

**PATIENT SELF-TESTING FOR MONITORING OF PROTHROMBIN TIME
INTERNATIONAL NORMALIZED RATIO IN PATIENTS ON WARFARIN
ANTICOAGULATION THERAPY**

1. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive:

a. Updates all responsibilities in paragraph 2 and adds responsibilities for the National Director, Pathology and Laboratory Medicine Service (P&LMS), Diagnostic Services.

b. Updates the title for the Anticoagulation Patient Self-Testing (PST) Program Manager who is designated by the Department of Veterans Affairs (VA) medical facility Director in VA medical facilities with an Anticoagulation PST program.

c. Removes a requirement that VA medical facilities develop a policy for international normalized ratio PST and allows for VA medical facilities to create local processes instead.

d. Moves information regarding the PST device validation procedure located at [https://vaww.lab.med.va.gov/References Directives and Regulations P.asp](https://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp). **NOTE:** *This is an internal VA website that is not available to the public.*

2. RELATED ISSUES: VHA Directive 1106, Pathology and Laboratory Medicine Service, dated July 27, 2018; VHA Directive 1108.16(1), Anticoagulation Therapy Management, dated January 29, 2021; VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, dated January 29, 2016.

3. POLICY OWNER: The National Director, P&LMS, Diagnostic Services (11DIAG2) is responsible for the content of this directive. Questions may be addressed to the Executive Director, P&LMS, at VHAPLMSProgramOffice@va.gov.

4. RESCISSIONS: VHA Directive 1138.01, Patient Self-Testing for Monitoring of Prothrombin Time International Normalized Ratio (INR) in Patients on Warfarin Anticoagulation Therapy, dated May 12, 2017, is rescinded.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of January 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

January 27, 2023

VHA DIRECTIVE 1138

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

/s/ Erica Scavella, M.D., FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services/CMO

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 Publications Distribution List on January 31, 2023.

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**PATIENT SELF-TESTING FOR MONITORING OF PROTHROMBIN TIME
INTERNATIONAL NORMALIZED RATIO IN PATIENTS ON WARFARIN
ANTICOAGULATION THERAPY**

1. POLICY

It is Veterans Health Administration (VHA) policy that patient self-testing (PST) may be considered as an alternative method of prothrombin time (PT) by international normalized ratio (INR) monitoring for patients who have their warfarin therapy managed by a Department of Veterans Affairs (VA) medical facility under the circumstances outlined in paragraph 4. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. 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 Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for supporting the Office of Pathology and Laboratory Medicine Services (P&LMS), Diagnostic Services with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer is responsible for:

(1) Communicating the content of this directive and the operational processes to the appropriate supporting clinics that participate in the Anticoagulation PST Program.

(2) Providing the resources and staffing necessary to support this directive.

d. **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 (VISN).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

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

e. **Executive Director, Pathology and Laboratory Medicine Services, Diagnostic Services.** The Executive Director, P&LMS, Diagnostic Services, is responsible for:

(1) Providing oversight for VISN and VA medical facility compliance with this directive and ensuring corrective action is taken when non-compliance is identified.

(2) Collaborating and providing consultation to the Anticoagulation PST Program Manager in the development of protocols for testing, criteria of acceptability and validation evaluation.

(3) Serving as a subject matter expert for the individual PST device validation process.

(4) Ensuring compliance with correlation requirements for clinical laboratory instrumentation (assessment of accuracy). See paragraph 5. **NOTE:** *For the purposes of this directive, accuracy of a system is determined by performing testing on specimens of known value or by comparing the results of the PST device with a method for which the known value has already been verified.*

f. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Ensuring that PT/INR testing is available for all eligible patients treated with warfarin.

(3) Approving the use of PST within the VISN as an alternative means of providing PT/INR testing.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Providing oversight of and maintaining an Anticoagulation PST Program, if a decision is made to provide this program, to ensure access, quality and compliance with this directive and the VA medical facility Anticoagulation Management Program required in VHA Directive 1108.16(1), Anticoagulation Therapy Management, dated January 29, 2021.

(2) Designating an Anticoagulation PST Program Manager, (e.g., pharmacist, nurse, primary care provider), to lead the Anticoagulation PST Program if implemented and develop processes following guidelines defined in this directive and with the same standards mandated in VHA Directive 1108.16(1).

(3) Ensuring that all VA medical facility staff involved in anticoagulation management are educated and demonstrate understanding of related VHA policy and requirements.

(4) Determining whether PST will be utilized as an alternative means of providing PT/INR testing.

h. VA Medical Facility Chief of Staff and Associate Director for Patient Care Services. The VA medical facility Chief of Staff and Associate Director for Patient Care Services are responsible for:

(1) Ensuring that patients are discharged from the Anticoagulation PST Program and an alternative monitoring method is instituted, if the patient's VA medical facility anticoagulation therapy provider determines that continuation with anticoagulation therapy is not in the best interest of the patient.

(2) Ensuring there are processes in place for laboratory confirmation for PST results when clinically warranted, including results from VA contracted providers such as Independent Diagnostic Testing Facilities (IDTFs).

(3) Ensuring the VA medical facility anticoagulation therapy provider establishes a target therapeutic range for INR based upon current clinical guidelines for specific diseases and a threshold for the acceptable upper limit that would require laboratory confirmation.

(4) Ensuring method validation is performed in accordance with the protocol located at [https://vaww.lab.med.va.gov/References Directives and Regulations P.asp](https://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp) through a collaborative process between the VA medical facility anticoagulation therapy provider prior to the implementation of an Anticoagulation PST Program. **NOTE:** *This is an internal VA website that is not available to the public.*

(5) Ensuring an individual PST device validation study is performed between each anticoagulation therapy PST device and VA medical facility laboratory device at minimum on an annual basis.

(6) Ensuring VA health care providers serving as the anticoagulation therapy PST trainer to patients in the VA medical facility Anticoagulation PST Program demonstrate ongoing competency in the use of PST devices in order to validate that patients are using them correctly.

(7) Ensuring VA medical facility anticoagulation therapy providers and support staff providing warfarin therapy management are following VHA Directive 1108.16(1) and this directive for anticoagulation therapy PST of INR.

(8) Partnering with the VA medical facility rehabilitation professionals to ensure access to and accuracy of anticoagulation therapy PST for patients with impairments.

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

(1) Ensuring pharmacists in the Anticoagulation PST Program are following VA medical facility processes for anticoagulation therapy, VHA Directive 1108.16(1) and this directive for anticoagulation therapy PST of INR.

(2) Ensuring anticoagulation therapy pharmacy staff who are educating patients enrolled in the Anticoagulation PST Program demonstrate ongoing competency in use of anticoagulation therapy PST devices in order to validate that patients are using the devices correctly.

j. **VA Medical Facility Chief, Pathology and Laboratory Medicine Service.** The VA medical facility Chief, P&LMS is responsible for:

(1) Serving as a consultant to the Anticoagulation PST Program Manager.

(2) Participating in anticoagulation therapy PST device selection and validation process.

(3) Concurring with the anticoagulation therapy PST trainer education criteria in accordance with paragraph 7.

(4) Ensuring onsite laboratory requirements for PST devices are met (e.g., correlation of meters, International Sensitivity Index (ISI)) in accordance with laboratory standards. **NOTE:** *As defined in VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, dated January 29, 2016, and 42 C.F.R § 493, PST is not subject to Clinical Laboratory Improvement Amendments of 1988 licensure and does not require proficiency testing under 38 C.F.R. § 17.3500. The VA medical facility Anticoagulation PST Program falls under the scope of oversight of the VA medical facility Anticoagulant PST Program Manager as detailed below in paragraph 2.i. and, does not fall under the scope of the clinical laboratory. Since PST is not performed in a clinical laboratory, current accreditation standards (e.g., The Joint Commission, College of American Pathologists) prohibit laboratory test results from being co-mingled or recorded in the clinical laboratory results section of patient electronic health records (EHR).*

k. **VA Medical Facility Anticoagulation Patient Self-Testing Program Manager.** The VA medical facility Anticoagulation PST Program Manager is responsible for the daily operations and decision making for the Anticoagulation PST Program and is responsible for:

(1) Developing, implementing and conducting quality management of the Anticoagulation PST Program operations.

(2) Including the Anticoagulation PST Program in the VA medical facility overall quality monitoring activities related to anticoagulation therapy.

(3) Establishing quality metrics and reporting quality metrics information on the PST component of the Anticoagulation PST Program to the appropriate VA medical facility committee for action.

(4) Ensuring the VA medical facility anticoagulation therapy provider obtains laboratory confirmation when clinically warranted from an accredited laboratory for a PST INR result. **NOTE:** *See VHA Directive 1108.16(1) for the laboratory value range.*

(5) Ensuring there is a standardized and consistent process established for documenting, in the patient's EHR, reported PST INR results from either the patient or VA contracted providers and ensuring staff receive local training on how to readily retrieve this information from the EHR at the VA medical facility. **NOTE: PST INR results are not part of the official patient laboratory results, therefore results must be documented in the patient's EHR using the progress note template.**

(6) Ensuring anticoagulation therapy PST devices are fully validated and tested according to the required Individual PST device validation protocol located at [https://vaww.lab.med.va.gov/References Directives and Regulations P.asp](https://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp), prior to issuance to a patient or, in the case of patient provided equipment, before the device is utilized for PST in the Anticoagulation PST Program. **NOTE: This is an internal VA website that is not available to the public.**

(7) Developing processes for proper disposition or disposal of returned or damaged PST equipment.

(8) Ensuring the development of patient and provider education and training guidelines as outlined in paragraph 7.

(9) Conducting competency assessments for the anticoagulation therapy PST trainer.

I. VA Medical Facility Anticoagulation Therapy Provider. The VA medical facility anticoagulation therapy provider who manages warfarin therapy is responsible for:

(1) Establishing INR target ranges for each patient based upon current clinical guidelines for specific diseases.

(2) Ensuring that an INR from an accredited laboratory is obtained at a minimum of once per year for patients that are monitored through anticoagulation therapy PST or under the circumstances listed in paragraph 6.c.

(3) Ensuring when unexpected or unusual PST INR results are obtained, the patient's PST INR is confirmed by an INR performed at an accredited laboratory and the PST device is confirmed to be functioning properly.

(4) Independently verify the patient's competency in using the INR self-testing equipment through actual correct demonstration of use of the product and knowledge test.

m. VA Medical Facility Anticoagulation Therapy Patient Self-Testing Trainer. An anticoagulation therapy PST trainer is a VA health care provider (e.g., nurse, physician assistant, pharmacist) with documented competencies in operation and patient education of INR PST devices. The VA medical facility anticoagulation therapy PST trainer is responsible for:

(1) Educating the patient on the use of INR PST devices (e.g., cleaning, general maintenance instructions, storage conditions, operations) as outlined in paragraph 7.

(2) Ensuring the patient communicates the PST results to the anticoagulation therapy provider on the same day as the patient conducted the PST.

(3) Determining that the patient is eligible for the Anticoagulation PST Program following guidance on patient eligibility criteria in paragraph 4.

3. USE OF PATIENT SELF-TESTING RESULTS

a. Anticoagulation therapy PST results may be used to:

(1) Confirm that INR levels conform to the targeted therapeutic range established by the VA medical facility anticoagulation therapy provider.

(2) Detect instances where INR levels are sub- or supra-therapeutic, so that subsequent instructions for warfarin adjustment may be provided by VA medical facility anticoagulation therapy providers for the quick and safe return of the patient's INR to therapeutic range.

b. PST results will not be used to:

(1) Make substantive changes to the patient's anticoagulation therapy regime such as deciding to discontinue warfarin or changing the patient's target INR goal.

(2) Adjust the patient's warfarin doses without contacting the VA medical facility anticoagulation therapy provider.

c. At a minimum of once per year, or more often if clinically indicated, the VA medical facility anticoagulation therapy provider determines if an INR from an accredited laboratory is needed under the following circumstances:

(1) When an INR result from the PST device is above the acceptable upper limit as determined by the manufacturer's written recommendations.

(2) When deemed necessary by the VA anticoagulation therapy provider to promote patient safety (e.g., patient's INR is therapeutic but the patient or caregiver reports persistent signs and symptoms of bleeding).

(3) When an unexpected or unusual PST INR results are obtained, the anticoagulation therapy PST device should be checked for proper functioning.

d. If the VA medical facility anticoagulation therapy provider determines that continuation with PST is a patient safety concern, an alternative PT/INR testing method will be implemented.

4. VA MEDICAL FACILITY REQUIREMENTS TO ESTABLISH AN ANTICOAGULATION PATIENT SELF TESTING PROGRAM

a. Each VA medical facility which adopts an anticoagulation therapy PST program must develop local processes defining the parameters and specific procedures for training and competency of staff, patients or their caregivers as defined in this directive and the same standards mandated in VHA Directive 1108.16(1), with documentation of patient encounters and follow-up in the patient's EHR.

b. VA medical facility patient eligibility criteria for anticoagulation therapy PST for INR testing must include the following:

(1) Patients require chronic warfarin therapy; have been on warfarin therapy for a minimum of 3 months and they are stably anticoagulated with the same standards of care as mandated in VHA Directive 1108.16(1) and are committed to testing as directed and follow the processes and standards of care for anticoagulation therapy PST established by the VA medical facility. Patients and caregivers must receive education regarding anticoagulation therapy by the VA medical facility anticoagulation therapy PST trainer who documents completion in the patient's EHR.

(2) Anticoagulation therapy PST trainer determination that patients or their caregivers have the necessary vision, hearing, dexterity, language and cognitive skills to perform anticoagulation therapy PST.

(3) Patients and their caregivers undergo a face-to-face anticoagulation therapy PST training individually or in group setting by an anticoagulation therapy PST trainer and demonstrate competency through both demonstration and knowledge-based testing, which can also be done virtually through approved telehealth modalities.

(4) The anticoagulation therapy provider is able to maintain regular communication with patients for anticoagulation therapy PST.

(5) Patients with known or suspected lupus anticoagulant or antiphospholipid antibody syndrome will not be eligible to participate in anticoagulation therapy PST.

(6) PST anticoagulation therapy for PT/INR testing will be discontinued if patients do not meet the eligibility criteria or if patient safety concerns arise.

(7) Anticoagulation therapy PST device should not be used more frequently than once a week unless otherwise indicated by a clinical provider.

5. PATIENT SELF-TESTING DEVICE/SUPPLIES SELECTION CRITERIA

Only those devices receiving Food and Drug Administration (FDA) approval for PST are eligible for VHA to purchase and issue to patients. **NOTE:** *Quality and comparability must be the primary drivers for the selection of the PST device. Cost must not be used as the sole determinant of the test device selection.*

a. The following criteria must be considered when making a selection:

(1) Reliability in multiple home environment settings and under varying conditions of temperature, humidity, light and physical handling.

(2) Ease of use.

(3) Precision correlation with the clinical laboratory and other testing sites within VA. Correlation studies must be performed for each unique device type/method used for PT/INR testing within the clinical laboratory, VA medical facilities or at Community-Based Outpatient Clinics (CBOCs) where the patient receives anticoagulation therapy.

(4) Easily understood manufacturer instructions/package insert.

(5) Evaluation of method (device) limitations.

(6) Manufacturer support for troubleshooting.

b. The anticoagulation therapy PST device and supplies must be selected in accordance with Federal acquisition regulations through national or VISN-level contracts.

c. The anticoagulation therapy PST device and corresponding supplies needed for PST PT/INR testing may be supplied by a third-party contractor (e.g., IDTF) under VA contract management. **NOTE:** *PST training devices are purchased and distributed through the Supply Chain Management in which the anticoagulation therapy PST trainer trains the patient in the use of the device. Veteran specific devices are purchased by Prosthetic and Sensory Aids Service.*

d. At the request of the patient and in order to ensure uninterrupted care for patients transitioning to VA, VA medical facilities may but are not obligated to support testing performed on devices that the patient obtained from non-VA sources. **NOTE:** *See VHA Directive 6506, Review and Use of Patient-Generated Health Data Under The Office of Connected Care, dated April 19, 2021. This includes:*

(1) The devices and reagents are FDA-approved for this purpose.

(2) The VA medical facility provider staff are familiar with the performance characteristics of the instrumentation and deemed competent to assess patient competency and assess device function.

(3) The patient meets the selection, training and competency requirements.

(4) The equipment is functioning properly and the device model and make has been validated according to the validation protocol located at https://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp. **NOTE:** *This is an internal VA website that is not available to the public.*

(5) The patient agrees to the other terms and requirements for participation in of the Anticoagulation PST Program.

(6) The patient must be transitioned to a VA-provided device as soon as possible.

e. The anticoagulation therapy PST device must be tested and certified ready to use by the VA medical facility Anticoagulation PST Program Manager before it is issued to the patient. As part of annual re-validation, patients must, at a minimum of once per year, bring in their PST device to the VA medical facility and the results of the PST device are validated by the VA medical facility's accredited laboratory. This includes equipment provided by a third party (i.e., IDTF or patient-provided device).

f. When the anticoagulation therapy PST device is supplied by a VA-contracted provider and IDTF is serving as the intermediary between the patient and VA medical facility anticoagulation therapy provider for communication of test results, the INR target ranges established by the VA medical facility anticoagulation therapy provider, based upon current clinical guidelines for specific diseases, must be conveyed to the provider on the prescription form and documented in the patient's EHR.

6. PATIENT SELF-TESTING PROGRAM REQUIREMENTS

a. PST may be considered as an alternative method of PT by INR testing for patients who have their warfarin therapy managed by a VA medical facility under the following circumstances:

- (1) In cases when more frequent PT/INR testing may reduce the potential for harm;
- (2) When venipuncture access sites are limited; and
- (3) When otherwise determined to be clinically appropriate (see paragraph 7).

b. The VA medical facility anticoagulation therapy provider documents PST INR test results as communicated by patients who agree to perform PT/INR testing by PST.

c. The VA medical facility anticoagulation therapy provider must document PST INR test results within 24 hours as communicated by the patient or VA contracted provider, within clinic hours, so the patients can be provided with instructions for warfarin dosage adjustments and retesting if needed. Patients or caregivers may not use the results of PST to adjust the patient's warfarin therapy.

d. A standardized and consistent process for documenting, in the patient's EHR, reported PST INR results from either the patient or VA contracted provider must be in place and staff must be aware of how to readily retrieve this information as outlined in paragraph 5.c.

e. VA medical facility anticoagulation therapy providers or their designee must contact patients and monitor the PST INR results.

f. VA medical facility processes for the Anticoagulation PST Program must establish clear guidelines for patient discharge from the Anticoagulation PST Program, with PST device and supplies returned to the supplier (i.e., when the supplier is VA or IDTF). Criteria that could be used for discharge include need for repeated calls to review basic PST instructions, excessive use of testing supplies, refusal to test according to VA medical facility processes, and refusal to return phone calls or respond to letters by providers. Patients discharged from the Anticoagulation PST Program must be referred for anticoagulation therapy monitoring with laboratory-performed or point-of-care PT/INR testing at the VA medical facility.

g. Each VA medical facility must develop local processes for when a laboratory confirmation from an accredited laboratory is clinically warranted for a PST INR result as outlined in paragraph 5.

7. PATIENT EDUCATION AND TRAINING

Patient education is critical to establishing a safe and comprehensive Anticoagulation PST Program. Results for PT/INR testing may vary dependent upon the methods used (e.g., accredited lab, point-of-care testing device or PST device), the competency of the person performing the test and the accuracy of the testing equipment or device. Prior to the implementation of an Anticoagulation PST Program, the VA medical facility Anticoagulation PST Program Manager must ensure the following are developed or followed:

a. Comprehensive education and training tailored for the patient enrolled in the program, defined training that includes demonstration and on-going competencies for educating staff and a comprehensive communication plan with a one-on-one plan between the patient and provider or health care team must be established to help ensure safety.

b. Ongoing patient communication is critical for the success of the program. Except for initial training and ongoing competencies which require face to face training, additional communication may be facilitated and enhanced through the use of clinical video telehealth encounters.

c. If patient training is provided from a third-party contractor (i.e., IDTF), each time the patient is provided training or assessed for competency, the patient training and competency records must be obtained by the provider prior to managing the patient's anticoagulation therapy under the Anticoagulation PST Program, reviewed for accuracy and documented in the patient's EHR. **NOTE:** *This may be accomplished by scanning. If patient records cannot be obtained, the anticoagulation therapy provider must independently verify the patient's competency in using the INR self-testing equipment through actual correct demonstration of use of the product and knowledge test.*

d. Before an anticoagulation therapy PST device is issued through VA to a patient, the patient or caregiver must be educated on use of the machine and able to demonstrate competency through actual correct demonstration of use of the product

and knowledge test. Where the patient will use a device obtained from a non-VA source, the patient or caregiver must be able to demonstrate competency through actual correct demonstration of the use of the device and knowledge test before the device is utilized for testing in the Anticoagulation PST Program.

e. Patients with mobility impairments may use prosthetic or assistive devices prescribed for their impairment, to use the PST device. If patient with physical or visual impairments are not able to complete self-testing, patients can be referred to VA medical facility rehabilitation professionals to adjust prosthetic or assistive devices, provide targeted training or provide more effective devices for self-testing, if feasible.

f. Education provided by the anticoagulation therapy PST trainer must also cover the following topics at a minimum: **NOTE:** *Additional topics may be added by the VA medical facility Anticoagulation PST Program Manager.*

(1) Importance of not self-adjusting warfarin.

(2) Frequency of testing.

(3) Target range.

(4) How to communicate the PST INR results to the VA medical facility anticoagulation therapy provider and care team.

(5) Time standards for communication of test results to achieve optimal coagulation therapy management.

(6) Who and how to contact someone with questions regarding equipment and self-testing procedures.

(7) Situations when it will be necessary for the patient to comply with laboratory testing (e.g., signs and symptoms of adverse effects such as bleeding, confirmation of an out-of-range INR or when deemed necessary by the anticoagulation therapy provider to ensure the continued safe use of warfarin).

(8) Knowing when to seek medical attention and the importance of reporting any signs and symptoms of bleeding or thromboembolism immediately even if INR self-testing result is in therapeutic range.

(9) Annual re-validation requirements (see paragraph 5.e.).

g. The anticoagulation therapy PST trainer must also include comprehensive written material covering the above topics related to anticoagulation therapy PST in addition to other education topics related to the patient and caregiver education on anticoagulation therapy. **NOTE:** *A VA medical facility anticoagulation therapy PST trainer may be a nurse, physician assistant, pharmacist or other VA health care provider.*

h. All patient education and competency assessments must be documented by the VA health care provider in the patient's EHR.

8. TRAINING

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

b. Staff members that serve as the direct educators of patients enrolled in VA INR PST must demonstrate on-going competency in use of the device in order to validate the patient is using the device correctly. Staff members must also know how to obtain support in the event of device malfunction or other problems.

c. VA anticoagulation therapy providers must be familiar with performance characteristics of all the devices used by their panel of patients, including devices provided by a third-party contractor (i.e., IDTF or patient-provided equipment).

9. RECORDS MANAGEMENT

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

10. BACKGROUND

a. A VA-funded cooperative study demonstrated that, compared with monthly high-quality clinic testing, weekly PST yielded similar results in reducing the risk of stroke, major bleeding episodes and death among patients taking warfarin therapy. The study recommended that PST be considered for patients whose access to high-quality anticoagulation care is limited by disability, geographic distance or other factors, if the alternative would be to withhold a highly effective treatment.

b. PST should only be supported in specific clinical circumstances and with consideration of key associated policy needs including appropriate patient selection and monitoring, patient and provider education and training, appropriate understanding of platform characteristics of the instruments to be used for PST and associated VA national surveillance to ensure quality and safety of PST.

c. Standardization provides for improvements in patient care related to a patient's ability to obtain supplies from any VA medical facility, staff competency in educating patients on the operation of a particular device, consistent interpretation of PST results and individual PST device validation process. To the greatest extent possible, standardization of the device base must be a prime consideration in the device selection process.

11. DEFINITIONS

a. **Accuracy.** Accuracy is the extent to which a value from a test reflects or agrees with the reference value of the analyte being tested, measured statistically by standard deviations.

b. **Annual Re-Validation.** Annual re-validation is a minimum of once per year requirement, in which the patient must bring the PST device back to the VA medical facility that issued the device for comparison to a laboratory testing reference method.

c. **Anticoagulation Therapy.** Anticoagulation therapy is the therapeutic use of anticoagulants (e.g., warfarin) to discourage formation of blood clots within a blood vessel.

d. **Correlation.** For the purposes of this directive, correlation is the relationship between test results obtained on the PST device and systems utilized in the clinical laboratory. Correlation studies must be performed by the VA clinical laboratory between the PST device and each unique INR test method/system used to monitor the Anticoagulation PST Program, such as point-of-care testing performed at CBOCs.

e. **Individual Patient Self-Testing Device Validation.** Individual PST device validation is a study performed on each PST device before it is issued to a patient to ensure the device is working properly and to ensure the patient can obtain accurate results.

f. **International Normalized Ratio.** INR is the standardized measure of PT, which is used to determine the clotting tendency of blood. The INR is the ratio of a patient's PT to a normal (control) sample, raised to the power of the ISI value of the reagent system used.

g. **International Sensitivity Index.** ISI is a measure of thromboplastin sensitivity to an international standard. Each lot number of thromboplastin used in PT or PT/INR testing is assigned its own unique ISI value from the manufacturer.

h. **Independent Diagnostic Testing Facility.** IDTFs are contracted facilities (i.e., non-physician-owned, non-hospital-affiliated) and are subject to the general supervision of a licensed physician proficient in PST. The primary role of the IDTF is to inventory, finance and manage the logistics associated with the ancillary PST equipment and related supplies. IDTFs are also equipped to handle certain ancillary initial and ongoing services needed to support PST patients according to written instructions provided to the IDTF by the patient's treating physician. These services include providing initial PST training, providing ongoing patient compliance reminders and ensuring that the anticoagulation clinic receives test results requiring immediate medical attention.

i. **Patient Self-Testing.** PST is the use of testing devices approved by FDA for home monitoring of warfarin therapy. PST is conducted at the patient's residence and monitors INR to ensure patients are receiving the appropriate dosage of warfarin. PST must be ordered electronically by the patient's VA medical facility anticoagulation

therapy provider, who may also discontinue PST if the patient is no longer willing or able to perform testing according to instructions.

j. **Precision.** For the purposes of this directive, precision is the capability of the test method to consistently reproduce the same measured result when the same specimen is retested.

k. **Validation.** For the purposes of this directive, validation is the process used to confirm quality, reliability and consistency of a testing device and to verify the test method is suitable for its intended use.

12. REFERENCES

- a. 38 U.S.C. § 7301(b).
- b. 38 C.F.R. § 17.3500.
- c. 42 C.F.R § 493.
- d. VHA Directive 1108.16(1), Anticoagulation Therapy Management, dated January 29, 2021.
- e. VHA Directive 6506, Review and Use of Patient-Generated Health Data Under The Office of Connected Care, dated April 19, 2021.
- f. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, dated January 29, 2016.
- g. Patient Self-Testing (PST) Device Validation Procedure:
https://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp. **NOTE:**
This is an internal VA website that is not available to the public.