share Point site https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

d. This assessment demonstrated that in the 12 months ending fiscal year 2019 quarter one, there were more than 1,709,747 anticoagulation encounters generated, greater than 75% completed through telephone care. The majority of Anticoagulation Program Managers also serve as anticoagulation providers. It is essential to ensure adequate administration time, at a minimum of eight hours per week, to provide program oversight and compliance with the quality monitoring program requirements as outlined in paragraph 5.g.(2) and Appendix A.

3. DEFINITIONS

a. **Algorithm.** An algorithm, also known as evidence-based practice guidelines, refers to a standardized care process which outlines steps used to manage a Veteran's anticoagulation therapy and is utilized at the VA medical facility. ***NOTE:*** *Algorithms must be evidence-based, approved by the VA medical facility Pharmacy and Therapeutics (P&T) Committee and Executive Council of the Medical Staff (ECMS), (see paragraph 5. g.)*. An algorithm may contain protocols which outline specific actions to be implemented based on patient parameters by designated individuals for anticoagulation patient care management, (e.g., unfractionated heparin protocols by nursing staff). ***NOTE:*** *Any actions or processes outlined in algorithms or protocols must be within the scope of practice of the individual performing the function and competency must be assessed on an ongoing basis by the Chief of Pharmacy or designee, as appropriate (see paragraph 5.i.)*.

b. **Anticoagulant.** An anticoagulant is a medication that inhibits blood coagulation. Anticoagulants include, but are not limited to, warfarin, unfractionated heparin, low molecular weight heparin, other parenteral anticoagulants (e.g., fondaparinux, argatroban) and direct oral anticoagulants (DOACs) such as dabigatran, rivaroxaban, apixaban or edoxaban. ***NOTE:*** *For purposes of this directive, the term anticoagulant refers to long-term anticoagulation therapy or prophylaxis (e.g., atrial fibrillation) and does not include situations in which short-term prophylactic anticoagulation is used for*

venous thromboembolism prevention (e.g., related to procedures or hospitalization), where very low doses of anticoagulants (e.g., rivaroxaban 2.5mg twice daily) are used for the prevention of major adverse cardiovascular events or medications whose primary purpose is to inhibit platelet function (e.g., aspirin).

c. **Anticoagulation Management Program.** The term anticoagulation management program refers to a coordinated program wherein anticoagulation providers manage Veterans on anticoagulants in the inpatient and outpatient settings. A centralized anticoagulation program is a component of the anticoagulation management program for Veterans (e.g., parent facility and Community-Based Outpatient Clinics (CBOCs)) and preferred method for providing services to patients on anticoagulant therapy. In addition to clinical practice, the program also encompasses broader functions including coordinating compliance and quality control of programs relevant to anticoagulation management at the VA medical facility.

d. **Anticoagulation Program Champion.** The Anticoagulation Program Champion, who servers to support the Anticoagulation Program Manager and co-lead in the development, implementation, function and evaluation of stewardship activities, must be either a physician, a nurse practitioner or a clinical nurse specialist with credentials that include advance training and expertise in anticoagulation management.

e. **Anticoagulation Ancillary Team Members.** Anticoagulation ancillary team members refers to registered nurses and other professionals assigned to the anticoagulation management program to perform day-to-day administrative and clinical support functions in conjunction with Anticoagulation providers. Anticoagulation ancillary team members may include, but are not limited to, pharmacy technicians, nurses, health technicians and clerical associates.

f. **Centralized Anticoagulation Program.** A centralized anticoagulation program is a single, specialty clinic managed by a designated core group of anticoagulation providers and ancillary team members dedicated to providing care to all patients receiving anticoagulation therapy across the continuum of care. In addition to centralized staffing, these clinics utilize structured procedures for managing patients, policies and include anticoagulant patients from the parent VA medical facility and corresponding CBOCs (excludes contracted clinics).

g. **Direct Oral Anticoagulant.** DOAC encompasses several drug classes and includes, but is not limited to, dabigatran, rivaroxaban, apixaban and edoxaban. DOAC refers to non-warfarin oral anticoagulant medications that target one or more specific steps in the coagulation process.

h. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. ***NOTE:*** *The*

purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.

i. **Parent VA Medical Facility.** For purposes of this directive, a parent VA medical facility (parent facility), also called the primary facility, is a stand-alone medical facility or it may be the parent facility of an integrated set of facilities. In this directive, parent facility refers to a VA medical facility's three-digit station number.

j. **Peri-procedural Management.** Peri-procedural management, also known as bridging, is the temporary use of a short and immediate acting injectable anticoagulant (usually a heparin) during periods when INR level is sub-therapeutic (e.g., when warfarin therapy is started) or when warfarin is being held to perform invasive procedures. The aim of peri-procedural management is to minimize thromboembolic events and major bleeding events during the peri-procedural period. This involves engaging in risk-benefit assessments of both the embolic risk of the patient and the bleeding risk of the procedure, to determine if the anticoagulant should be held pre-operatively and for what duration (i.e., when to safely restarted post-operatively). A risk-benefit assessment would also include if the use of peri-operative bridging is necessary and safe for the patient.

4. POLICY

It is VHA policy that every VA medical facility must maintain a centralized evidence-based anticoagulation management program. The program must provide coordinated processes and procedures ensuring Veterans are appropriately treated and monitored, to ensure safety of anticoagulation therapy through transitions of care. It is VHA policy that all VA medical facilities will implement all requirements of this directive within 12-months of publication.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health Patient Care Services is responsible for supporting the implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors in resolving implementation and compliance challenges.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **<u>Chief Consultant, Pharmacy Benefits Management Services.</u>** The Chief Consultant, PBM, is responsible for:

(1) Ensuring the development and dissemination of criteria-for-use and practice guidelines for utilization by anticoagulation management programs in accordance with VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016. ***NOTE:*** *VA medical facility requirements for evidence-based guidelines are found in paragraph 6 of this directive.*

(2) Development and dissemination of quality assurance threshold values for use by VA medical facilities for their anticoagulation quality monitoring programs as described in paragraph 6. ***NOTE:*** *Threshold values change based on current evidence and require updates and reviews by PMB. Changes to the threshold values are immediately communicated by PBM to the field*.

(3) Serving as an advisor to VA medical facilities on aspects related to anticoagulation management programs.

e. **<u>Veterans Integrated Services Network Director.</u>** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

f. **<u>Veterans Integrated Services Network Pharmacist Executive.</u>** The VISN Pharmacist Executive is responsible for:

(1) Providing oversight support for anticoagulation quality monitoring programs, including monitoring facility action plans within their respective VA medical facilities.

(2) Guiding VA medical facilities to develop sustainable action plan targets in compliance with paragraph 6.j. of this directive.

g. **<u>VA Medical Facility Director.</u>** The VA medical facility Director is responsible for:

(1) Ensuring the Anticoagulation Therapy Management program encompasses the management of all Veterans (e.g., inpatient and outpatient) on anticoagulants at the parent VA medical facility and corresponding CBOCs as outlined in paragraph 6 of this directive.

(2) Designating an Anticoagulation Program Manager, who is a pharmacist (e.g., clinical pharmacy specialist, pharmacy program manager), to lead the VA medical facility's Anticoagulation Management Program and has been provided with appropriate dedicated time as outlined in Appendix A to fulfill their duties. ***NOTE:*** *This role involves a considerable time commitment and the dedicated effort of a highly committed individual to ensure a program that is high functioning, successful and sustainable. A minimum of eight hours of administrative time per week is recommended.*

(3) Ensuring an Anticoagulation Program Champion, who must be either a physician or an APRN, with credentials that include advance training and expertise in

anticoagulation management, has been designated by the VA medical facility Chief of Staff, to support the Anticoagulation Program Manager and co-lead in the development, implementation and evaluation of stewardship activities.

(4) Ensuring dedicated staff and resources are allotted for the anticoagulation management program to provide safe and appropriate care as defined in Appendix A.

(5) Ensuring care is coordinated for traveling Veterans on anticoagulants in accordance with VHA Handbook 1101.11(3), Coordinated Care Policy for Traveling Veterans, dated April 22, 2015.

(6) Ensuring the VA medical facility Anticoagulation Management Program incorporates standardized algorithms for the management of Veterans on anticoagulants for the following situations (see paragraph 6.b.):

(a) Initiation of warfarin.

(b) Maintenance of warfarin.

(c) Peri-procedural management of anticoagulants.

(d) The use of weight-based, unfractionated heparin.

(7) Ensuring anticoagulants are included on the VA medical facility's list of high-alert medications located on the VA medical facility's intranet site.

(8) Ensuring the VA medical facility uses programmable infusion pumps for inpatient Veterans receiving parenteral anticoagulants, including, but not limited to unfractionated heparin, argatroban and bivalirudin.

h. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for:

(1) Serving as the ECMS Committee chair. The ECMS must comply with activities outlined in this directive including, but not limited to, oversight of the Anticoagulation Management Program (see paragraph 5.g.(6)(a)-(d)).

(2) Appointing an Anticoagulation Program Champion, who must be either a physician, a nurse practitioner or a clinical nurse specialist, with credentials that include advance training and expertise in anticoagulation management to co-lead the Anticoagulation Management Program. ***NOTE:*** *The Anticoagulation Program Champion serves collaboratively with the Anticoagulation Program Manager to advocate for, provide consultation on anticoagulation issues and support anticoagulation initiatives and stewardship activities at the VA medical facility level. When the position is designated as either a NP or CNS, then the ADPCS will collaborate with the COS to identify and appoint a Program Champion.*

(3) Ensuring that the Anticoagulation Program quality assurance monitors and biannual Pharmacy and Therapeutics (P&T) Committee reporting trends are reviewed and reported to ECMS.

i. **VA Medical Facility Chief, Pharmacy Service.** The VA medical facility Chief, Pharmacy Service, is responsible for:

(1) Ensuring dispensed pharmaceuticals for inpatient Veterans are restricted to unit dose products, pre-filled syringes or pre-mixed infusion bags for anticoagulants when these types of products are available.

(2) Ensuring the number of concentrations and quantities of heparin vials stocked in patient care and procedural areas are limited to the minimum needed to address patient care needs. ***NOTE:*** *No multi-dose heparin product more concentrated than 5,000 units per milliliter is stocked without the prior approval of the Chief of Pharmacy*.

(3) Ensuring safe storage of anticoagulants in automated medication dispensing systems as well as the barcode scanning capability for inventory replenishment and administration, in accordance with VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.

(4) Ensuring that actions or processes outlined in algorithms or protocols be within the scope of practice of the individual performing the function and competency, in accordance with VHA Handbook 1108.11(1), Clinical Pharmacy Services, dated July 1, 2015.

j. **VA Medical Facility Anticoagulation Program Manager.** The VA medical facility Anticoagulation Program Manager is a clinical pharmacist serving as a lead for the anticoagulation management program. ***NOTE:*** *The term clinical pharmacist includes all levels of pharmacists depending on their assignment as outlined in VA Handbook 5005, VA Pharmacist Qualifications Standards, dated August 1, 2019. Typically, this position is a clinical pharmacy specialist or program manager*. The VA medical facility Anticoagulation Program Manager is responsible for:

(1) Ensuring that the VA medical facility anticoagulation program meets the requirements in this directive.

(2) Serving as the lead subject matter expert (SME) in the oversight, design, implementation and function of the anticoagulation management program.

(3) Maintaining a high standard for ensuring the quality monitoring program in the area of anticoagulation therapy.

(4) Collaborating on the development processes and procedures in areas where anticoagulants are used with practice area leads.

(5) Standardizing practice for the anticoagulation management program through activities such as educational initiatives, regular staff meetings and journal clubs.

(6) Promoting standardized practice tools (e.g., DOAC dashboard, Anticoagulator).

(7) Coordinating quality monitoring program activities for the anticoagulation management program. These activities are reported through the P&T Committee at a minimum of twice per year, consistent with the requirements outlined in paragraph 6, to include:

(a) Data analysis and trends to evaluate the appropriateness of anticoagulation therapy management.

(b) Action plans developed by the Anticoagulation Program Manager and Anticoagulation Program Champion for any elements identified through the quality monitoring program that fall outside established thresholds delineated by PBM in subparagraph 5.d.2. ***NOTE*:** *The quality monitoring program includes reports for tracking and treading laboratory values with defined objective target thresholds at the national, VISN and VA medical facility levels. (See paragraph 6.j.)*

(8) Ensuring availability of anticoagulation patient education materials and classes, as applicable.

k. **VA Medical Facility Chief, Nutrition and Food Services.** The VA medical facility Chief, Nutrition and Food Services (NFS) is responsible for:

(1) Ensuring VA medical facility menus provide a consistent amount of Vitamin K on a weekly basis.

(2) Collaborating with VA medical staff, to ensure that appropriate drug-nutrient interaction education is provided to Veterans.

l. **VA Medical Facility Chief or Director, Pathology and Laboratory Medicine Service.** The VA medical facility Chief or Director, Pathology and Laboratory Medicine Service is responsible for:

(1) Designating in the laboratory software package a critical INRvalue of 4.5 or greater.

(2) Ensuring the communication of critical INR results from the laboratory to the ordering provider or designated surrogate, in accordance with VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015.

(3) Ensuring the availability of reliable testing of heparin levels (e.g., activated partial thromboplastin time (aPTT), factor Xa levels, Heparin curve/Anti-Xa levels), heparin associated antibodies and a serotonin release assay for the evaluation of heparin induced thrombocytopenia.

(4) Ensuring the availability of reliable laboratory INRs, in accordance with VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS), dated January 29, 2016.

(5) Fulfilment of duties described in VHA Directive 1138.1, Patient Self-Testing for Monitoring of Prothrombin Time International Normalized Ratio in Patients on Warfarin Anticoagulation Therapy for sites with Patient self-testing.

m. **VA Medical Facility Anticoagulation Program Champion.** The VA medical facility Anticoagulation Program Champion is responsible for:

(1) Serving as co-lead to support the Anticoagulation Program Manager in the development, implementation, function and evaluation of stewardship activities.

(2) Providing oversight on processes and procedures in areas where anticoagulants are used with practice area leads.

(3) Advocating standardized practice tools (e.g., DOAC dashboard, Anticoagulator).

(4) Reporting quality monitoring program activities, action plans, trends and metric results for the anticoagulation management program through the P&T Committee (or appropriate VA medical facility governing body).

n. **VA Medical Facility Anticoagulation Provider.** VA medical facility anticoagulation provider refers to a provider who is currently trained and skilled in managing anticoagulant therapy with medication prescriptive authority outlined in either their clinical privileges or scope of practice. Anticoagulation providers may include clinical pharmacists, nurse practitioners, clinical nurse specialists, physician assistants and physicians. The anticoagulation provider is an active member of the anticoagulation management program and has prescriptive authority defined in their scope of practice or clinical privileges that includes anticoagulants. VA medical facility anticoagulation providers are responsible for:

(1) Managing anticoagulation Veterans in accordance with VA medical facility processes including, but not limited to, coordination of anticoagulation management for Veterans transitioning between care settings (e.g., inpatient to outpatient).

(2) Managing peri-procedural anticoagulation therapy.

(3) Serving as SME on anticoagulation therapy topics ranging from anticoagulation management to Veterans and health care professionals throughout the VA medical facility, to managing bleeding complications with the appropriate reversal agents for DOACs, warfarin and heparin.

(4) Delivering initial and ongoing patient and family education that includes the importance of follow-up monitoring, compliance issues, dietary restrictions and potential for adverse drug reactions and interactions, in accordance with required components of the anticoagulation program that can be found in paragraph 6 of this directive.

(5) Determining whether a traveling Veteran on warfarin therapy requires care coordination while traveling in accordance with VHA Handbook 1101.11(3), Care Coordination for Traveling Veterans, dated April 22, 2015.

(6) Performing and facilitating the day-to-day operations of the anticoagulation management program, consistent with paragraph 6 of this directive.

(7) Documenting the appropriate International Classification of Diseases (ICD) Diagnosis Codes to the problem list of Veterans on long-term anticoagulation therapy. In addition, appropriate Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes may be used as applicable. ***NOTE:*** *The current ICD, Tenth Revision (ICD-10) diagnosis code is z79.01 for "Long-term current use of anticoagulants."*

6. REQUIRED COMPONENTS OF THE ANTICOAGULATION PROGRAM

The following are required components of the Anticoagulation Program:

a. During normal business hours, the anticoagulation management program must have a direct telephone extension that is staffed by trained administrative personnel and accessible to facility staff and anticoagulation Veterans. VA medical facilities must also have a clearly defined process for addressing patient calls and facility staff questions regarding anticoagulation outside of normal business hours, in accordance with VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures.

b. Practice guidelines and criteria for use documents support the development of VA medical facility-level anticoagulation management program algorithms. Algorithms and practice guidelines must be adopted for use across the VA medical facility using the most current evidence-based published guidelines, as determined by the facility P&T committee. The anticoagulation management program should include each type of anticoagulation medication, drug initiation and maintenance, reversal of anticoagulation and management of bleeding events, in accordance with the elements paragraph 6.c.

c. Each algorithm should contain the following elements:

(1) How the anticoagulation management program is informed of Veterans on anticoagulation therapy undergoing procedures.

(2) The prescriber responsible for suspending anticoagulation therapy. ***NOTE:*** *It is highly recommended that the anticoagulation provider be responsible to suspend anticoagulation therapy with warfarin, with input from the surgeon or the primary care provider, as needed.*

(3) The prescriber responsible for restarting anticoagulation therapy*.* ***NOTE:*** *It is highly recommended that the decision of when to restart therapy should be made by the provider performing the procedure with communication to the anticoagulation provider as appropriate.*

(4) The prescriber responsible for providing peri-procedural anticoagulation therapy management. ***NOTE:*** *It is highly recommended that the anticoagulation provider be responsible for providing peri-procedural management. In some circumstances it may be necessary for the patient's primary care provider to provide peri-procedural*

management, however it is imperative that there be communication with the anticoagulation provider when this occurs.

(5) Weight-based, unfractionated heparin (includes heparin bolus and infusion dosing). The algorithm must require the prescriber to document the patient's weight or body surface used to determine appropriate dose to allow an independent review of the calculation by a clinical pharmacist prior to administration. A written medication order in EHR is required for initiation and maintenance heparin infusion per protocol as approved by P&T and ECMS.

(6) **Use of Reversal Agents.** Evidence-based practice guidelines and protocols should take into consideration recommendations from PBM and other professional society clinical practice guidance documents for reversal of anticoagulation and management of bleeding events related to each anticoagulant medication. To reduce the likelihood of a medication event with these infrequently used agents, the development and usage of standardized medication order sets is recommended for reversal agents.

d. The following algorithms are required to be in place across the VA medical facility:

(1) **Initiation of Warfarin.** The algorithm must ensure that all Veterans initiated on warfarin must have an INR measurement within seven days of initiation, although INR measurement within four days is recommended. Veterans currently stabilized on warfarin outside VA are exempted from this requirement.

(2) **Maintenance of Warfarin.** The algorithm must encompass guidance and recommendations for management of critical INR values and bleeding and maximum follow-up intervals for Veterans receiving ongoing warfarin therapy. See paragraph 6.b.

(3) **Peri-Procedural Management of Anticoagulants.** The algorithm must encompass intentional interruptions (e.g., surgical interventions) of anticoagulation therapy (e.g., warfarin, DOACs).

e. The VA medical facility must define laboratory tests utilized to monitor Veterans on anticoagulants and all laboratory tests (i.e., VA and non-VA) associated with anticoagulants.

(1) The following are required baseline laboratory tests for Veterans on anticoagulation therapy:

(a) Heparin. Complete blood count (CBC), activated partial thromboplastin time (aPTT).

(b) LMWH and Factor Xa Inhibitors (Fondaparinux). CBC, serum creatinine.

(c) Warfarin. CBC, prothrombin time (PT), INR. ***NOTE:*** *Initial INR should not be performed using point of care testing* (*POCT) devices.*

(d) DOAC. CBC (including platelets), serum creatinine. Liver function tests may be considered in Veterans with history or risk of hepatic insufficiency (e.g., cirrhosis, viral hepatitis, alcohol abuse, heart failure, etc.). Prothrombin time (PT)/partial thromboplastin (aPTT) may be useful to have for future reference in case of an emergency to detect presence or absence of DOAC effect.

(2) The following are required ongoing laboratory tests for Veterans on anticoagulation therapy:

(a) Heparin. CBC, aPTT or Anti-Xa.

(b) LMWH and Factor Xa Inhibitors (Fondaparinux). CBC, serum creatinine.

(c) Warfarin. CBC, PT, INR.

(d) DOAC: Serum creatinine as clinically appropriate, CBC (including platelets) must be monitored at least annually or more frequently as the clinical situation dictates, such as acute infections. Liver function testing may be considered in Veterans with underlying liver disease or when the clinical situation dictates.

f. The VA medical facility must establish a defined process that ensures appropriate follow-up for Veterans identified with a critical drug-drug interaction with anticoagulant medications. Anticoagulation providers must be notified of critical drug interactions, in accordance with VHA Handbook 1106.01. The anticoagulation provider is responsible for:

(1) The assessment of the interaction.

(2) Adjustment of the anticoagulant dose, as appropriate.

(3) Order and follow-up of subsequent laboratory tests.

(4) Communication that will occur between the ordering prescriber and the anticoagulation provider.

g. The VA medical facility must define processes to minimize the risk associated with incorrect tablet strength dosing errors with warfarin. Whenever possible, Veterans should only be prescribed one tablet strength of warfarin to minimize risk for confusion. Additional strategies may include, but are not limited to:

(1) Limiting the number of warfarin strengths dispensed for outpatient prescriptions (e.g., 2 mg and 5 mg tablets only).

(2) Creating a separate outpatient orderable items for each warfarin tablet strength.

(3) Providing written patient education with instructions whenever a dose change is made.

(4) Limiting outpatient warfarin ordering to specific prescribers.

(5) Using standardized quick order sets that promote uniformity of dosing.

h. The VA medical facility must ensure that critical INRs have appropriate action and documentation has occurred within 24 hours of the critical INR result. All non-critical INR results for Veterans on warfarin therapy must be evaluated in a timely manner, in accordance with VHA Handbook 1106.01.

i. Outpatient prescriptions for warfarin should be labeled appropriately to avoid patient confusion with changes to the instructions for use.

j. An ongoing quality monitoring program must be in place to evaluate the anticoagulation management program. This provides the opportunity to identify practice improvements, ensures appropriate action is taken to improve the practice and measures the effectiveness of those actions at a minimum twice per year. The plan must include reports for tracking and trending laboratory values with defined objective target thresholds at the national, VISN and VA medical facility levels, which include:

(1) Warfarin therapy:

(a) Time in therapeutic range (TTR) as determined by the national TTR report. (See https://spsites.cdw.va.gov/sites/PBM_CPPO/Pages/AnticoagulationTTR.aspx.). ***NOTE:*** *This is an internal VA website that is not available to the public.*

(b) Portion of Veterans on warfarin that have not had an INR in the last 56 days.

(c) Other reports determined by the VA medical facility that assess the quality of care provided at the VA medical facility level.

NOTE: *Appropriate capture of non-VA INR values and non-VA warfarin prescriptions, will greatly improve the accuracy of the quality assurance plan. The use of a health factor to capture such information is highly recommended.*

(2) DOAC therapy:

(a) Adherence monitoring using national population management data reports (e.g., national DOAC dashboard such as the MedSafe DOAC Dashboard, available at https://spsites.cdw.va.gov/sites/PBM_MedSafeRpts/DOAC/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(b) Renally adjusted dosage modifications.

(3) Proportion of Veterans with pathologic bleeding events.

(4) Proportion of Veterans with thromboembolic events. Proportion of Veterans requiring reversal agents.

(5) Patient incidents and near misses associated with an anticoagulant. Adverse drug events (ADEs) involving anticoagulants should be assessed and analyzed in

accordance with the VA medical facility Pharmacy and Therapeutics (P&T) Committee and VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.

(6) Actions plans are developed for any elements identified through the quality monitoring program that fall outside established target thresholds delineated by PBM in paragraph 5.d.(2).

7. TRAINING

a. There are no mandatory training requirements associated with this directive.

b. The VA medical facility must outline any educational programs or training requirements for staff caring for Veterans on anticoagulants. This training may include options such as Talent Management Service (TMS) courses, internally developed training programs, external training opportunities. The approach must be individualized to the staff and the VA medical facility needs determined by the Chief of Staff and the Anticoagulation Program Manager and may include items such as results of anticoagulation quality assurance program and performance improvement activities, emerging information regarding anticoagulants, as appropriate.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

9. REFERENCES

a. 38 U.S.C. § 7301(b).

b. VA Handbook 5005, VA Pharmacist Qualifications Standards, dated August 1, 2019.

c. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.

d. VHA Directive 1088, Communicating Test Results to Providers and Patients, dated October 7, 2015.

e. VHA Directive 1108.06, Inpatient Pharmacy Services, February 8, 2017.

f. VHA Directive 1138.01, Patient Self-testing for Monitoring of Prothrombin Time International Ratio (INR) in Patients on Warfarin Anticoagulation Therapy, dated May 12, 2017.

g. VHA Directive 1230(1), Outpatient Clinic Scheduling Resources, dated April 26, 2019.

h. VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.

i. VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014.

j. VHA Handbook 1101.11(3), Coordinated Care Policy for Traveling Veterans, dated April 22, 2015.

k. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, dated January 29, 2016.

l. VHA Handbook 1108.05, Outpatient Pharmacy Services, dated June 16, 2016.

m. VHA Handbook 1108.11(1), Clinical Pharmacy Services, dated July 1, 2015.

n. National Patient Safety Goals 2019, The Joint Commission https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2019.pdf. ***NOTE:*** *This linked document is outside the VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

APPENDIX A

STRUCTURE AND ORGANIZATION OF THE ANTICOAGULATION MANAGEMENT PROGRAM

Every Department of Veterans Affairs (VA) medical facility must maintain a centralized evidence-based anticoagulation management program. This includes the care provided to all Veterans on anticoagulants. This appendix outlines requirements for the structure and organization of the anticoagulation program. All Veterans receiving warfarin or long-term parenteral anticoagulants from VA on an ongoing basis, must be managed by the anticoagulation management program. Exceptions to this structure and organization may exist; however, each VA medical facility Anticoagulation Program Manager must outline any exceptions.

1. Programs must be centralized and managed by a designated group of anticoagulation providers and anticoagulation ancillary team members. These programs must:

a. Utilize structured procedures and algorithms for managing anticoagulant Veterans.

b. Include anticoagulant Veterans from the parent facility and corresponding Community-Based Outpatient Clinics (excludes contract clinics).

c. Include VISN or regional hub and spoke models, as appropriate, in the centralized management approach.

2. The Anticoagulation Program Manager must be allotted adequate administrative time to perform leadership functions for the anticoagulation management program, including quality monitoring, promoting evidence-based practice and coordinating educational activities related to anticoagulation. ***NOTE:*** *A minimum of eight hours of administrative time per week is recommended based on strong practices identified.*

3. Programs must have dedicated anticoagulation clinical and administrative ancillary team members to ensure daily operational tasks of the program, as outlined in the Pharmacy Benefits Management (PBM) Guidance Staffing Recommendations for Centralized Anticoagulation Management Programs on PBM Clinical Pharmacy Practice Office (CPPO) SharePoint site: https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

4. Clinical and administrative ancillary team members must be optimized to assist the anticoagulation provider in providing direct patient care activities.

5. VA medical facility Anticoagulant Program Managers or designated supervisors of clinical and administrative ancillary team members assign tasks that are specific and appropriate to the skills and competency of the individual. ***NOTE:*** *A list of tasks for clinical and administrative support deemed appropriate for each level of team member*

is outlined in the PBM Guidance Staffing Recommendations for Centralized Anticoagulation Management Programs on the PBM CPPO SharePoint site:

https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx, ***NOTE:*** *This is an internal VA website that is not available to the public.*

a. Administrative ancillary team members (e.g., medical support assistants, unlicensed personnel) tasks include, but are not limited to, the following:

(1) Managing appointments and related activities for Veterans who are followed in the anticoagulation management program as outlined in VHA Directive 1230(1), Outpatient Clinic Scheduling Resources, dated July 15, 2016. ***NOTE:*** *VA medical facilities should evaluate appointment management activities that are assigned to anticoagulation providers and reassign clinical staff where appropriate.*

(2) Managing faxes, telephone communications (e.g., answering and triaging patient telephone calls), contacting Veterans who have missed appointments, sending letters to Veterans, communicating with outside laboratories and other similar tasks.

b. Clinical ancillary team members (e.g., nurses and clinical pharmacy technicians) tasks include, but are not limited to, the following:

(1) Managing international normalized ratio -in-range Veterans, managing staff-to-staff communications, triaging unexpected lab results, checking the electronic health record for provider response.

(2) Clarifying dosing information for Veterans and medical history with family members or caregivers.

(3) Performing point of care testing, medication reconciliation and other similar tasks.

6. Programs must use telephone care and consider other virtual care modalities such as VA Video Connect, as the primary modality of care utilized in the management of Veterans on anticoagulants, in particular warfarin. Such modalities increase efficiency, access and have been shown to be effective in the management approach.

7. Programs must utilize a population management approach to effectively and efficiently manage Veterans on direct oral anticoagulants (DOACs) focused to reduce the need for face to face visits.

8. Programs must have a sufficient staff-to-patient ratio to provide safe and appropriate care individualized by the VA medical facility. Staffing must include adequate clinical and administrative ancillary team members (e.g., clinical pharmacy technician, medical support assistant and nursing). Staffing ratios for warfarin therapy has been objectively determined and specific recommendations are outlined in the PBM Guidance Staffing Recommendations for Centralized Anticoagulation Management Programs on the PBM CPPO SharePoint site:
https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx

***NOTE:** While DOACs require less intensive monitoring that warfarin, staffing ratios based on the number of patients receiving DOAC therapy have not been determined. This is an internal VA website that is not available to the public.*

9. Clinical pharmacy staffing models must be evaluated at least annually, based on the needs of the facility, complexity, size and clinical programs available and are discussed with leadership, as appropriate, in accordance with VHA Handbook 1108.11(1), Clinical Pharmacy Services, dated July 1, 2015. This includes:

a. Evaluating the number and complexity of Veterans receiving anticoagulation

b. Evaluating tasks performed by clinical and administrative ancillary team members and optimizing as appropriate, as outlined in the PBM Guidance Staffing Recommendations for Centralized Anticoagulation Management Programs on the PBM CPPO SharePoint site https://dvagov.sharepoint.com/sites/VHAClinicalPharmacy/Pages/Homepage.aspx

c. Evaluating and implementing optimized care modalities including telephone and virtual care.

d. Evaluating the components of anticoagulation management program that staff oversee.

10. Staffing should ensure coverage for scheduled and unscheduled leave, as well as non-direct patient care services.

APPENDIX B

ADDITIONAL ANTICOAGULATION THERAPY MANAGEMENT RESOURCES

a. Antithrombotic Therapy for VTE Diseases: American College of Chest Physicians Guideline and Expert Panel Report. CHEST. 2016; 149 (2):315-352: February Supplement.

b. Antithrombotic Therapy for Atrial Fibrillation: American College of Chest Physicians Guideline and Expert Panel Report. CHEST 2018; 154(5):1121-1201.

c. Institute for Safe Medication Practices: Medication Safety Self-Assessment for Antithrombotic Therapy 2017.

d. Kuhn H, Park A, Kim B, et. al. Proportion of Work Appropriate For Pharmacy Technicians in Anticoagulation Clinics. Am J Health-Syst Pharm 2016;73(5):322-27.

e. Ourth HL, Folstad J, Mambourg SE, et al. Evaluating the Impact Of Pharmacist Functions That Pharmacy Technicians Could Perform In An Anticoagulation Clinic On Operational Efficiency. American Journal of Health-System Pharmacy 2019; Aug 1;76(16):1248-1253.

f. Reversal of direct oral anticoagulants: Guidance from the Anticoagulation Forum. Am J Hematol. 2019;1-13.

g. Rose AJ, Berlowitz DR, Miller DR, et al. INR Targets And Site-Level Anticoagulation Control: Results From The Veterans Affairs Study to Improve Anticoagulation (VARIA). J Thromb Haemost 2012; 10: 590–5.

h. Rose AJ, Hylek EM, Berlowitz DR, et al. Prompt Repeat Testing After Out-of-Range INR Values A Quality Indicator for Anticoagulation Care. Circ Cardiovasc Qual Outcomes. 2011; 4:276-282.

i. Rose AJ, Hylek EM, Oronoff A, et al. Risk-Adjusted Percent Time in Therapeutic Range as a Quality Indicator for Outpatient Oral Anticoagulation, Results of the Veterans Affairs Study to Improve Anticoagulation (VARIA). Circ Cardiovasc Qual Outcomes. 2011; 4:22-29.

j. Rose AJ, Park, A, Gillespie C, et al. Results of a Regional Effort to Improve Warfarin Management. Annals of Pharmacotherapy 2017, Vol 51(5): 373-379.

k. Rose AJ, Petrakis BA, Callahan P, et al. Organizational Characteristics of High- and Low-Performing Anticoagulation Clinics in the Veterans Health Administration. HSR: Health Services Research 2012; 47:4: 1541-1560.

l. Rose AJ, Vaiana M. Evidence-Based Best Practices for Outpatient Management of Warfarin. Annals of Pharmacotherapy 2018, Vol. 52(10) 1042-1046.

m. 2017 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants. Journal of the American College of Cardiology 2017.