Attachment 16 - TVHS Memorandums

The following documents are included in this Attachment:

TVHS Memorandum 626-11-11-01	Management of Impaired Practitioner
TVHS Memorandum 626-11-11-25	Credentialing and Privileging Program – as Amended
TVHS Memorandum 626-12-00-43	Patient/Resident Rights and Responsibilities
TVHS Memorandum 626-12-11-16	Procedure for Reporting Test Results
TVHS Memorandum 626-12-11M-09	Patient Record Flags – Suicide Risk
TVHS Memorandum 626-12-136-09	Fee Basis Care
TVHS Memorandum 626-13-119-07	Medication Use Management
TVHS Memorandum 626-13-119-08	Adverse Drug Events
TVHS Memorandum 626-13-119-09	Controlled Substance Management
TVHS Memorandum 626-13-136-27	Scanning Policy (currently being updated)
TVHS Memorandum 626-14-11M-08	Management of Patients at Risk for Psychiatric Emergency
TVHS Memorandum 626-14-11M-16	Initial Management of Mental Health Requests
TVHS Memorandum 626-14-119-16	Medication Reconciliation
TVHS Memorandum 626-14-136-32	Records Management

NOTE: No public access is currently available to view these documents. However, once a contract is awarded these documents and subsequently revised and updated documents can be located at the following website:

http://vaww.tennesseevalley.va.gov/docs/memo.aspx

MANAGEMENT OF THE IMPAIRED PRACTITIONER

- **1. PURPOSE:** The purpose of this policy is to provide guidance to Service Chiefs/Care Line Managers and members of the Medical Staff about prevention of physical, psychiatric, or emotional illness; and to facilitate confidential diagnosis, treatment, and rehabilitation of staff who suffer from a potentially impairing condition.
- 2. POLICY: The Tennessee Valley Healthcare System (TVHS) has an obligation to protect patients from harm. The medical staff and leadership will be cognizant of the physical and mental health of its Licensed Independent Practitioners (LIPs) and Mid-Level Practitioners (hereinafter referred to as "practitioners"). This policy outlines the process of providing assistance and rehabilitation, rather than discipline, to aid a practitioner in retaining or regaining optimal professional functioning, consistent with the protection of patients. If at any time during the diagnosis, treatment, or rehabilitation phase of the process it is determined that a practitioner is unable to safely perform the privileges/scope of practice/functional statement he/she has been granted, the matter is forwarded to the Health System Director and the Chief of Staff for review and appropriate corrective action in accordance with Veterans Health Administration (VHA) and health care system policy.

3. DEFINITIONS: (in alphabetical order)

- a. <u>Alcohol Abuse</u>: A disorder characterized by repeated excessive drinking which interferes with the individual's health, interpersonal relations, economic functioning, or professional conduct. An alcoholic is an individual who is alcohol dependent. A problem drinker is any employee whose use of alcohol frequently affects him/her adversely. An individual does not have to be alcohol dependent for his/her alcohol use to be problematic.
- b. <u>Bio-psychosocial problems</u>: A term encompassing an individual's physical, mental and social status. For the purpose of this policy, biopsychosocial may include: physical, emotional, financial, marital, family, legal or vocational problems that are adversely affecting the employee's job performance and/or conduct.
- c. <u>Employee Assistance Program (EAP)</u>: a service offering 24/7 access to a diverse national clinician network. EAP clinicians provide confidential, face-to-face and telephonic assessments and short-term counseling services to employees in need of assistance with substance abuse, bio-psychosocial problems, or life stresses. EAP consultants also support managers and employers with on-site trainings, critical incident debriefings, organizational consultation and expert human resources consultation.
- d. <u>Formal referral</u>: A referral of an employee by a supervisor or other staff members, where there is reasonable cause to believe that a practitioner is providing unsafe care and treatment.
- e. <u>Impairment</u>: The inability or immediate impending inability of a healthcare professional to practice his or her health profession in a manner that conforms to the standards of acceptable and prevailing practice for that health profession due to the health professional's substance abuse, chemical dependency, physical or mental illness.

- f. <u>Licensed Independent Practitioners (LIP)</u>: Refers to any individual permitted by law and by the VA TVHS to provide care and service without direction or supervision, within the scope of the individual's license and consistent with individually granted privileges. In this organization, this includes physicians, dentists, optometrists and psychologists. It may also include individuals who can practice independently, who meet this criterion for independent practice.
- g. <u>Mandatory referrals</u>: The referral of an employee who has been found to be using illegal drugs, as mandated by the Department of Veterans Affairs Drug Free Workplace Program.
- h. <u>Medical Staff</u>: The body of all LIP's and other practitioners credentialed through the medical staff process who are subject to the medical staff Bylaws. The medical staff includes both members of the organized medical staff and non-members of the organized medical staff who provide healthcare services.
- i. <u>Mid-Level Practitioner</u>: Mid-Level Practitioners are those healthcare professionals who are not physicians and dentists and who, most often, function within a Scope of Practice but may practice independently on defined clinical privileges as defined in the Bylaws. Mid-Level Practitioners include: physician assistants (PAs), Pharmacists (PharmDs), and advanced practice nurses (APRN, CRNA and CRNP).
- j. **Physical illness**: An illness pertaining to the body in which normal or appropriate functioning of the body is impaired in some manner.
- k. <u>Physical Standards Board</u>: Responsible board for determining the physical and mental fitness and for recommending action based on examination of findings. A board may recommend acceptance or rejection of a person for physical or mental reasons. The Physical Standards Board may have the same membership as the local physician Professional Standards Board or members may be designated for this purpose by the healthcare facility Director.
- 1. <u>Self-referral</u>: The employee or provider recognizes that he/she has a physical, psychiatric or emotional illness and needs assistance in correcting the problem.
- m. <u>Substance Abuse</u>: A disorder characterized by the use of a drug in a manner or to a degree which interferes with the individual's health, interpersonal relations, economic functioning, professional conduct, or social standing.

4. RESPONSIBILITY

a. The Chief of Staff and Clinical Service Chiefs are responsible for ensuring that all members of the Medical Staff and other practitioners receive information addressing prevention of physical, psychiatric or emotional illness and options available for the diagnosis, treatment and rehabilitation of practitioners who suffer potentially impairing conditions.

- b. The Professional Standards Board is responsible for promoting the physical, personal, and professional well being of the medical staff and may make appropriate referrals to the Employee Assistance Program (EAP). The EAP mission is to optimize employee wellness and employer productivity by identifying and resolving tomorrow's problems today. Their philosophy is that most personal and workplace problems can be resolved successfully through the variety of services offered.
- c. The Human Resources Management Officer will render advice and assistance on the administrative aspects of the program and work closely with the Occupational Health Physician or Occupational Healthcare Provider in establishing assessments by a Physical Standards Board when requested by the Chief of Staff and/or Health System Director.

5. PROCEDURES

- a. Education of the Medical Staff about the illness and impairment recognition issues specific to practitioners:
- (1) Practitioners will be issued written information regarding illness and impairment issues at the time of initial appointment and reappointment by their supervisors or Service Chiefs (Attachment A).
- (2) Information about the Employee Assistance Program and how to access services of the EAP will be provided to practitioners at the time of initial appointment and reappointment (Attachment B).
 - b. Referral of the Impaired Practitioner:
- (1) Practitioners are encouraged to self-refer to a program for assistance with mental illness, emotional or physical problems; assistance in the self-referral may be obtained from their supervisor, Service Chief, or the Chief of Staff.
- (2) Clinical Service Chiefs are responsible for recognizing signs and symptoms of substance abuse, chemical dependency, physical and/or mental illness adversely affecting employees' job performance and/or conduct and making appropriate referrals.
- (3) Any individual within the organization has the responsibility to report concerns regarding unsafe treatment by practitioners. These reports are to be made directly to the practitioner's Service Chief or Chief of Staff. Reports may also be made directly to the Health System Director. Informant confidentiality will be maintained to the extent allowed by law.
- (4) All complaints, allegations or concerns regarding the potential impairment of a practitioner will be thoroughly investigated.
- (5) The affected practitioner will be referred to the appropriate professional internal or external resources for diagnosis and treatment of the condition or concern.

- c. The confidentiality of the individual will be strictly maintained, with the following exceptions:
 - (1) State and Federal regulatory limitations (if applicable)
 - (2) Ethical obligations
 - (3) When maintaining confidentiality threatens the safety of a patient or patients
- (4) In all instances, every effort to protect the confidentiality of the individual referred for assistance will be made
- d. An evaluation of the credibility of a complaint, allegation or concern will be made by the Chief of Staff, and the appropriate service chief, with the assistance of the Human Resources Management Officer. In cases of known or suspected impairment due to physical, mental illness or chemical dependence, the Chief of Staff may request an assessment by the Physical Standards Board and the Occupational Health Physician.
- e. In cases of known or suspected impairment due to physical and/or mental illness, the Chief of Staff may request the Health System Director to authorize a physical examination. Such examination will be requested customarily after a practitioner has undergone surgery or sustained illnesses or injuries, which have a reasonable risk of impairing professional functioning. Examples are intracranial surgery, cardiopulmonary bypass, severe trauma, hospitalization requiring intensive care, psychiatric hospitalization, and use of neuroleptic medication or chemical dependency rehabilitation. This list is not meant to be comprehensive and is intended only to clarify the types of conditions around which a reasonable and good faith concern of impairment may be raised.
- f. The occurrence of hospitalization or treatment is a basis for inquiry only and is not conclusive of impairment. The fitness for duty examination will be tailored to the clinical circumstances and may involve a physical examination, imaging studies, neuropsychological testing or other indicated measures.
- g. If credible evidence of impairment is found after appropriate investigation, as part of the intervention, the practitioner will be referred to an appropriate treatment facility and the practitioner's progress will be monitored by his supervisor. The method of monitoring will be determined by the Physical Standards Board. Monitoring will continue until the Board is able to verify that the impairment for which the practitioner was referred to the program:
 - (1) Has resolved
 - (2) No longer impacts the quality of patient care provided by the practitioner
- h. All allegations, concerns or complaints will be brought before the Physical Standards Board to be investigated and evaluated by the committee as a whole. Any practitioner under

investigation may provide information to the Board which he/she feels may clarify any allegation, concern or issue brought before the Board.

- i. The Physical Standards Board will submit its report to the Chief of Staff and the Health System Director for necessary action. If the Board determines a person to be physically and/or mentally incapable of performing the duties of the assignment, the appropriate course of action shall be taken, in accordance with VHA regulations.
- j. While the goal of this process is to provide assistance rather than disciplinary action, in some instances, the Physical Standards Board may recommend to the Health System Director discipline of the practitioner as a necessary action to improve or resolve quality of patient care issues. Any requests for disciplinary action will be forwarded to the Chief of Staff and the Health System Director for approval and in accordance with VHA regulations.
- k. A practitioner's return to work will be based on the health and well-being of the practitioner, the safety of patients, and the practitioner's competency. Therefore, each case must be assessed independently and the return to work will be structured accordingly. If the Physical Standards Board determines a person to be physically and/or mentally capable of performing the duties of the assignment, a written plan submitted by the Physical Standards Board that has been subsequently approved by the Professional Standards Board should be conveyed to the Service Chief. The following courses of action may be taken:
- (1) If the nature of the physical condition is one that may be corrected by remedial treatment sick leave, annual leave or leave without pay may be granted as appropriate.
- (2) A successful program assists the employee in overcoming a personal problem so that performance and/or conduct improves and corrective action, such as disciplinary, adverse or other performance-based actions, becomes unnecessary.

6. REFERENCES

- a. VA Directive 5383, VA Drug-Free Workplace Program
- b. VA Handbook 5019, Part III, Physical Standards Board
- c. The Joint Commission
- d. "Physician Well-Being Program" http://www.mc.vanderbilt.edu
- 7. RESCISSION: TVHS Memorandum 626-09-11-01 dated April 22, 2009.

8. RESPONSIBILITY AND REVIEW DATE: The Office of the Chief of Staff will review annually and republish within three years not later than January 31, 2015.

/s/ Juan A. Morales, RN, MSN 12/20/2011

Juan A. Morales, RN, MSN Health System Director

Attachments:

- A. Common Warning Signs of the Impaired Practitioner
- B. Acknowledgement of Receipt of Information Statement

ATTACHMENT A

COMMON WARNING SIGNS OF THE IMPAIRED PRACTITIONER

Attitude/Behavior Changes:

- Rapidly turns from compassionate and caring to abrupt, caustic
- Withdraws from friends and activities
- Becomes mistrusting, anxious, depressed, irritable

Physical Changes:

- Loss of appetite or reduced level of exercise
- Looks tried; admits to insomnia
- Personal hygiene deteriorates
- Physical problems are self-treated

Performance Changes:

- Misses appointments
- Makes rounds at unusual hour
- Can't be reached when on call
- Sloppy charting
- Smell of alcohol on breath during the day

Relationship Changes:

- Family communication deteriorates
- Frequent arguments, spouse blamed
- Occurrence of spouse/child abuse
- Children may exhibit poor school performance
- Jealousy, infidelity leading to separation/divorce

ATTACHMENT B

ACKNOWLEDGEMENT OF RECEIPT OF INFORMATION STATEMENT

It is the intent of this facility to provide the Medical Staff with information regarding the impaired practitioner program policy at the time of initial privileging and/or re-privileging (or scope of practice/functional statement). An impaired practitioner is one with a chemical dependency, mental illness, physical illness, or aging problems who may be unable to care for his or her patients with reasonable skill, attention or safety. Many physicians and health care personnel are uninformed about chemical dependence and mental illness. These are treatable diseases that can be managed.

TVHS has provided you with a copy of the Management of the Impaired Practitioner policy and a review of common signs of impairment. Should you have any questions or concerns, please do not hesitate to contact the Chief of Staff or your Service Chief.

For information about the Employee Assistance Program (EAP) or to request services, call 800-869-0276, contact your Human Resources representative or you may securely request services from the Member Access Section of EAP's website, www.eapconsultants.com.

I have received a copy of the policy, "Management of the Impaired Practitioner", including Attachments.

Print Name:	Date:	
Signature:		
Service or Care Line:		

CREDENTIALING AND PRIVILEGING PROGRAM

Amendment to Healthcare System Memorandum 626-11-11-25 Dated: February 22, 2011

- **1. AMENDMENT:** Paragraph h should be added to paragraph seven in the original publication to include Attachments D, E and F.
 - h. Appointment Expiration: Upon receipt of information that a Medical Staff Member will be relinquishing their appointment at the Tennessee Valley Healthcare System, the Service Chief is responsible for notifying the provider that his/her privileges will also be terminated (Attachment D). Copies of this notification will be provided to Human Resources and the Medical Staff Office. In addition, the Service Chief will complete a review of the member's clinical activity within 7 days of leaving VA employment and will document this review on Attachment E. Completion of this form will serve as documentation of the initial review in accordance with VHA Handbook 1100.18, reporting to State Licensing Boards, and will be filed in the Credentialing and Privileging file of the provider.

2. REFERENCES:

- **a.** VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards
- **b.** VHA Handbook 1100.19, Credentialing and Privileging
- 3. RESCISSION: None
- **4. RESPONSIBILITY AND REVIEW DATE:** Three years from the date of the original policy.

/s/ Juan A. Morales, RN, MSN 8/9/2012 Juan A. Morales, RN, MSN Health System Director

Attachments:

- D. Notification Letter of Expiration of Privileges
- E. Provider Exit Review
- F. Index

ATTACHMENT D



DEPARTMENT OF VETERANS AFFAIRS
TENNESSEE VALLEY HEALTHCARE SYSTEM
1310 24th Avenue South
Nashville, Tennessee 37212
Murfreesboro, TN 37129

DATE

PROVIDER ADDRESS

Dear Dr,
Effective, we have been advised that you are no longer providing care to our patients; therefore, your privileges are being terminated and you will no longer be scheduled to provide patient care at our medical center. This is in no way considered an adverse action. Your privileges were in good standing with our medical center.
Please know that we appreciate very much the care which you have provided for our veteran patients during the term of your clinical privileges at this medical center.
If you have any questions about this matter, please do not hesitate to contact (name of administrative officer) at (phone).
Sincerely yours,

NAME Service Chief

cc: Human Resources (05) Medical Staff Office (11-MSO)

ATTACHMENT E Provider Exit Review

Provider's Name:	Service:
Date of Clearance from Facility:	
Reason:	Transferred to another VA
Transferred to another Service	Retired
Other	
	STAFF OFFICE (11-MSO) WITHIN 7 DAYS OF VA EMPLOYMENT
Care provided by this licensed health care pr	rofessional: (CHECK ONE ITEM BELOW)
	clinical practice, and there was no concern for the ractice expected of competent professional, as well to carry out those responsibilities.)
Met generally accepted standards of cadditional training related to	clinical practice, however, may require proctoring or
	ndards of practice as to raise reasonable concern for circumstances, a reasonable person would be by the licensed health care professional.)

The following are examples of substandard actions that could provide basis for reasonable concern for the safety of patients, and thus would warrant a **COMPREHENSIVE REVIEW** for the potential reporting in accordance with VHA Handbook 1100.18, Reporting State Licensing Board):

- Significant deficiencies in clinical practice, for example, lack of diagnostic or treatment capability; multiple errors in transcribing, administering or documenting medications; inability to perform clinical procedures considered basic to the performance of one's occupation; or performing procedures not included in one's clinical privileges in other than emergency situations;
- 2) Patient neglect or abandonment;
- 3) Mental health impairment sufficient to cause the individual to make judgment errors affecting patient safety, to behave inappropriately in the patient care environment, or to provide unsafe patient care;

ATTACHMENT E, continued

- 4) Physical health impairment sufficient to cause the individual to provide unsafe patient care;
- 5) Substance abuse when it affects the individual's ability to perform appropriately as a health care provider in the patient care environment.
- 6) Falsification of credentials;
- 7) Falsification of medical records or prescriptions;
- 8) Theft of drugs;
- 9) Inappropriate dispending of drugs;
- 10) Unethical behavior or moral turpitude (such as sexual misconduct toward any patient involved in VA health care;
- 11) Patient abuse, including mental, physical, sexual, and verbal abuse, and including any action or behavior that conflicts with a patient's rights identified in the Title 38, Code of Federal Regulations (CFR); intentional omission of care; willful violations of a patient's privacy; willful physical injury or intimidation, harassment or ridicule of a patient; or
- 12) Falsification of research findings, regardless of where the research was carried out or the funding source as long as involved in some aspect of operations of the VA.

SERVICE CHIEF SIGNATURE	DATE	

ATTACHMENT F

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CREDENTIALING AND PRIVILEGING PROGRAM

1. PURPOSE: To state the policy, procedures and responsibilities for the credentialed, privileged and appointed membership of the Medical Staff of Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) and all other licensed, registered or certified healthcare workers under a scope of practice.

NOTE: This policy does **not** reflect the process utilized for the credentialing of Dependent Providers. See TVHS Memorandum 626-10-05-24, "Credentialing of Dependent Health Care Providers".

2. POLICY: VA TVHS shall maintain a credentialing and privileging program whereby healthcare professionals are appointed to and maintained on the Medical Staff according to rules and regulations established by the Veterans Health Administration (VHA) and in accordance with regulatory agencies to ensure that only the highest quality applicants are appointed to ensure the highest quality patient care. This policy has no inconsistencies with the Medical Staff Bylaws, Rules and Regulations and is consistent with the law, Department of Veterans Affairs (VA) regulations, Veterans Integrated Service Network (VISN) 9 Directives, or other TVHS policies.

3. BACKGROUND:

- a. All VA TVHS healthcare professionals who are permitted by law and this healthcare system to provide patient care services independently will be credentialed and privileged as defined in this policy. The requirements of The Joint Commission (TJC) standards and VHA policies have been used to define the credentialing, privileging, reappraisal and reprivileging processes.
 - b. Active and Associate Medical Staff members are classified under one of the following:
 - (1) Full Time
 - (2) Part Time
 - (3) Contract
 - (4) Sharing Agreement
 - (5) On-Station Fee-Basis
 - (6) Off-Station Fee-Basis
 - (7) Telemedicine
 - (8) Without Compensation (WOC)
 - (9) Intermittent
 - (10) Consultant

- c. The credentialing and privileging requirements of this policy apply to professionally licensed physicians, osteopaths, dentists, optometrists, podiatrists, physician assistants, advance practice nurses, clinical nurse specialists, clinical psychologists and clinical pharmacy specialists. Research or administrative positions not involved in patient care are credentialed but may not always request clinical privileges. The credentialing portion of this policy is also applicable to allied health professionals, including Advanced Practice Registered Nurses (APRN) and Physician Assistants (PA) even though these practitioners may not practice as licensed independent practitioners (see Definitions).
- d. Policy and procedures related to the denial, failure to renew, reduction, and revocation of clinical privileges, where based on professional competence, professional misconduct, or substandard care, apply to all health care professionals who are granted privileged within the scope of this policy.
- e. VetPro, VHA's electronic credentialing system, must be used for credentialing all providers who are credentialed and/or privileged or have a scope of practice. One component of VHA's Patient Safety Program is quality credentialing and the use of VetPro is necessary to reduce the potential for human error in the credentialing process. In addition, documentation other than in Vet Pro that is required by this policy must be maintained in a paper or electronic medium. The requirements of this policy are the same whether carried out on paper or electronically. For example, if a signature is required and the mechanism in use is electronic, than that modality must provide for an electronic signature.
- f. Credentialing and privileging must be completed prior to initial appointment or reappointment and before transfer from another medical facility. If the primary source verification(s) of the practitioner's credentials are on file (paper or electronic), those credentials that were verified at the time of initial appointment and are not time-limited or specifically required by this policy or TJC to be updated or re-verified can be considered verified.
- g. All credentialing procedures described in this policy are applicable to the Chief of Staff (COS) and facility Director. The Chief of Staff is the individual appointed by the Governing Body whose responsibilities are both administrative and clinical in nature. Clinical responsibilities are defined as those involving professional capability as a practitioner such as to require the exercise of clinical judgment with respect to patient care. The Chief of Staff is President of the Medical Staff.
- h. This policy does not apply to residents unless they function outside the scope of their training program, e.g., act as Medical Officers of the Day (MOD), perform Compensation and Pension exams, or have been boarded, credentialed, and/or received privileges in another specialty.

4. **DEFINITIONS**:

a. <u>Allied Health Professional</u>. Allied health professional refers to advanced practice nurses, audiologists, physician assistants (PA), dental hygienists, dietitians, kinesiotherapists, medical technologist, occupational therapists, pharmacists, clinical pharmacy specialists, physical therapists, recreational therapists, registered nurses (RN), respiratory therapists, clinical social workers, speech pathologists, licensed practical nurses (LPN), diagnostic radiologic technologists, corrective therapists, creative arts therapists, medical technicians, orthotists, prosthetists, and other qualified members of the health profession (ie. Hybrid Title 38).

- b. <u>Appointment:</u> Appointment refers to appointment to the Medical Staff. It does not refer to appointment as a VA employee unless specified as such, but is based on having an appropriate personnel appointment action, scarce medical specialty contract or other authority for providing patient care services in the healthcare system. Both VA employees and contractors may receive appointments to the Medical Staff.
- c. <u>Authenticated Copy:</u> An authenticated or certified copy means that each page of the document is a true copy of the original document and each page is stamped "authenticated copy of original" and dated and signed by the person doing the authentication. Facsimile copies of verification documents may not be used for final verification.
- d. <u>Clinical Privileging or Privileging:</u> Clinical privileging is the process by which a practitioner, licensed for independent practice (i.e., without supervision, direction, required sponsor, preceptor, mandatory collaboration, etc.), is permitted by law and the healthcare system to practice independently to provide specified medical or other patient care services within the scope of the individual's license based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training and licensure. Clinical privileges are facility specific and provider specific as well as setting specific.
- e. <u>Competency</u>: Competency is documented demonstration of an individual having the requisite or adequate abilities or qualities capable to perform up to a defined expectation.
- f. <u>Credentialing</u>: The term "credentialing" refers to the systematic process of screening and evaluating qualifications and other credentials, including licensure, required education, relevant training and experience, and current competence and health status.
- g. <u>Current:</u> The term "current" applies to the timeliness of the verification and use for the credentialing and privileging process. No credential is current and no query of the Federation of State Licensing Boards (FSMB) or the National Practitioner Data Bank (NPDB)-Health Integrity and Protection Data Bank (HIPDB) is current if performed prior to submission of a complete application by the practitioner to include submission of VetPro. At the time of initial appointment, all credentials must be current within 180 days of submission of a complete application. For reappointment, all time-limited credentials must be current within 180 days of submission of the application for reappointment including peer appraisals, confirmation of National Practitioner Data Bank (NPDB) Health Integrity and Protection Data Bank (HIPDB), Proactive Disclosure Service (PDS) annual registration, and other credentials with expirations.
- h. <u>Fifth Pathway Program</u>: This program is available to U.S. Citizens and/or legal residents who matriculate at a foreign medical school (outside the United States, Puerto Rico or Canada) that is listed in the World Directory of Medical Schools published by the World Health Organization. This program was created as a substitute for internship and/or social service requirements, allowing students to complete six (6) years of requirements in five (5) years.
- i. <u>Focused Professional Practice Evaluation (FPPE):</u> An FPPE is a prospectively planned and timed-limited evaluation process that allows the medical staff to focus evaluation on a specific aspect of a practitioner's performance, when data from the Ongoing Professional Practice Evaluation indicates a potential problem, or meets triggers outlined in the Bylaws. The practitioner's service chief (or appropriate peer if a different specialty) plans and implements the

- FPPE. Results are submitted to the Professional Standards Board (PSB) for considering in its recommendations to the Health System Director to maintain, revise, or reduce a practitioner's privileges. The FPPE is maintained in the service-level provider 6 part competency folder, part VI.
- j. <u>Independent Practitioner</u>: The term "independent practitioner: is any individual permitted by law (the statute which defines the terms and conditions of the practitioner's license) and the facility to provide patient care services independently; i.e., without supervision or direction, within the scope of the individual's license and in accordance with individually-granted clinical privileges. This is also referred to as a licensed independent practitioner (LIP).
- k. <u>Licensed Independent Practitioner</u>: Licensed independent practitioners include physicians, dentists, clinical psychologists, podiatrists, and optometrists. These individuals are permitted by law and by TVHS to provide patient care services without direction or supervision, within the scope of his/her license and in accordance with any individually granted clinical privileges. Only LIPs may be granted clinical privileges.
- 1. <u>Licensure</u>: Licensure refers to the official or legal permission to practice in an occupation, as evidenced by documentation issued by a state, territory, commonwealth or the District of Columbia (hereinafter referred to as "state") in the form of a license, registration or certification.
- m. <u>Medical Executive Board</u>: The Medical Executive Board (MEB) is the Executive Committee of the Medical Staff, chaired by the Chief of Staff and empowered to act on behalf of the medical staff. It carries out its work within the medical staff functions of governance, leadership, and performance improvement activities.
- n. <u>Medical Staff</u>: All fully licensed and appointed physicians, dentists, podiatrists, optometrists, and clinical psychologists.
- o. <u>Mentoring</u>: Mentoring is a process for the informal transmission of knowledge, social capital, and the psychosocial support perceived by the recipient as relevant to work, career, or professional development; mentoring entails informal communication, usually face-to-face and during a sustained period of time, between a person who is perceived to have greater relevant knowledge, wisdom, or experience (the mentor) and a person who is perceived to have less (the protégé).
- p. <u>One Standard of Care</u>: The term "one standard of care" means that one standard of care must be guaranteed for any given treatment or procedure regardless of the practitioner, service, or location within the facility. In the context of credentialing and privileging, the requirements or standards must be the same for granting privileges to perform any given procedure, if performed by more than one service.
- q. <u>Ongoing Professional Practice Evaluation (OPPE</u>): An OPPE is an ongoing process of continual monitoring and assessment of the clinical competence of all Medical Staff with privileges based on objective, measurable criteria of performance. The process allows for any potential problems with a practitioner's performance to be identified and resolved as soon as possible, and supports the evidence-based privileges renewal process. The OPPE is maintained in the service 6 part competency folder.

- r. **Primary Source Verification:** Primary source verification is documentation from the original source of a specific credential that verifies the accuracy of a qualification reported by an individual practitioner. This can be documented in the form of a letter, report of telephone contact or secure electronic communication with the original source.
- s. **Proctoring:** Proctoring is the activity by which a practitioner is assigned to observe the practice of another practitioner performing specified activities and to provide required reports on those observations. The proctor must have clinical privileges for the activity being performed, but must not be directly involved in the care observed practitioner is delivering. Proctoring that requires a proctor to do more than just observe, i.e., exercise control or impart knowledge, skill, or attitude to another practitioner to ensure appropriate, timely, and effective patient care, constitutes supervision. Such supervision may be a reduction of privileges.
- t. **Professional Standards Board:** The Professional Standards Board (PSB) acts for the Medical Executive Board in matters concerning appointments, disciplinary matters and probationary reviews of physicians, dentists, podiatrists, psychologists, optometrist, advanced practice nurses, and physician assistants. Membership may include the Chief of Staff, Deputy Chief of Staff, designated Clinical Service Chiefs or Care Line Managers (Extended Care, Anesthesia, Dental, Medicine, MHCL, Neurology, Pathology and Laboratory, Primary Care, Medical Imaging Services, Surgery, Transplant, Compensation and Pension, PM&R), a representative from Credentialing and Privileging, a representative from Human Resource Management Service, a physician assistant and nurse practitioner, and the Service or Section Chief representing the specialty of the individual whose credentials are under review. A quorum of 51 percent of voting members must be present to make recommendations to the VA TVHS Director. The activities and functions of this board are defined by VA regulations. The Chief of Staff or designee is Chairman of the PSB.
- u. <u>Reappraisal:</u> The mandatory two-year review and evaluation of the credentials, clinical competence, and health status of all professionals requiring credentialing.
- v. **Recredentialing:** Recredentialing is an evaluation process of the professional credentials and clinical competence of the medical staff that have been granted clinical privileges. The process is conducted not more than two (2) years.
- w. **Reduction of Privileges:** A process of restricting performance of specific procedures or prescribing and/or dispensing controlled substances. The reduction may be time limited and/or have restoration contingent upon some condition, such as demonstration of recovery from a medically disabling condition or further training in a particular area.
- x. <u>Registration or Certification</u>: Official documentation by a professional organization that one has fulfilled the requirements or met the standard or skill to practice the profession.
- y. **Relinquishment of Privilege(s):** A provider can voluntarily relinquish a privilege or privileges at the time of reprivileging or any time during the two (2) year cycle for a specified period of time or permanently. This request is reviewed by the Service Chief and documented at the Professional Standards Board.

- z. **Reprivileging:** The process of reviewing and granting privileges to practitioners who currently have clinical privileges at VA TVHS.
 - aa. **Revocation of Privileges:** The permanent loss of all clinical privileges at TVHS.
- bb. <u>Teleconsulting</u>: Teleconsulting is the provision of advice on a diagnosis, prognosis and/or therapy from a licensed independent provider to another licensed independent provider using electronic communications and information technology to support the care provided when distance separates the participants and where hands-on care is delivered at the site of the patient by a licensed independent healthcare provider.
- cc. <u>Telemedicine</u>: Telemedicine is the provision of care by a licensed independent healthcare provider that directs, diagnoses or otherwise provides clinical treatment delivered using electronic communications and information technology when distance separates the provider and the patient.
- **Note:** A crucial consideration in making a distinction between consultation and care is that teleconsultation occurs when the consultant involved recommends diagnoses, treatments, etc., to the consulting provider requesting the consult, but does not actually write orders or assume the care of the patient. If the consultant diagnoses, writes orders or assumes care in any way, this constitutes "care" and requires privileges. A Medical Staff appointment is required if the provider is entering documentation into the medical record, e.g., via teleradiology.
- dd. <u>VetPro:</u> VetPro is an Internet-enabled databank for the credentialing of VHA healthcare providers that facilitates completion of a uniform, accurate and complete credentials file.

5. RESPONSIBILITIES:

- a. The VISN Chief Medical Officer (CMO) is responsible for oversight of the credentialing and/or privileging process of the facilities within the VISN. The VISN 9 CMO may be credentialed and privileged through the TVHS Professional Standards Board. The process for requesting clinical privileges follows the procedures in this policy, as outlined for other practitioners. The process for forwarding a credentials file to the CMO for review prior to appointment is outlined in **Attachment B**, along with the review form.
- b. <u>The Health System Director</u>: The ultimate responsibility for credentialing and privileging resides with the Health System Director. The Health System Director is responsible for ensuring that:
- (1) The labor-management obligations are met prior to implementing this credentialing and privileging program for Title 5 independent practitioners who are represented by a professional bargaining unit.
- (2) Medical Staff Leadership and all staff with responsibility for the credentialing and privileging process complete the one time training determined by the Office of Quality and Performance (OQP) within three (3) months of assuming their position. This training is accessed through the VA Learning Management System. It also includes the Chief of Staff, System Director, Credentialing staff, and Quality Management professionals, including the Risk Manager.

- c. <u>Chief of Staff:</u> The Chief of Staff (COS) is responsible for maintenance of the credentialing and privileging program for the healthcare professionals designated in this policy. He/she is responsible for ensuring all credentialing and privileging functions and the Medical Staff Bylaws are consistent with VHA Handbook 1100.19, Credentialing and Privileging, and any other VHA policy related to the Medical Staff Bylaws.
- d. **Service Chiefs/Care Line Managers:** Service Chiefs/Care Line Managers are responsible for:
- (1) Recommending the criteria for clinical privileges that are relevant to the care provided in the service;
- (2) Reviewing all credentials and requested clinical privileges and making recommendations regarding appointment and privileging action; and
- (3) Continuous surveillance of the professional performance of those who provide patient care services with delineated clinical privileges (ongoing professional practice evaluations).
- e. <u>Applicants and Practitioners</u>: Applicants and practitioners must provide evidence of licensure, registration, certification and/or other relevant credentials for verification prior to appointment and throughout the employment process, as requested. They must agree to accept the professional obligations delineated in the Medical Staff Bylaws provided to them. They are responsible for keeping the healthcare system appraised of anything that would adversely affect or otherwise limit their clinical privileges. All applicants and practitioners are required to be credentialed through VetPro.
- f. <u>Credentialing Staff</u>: The Credentialing staff is responsible for the implementation of policies and procedures in accordance with VHA Directives, Handbooks, and The Joint Commission standards. They ensure that individuals requiring credentialing are processed through VetPro; prepare and maintain credentialing folders; provide pertinent information to the Professional Standards Board; and ensure that all required signatures have been obtained. The Credentialing Staff is also responsible for providing the facility Privacy Officer with the number of disclosures each year for the Annual Freedom of Information Act (FOIA) Report. Disclosures include releasing any patient or employee data, including physicians and allied health professionals, to third parties.
- **6. PROCEDURES: Credentialing** *This section describes requirements for credentialing for initial appointments, reappointments and reappointments after a break in service.*
- a. <u>Healthcare professionals</u> (licensed independent practitioners and allied health professionals) must be fully credentialed prior to initial appointment or reappointment except for expedited appointments to the Medical Staff and temporary appointments for urgent patient care needs. Credentialing is required to ensure that an applicant has the required education, training, experience, physical and mental health and skill to fulfill the requirements of the position and to support the requested clinical privileges. This section contains the administrative requirements and procedures related to the initial credentialing and recredentialing.

- (1) The credentialing process includes verification, through the appropriate primary sources, of the individual's professional education; training; licensure; certification and review of health status; previous experience, including any gaps [greater than thirty (30) days] in training and employment; clinical privileges; professional references; malpractice history and adverse actions; or criminal violations, as appropriate. Medical Staff appointment and employment commitments must not be made until the credentialing process is complete, except as identified under Section 7 of this policy. This includes screening through the appropriate State Licensing Board (SLB), FSMB and the PDS-NPDB-HIPDB. All information obtained through the credentialing process will be carefully considered before appointment and privileging decision actions are made.
- (2) The applicant has the burden of obtaining and producing all needed information for a proper evaluation of professional competence, character, ethics and other qualifications. The information must be complete and verifiable. The applicant has the responsibility for furnishing information that will help resolve any questions concerning these qualifications. Failure to provide necessary information within ninety (90) calendar days may serve as a basis for denial of Medical Staff appointment and/or privileges, as defined in the Medical Staff Bylaws and Rules and Regulations.
- (3) All applicants applying for clinical privileges must be provided with a copy of the Medical Staff Bylaws and Medical Staff Rules and Regulations, and must agree in writing to accept the professional obligations reflected therein.
- (4) The applicable service chief/care line manager reviews the credentialing folder and requested privileges and makes recommendations regarding appointment. The folder and recommendations are reviewed by the Professional Standards Board and then submitted with recommendations to the Medical Executive Board.
- b. **Application Forms:** Candidates seeking appointment or reappointment must complete appropriate forms for the position for which they are applying.

Note: A copy of the appropriate application form and any supplemental form(s) are maintained electronically in VetPro and may be filed in Section I of the credentialing and privileging folder. If the applicant provides a resume or curriculum vitae, this is also filed in Section I.

- (1) All candidates requiring credentialing in accordance with this policy must complete an electronic submission of VetPro. VetPro's supplemental information form requires applicants to answer questions to meet The Joint Commission and VHA requirements. This supplemental information form requires the applicant to provide information concerning malpractice, adverse actions against licensure, privileges, hospital membership, research, etc.
- (2) An applicant is required to provide information on all educational, training and employment experiences, including all gaps greater than thirty (30) days in the candidate's history.
- (3) The sign and submit screen in VetPro addresses the applicant's agreement to provide continuous care and to accept the professional obligations defined in the Medical Staff Bylaws, Rules and Regulations of the facility, as well as attesting to the accuracy and completeness of the information submitted.

(4) If the delay between the candidate's appointment and reporting for duty is greater than 180 calendar days, the credentialing staff must update all time-limited credentials and information including but not limited to licensure, current competence and supplemental questions. The updated information must be verified prior to the candidate reporting for duty. Verification of a time-limited credential cannot be greater than 120 days old at the time a practitioner reports for duty. This requirement includes a response from the NPDB-HIPDB. Delays from the candidate's application to reporting for duty most frequently occur in the case of an individual for whom special waivers (i.e., visa waiver) may be required. Since these processes can be time-consuming, information on the candidate's practice or non-practice during the period of delay must be obtained to ensure the most appropriate placement of the candidate.

c. **Documentation Requirements:**

- (1) Each LIP and allied health professional must have a credentialing file established electronically in VetPro with any paper documents maintained according to the requirements of the standardized folder identified in the **Attachment B**. Other credentialed LIP's have a credentialing file maintained in the same system of records even though they may not be granted clinical privileges. Duplication of information documented and maintained in the electronic VetPro file for filing in the paper credentialing and privileging file is not necessary and is discouraged.
- (2) Information obtained for use in the credentialing process must be primary source verified, unless otherwise noted, and documented in writing either by letter, report of contact or web verification. The credentialing staff is expected to secure all credentialing and privileging documents. Any facsimile copy must be followed up with an original document.
- (3) When using an Internet source for verification, the following criteria must be considered in determining appropriateness as primary source verification:
- (a) The website disclaimer must be reviewed to determine the organization's attestation to the accuracy and timeliness of the information. If there is no disclaimer, the web verification needs to be seriously considered as not adequate for verification.
- (b) There must be evidence that the site is maintained by the verifying entity and that the verification data cannot be modified by outside sources. If not maintained by the verifying entity, the site must include an endorsement by the entity that the site is primary source verification or the transmission is in an encrypted format.
 - (c) The site must provide information on the status of the license and adverse action information.
 - (d) To avoid issues arising with surveyors, print the disclaimer when the verification is printed.
- (4) There must be follow-up of any discrepancy found in information obtained during the verification process. The practitioner has the right to correct any information that is factually incorrect by documenting the new information with a comment that previously provided information was not correct. Follow-up with the verifying entity will be necessary to determine the reason for the discrepancy if the practitioner says the information provided is factually incorrect.

(5) LIPs and allied healthcare professionals with multiple licenses, registrations and/or certifications are responsible for maintaining these credentials in good standing and informing the Director, or designee, of any changes in the status of these credentials. The Director is responsible for establishing a mechanism to ensure that multiple licenses, registrations and/or certifications are consistently held in good standing or, if allowed to lapse, are relinquished in good standing. The practitioner is required to provide a written explanation for any credentials that were held previously but which are no longer held or are no longer full and unrestricted. The verifying official must contact the state board(s) or issuing organization(s) to verify information provided regarding the change.

Note: There are circumstances when verification from a foreign country is not possible or could prove harmful to the practitioner and/or family. In these instances, full documentation of efforts and circumstances, including a statement of justification, should be made in the form of a report of contact and filed in the credentialing and privileging file in lieu of the document sought.

(6) If the search for documents is unsuccessful or primary source documents are not received after a minimum of two requests, full written documentation of these efforts, in the form of a report of contact, will be placed in the folder in lieu of the document sought. It is suggested that no more than thirty (30) days elapse before the attempt is deemed unsuccessful. The practitioner should be notified and assist in obtaining the necessary documentation through a secondary source.

(7) Verification of Educational Credentials

- (a) For healthcare professionals who are requesting clinical privileges, primary source verification of all residencies, fellowships, advanced education, clinical practice programs, etc., from the appropriate program director or school is required. If a physician or dentist participated in an internship(s) equivalent to the current residency years PG 1, 2 and 3, it is necessary to obtain primary source verification of the internship(s). Any fees charged by institutions to verify education credentials will be paid by the healthcare system.
- (b) For foreign medical school graduates, healthcare system officials must verify with the Education Commission for Foreign Medical Graduates (ECFMG) that the applicant has met requirements for certification, if claimed. The ECFMG is not applicable for graduates from Canadian or Puerto Rican medical schools. Documentation of completion of a "Fifth Pathway" may be substituted for ECFMG certification. Additionally, TJC accepts the primary source verification of ECFMG for foreign medical school graduation. Documentation of this verification must meet the requirements of this policy.
- (c) All efforts to verify education must be documented even if it is not possible to verify education, e.g., the school has closed, the school is in a foreign country and no response can be obtained or other reason. In any case, the credentialing staff must verify and document that candidates meet appropriate VA qualification standards prior to appointment as an employee. The credentialing staff is encouraged to obtain additional information concerning the education of the applicant from other authoritative sources.
- (d) Applicants are required to provide information on all educational and training experiences including all gaps greater than thirty (30) days in educational history. Primary source verification

must be sought on medical, dental and professional school graduation and all residency and fellowship training, as well as internships for non-physician and non-dentist applicants.

- (e) An educational institution may designate an organization as its agent for primary source verification for credentialing. The verification from the agent is acceptable (e.g., National Student Clearinghouse). Documentation of this designation must be on file.
- (f) For other healthcare providers, at a minimum, the level of education that is the entry level for the profession or permits licensure must be verified, as well as all other advanced education used to support the granting of clinical privileges, if applicable. For example, for an advanced practice registered nurse (APRN), the qualifying degree for the RN and the advanced APRN education must be verified.
- (g) Primary source verification of other advanced educational and clinical practice programs is required if the applicant offers this credential as a primary support for the requested specialized clinical privileges.
- (h) Educational Profile for Physicians: Facilities may obtain from the American Medical Association (AMA) or American Osteopathic Association (AOA) Physician Database, a profile listing all medical education a physician candidate has received in this country. Other information is listed for follow-up as necessary. The AMA Physician Masterfile is a TJC-designated equivalent for primary source verification requirements for physicians' and osteopaths' education, and completion through residency training. In instances where the AMA Profile does not stipulate primary source verification was obtained, efforts to verify will be documented in the credentialing and privileging folder.
- (i) Verification of all education and training is filed in Section III of the credentialing and privileging folder and in the appropriate portion of VetPro.

(8) <u>Verifying Specialty Board Certification:</u>

(a) Physician Service Chiefs: Physician Service Chiefs must be certified by an appropriate specialty board or possess comparable competence. For candidates not board certified or board certified in a specialty not appropriate for the assignment, the Professional Standards Board must affirmatively establish and document, through the privilege delineation process, that the person possesses comparable competence. If the service chief is not board certified, the credentialing and privileging file must contain documentation that the individual has been determined to be equally qualified based on experience and provider-specific data. Appointment of service chiefs without board certification will comply with VHA policy for these appointments as appropriate. Verification must be from the primary source by direct contact or other means of communication with the primary source, such as by the use of a public listing of specialists in a book or website or other electronic medium as long as the listing is maintained by the primary source and there is no disclaimer regarding authenticity. If listings of specialists are used to verify specialty certification, they must be from recently issued copies of the publication(s) and include authentic copies of the cover page indicating publication date and the page listing the practitioner. This information must be included in the practitioner's folder (electronic or paper) as follows:

- 1. Physicians: Board certification may be verified through the Official ABMS Directory of Board Certified Medical Specialists published by the American Board of Medical Specialists (ABMS), or by acceptable Internet verification or by direct communication with officials of the appropriate board. A letter from the board addressed to the healthcare system is acceptable for those recently certified. The electronic matching through VetPro is primary source verification because it is performed through an electronic version of the Official ABMS Directory of Board Certified Medical Specialists. Osteopathic board certification may be verified through the American Osteopathic Association Physician Database.
- <u>2.</u> <u>Dentists</u>: Board certification may be verified by contacting the appropriate dental specialty board. Addresses of these boards may be obtained from the American Dental Association (ADA).
- 3. <u>Podiatrists</u>: Three (3) specialties are currently recognized by the House of Delegates, American Podiatric Medical Association and VA: the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and the American Board of Podiatric Public Health. Addresses of these boards may be obtained from the latest American Podiatric Directory.
- 4. Other Allied Health Professionals: Board certification and other specialty certificates must be primary source verified by contacting the appropriate board or certifying organization.
- (b) <u>Evidence of Continuing Certification</u>: Board certification and other specialty certificates which are time limited or carry an expiration date must be reviewed and documented prior to expiration.
- (c) Verification must be from the primary source by direct contact or other means of communication with the primary source such as by the use of a public listing of specialists in a book or Web site, or other electronic medium as long as the listing is maintained by the primary source and there is no disclaimer regarding authenticity. If listings of specialists are used to verify specialty certification, they must be from recently issued copies of the publication(s), with authentic copy of the cover page indicating publication date and the page listing the practitioner. This information is included in the practitioner's folder.
- (d) Verification of specialty certification is filed in Section III of the credentialing and privileging folder and in the Board Certification portion of VetPro.

d. Licensure:

- (1) Requirement for Full, Active, Current and Unrestricted Licensure: Applicants being credentialed in preparation for applying for clinical privileges must possess at least one full, active, current and unrestricted license that authorizes the licensee to practice in the state of licensure and outside VA without any change being needed in the status of the license. For new appointments after a break in service, all licenses active at the time of separation must be primary source verified for any change in status.
- (2) <u>Qualification Requirements of Title 38 United States Code (U.S.C.) Section 7402(f)</u>
 Applicants being credentialed for a position identified in 38 U.S.C. Section 7402(b) (other than a Director) for whom state licensure, registration or certification is required and who possess or have

possessed more than one license (as applicable to the position) are subject to the following provisions:

- (a) Applicants and individuals appointed on or after November 30, 1999, who have been licensed, registered or certified (as applicable to such position) in more than one (1) state and who had such license, registration or certification revoked for professional misconduct, professional incompetence or substandard care by any of those states or voluntarily relinquished a license, registration or certification in any of those states after being notified in writing by that state of potential termination for professional misconduct, professional incompetence or substandard care are not eligible for appointment, unless the revoked or surrendered license, registration or certification is restored to a full and unrestricted status. Covered licensure actions are based on the date the credential was required by statute or the position's qualification standards. (See the section on licensure in VHA Handbook 1100.19, Credentialing and Privileging, for an example. Appendix B in that document lists occupations, job series, type of credential and date first required by VA.)
- (b) Individuals who were appointed <u>before</u> November 30, 1999, who have maintained continuous appointment since that date and who are identified as having been licensed, registered or certified (as applicable to such position) in more than one state and, on or after November 30, 1999, who have had such revoked for professional misconduct, professional incompetence or substandard care by any of those states or voluntarily relinquished a license, registration or certification in any of those states after being notified in writing by that state of potential termination for professional misconduct, professional incompetence or substandard care are not eligible for continued employment in such position unless the revoked or surrendered license, registration or certification is restored to a full and unrestricted status. Individuals who were appointed prior to November 30, 1999, and have been on continuous appointment since that date are not disqualified for employment by any license, registration or certification revocations or voluntary surrenders that predate November 30, 1999, provided they possess one full and unrestricted license as applicable to the position.
- (c) Where a license, registration or certification (as applicable to the position) has been surrendered, confirmation must be obtained from the primary source that the individual was notified in writing of the potential for termination for professional misconduct, professional incompetence or substandard care. If the entity does verify written notification was provided, the individual is not eligible for employment unless the surrendered credential is fully restored.
- (d) Where the State licensing, registration or certifying entity fully restores the revoked or surrendered credential, the eligibility of the provider for employment is restored. These individuals would be subject to the same employment process that applies to all individuals in the same job category who are entering the VA employment process. In addition to the credentialing requirements for the position, there must be a complete review of the facts and circumstances concerning the action taken against the State license, registration or certification and the impact of the action on the professional conduct of the applicant. This review must be documented in the licensure section of the credentials file.
- (e) This policy applies to licensure, registration or certification required, as applicable, to the position subsequent to the publication of this policy and required by statute or VA qualification standards, effective with the date the credential is required.

- (f) When a practitioner enters into an agreement (disciplinary or non-disciplinary) with a State licensing board to not practice the occupation in a State, the practitioner is required to notify the TVHS Credentialing Staff of the agreement. This must include information concerning the circumstances surrounding the agreement. This includes information from the primary source of the specific written notification provided to the practitioner, including, but not limited to: notice of the potential for termination of licensure for professional misconduct, professional incompetence, or substandard care. If the entity does verify written notification was provided, all associated documentation must be obtained and incorporated into the credentialing and privileging file and VetPro. The practitioner must be afforded an opportunity to explain in writing, the circumstances leading to the agreement. Facility officials must evaluate the primary source information and the individual's explanation of the specific circumstances, documenting this review in the credentialing and privileging file and VetPro.
- **NOTE:** It may be necessary to obtain a signed VA Form 10-0459, Credentialing Release of Information Authorization request from the practitioner, requesting the State licensing board to disclose to VA all malpractice judgments and disciplinary actions as well as all open investigations and outstanding allegations and investigations. Failure by the practitioner to sign VA Form 10-0459 may be grounds for disciplinary action or decision not to appoint.
- (g) There may be instances where actions have been taken against an applicant's license for a clinically-diagnosed illness. Those applicants are eligible for appointment where they are acknowledged by the licensing, registering, or certifying entity as stable, the licensure action did not involve substandard care, professional misconduct, or professional incompetence and the license, certificate, or registration is fully restored. A thorough analysis of the information obtained from the entity must be documented, signed by the appropriate reviewers and approving officials, and filed in the licensure section of the Credentialing and Privileging folder.
- (3) Exceptions to Licensure: As part of the credentialing process, the status of an applicant's licensure and that of any required or claimed certifications must be reviewed and primary source verified. Except as provided in VA Handbook 5005, Part II, Chapter 3, subparagraph 14b, all LIPs must have a full, active, current and unrestricted license to practice in any State, Territory or Commonwealth of the United States or in the District of Columbia. The only exceptions are as follows:
- (a) An individual who has met all the professional requirements for admission to the State licensure examination and has passed the examination, but who has been issued a State license which is limited on the basis of non-citizenship or not meeting the residence requirements of the State.
- (b) An individual who has been granted an institutional license by the state which permits faculty appointment and full, unrestricted clinical practice at a specified educational institution and its affiliates, including VA TVHS, or an institutional license which permits full, unrestricted clinical practice at VA TVHS. This exception is only used to appoint an individual who is a well qualified, recognized expert in the individual's field, such as a visiting scholar, clinician and/or research scientist, and only under authority of 38 U.S.C. 7405. It may not be used to appoint an individual whose institutional license is based on action taken by a SLB.

- (c) An individual who has met all the professional requirements for admission to the state licensure examination and has passed the examination, but who has been issued a time-limited or temporary state license or permit pending a meeting of the SLB to give final approval to the candidate's request for licensure. The license must be active, current and permit a full, unrestricted practice. Appointments of healthcare professionals with such licenses must be made under authority of 38 U.S.C. 7405 and are time-limited not to exceed the expiration date of licensure.
- (d) A resident who holds a license which geographically limits the area in which practice is permitted or which limits a resident to practice only in specific healthcare facilities, but that authorizes the individual to independently exercise all the professional and therapeutic prerogatives of the occupation. In some states, such a license may be issued to residents in order to permit them to engage in outside professional employment during the period of residency training. The exception does not permit the employment of a resident who holds a license which is issued solely to allow the individual to participate in residency training.
- (e) There may be changes in state licensure requirements and administrative delay by SLBs in processing renewal applications for licensure.

(For information see VA Handbook 5005, Part II, Chapter 3, Section A, paragraphs 13f and 13g.)

- (4) SLBs may restrict the license of a practitioner for a variety of reasons. Among other restrictions, an SLB may suspend the licensee's ability to independently prescribe controlled substances or other drugs, selectively limit the authority to prescribe a particular type or schedule of drugs, accept a practitioner's offer or voluntary agreement to limit authority to prescribe, or provide an "inactive" category of licensure. In such cases, the license must be considered restricted for VA purposes regardless of the official SLB status.
- (5) Some states authorize a grace period after the licensure, certification, and/or registration expiration date during which an individual is considered to be fully licensed and/or registered whether or not the individual has applied for renewal on a timely basis. Healthcare system officials will not initiate separation procedures for failure to maintain licensure or registration on a practitioner whose only license and/or registration has expired if the State has such a grace period and considers the practitioner to be fully and currently licensed and/or registered.

(6) FSMB Screening of Physician Applicants:

- (a) Physician applicants including physician residents who function outside of the scope of their training program, e.g., who are appointed as Admitting Officer of the Day, must be screened with the FSMB prior to appointment.
- (b) The FSMB is a disciplinary information service and reports only those disciplinary actions resulting from formal actions taken by reporting medical licensing and disciplinary boards or similar official sources. The screening with the FSMB must be performed through VetPro. Once education has been verified in VetPro, the query can be electronically submitted. Responses are received by VetPro and displayed on the License screen. Screening applicants with the FSMB does not abrogate the medical facility's responsibility for verifying current and previously held medical licenses with the SLBs .

- (c) Appointment to the medical staff and granting of clinical privileges is not complete until screening against the FSMB Disciplinary Files is documented in VetPro. It must be documented in VetPro that information obtained through screening against the FSMB Disciplinary Files is verified through the primary source and that this information has been considered during the appointment process. If additional information is needed from the practitioner in response to this information, that must be obtained through, and documented in VetPro.
- (d) Those practitioners who were screened against the FSMB Disciplinary Files by VA Central Office in 2002, or subsequent to this date were screened through VetPro, are placed in VHAs FSMB Disciplinary Alerts Service. Practitioners entered into the VHA's FSMB Disciplinary Alerts Service are continuously monitored. Orders reported to the FSMB from licensing entities, as well as the Department of Health and Human Service (DHHS) OIG and the Department of Defense (DOD), initiate an electronic alert that an action has been reported to VHA's Credentialing and Privileging Program Director.
- <u>1</u>. The registration of practitioners into this system is based on these queries and only on these queries.
 - 2. This monitoring is on-going for registered practitioners.
- <u>3</u>. Alerts received by VHA's Credentialing and Privileging Program Director must be forwarded to the appropriate VA facility for primary source verification and appropriate action. The disciplinary information that pertains to the practitioner can then be downloaded and forwarded to the appropriate facility for review and inclusion in the practitioner's credentials file.
- 4. Facility credentialing staff must obtain primary source information from the State licensing board for all actions related to the disciplinary alert. Complete documentation of this action, including the practitioner's statement, is to be scanned into VetPro before filing in the paper credentials file. Medical staff leadership is to review all documentation to determine the impact on the practitioner's continued ability to practice within the scope of privileges granted. This review must be completed within 30 days of the notice to the facility staff of the alert and completed documented in VetPro prior to filing in the paper file.
- <u>5</u>. Practitioner names must be removed from the VHA FSMB Disciplinary Alerts Service when the practitioner file is inactivated in VetPro, or when the practitioner's appointment lapses in VetPro.
 - (7) Appointment of Candidates with Previous or Current Adverse Action Involving Licensure
- (a) Physicians, dentists or other licensed practitioners who have had a license or licenses restricted, suspended, limited, issued and/or placed on probationary status or denied upon application may be appointed under the appointment procedures that apply to other physicians, dentists or other healthcare professionals.
- (b) Officials included in the appointment process are to thoroughly review and document the review of all SLB documentation (e.g., findings of fact detailing the basis for the action against the applicant's license, stipulation agreements, consent orders and final orders), as well as the applicant's subsequent professional conduct and behavior before determining whether the applicant

can successfully serve as a physician, dentist or other healthcare practitioner in the healthcare system.

- (c) To be eligible for appointment, an applicant or employee must meet current legal requirements for licensure. (See 38 U.S.C. §§ 7402(b) and (f), and paragraphs 6g(1) and 6g(2) of this policy.)
- (d) If action was taken against the applicant's sole license, or against all the applicant's licenses, a review by the Chief, Human Resources Management, or the Regional Counsel is necessary to determine whether the applicant meets VA's licensure requirements. Documentation of this review must include the reason for the review, the rationale for conclusions reached and the recommended action. All this must be filed in the Credentialing and Privileging folder and the appropriate section of VetPro.
- (e) Healthcare professionals who have a current, full and unrestricted license in one or more states, but who currently have or have ever had a license, registration or certification restricted, suspended, limited, issued and/or placed on probationary status or denied upon application, must not be appointed without a thorough, documented review. The credentials file must be reviewed with Regional Counsel, or designee, to determine if the practitioner meets appointment requirements. Documentation must include the reasons for the review, the rationale for the conclusions reached and the recommended action. The review and the rationale for the conclusions must be forwarded to the VISN Chief Medical Officer for concurrence and approval of the appointment. All associated documentation must be filed in the credentialing and privileging folder and the appropriate section of VetPro.

(8) <u>Verification with State Licensing Boards</u>:

- (a) Verification can be made through a letter or by telephone and documented in a report of contact. Electronic means of verification are also acceptable as long as the site is maintained by the primary source and there is no disclaimer regarding authenticity. If verification of licensure is made by telephone or electronic means, a written request for verification must be made within five (5) working days accompanied by VA Form 10-0459 signed by the practitioner requesting verification and disclosure of requested information concerning each:
- <u>1</u>. Lawsuit, Civil Action or other claim brought against the practitioner for malpractice or negligence;
- <u>2</u>. Disciplinary action taken or under consideration, including any open or previously concluded investigations; and
- <u>3</u>. Or any changes in the status of the license and all supporting documentation related to the information provided.
 - (b) May be delegated by the facility Director at the request of the COS.
- (c) Must be completed in writing with 30 days of appointment and scanned into VetPro prior to being filed in the paper credentials file.

(d) Responsibility for contacting SLBs is delegated to the credentialing staff. If the State is unwilling to provide primary source verification of licensure, the credentialing staff must document the state's refusal and secure an authenticated copy of the license from the applicant. If the reason for the SLB's refusal is payment of a fee, VA TVHS will pay the fee if the review is for an initial appointment.

Note: Although credentialing is required for physician assistants, licensure is not required for employment; therefore verification of licensure is only required if claimed.

e. Drug Enforcement Agency (DEA) Certification:

(1) Physicians, dentists and certain other professional practitioners may apply for and be granted renewable certification by the Federal and/or State DEA to prescribe controlled substances as part of their practice. Certification must be verified for individuals who claim on the application form to currently hold or to have previously held DEA certification. Individual certification by DEA is not required for VA practice since practitioners may use the healthcare system's institutional DEA certificate with a suffix.

NOTE: Where a practitioner's state of licensure requires individual DEA certification to be authorized to prescribe controlled substances, the practitioner may not be granted prescriptive authority for controlled substances without such individual DEA certification. Questions regarding whether the healthcare system's institutional DEA certification with a suffix meets the State's requirement for individual certification are to be directed to the Regional Counsel.

NOTE: In order to prescribe controlled substances, contact licensed health care professionals who practice outside VA facilities but possess individual DEA registration in the State of practice In order to obtain such individual DEA registration in the State of Practice, the practitioner needs to be licensed by that State. However, contract licensed health care professionals who are practicing with VA facilities may rely on the facility's institutional DEA certification with a suffix.

- (2) <u>Application</u>. Each applicant possessing a DEA certificate must document information about the current or most recent DEA certificate on the appropriate VA application form. Any applicant whose DEA certification (Federal and/or State) has ever been revoked, suspended, limited, restricted in any way or voluntarily or involuntarily relinquished or not renewed is required to furnish a written explanation at the time of filing the application and at the time of reappraisal.
- (3) Restricted Certificates. A State agency may obtain a voluntary agreement from an individual not to apply for renewal of certification, or may decide not to approve the individual's application for renewal as a part of the disciplinary action taken in connection with the individual's professional practice. While there are a number of reasons a license may be restricted which are unrelated to DEA certification, an individual's state license is considered restricted or impaired for purposes of VA employment if a SLB has: 1) suspended the person' authority to prescribe controlled substances or other drugs; 2) selectively limited the individual's authority to prescribe a particular type or schedule of drug; or 3) accepted an individual's offer for voluntary agreement to limit authority to prescribe.

(4) DEA Verification.

- (a) Federal DEA. A copy of the current DEA certification will be sighted prior to appointment and reappointment. Automatic verification of Federal DEA certification can be performed in VetPro when a match can be made against the current Federal DEA certification information maintained in VetPro that is updated monthly. If verification cannot be made electronically, an authenticated copy of the DEA certificate must be scanned in VetPro and will be maintained in the credentialing and privileging folder. A report of contact is required documenting the reasons for non-renewal of a previously held DEA Certification.
- (b) State DEA. Verification can be made through a letter or by telephone and documented on a report of contact. Electronic means of verification are also acceptable as long as the site is maintained by the primary source and there is no disclaimer regarding authenticity. If the state is unwilling to provide primary source verification of licensure, the facility will document the state's refusal and secure an authenticated copy of the license from the applicant. Any fees charged by SLBs to verify licensure(s) will be paid by the facility.

f. Employment Histories and Pre-employment References:

- (1) For practitioners requesting clinical privileges, at least three (3) references must be obtained, including at least one from the current or most recent employer(s) or institution(s) where the applicant holds or held privileges.
- (2) For any candidate whose most recent employment has been private practice for whom employment histories may be difficult to obtain, the credentialing staff must contact any institution(s) where clinical privileges are and/or were held, professional organizations, references listed on the application form and/or other agencies, institutions or persons who would have reason to know the individual's professional qualifications. Additional information may be required to fully evaluate the educational background and/or prior experiences of an applicant.
- (3) VA Form Letter 10-341a. Appraisal of Applicant, the reference letter printed from VetPro, or any other acceptable reference letter may be used to obtain references. Additional information may be required to fully evaluate the educational background and/or prior experiences of an applicant. Initial and/or follow-up telephone or personal contact with those individuals having knowledge of an applicant's qualifications and suitability are encouraged as a means of obtaining a complete understanding of the composite employment record.
- (4) All references must be documented in writing. Written records of telephone or personal contacts must include who was spoken to, that person's position and title, the date of the contact, a summary of the specific information provided, the name of the organization (if appropriate), and the reason why a telephone or personal contact was made in lieu of a written communication. Reports of contact are to be filed with other references in the Official Personnel Folder or, for Title 38 employees who have personnel folders, in the Merged Records Personnel Folder (MRPF) and in the Credentialing and Privileging folder, including VetPro.
- (5) For applicants requesting clinical privileges, the credentialing staff must send a minimum of two requests to verify that the practitioner's currently held or most recently held clinical privileges are or were in good standing with no adverse actions or reductions for the specified period. For those healthcare professionals who have recently completed a training program, one reference needs to be from the program director attesting to the individual's competency and skill. Although there

is no specific requirement for how many years of personal history is required, work experience and previous employment is to be verified and the healthcare system is to make a reasonable attempt to verify all experience that is relevant to the privileges being requested. In many instances this could be many years ago if the practitioner has been in practice for a long period of time.

- (6) Ideally, references need to be from authoritative sources, which may require that healthcare system officials obtain information from sources other than the references listed by the applicant. As appropriate to the occupation for which the applicant is being considered, references need to contain specific information about the individual's scope of practice and level of performance. For example, information on:
- (a) The number and types of procedures performed, range of cases managed, appropriateness of care offered, outcomes of care provided, etc.
- (b) The applicant's medical and clinical knowledge, interpersonal skills, communication, clinical judgment, technical skills, and professionalism as reflected in results of quality improvement activities, peer review, and/or references, as appropriate.
- (c) The applicant's health status in relation to proposed duties of the position and, if applicable, to clinical privileges being requested.
- (7) Employment information and references are filed in Section V of the Credentialing and Privileging folder and the appropriate portion of VetPro.

g. Health Status:

- (1) All applicants and employees, whether paid or appointed or on a WOC basis, who request clinical privileges, including those who have a new appointment after a break in service, whether utilized on a full-time, part-time or intermittent basis, as fee basis consultants or attendings or on an on-station contract or on-station sharing agreement basis, are required to declare on the appropriate health status form that there are no physical or mental health conditions that would adversely affect their ability to carry out the requested responsibilities. This requirement also applies to all who are required to be credentialed in accordance with this policy.
- (2) This declaration of health must be confirmed by a physician designated by or acceptable to the healthcare system, such as the employee health physician or physician supervisor from the individual's previous employment. Confirmation, at a minimum, is to be in the form of a countersignature by the confirming physician. The confirming physician may not be related to the applicant by blood or marriage. Additional information may be sought from appropriate source(s), if warranted.
- (3) All references must be queried as to the applicant's physical and mental capability to fulfill the requirement of the clinical privileges being sought.
- (4) The documentation of health and relevant supporting information must be filed in Section V of the credentialing and privileging folder and the Personal Profile Screen of VetPro.

h. Malpractice Considerations:

- (1) At the time of application, initial hire, a new appointment after a break in service or reappraisal, each applicant, employee, contract practitioner or returning practitioner is asked to give detailed written explanations of any involvement in administrative, professional or judicial proceedings, including Federal tort claims in which malpractice is or was alleged, and to provide a written explanation of the circumstances or change in status. A full evaluation of the circumstances must be made by officials participating in the credentialing, selection and approval processes prior to making any recommendation or decision on the candidate's suitability for VA appointment or reappointment. A review of clinical privileges, as appropriate, must be initiated if clinical competence issues are involved.
- (2) Efforts should be made to obtain primary source information regarding the issues involved and the facts of the cases. The credentialing and privileging folder must contain an explanatory statement by the practitioner, documented in the supplemental questions, <u>and</u> evidence that the healthcare system evaluated the facts regarding resolution of the malpractice case(s), <u>as well as</u> a statement of adjudication by an insurance company, court of jurisdiction or statement of claim status from the attorney. A good faith effort to obtain this information must be documented by a copy of the refusal letter or report of contact. A practitioner's statement included in the NPDB-HIPDB report does not satisfy the need for the practitioner to provide an explanation.
- (3) Healthcare system officials must evaluate the individual's explanation of specific circumstances in conjunction with the primary source information related to the payment in each case. This evaluation will consider VA's obligation as a healthcare provider to exercise reasonable care in determining that healthcare professionals are properly qualified, recognizing that many allegations of malpractice are proven groundless. See paragraph l(7), below, for requirements for VISN review. Questions concerning legal aspects of a particular case must be directed to the Regional Counsel or the General Counsel.
- (4) NPDB-HIPDB reports contain information regarding any malpractice payment made on behalf of the practitioner. This information is considered a secondary source and does not meet the standard of primary source verification. Primary source verification must be obtained on this information from the appropriate sources.

i. NPDB-HIPDB Screening:

- (1) Proper screening through the NPDB-HIPDB is required for applicants, including physician residents who function outside of the scope of their training program, e.g., those appointed as Admitting Officer of the Day, all members of the Medical Staff and other healthcare professionals who hold clinical privileges, who are or have ever been licensed to practice their profession or occupation in any job title represented in the NPDB and HIPDB Guidebooks, or who are required to be credentialed in accordance with this policy. (See VHA Handbook 1100.19, Credentialing and Privileging, for additional requirements related to NPDB-HIPDB screening, including procedures that must be followed relating to appointment and termination of employment under Title 5 and Title 38 in cases where adverse information is uncovered.)
- (2) The NPDB-HIPDB is a secondary flagging system intended to facilitate a comprehensive review of licensed independent practitioners and allied health professionals' credentials. The information contained in the NPDB-HIPDB is intended to direct discrete inquiry into, and scrutiny of, specific areas of a practitioner's licensure, professional society memberships, medical

malpractice payment history, federal healthcare program exclusion status and record of clinical privileges. The information received in response to an NPDB-HIPDB query is to be considered together with other relevant data in evaluating a practitioner's credentials; it is intended to augment, not replace, traditional forms of credentials review. NPDB-HIPDB screening is required prior to appointment, including reappointment and transfer from another VA facility, whether or not VA requires licensure for appointment, reappointment or transfer. This screening must be accomplished by enrolling the practitioner in the NPDB-HIPDB PDS. This provides on-going monitoring of health care practitioners.

NOTE: All practitioners must be enrolled in the NPDB-HIPDB PDS within thirty (30) days of the availability to do so through VetPro regardless of their current appointment status. Guidance on the enrollment process distributed separately.

- (a) After initial enrollment, each facility is required to renew the enrollment for each practitioner in the NPDB-HIPDB PDS on, or before, the expiration of the annual enrollment; and
- (b) To confirm enrollment of practitioners in the NPDB-HIPDB PDS system through review of practitioner names from VetPro against NPDB-HIPDB PDS.

NOTE: If currently detailed to another VA facility or service another facility as a consultant, the receiving facility must enroll the practitioner in the NPDB-HIPDB PDS, in addition to the main facility.

(3) These procedures apply to all physicians, dentists and other healthcare practitioners who are appointed to the Medical Staff or who hold clinical privileges whether utilized on a full-time, part-time, intermittent, consultant, attending, without compensation (WOC), on-station fee-basis, on-station scarce medical specialty contract or on-station sharing agreement basis.

NOTE: The requirements to enroll and monitor practitioners through the NPDB-HIPDB PDS does not apply to trainees other than those who function as staff outside the scope of their training program; i.e., residents who serve as Admitting Officers of the Day.

- (4) VetPro maintains evidence of query submission and response received, as well as any reports obtained in response to the query, and it meets the NPDB-HIPDB requirements.
- (5) Because the NPDB-HIPDB is a secondary information source, any reported information must be validated by appropriate VA officials with the primary source, i.e., SLB, health care entity, malpractice payer to include, but not limited to the circumstances for payment (i.g., payment history in and of itself is not sufficient).
- (6) Screening applicants and appointees with the NPDB-HIPDB and enrollment in the NPDB-HIPDB PDS does not abrogate the COS's and appropriate service chief's responsibility for verifying all information prior to appointment, privileging and/or re-privileging, or proposed HRM action.
- (7) If the NPDB-HIPDB screen shows adverse action or malpractice reports, an evaluation of the circumstances and documentation thereof, is required. This evaluation needs to follow the guidelines outlined in preceding paragraphs.

- (8) The facility Director is the authorized representative who authorizes all submissions to the NPDB-HIPDB. Any delegation of that authority to other facility officials is to be documented, in writing, to include date of delegation, circumstances governing delegation, and title (not name) of the official who may make requests.
- (9) NPDB-HIPDB screening information is filed in Section VI of the Credentialing and Privileging folder and the appropriate section of VetPro.

j. <u>Appointment and Termination of Employment under Title 5 and Title 38 staff relative to NPDB-HIPDB Screening:</u>

- (1) Clinically privileged and otherwise credentialed practitioners affected by this policy are to be appointed only after enrollment in the NPDB-HIPDB PDS has been initiated, including Temporary Appointment for Urgent Patient Care Needs and Expedited Appointments.
- (2) If the NPDB-HIPDB screen through enrollment in the NPDB-HIPDB PDS shows action against clinical privileges, adverse action regarding professional society membership, medical malpractice payment for the benefit of the practitioner, or Federal health care program exclusion, facility officials must verify that the practitioner fully disclosed all related information required and requested by VA in its pre-employment, credentialing, and/or clinical privileging procedures.
- (3) The practitioner may be employed or continued in employment <u>only</u> after applicable procedural requirements are met.
- (4) Any notification from the NPDB-HIPDB PDS must be reported to the Director, Credentialing and Privileging, or designee, within two (2) workdays of receipt of the report. This includes reports received on initial enrollment in the service, and all subsequent reports received.
- (5) Following are the types of reports that a facility might receive and the action, or source of guidance for action, to be used in each case.

NOTE: The NPDB-HIPDB reports are maintained electronically in VetPro.

- (a) If an NPDB-HIPDB report indicates any multiple of the following actions, requirements for each must be met.
- 1. Evidence of Disciplinary Action by any SLB. Documentation of thorough review by officials involved in the appointment process of information obtained from the primary source SLB taking the disciplinary action.
- 2. Adverse Action Taken Against Clinical Privileges. A reference from the facility(ies) or health care organization that took the action against the clinical privileges, detailing the privileges held and reason for adverse action, must be included with the credentialing information. Documentation of a thorough review by officials involved in the appointment process must be included.

- <u>3</u>. <u>Adverse Action Regarding Professional Society Membership.</u> Particulars of the action must be verified with the professional society and documentation of the thorough review by officials involved in the appointment process included with credentialing information.
- 4. Medical Malpractice Payment for the Benefit of the Practitioner. Facility officials must evaluate the primary source information (e.g., information obtained from the insurance company or court records, etc.) and the individual's explanation of specific circumstances in each case. They may require the practitioner to provide copies of documents pertaining to the case. Questions regarding legal aspects of a particular case are to be directed to Regional Counsel. Documentation of all efforts in this regard must be a part of the credentialing information.
- (b) Reviews conducted subsequent to NPDB-HIPDB reports are to be thoroughly documented in the credentialing and privileging record (electronic and paper). Reviews include, but are not limited to, the Service Chief's as well as the preliminary review of the Executive Committee of the Medical Staff and could result in a decision to recommend:
- <u>1</u>. Appointment, or continue in an appointed status with no change in originally anticipated action.
- <u>2</u>. Appointment, or continue appointment status with changes, including, but not limited to, modification of clinical privileges or provision of training.
 - <u>3</u>. Non-appointment or termination.
- (c) In order to ensure an appropriate review is completed in the credentialing process, a higher-level review must be performed by the VISN CMO to ensure that all circumstances, including the individual's explanation of the specific circumstances in each case, are weighed against the primary source verification and that the appointment is still appropriate. The VISN CMO review must be completed <u>prior</u> to presentation to the Executive Committee of the Medical Staff, for review and recommendation to continue the appointment and privileging process.
 - 1. Circumstances requiring review by the VISN CMO are:
 - <u>a</u>. Three or more medical malpractice payments in payment history,
 - b. A single medical malpractice payment of \$550,000 or more, or
 - c. Two medical malpractice payments totaling \$1,000,000 or more

NOTE: This second level review is in no way an indication that practitioners who meet these criteria are more likely to have clinical practice issues.

<u>2</u>. The VISN CMO, in this oversight role, may request additional information as to the specific circumstance of the report or the facility's review process. The VISN CMO review must be documented on the Service Chief's Approval screen in VetPro as an additional entry recommending appointment in these cases.

NOTE: Files previously reviewed with no change in information do not need to be submitted for VISN CMO review. If there is any change in information at the time of reappraisal, including those files which meet the preceding criteria but not previously reviewed by the VISN CMO on or before October 10, 2007, must be referred to the VISN CMO for review.

- (d) Once requirements for consideration and evaluation of any action reported by NPDB-HIPDB have been completed, the appointment or continued appointment decision, if appropriate, must be made following guidance in this Handbook; Title 5 policies and procedures specified in Title 5 Code of Federal Regulations (CFR) 315, 731, or 752; Federal or VA acquisition regulations; VA Directive and Handbook 0710; and VA Directive and Handbook 5021, as they apply to the category of practitioner.
- (e) When any initial or subsequent NPDB-HIPDB report calls into question the professional competence or conduct of an individual appointed by VA, the facts and circumstances are to be reviewed to determine what action would be appropriate, including such actions as revision of clinical privileges, removal, etc. Such actions must be closely coordinated with the Human Resource Management Service (and in the case of contracts and sharing agreements with Acquisition and Materiel Management Service) to ensure that they are processed in accordance with applicable requirements.
- (6) The Director, Credentialing and Privileging, or designee, must monitor the fact that a report was received by the facility until the review of the circumstances and any necessary action by facility staff is documented in VetPro. Facility staff must provide updates every 30 days until all information is collected and any necessary action documented; however, closure is expected within 90 days of receipt of the report.
- k. <u>Credentialing for Telehealth and Teleconsultation.</u> When the staff of a facility determines that telemedicine and/or teleconsultation is in the best interest of quality patient care, appropriate credentialing and privileging is required.
- (1) The facility Director(s) must ensure appropriate mechanisms are in place for verifying and undertaking privileging of off-site providers who deliver services using telemedicine or teleconsultation both at the site providing telemedicine or teleconsultation and the site receiving these services, in order to insure that the care delivered fits within the resources of the facility(ies) and scope of practice of the practitioners.
- (a) All practitioners treating patients using telemedicine and teleconsultation must be qualified to deliver the required level of consultation, care, and treatment with the appropriate credentialing and privileging, regardless of the technology used, and they must be credentialed and privileged to deliver that care. This ensures that mechanisms are provided for appropriate appointment, credentialing, and privileging of providers both at the site providing the telemedicine and/or teleconsultation and at the site receiving these services, in order to ensure the care delivered fits within the resources of the facility and scope of practice of the practitioners.
- (b) The practitioner providing the telemedicine and/or teleconsultation services must be credentialed and privileged in accordance with this Handbook.

- (2) **Teleconsultation.** The practitioner providing only teleconsultation services must be appointed, credentialed, and privileged at the site at which the practitioner is physically located when providing teleconsultation services.
- (a) These practitioner's credentials must be shared with the facility receiving the teleconsultation services using shared access of the VetPro file.
- (b) With the exception of the separate NPDB-HIPDB query discussed in subparagraph 5n(3), the practitioner providing teleconsultation services does not have to be separately appointed or credentialed at the facility or site where the patient is physically located.
- (c) When the practitioner provides only teleconsultation by offering advice that supports care provided by the on-site licensed independent privileged provider, a copy of the practitioner's current clinical privileges must be made available to the facility or site where the patient is physically located. The practitioner providing teleconsultation services does not have to be separately privileged at the facility or site where the patient is physically located.
- (3) **Telemedicine.** When telemedicine services are being provided by the practitioner who directs, diagnoses, or otherwise provides clinical treatment (i.e., teleradiology, teledermatology, etc.) to a patient using a telemedicine link, the practitioner must be appointed, credentialed, and privileged at the facility which receives the telemedicine services (patient site), as well as at the site providing the services.
- (a) A separate delineation and granting of privileges must be made by the facility receiving the telemedicine services. Appropriate credentialing needs to be performed by the facility receiving the telemedicine services prior to the granting of these privileges, including response to the Supplemental Questions, licensure verification, confirmation of current competency, and a NPDB-HIPDB query.
- **NOTE:** Telemedicine involves the use of technology and is therefore a modality for the delivery of existing clinical practices. As such, there are no separate or distinct privileges for telemedicine. When considering the granting of privileges at the facility where the practitioner is physically based, the general privileging process needs to include the appropriateness of using telemedicine to deliver services and this site is considered a separate site of care in the establishment of privileges. Any consideration concerning the appropriate utilization of telemedicine equipment by the practitioner needs to be considered as part of the privileging process by the facility where the practitioner is physically located.
- (b) Before a remote practitioner conducts either telemedicine and/or teleconsultation with another facility or site, the facility or site where the patient is physically located must enroll the practitioner in the NPDB-HIPDB PDS. The NPDB-HIPDB PDS registration must be renewed in accordance with credentialing and reappraisal requirements of this policy.
- **NOTE:** If this is not done, it must be clearly documented why an NPDB-HIPDB query was not completed before the practitioner engages in patient care using telemedicine and/or teleconsultation.

- (4) Contracts for Telemedicine and/or Teleconsultation Services. Contracts for telemedicine and/or teleconsultation services need to require that these services be performed by appropriately-licensed individuals. Unless otherwise required by the specific contract or Federal law (such as the Federal Controlled Substances Act), contract health care professionals must meet the same licensure requirements imposed on VA employees in the same profession whether they are on VA (Federal) property or not when providing telemedicine or teleconsultation services.
- **NOTE:** Some states do not allow telemedicine and/or teleconsultation across state lines, unless the provider is licensed in the state where the patient is physically located. In these states, the clinical indemnity coverage of contract practitioners may be void, even if they are credentialed and privileged by VA. Prior to the commencement of services by the contract practitioners providing telemedicine and/or teleconsultation or remotely monitoring physiology data from veteran patients, the State regulatory agency in the state in which the practitioner is physically located as well as the state where the patient is physically located, must be consulted. When dealing with Federal entities, additional licenses that authorize the provision of telemedicine and/or teleconsultation services in the relevant states may not be required. The opinion of the Regional Counsel needs to be sought in these matters.
- 1. <u>Expedited Appointments to the Medical Staff</u>: There may be instances where expediting a Medical Staff appointment for licensed independent providers (excluding CRNAs, Advanced Practice Nurses, and Nurse Practitioners) is in the best interest of quality patient care. The Medical Staff Bylaws permit an expedited process as described in this policy.
- (1) The credentialing process for the expedited appointment to the Medical Staff (excluding CRNAs, Advance Practice Nurses and Nurse Practitioners) <u>cannot</u> begin until the LIP completes the credentials package, including but not limited to a complete application; therefore, the provider must submit this information through VetPro and documentation of credentials must also be retained in VetPro.
 - (2) Credentialing requirements for this process must include confirmation of:
 - The physician's education and training, which, if necessary, can be accomplished in 24 hours through the purchase of the American Medical Association's Physician Profile;
 - One active, current, unrestricted license verified by the primary source state;
 - Confirmation on the declaration of health, by a physician designated by or acceptable to the healthcare system, of the applicant's physical and mental capability to fulfill the requirement of the clinical privileges being sought;
 - Query of licensure history through the FSMB Action Data Center with no report documented;
 - Confirmation from two peer references who are knowledgeable of and confirm the physician's competence, including at least one from the current or most recent employer(s) or institution(s) where the applicant holds or held privileges, or who would have reason to know the individual's professional qualifications.

- Current comparable privileges held in another institution; and
- An NPDB-HIPDB query with documentation of no match.
- (3) If all credentialing elements are reviewed and no current or previously successful challenges to any of the credentials are noted, and there is no history of malpractice payment, a delegated subcommittee of the Medical Executive Board consisting of at least two members of the full committee may recommend appointment to the Medical Staff. Full credentialing must be completed within sixty (60) calendar days and presented to the Medical Executive Board for ratification.
- (4) The expedited appointment process may only be used for what are considered "clean" applications. The expedited appointment process cannot be used if the application is not complete (including answers to supplemental questions, declaration of health and Bylaws attestation); if there are current or previously successful challenges to licensure; ANY history of involuntary termination of Medical Staff membership at another organization, involuntary limitation, reduction, denial or loss of clinical privileges; or there has been a final judgment adverse to the applicant in a professional liability action. (For further requirements applicable to the expedited appointment process, see VHA Handbook 1100.19, Credentialing and Privileging, paragraph 50.)
- (5) This recommendation by the delegated subcommittee of the Medical Executive Board must be acted upon by the facility Director. The sixty (60) calendar days for the completion of the full credentialing process begins with the date of the Director's signature.
- (6) This process does not relieve the local VHA medical treatment facilities from reviewing the DHHS, OIG's List of Excluded Individuals and Entities (LEIE) for information on whether a provider is excluded from receiving or directing the expenditure of Federal health care program funds for items or services the provider provides, orders, or prescribes while excluded.
- (7) Expedited appointment to the medical staff process does not relieve VHA medical treatment facilities from any appointment requirements as defined by the Human Resources Management Program and acquisition requirements.
- (8) For those providers where there is evidence of a current or previously successful challenge to <u>any</u> credential or <u>any</u> current or previous administrative or judicial action, the expedited process <u>cannot</u> be used and complete credentialing must be accomplished for consideration by the Medical Executive Board.
- (9) This is a one-time appointment process for initial appointment to the medical staff and may not exceed sixty calendar days. It may not be extended or renewed. The complete appointment process must be completed within sixty calendar days of the Expedited Appointment or the medical staff appointment is automatically terminated. The effective date of appointment is the date that the expedited appointment is signed by the Health System Director, even though ratification of the appointment is accomplished within sixty calendar days (the effective date does not change).

m. Temporary Medical Staff Appointments for Urgent Patient Care Needs:

- (1) Temporary appointments are for emergent or urgent patient care only and NOT to be used for administrative convenience.
- (2) Temporary Medical Staff (excluding CRNAs, Advanced Practice Nurses, and Nurse Practitioners) appointments for urgent patient care needs may require appointment before full credentialing information has been received. Since credentialing is a key component in any patient safety program, the appointment of providers with less than complete credentials packages warrants serious consideration and thorough review of the available information. Examples include:
- (a) A situation where a physician becomes ill or takes a leave of absence and an LIP must cover the physician's practice until the physician returns.
- (b) A situation where a specific LIP with a specific skill is needed to augment the care to a patient that the patient's current privileged LIP does not possess.
- (3) The healthcare system must use defined criteria for those instances, which may include the preceding examples, in which temporary appointments for urgent patient care needs are appropriate. Criteria must include the circumstances under which they will be used and the applicable criteria.
- (4) When there is an emergent or urgent patient care need, a temporary appointment may be made in accordance with VA Handbook 5005, Staffing, Part II, by the healthcare system Director before receipt of references or verification of other information and action by the Professional Standards Board. Minimum required evidence includes:
 - Verification of at least one, active, current, unrestricted license with no previous or pending actions;
 - Confirmation of current comparable clinical privileges;
 - Response from NPDB-HIPDB PDS with no match;
 - Response from FSMB with no reports;
 - Receipt of at least one (1) reference from a peer who is knowledgeable of and confirms the
 provider's competence, and who has reason to know the individual's professional
 qualifications; and
 - Documentation by the Health System Director of the specific patient care situation that warranted such an appointment.
- (5) Temporary appointments must be completed in VetPro including the NPDB-HIPDB PDS registration and response and the FSMB query and response. These appointments may not be renewed or repeated. An application through VetPro must be completed within three (3) calendar days of the date the appointment is effective. This includes Supplemental Questions, a Declaration of Health, and a Release of Information. This additional information facilitates the required

completion of the practitioner credentialing for these practitioners used in urgent patient care needs situations, as well as providing additional information for evaluation of the current Temporary Appointment and reducing any potential risk to patients.

- (6) If the Temporary appointment is not converted to another form of medical staff appointment, complete credentialing must be completed, even if completion occurs after the practitioner's temporary appointment is terminated or expires. At a minimum, the LIP must submit a VetPro application, and all credentials must be verified. If unfavorable information was discovered during the course of the credentialing, a review of the care provided may be warranted to ensure that patient care standards have been met.
- n. **Reappraisal:** Reappraisal is the process of evaluating the professional credentials, clinical competence and health status (as it relates to the ability to perform the requested clinical privileges) of practitioners who hold clinical privileges within the healthcare system. The reappraisal process must include: the practitioner's statements regarding successful or pending challenges to any licensure or registration; voluntary or involuntary relinquishment of licensure or registration; limitation, reduction or loss of privileges at another hospital; documentation as to the applicant's health status; relevant practitioner-specific data as compared to aggregate data, when available; morbidity and mortality data; when available; loss of Medical Staff membership; pending malpractice claims or malpractice claims closed since last reappraisal or initial appointment; mental and physical status; and any other reasonable indicators of continuing qualification and competency; additional information regarding current and/or changes in licensure and/or registration status (primary source verification is required at the time of expiration of the license and at the time of reappointment); NPDB-HIPDB query results; peer recommendations; continuing medical education and continuing education units; and verification regarding the status of clinical privileges held at other institutions (if applicable). Information from VA Form 10-2623, Proficiency Report, or VA Form 3482b, Performance Appraisal, may be used.
- (1) Healthcare professionals (LIPs and Allied Health Professionals) with multiple licenses, registrations and/or certifications are responsible for maintaining these credentials in good standing and informing the healthcare system Director or designee of any changes in the status of these credentials at the earliest date after notification is received by the individual. At the time of expiration of any license, and at the time of reappraisal prior to reappointment, the practitioner must provide a signed release of information VA Form 10-0459 which authorizes the primary source to provide VA with written verification of requested information and to disclose information concerning each lawsuit, civil action or other claim brought against the practitioner for malpractice or negligence; each disciplinary action taken or under consideration; any open or previously concluded investigations; any changes in the status of the license; and all supporting documentation related to the information provided.
- (2) If at any time after the initial appointment it is noted that a provider has a license revoked for substandard care, professional misconduct or professional incompetence, immediate consultation with the Regional Counsel is required in order to ensure the practitioner meets current legal requirements for licensure.
- (3) The Health System Director is responsible for establishing a mechanism to ensure that multiple licenses, registrations, and/or certifications are consistently held in good standing or, if allowed to lapse, are relinquished in good standing.

- (a) For credentials that were held previously but are no longer held or are no longer full and unrestricted, the practitioner must be asked to provide a written explanation of the reason(s).
- (b) The verifying official must contact the SLB(s) or issuing organization(s) to verify the reason(s) for any change.
- o. <u>Transfer of Credentials</u>: When practitioners are assigned to more than one (1) healthcare facility for clinical practice, the primary or originating facility must convey all relevant credentials information to the gaining or satellite facility. This may be accomplished by forwarding an authenticated true copy of the credentialing and privileging folder to the receiving facility. The VetPro electronic credentials file must be shared with the gaining or satellite facility. A copy of the original employment application, VA Form 10-2850, Application for Physicians, Dentists, Podiatrists, Optometrists and Chiropractors, or other appropriate appointment information must be provided to the gaining facility. The authenticated copy is joined with the formal application for clinical privileges and any other facility specific forms. The gaining facility may use its own customary forms or format for notifying practitioners of their clinical appointments and documenting same. The gaining facility must query the NPDB-HIPDB, obtain primary source verification of all active licenses, accept the transferred credentials, appoint the practitioner and grant the appropriate clinical privileges before the practitioner can engage in patient care.
- p. <u>Disposition of Credentialing and Privileging Files</u>: When a VA practitioner separates from VA practice the credentialing and privileging folder must be maintained by the last facility of appointment and then retired to the Federal Records Center (FRC) three years after the separation. The Records Officer at each facility is responsible to advise on the disposition of records.
- (1) When a VA practitioner transfers from one VA facility to another, the original Credentialing and Privileging folder needs to be transferred to the gaining facility immediately upon transfer.
- **NOTE:** This needs to be accomplished by a means that allows for tracking of the file through the transfer process, e.g., overnight mail or certified mail return receipt requested. These folders contain Personally Identifiable Information (PII), therefore, whatever means is used to transmit these folders must be in accordance with VA policy regarding transmission of PII, currently stated in VA Directive 6502.1 and any subsequent revisions.
- (2) Credentialing and Privileging folders on applicants not selected for VA practice are to be destroyed 2 years after non-selection, or when no longer needed for reference, whichever is sooner.
- (3) Electronic credentialing files in VetPro must be inactivated through the File Administration Screen at the time of separation or non-selection.
- (4) Credentialing folders may be thinned if they become difficult to manage, but the backup material must be available in the facility.

Privileging:

a. Privileges must be <u>facility specific</u> (TVHS only). This means that privileges can only be granted within the scope of VA TVHS's mission. Only privileges for procedures actually provided

by VA TVHS may be granted to a practitioner. The delineation of clinical privileges must also be setting specific and provider specific. Setting specific areas for TVHS include:

Nashville Campus	Includes inpatient, outpatient, ED,
	ICU, OR/Procedure areas
Alvin C. York Campus	Includes inpatient, outpatient, ED,
	ICU, CLC, OR/Procedure areas
Both Nashville and Alvin C. York	All areas as above
Community Based Outpatient	Outpatient, ED, Procedure areas
Clinic	as applicable to the CBOC
Contract Clinic	Outpatient
Telemedicine	Telemental Health, Camris

- b. Only practitioners who are licensed and permitted by law and the healthcare system to practice independently may be granted clinical privileges.
- c. Clinical privileging is the process by which the institution grants the practitioner permission to <u>independently</u> provide specified medical or other patient care services, within the scope of the practitioner's license and/or an individual's clinical competence as determined by peer references, professional experience, health status (as it relates to the individual's ability to perform the requested clinical privileges), education, training, and licensure and registration. Service Chiefs are responsible for screening credentials in VetPro.
- d. Review of Clinical Privileges. Applicants completing application forms are required to respond to questions concerning clinical privileges at VA and non-VA facilities. A minimum of two efforts to obtain verification of clinical privileges currently, or most recently, held at other institutions is to be made and documented in writing in the credentialing and privileging folder. That verification needs to indicate whether the privileges are (or were) in good standing with no adverse actions or reductions for the specified period of time. If the verification indicates that there are pending or were previous adverse actions or reductions for the specified period of time, the particulars of the action or reduction must be obtained and documentation of a thorough review by officials involved in the appointment process must be included with credentialing information.
- e. <u>Procedures</u>. Privileges will be granted according to the procedures delineated in this policy, which must be reflected in the Medical Staff Bylaws, Rules and Regulations. Clinical privileges are granted for a period not to exceed two years. Clinical privileges are not to be extended beyond the two-year period, which begins from the date the privileges are signed, dated and approved by the Health System Director. However, clinical privileges granted to contractors may not extend beyond the contract period. Each new contract period requires reappraisal and reprivileging. The process for the renewal of clinical privileges must be initiated three (3) months before the privileges expire. It is the responsibility of the healthcare system and the practitioner to ensure that privileges are reviewed and renewed by the expiration date in order to prevent a lapse in the practitioner's authority to treat patients. Applicants for privileges must be kept apprised of the status of their application and must be involved in clarification of issues as appropriate.

f. General Criteria for Privileging:

- (1) General criteria for privileging must be uniformly applied to all applicants. Such criteria are reviewed by Service Chiefs and presented to the MEB. These must include at least:
 - Evidence of current licensure and/or certification, as appropriate, verified with the primary source;
 - The applicant's specific relevant training and/or experience, verified with the primary source:
 - Current competence and health status (as it relates to the individual's ability to perform the requested clinical privileges);
 - Data from professional practice review by an organization(s) that currently privileges the applicant;
 - Peer and/or faculty recommendation; and
 - When renewing privileges, review of the practitioner's performance within the hospital.
 - Consideration of any information related to medical malpractice allegations or judgments, loss of Medical Staff membership, loss and/or reduction of clinical privileges or challenges to licensure.
- (2) Each Service Chief must establish additional criteria for granting of clinical privileges within the service consistent with the needs of the service and the healthcare system. Clinical privileges must be based on evidence of an individual's current competence. When privilege delineation is based primarily on experience, the individual's credentials record must reflect that experience, and the documentation must include the numbers, types and outcomes of related cases.

g. Delineation of Privileges:

- (1) Delineated clinical privileges are an accurate, detailed and specific description of the scope and content of patient care services for which a practitioner is qualified; they are based on credentials and performance and authorized by the healthcare system.
- (2) The criteria for the delineation of privileges are determined by the individual services, recommended by the Medical Executive Board as defined in the Medical Staff Bylaws and approved by the Health System Director. These criteria and delineated privileges are to be reviewed on an annual basis as defined in the Medical Staff Bylaws.
- (3) Privileges granted to an applicant must be <u>facility specific (TVHS only)</u>, based on the procedures and types of services that are provided within the healthcare facility. The requirements or standards for granting privileges to perform any given procedure, if performed by more than one service, must be the same. One standard of care must be guaranteed regardless of practitioner, service or location within the facility.
- (4) The healthcare system delineates the process for granting privileges by any combination of level of training and experience, patient risk categories and lists of procedures or treatments. The process to be used must be established by the individual services and recommended by the Medical Executive Board. The process by which privileges are delineated must be documented as part of the Medical Staff Bylaws. At a minimum, consideration needs to be given to evidence of relevant training or experience, current competence and ability to perform the privileges. Each clinical

service or specialty is responsible to follow the healthcare system's delineated policy in defining the levels or categories of privileges.

- (5) Privileges must be <u>service specific</u>. Practitioner must be assigned to, and have clinical privileges in, one clinical service, but they may be granted privileges in other clinical services. The granting of clinical privileges within any service is subject to the policies and procedures of that service and the authority of that service chief.
- (6) Privileges must be <u>setting specific</u> (see page 34). The settings in which care is delivered dictate the type(s) of care, treatment and services or procedures that a practitioner will be authorized to perform. Privileges are setting specific, requiring consideration of each unique setting's characteristics, such as adequate facilities, equipment and number and type of qualified support personnel and resources. Setting-specific privileges are granted based on the practitioner's qualifications and also on consideration of the procedures and types of care, treatment and services that can be performed or provided within the proposed setting. Practitioners who do not have the specified privileges for a specific setting are not to practice in that setting, even if they believe the privileges granted are comparable for that setting.

h. Initial Privileges:

- (1) Clinical privileges must be granted for all physicians, dentists and other healthcare professionals licensed for independent practice when they are involved in patient care. The intent of this process is to ensure that all physicians, dentists and other healthcare practitioners, when they are functioning independently in the provision of medical care, have privileges that define the scope of their actions, based on current competence within the scope of the mission of the healthcare system and other relevant criteria. Documentation of clinical activity is one component of the competency equation. The second component is whether or not the practitioner has had good outcomes in practice or when performing a procedure.
- (2) Clinical privilege requests must be initiated by the practitioner. The initial application for appointment must be accompanied by a separate request for the specific clinical privileges desired. The applicant has the responsibility to establish possession of the appropriate qualifications and the clinical competency to justify the request.
- (3) The applicant's request for privileges and all credentials offered to support the requested privileges must be provided for review to the service chief responsible for that particular specialty area. The service chief must review all credentialing information including health status (as it relates to the ability to perform the requested clinical privileges), experience, training, clinical competence, judgment, clinical and technical skills, professional references, conclusions from performance improvement activities that are not protected under 38 U.S.C 5705 and any other appropriate information. The documentation of this review must include, at least, a list of the documents reviewed and the rationale for the conclusions. The service chief recommends approval, disapproval or a modification of the requested clinical privileges. This recommendation may include a limited period of direct supervision, or proctoring, by an appropriately privileged practitioner for privileges when a practitioner has had a lapse in clinical activity or for those procedures that are high risk as defined by healthcare system policy.

- (4) Subsequent to the service chief's review and recommendation, the request for privileges along with the appointment recommendation must be submitted to the Professional Standards Board for review. The Professional Standards Board evaluates the applicant's credentials to determine if clinical competence is adequately demonstrated to support the granting of the requested privileges. Minutes must reflect the documents reviewed and the rationale for the stated conclusion. The recommendation of the Professional Standards Board is submitted to the Medical Executive Board for review and then to the Health System Director.
- (5) Residents who are appointed outside of their training program to work on a fee basis as Admitting Officer of the Day or providing compensation and pension examinations, must be licensed, credentialed and privileged for the duties they are expected to perform. In this capacity, they are not working under the auspices of a training program and must meet the same requirements as all physicians and dentists appointed at the healthcare system. The term resident also includes healthcare professionals in advanced post-graduate education programs who are typically referred to as fellows.
- (6) Copies of current clinical privileges must be available to hospital staff on a need-to-know basis in order to ensure providers are functioning within the scope of their clinical privileges. Operating rooms and intensive care units are examples of areas where staff must be aware of provider privileges. Copies of privileges may be given to individuals on a need-to-know basis (e.g., a service chief responsible for monitoring compliance with the privileges granted, or a pharmacist who verifies prescribing privileges or establishes limitations on prescribing for certain medical staff members). The mechanism is to be concurrent with the exercise of privileges, not retrospective.

NOTE: Practitioners performing procedures outside the scope of their privileges may be subject to disciplinary or administrative action.

- (7) The requesting and granting of clinical privileges for COSs and facility Directors must follow the procedures, as outlined for other practitioners. The request for privileges must be reviewed, and a recommendation made, by the relevant service chief responsible for the particular specialty area in which the COS or Director requests privileges. When considering clinical privileges for the COS an appropriate practitioner must chair the medical staff's Executive Committee and the COS must be absent from the deliberations. The medical staff's Executive Committee recommendation regarding approval of requested privileges is submitted directly to the facility Director for action.
- (8) The privileging of facility Director desiring clinical privileges must follow the procedures as outlined for new practitioners. The approval authority for the requested privileges is to be delegated to the Associate Director, who is authorized to act as facility Director for this purpose.
- (9) In those instances where a VISN CMO or Director, or other staff not directly employed by the facility (e.g., VA Central Office) is requesting clinical privileges, the process for such clinical privileges must follow the procedures, as outlined for other practitioners. The request for privileges must be reviewed, and a recommendation made, by the relevant service chief responsible for the particular specialty area. The medical staff's Executive Committee recommendations regarding approval of requested privileges must be submitted directly to the facility Director for action.

- (10) When a privileged practitioner is being considered for transfer, detail, or to serve as a consultant to another VA facility, transfer of credentials are to be accomplished as outlined in subparagraph 5r. Other than teleconsultation, in all cases, the practitioner must request privileges at the gaining facility and provide the facility with the required documentation. Since privileges are facility specific as well as practitioner specific, they are not transferable. The receiving facility must have the practitioner apply to the facility, complete the reappraisal process, including the verification of all time-limited credentials and a new registration with the NPDB-HIPDB PDS.
- (11) A denial of initial privileges, for whatever reason, is not reportable to the NPDB. Where it is determined for whatever reason that the initial application and request for clinical privileges should be denied, the credentialing file and appropriate minutes must document that a Medical Staff appointment is not being made and no privileges are being granted. Other documentation is at the discretion of the chairperson of the Professional Standards Board and the Health System Director. A do not appoint screen must be completed in VetPro documenting the date of the decision.
- (12) <u>Focused Professional Practice Evaluation (FPPE)</u>: An FPPE is a systematic process that results in information which confirms the current competency of a practitioner who is initially requesting privileges at this facility. Such an evaluation is a prospectively planned, time-limited process designed to assess privilege-specific competency of a practitioner who does not have documented evidence of competently performing the requested privilege(s). Focused initial professional practice evaluations are protected by the Privacy Act System of Records known as 77 VA 10Q.
 - (a) Triggers for an FPPE are:
 - (1) Unsatisfactory OPPE
- (2) A newly privileged practitioner has credentials to suggest competence, but additional information or a period of evaluation is needed to confirm competence in the organization's setting.
 - (3) A practitioner has requested a new clinical privilege.
 - (4) A practitioner requires supervision for a new procedure or modality.
- (<u>5</u>) The practitioner's competency has been questioned in relation to a sentinel event, a provider-specific tort settlement, a substantiated complaint, a significant safety violation, or repeated or egregious unprofessional behavior.
 - (6) A Level 3 protected peer review.
- (b) Practitioner's previous experience will determine the approach and extent of proctoring needed to confirm current competence. The practitioner's experience may fall into the following classes:
 - Class 1: A recent training program graduate from the current facility

- Class 2: A recent training program graduate from a different facility
- Class 3: A practitioner with experience of less than 1 year on another medical staff
- Class 4: A practitioner with experience of greater than 1 year on another medical staff

Practitioners in Class 1 may need minimal proctoring because the organization has had the opportunity to observe their current competence directly. Practitioners in Class 2 and 3 would be candidates for the full proctoring program. Practitioners in Class 4 would be candidates for limited proctoring, unless concerns exist regarding the recent frequency of use of the requested privileges.

- i. <u>Temporary Privileges for Urgent Patient Care Needs</u>: Temporary privileges for healthcare professionals in the event of emergent or urgent patient care needs may be granted by the Health System Director at the time of a temporary appointment. Such privileges must be based on verification of the following:
 - Current licensure
 - Relevant training or experience
 - Current competence
 - Ability to perform the privileges requested
 - Other criteria required by the organized Medical Staff bylaws
 - A query and evaluation of the NPDB information
 - A complete application
 - No current or previously unsuccessful challenge to licensure or registration
 - No subjection to involuntary termination of medical staff membership at another organization
 - No subjection to involuntary limitation, reduction, denial or loss of clinical privileges

The recommendation for temporary privileges must be made by the COS and approved by the Health System Director. Temporary privileges are not to exceed sixty calendar days.

- j. <u>Disaster Privileges</u>: Disaster privileges may be granted when the healthcare system's emergency management plan has been activated and the healthcare system is unable to handle immediate patient care needs. At a minimum the process for granting disaster privileges must include:
 - (1) Identification of the individual(s) responsible for granting disaster privileges.
- (2) A description of the responsibilities of the individual(s) responsible for granting disaster privileges.
- (3) A description of the mechanism to manage the activities of the health care professionals who are granted disaster privileges, as well as a mechanism to readily identify these individuals.
- (4) A description of the verification process at the time disaster privileges are granted which must include:
 - A current hospital photo identification card and evidence of current license to practice;

- Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT); or
- Identification indicating the individual has been granted authority to render patient care in emergency circumstances, such authority having been granted by a federal, state or municipal entity.
- (5) A specified period of time under which these health care professionals granted disaster privileges may practice on these disaster privileges. This period may not exceed ten (10) calendar days or the length of the declared disaster, whichever is shorter. At the end of this period the practitioner needs to be converted to Temporary Privileges defined by this policy or be relieved.
- (6) A defined process to ensure the verification process of the credentials and privileges of health care professionals who receive disaster privileges that begins as soon as the immediate situation is under control. This process must be identical to the process for granting Temporary Privileges and ultimately result in complete credentialing of these practitioners.
- (7) The medical staff will oversee the performance of providers given disaster privileges through direct observation or medical record review within the first 72 hours. Method of oversight will be determined on a case by case basis. If there are no competency issues, the provider's privileges will continue.
- (8) Volunteer Licensed Independent Practitioners (LIP) will be given special ID badges by Police and Security stating "Disaster Volunteer" identifying them from other LIPs.
- k. <u>On-Going Monitoring of Privileges:</u> This allows the facility to identify professional practice trends that impact the quality of care and patient safety. Such identification may require intervention by the medical staff leadership.
- (1) VHA has a robust quality management and performance improvement process. The information collected and analysis of patient care activities under this process is protected by 38 U.S.C. 5705 and may not be used during any portion of the review process for the granting of clinical privileges. The 38 U.S.C 5705-protected materials may trigger the need to perform a more in-depth review of a practitioner.
- (2) The criteria that would trigger a more in-depth review must be defined in advance, and be objective, measurable, and uniformly applied to all practitioners with similar privileges.
- (3) With very few exceptions, VHA data standing alone is not protected by 38 U.S.C. 5705. Its use would dictate the appropriate protections under law. Data that generates documents used to improve the quality of health care delivered or the utilization of health care resources is protected by 38 U.S.C. 5705. Data that is not previously identified as protected by 38 U.S.C. 5705 and is collected as provider-specific data could become part of a practitioner's provider profile, analyzed in the facility's defined on-going monitoring program, and compared to pre-defined facility triggers or de-identified quality management data.

1. Reappraisal and Reprivileging:

Reappraisal

- (a) Reappraisal is the process of re-evaluating the professional credentials, clinical competence and health status (as it relates to the ability to perform the requested clinical privileges) of practitioners who hold clinical privileges within the healthcare system.
- (b) Reappraisal for the granting of clinical privileges must be conducted for each practitioner at least every two years. However, reappraisal may be required more frequently for contractors, depending upon the length of the contract period.
 - (c) The reappraisal process must include:
 - The practitioner's statements regarding successful or pending challenges to any licensure or registration;
 - Voluntary or involuntary relinquishment of licensure or registration;
 - Limitation, reduction or loss (voluntary or involuntary) of privileges at another hospital;
 - Loss of Medical Staff membership;
 - Pending malpractice claims or malpractice claims closed since last reappraisal or initial appointment;
 - Mental and physical status (as it relates to the ability to perform the requested clinical privileges); and
 - Any other reasonable indicators of continuing qualifications.
- (d) If there is evidence of pending malpractice cases or malpractice cases closed since last reappraisal or initial appointment, every effort must be made and documented to obtain relevant information regarding the issues involved and the facts of the case(s). The credentialing and privileging folder must contain an explanatory statement by the practitioner and evidence that the healthcare system evaluated the facts regarding resolution of the malpractice case(s), as well as a statement of adjudication from the primary source to include, but not limited to, an insurance company, court of jurisdiction or statement of claim status from the attorney. In the case of the Federal Tort Claims Act (FTCA), information on the adjudication of the case may come from the risk manager, the Regional Counsel or the Office of Medical-Legal Affairs.
- (e) If there is evidence of voluntary or involuntary relinquishment of licensure or registration (as applicable to the position), evidence must be obtained that the practitioner meets VA's licensure requirements.
- (f) Additional information regarding licensure and/or registration status, NPDB-HIPDB querying results, peer recommendations, continuing medical education and continuing education accomplishments and information regarding the status of clinical privileges held at other

institutions, if applicable, must be secured for review. Information from VA Form 10-2623, Proficiency Reports, or VA Form 3482b, Performance Appraisal, may be considered.

- Peer references are best obtained from those of the same discipline or profession who
 practice with, and know the practitioner's practice. If possible at least one of the peer
 references needs to be obtained from someone of the same discipline or profession who can
 speak with authority on the practitioner's medical/clinical knowledge, technical and clinical
 skills, clinical judgment, interpersonal skills, communication skills, and professionalism.
 Peer references not containing all these elements are considered incomplete and returned to
 the reviewer.
- Where there is no one of the same discipline or profession with knowledge of the practitioner's practice, at least one peer reference must be obtained from a health care professional with essentially equal qualifications and comparable privileges with knowledge of the practitioner's performance and practice patterns. Careful consideration needs to be given to avoid the appearance of professional prejudice. A second peer reference can be obtained from a healthcare professional that has a referral relationship with the practitioner.
- In instances where at least one peer reference cannot be obtained from a peer of the same profession or a professional with comparable privileges, assistance for the peer reference needs to be sought from the VISN CMO or VHA Program Director for the profession.
- Evaluation of professional performance, judgment, and clinical and/or technical competence and skills is to be based in part on results of provider-specific performance improvement activities. Ongoing reviews conducted by service chiefs must be comprised of activities with defined criteria that emphasize the facility's performance improvement plan, appropriateness of care, patient safety, and desired outcomes and are not protected by 38 U.S.C. 5705. The individual providers' profiles may include provider-specific, non-38 U.S.C. 5705-protected data when applicable. For example, the provider-specific data may include the following information, when it is not generated as part of a 38 U.S.C. 5705protected activity: information from surgical case or invasive procedure review; infection control reviews; drug usage evaluation; medical record review; blood usage review; pharmacy and therapeutic review; and monitoring and evaluation of quality, utilization, risk, and appropriateness of care. The relevant provider specific data in these provider profiles can be compared to de-identified aggregate data (like the blood use evaluation summary) as long as the implicit and explicit identification of other providers cannot occur. De-identified aggregate data needs to include providers with comparable or similar privileges.

NOTE: Materials protected by 38 U.S.C. 5705 may not be used during any portion of the review process for the granting of clinical privileges. The 38 U.S.C 5705-protected materials may trigger the need to perform a more in-depth review; however, quality improvement information that is confidential and privileged in accordance with 38 U.S.C. 5705 may not be used for any part of the reappraisal process even in support of the privileges recommended or granted.

(g) The reappraisal process needs to include consideration of such factors as the number of procedures performed or major diagnoses treated, rates of complications compared with those of others doing similar procedures, and adverse results indicating patterns or trends in a practitioner's clinical practice. Relevant practitioner-specific data needs to be compared to the aggregate data of those privileged practitioners that hold the same or comparable privileges.

m. Re-privileging:

(1) Reprivileging is the process of granting privileges to a practitioner who currently holds privileges within the healthcare system. This process must be conducted at least every two years. However, clinical privileges granted to contractors may not extend beyond the contract period. Each new contract period requires reappraisal and reprivileging. Requests for privileges must be processed in the same manner as initial privileges. Practitioners must request privileges in a timely manner prior to the expiration date of current privileges.

Note: It is suggested that a minimum of two to three months be allowed to process privilege requests.

(2) The service chief must assess a minimum of two (2) peer recommendations and all other information that addresses professional performance (such as the results of ongoing professional practice evaluations (OPPE) as described in paragraph (c), below), judgment, clinical and/or technical skills, any disciplinary actions, challenges to licensure, loss of Medical Staff membership, changes in clinical privileges at another hospital, health status (as it relates to the ability to perform the requested clinical privileges) and involvement in any malpractice actions. The service chief must document (i.e., list documents reviewed and the rationale for conclusions reached) that the results of quality of care activities have been considered in recommending individual privileges and complete the service chief's approval screen in VetPro. Upon completion of this assessment, the service chief makes a recommendation as to the practitioner's request for clinical privileges.

Note: Materials protected by 38 U.S.C. 5705 may not be used during any portion of the review process for the granting of clinical privileges. The 38 U.S.C 5705-protected materials may trigger the need to perform a more in-depth review; however, quality improvement information that is confidential and privileged in accordance with 38 U.S.C. 5705 may not be used for any part of the reappraisal process even in support of the privileges recommended or granted.

- (3) The requested privileges and the service chief's recommendation must be presented, with the supporting credentialing, health status and clinical competence information, to the Professional Standards Board for review and recommendation to the Medical Executive Board. The decision of the Medical Executive Board must be documented (the minutes must reflect the documents reviewed and the rationale for the stated conclusion) and submitted to the Health System Director, as the approving authority, for final action.
- (4) Because facility mission and clinical techniques change over time, it is normal that clinical privileges may also change. The service chief must review, with the practitioner, the specific procedures and/or treatments that are being requested. Issues, such as documented changes in the facility mission, failure to perform operations and/or procedures in sufficient number, or frequency to maintain clinical competence in accordance with facility established criteria, or failure to use

privileges previously granted, will affect the service chief's recommendation for the granting of new privileges, or the granting of the continuation of privileges. These actions must be considered changes and are not to be construed as a reduction, restriction, loss, or revocation of clinical privileges. Such changes must be discussed between the service chief and the involved practitioner.

- (5) Practitioners may submit a request for modification of clinical privileges at any time. Requests to increase privileges must be accompanied by the appropriate documentation, which supports the practitioner's assertion of competence, i.e., advanced educational or clinical practice program, clinical practice information from other institution(s), references, etc. The request must be made through VetPro by opening the electronic record for re-credentialing. In addition to verifying all current credentials and competency associated with this request, active licenses must be verified and a verification of the NPDB-HIPDB PDS reports must be made. Requests for other changes need to be accompanied by an explanatory statement(s). The request for modification of clinical privileges, supporting documents, and practitioner's Credentialing and Privileging folder must be presented to the appropriate service chief for review. The service chief considers the additional information and the entire Credentialing and Privileging folder before making a recommendation to the medical staff's Executive Committee. The medical staff's Executive Committee then presents a recommendation to the facility Director for action.
- (6) The process of reappraisal and granting new clinical privileges for facility Directors and COSs is the same as outlined in preceding paragraphs. The facility Director's or COS's request for privileges must be reviewed, and a recommendation made by the relevant service chief responsible for the particular specialty area in which the privileges are requested. When the COS is being considered for privileging, the COS must be absent from the Executive Committee of the Medical Staff deliberations, which an appropriate practitioner chairs. The medical staff's Executive Committee recommendations related to the approval of the requested privileges must be submitted directly to the Director for action, or to the Associate Director who is authorized to act as facility Director for this purpose.
- n. <u>Ongoing Professional Practice Evaluation (OPPE):</u> An OPPE is a process that continuously evaluates a practitioner's professional performance to identify practice issues that may impact quality of care and patient safety. Criteria for an OPPE must be objective, measureable and uniformly applied to all providers granted that privilege. The OPPE report will remain confidential and will be handled as other medical staff peer review information.
- (a) The Service Chief, in conjunction with the Chief of Staff and PSB, develop an OPPE that is specialty-specific and inclusive of the six general areas noted below. Every six (6) months, the Service Chief will populate an OPPE with current information of each privileged provider in their service. The Service Chief will evaluate the individual performance of each staff member and their assessment will be discussed with the staff member. The OPPE recommendations are presented to the PSB who will concur with or change the recommendations based on their deliberation. The PSB will incorporate the OPPE when deciding on Medical Staff reappointment. This is a continuous evaluation process for all privileged providers. Monitoring can be performed by an external source if the Chief of Staff and PSB determine adequate monitoring cannot be accomplished internally.

- (b) The information resulting from the evaluation needs to be used to determine whether to continue, limit, or revoke any existing privilege(s) at the time the information is analyzed. Based on analysis, several possible actions could occur, including but not limited to:
 - Determining that the practitioner is performing well or within desired expectations and that no further action is warranted.
 - Determining that an issue exists that requires a Focused Professional Practice Evaluation.
 - Revoking the privilege because it is no longer required.
 - Suspending the privilege, that suspends the data collection, and notifies the practitioner that if they wish to reactivate the privilege they must request a reactivation.
 - Determining that zero performance should trigger a focused review (MS.4.30, EP 5) whenever the practitioner actually performs the privilege
 - Determining that the privilege should be continued because the organization's mission is to be able to provide the privilege to its patients.

Evidence of the PSB determinations in the form of minutes is to be included in each practitioner's credentials file at the time of each review of the data. The practitioner will be notified in writing by the Credentialing Staff of the determination made by the PSB.

- (c) The process will include an assessment for proficiency in the following six general areas:
- <u>1</u>. <u>Patient care and procedural skills</u>: Practitioner are expected to provide patient care that is compassionate, appropriate, and effective for the promotion of health, prevention of illness, treatment of disease, and care at the end of life.
- <u>2</u>. <u>Medical and clinical knowledge</u>: Practitioners are expected to demonstrate knowledge of established and evolving biomedical, clinical, and social sciences and the application of their knowledge to patient care and the education of others.
- <u>3</u>. <u>Practice-based learning and improvement</u>: Practitioners are expected to be able to use scientific evidence and methods to investigate, evaluate, and improve patient care practices.
- <u>4</u>. <u>Interpersonal and communication skills</u>: Practitioners are expected to demonstrate interpersonal and communication skills that enable them to establish and maintain professional relationships with patients, families, and other members of the health care team.
- <u>5</u>. <u>Professionalism</u>: Practitioners are expected to demonstrate behaviors that reflect a commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity, and a responsible attitude toward their patients and their profession.
- <u>6</u>. <u>Systems based practice</u>: Practitioners are expected to demonstrate both an understanding of the contexts and systems in which health care is provided and the ability to apply this knowledge to improve and optimize healthcare.
 - (d) Information for OPPE and FPPE are obtained from multiple sources, including:

- Chart review
- Direct observation
- Monitoring of diagnostic and treatment techniques
- Review of data including:
- o Invasive and non-invasive clinical procedure(s) performed and their outcomes
- o Concurrent review of the practitioner's assessment and treatment of patients
- o Pattern of blood and pharmaceutical usage
- o Requests for tests and procedures, medical records compliance
- o Length of stay patterns, utilization review patterns
- Medical record documentation and timeliness
- o Quality of care measures
- o Performance measure data
- o Morbidity and mortality data
- o Practitioner's use of consultants
- Other relevant criteria as determined by the Service
- Compliance with hospital policies and Bylaws, and Rules and Regulations of the Medical Staff
- Clinical standards
- Use of rates compared against established benchmarks or norms
- Discussion with other individuals involved in the care of each patient (i.e. consulting provider, assistants in surgery, nursing, or administrative personnel
- Peer review (internal or external)
- Compliance with mandatory training
- Proctoring
- Simulation
- (e) While some data apply to all practitioners, performance is different for different practitioners, so there may need to be specific data. In addition, since most practitioners practice well, there will need to be data on their actual performance as well as those with performance issues. The fact that a practitioner doesn't fall out on a pre-defined screening criteria, is not sufficient to meet the requirement for performance data on every practitioner. Zero data is data. Zero data can actually be evidence of good performance, i.e., no returns to the OR, no complications, no complaints, or no infections. When someone is not performing certain privileges, it would be important to know since it would not be acceptable to find at the two year reappointment that someone has not performed a privilege for two years.
- (f) Suggested sample sizes for medical record reviews according to The Joint Commission consist of the following: 5% or ten (10) cases quarterly, whichever is greater, will be appropriate.

o. Denial and Non-Renewal of Privileges:

(1) At the time of initial application and request for clinical privileges, if it is determined for whatever reason that the application should be denied, the credentialing and privileging folder and appropriate minutes must document that a Medical Staff appointment is not being made and no privileges are being granted. The Health System Director informs the applicant by letter of the

reason for denial. Other documentation is at the discretion of the chairperson of the committee(s) and the Health System Director. A do not appoint screen must be completed in VetPro documenting the date of this decision. This denial is not reportable to the NPDB.

- (2) At the time of reappraisal and renewal of clinical privileges, privileges that are denied or not renewed based on facility resources must be documented as such in the credentialing and privileging folder as well as the appropriate minutes. This action is not reportable to the NPDB.
- (3) For all other actions in which clinical privileges requested by a practitioner are denied or not renewed, the reason for denial must be documented. If the reason for denial or non-renewal is based on and considered to be related to professional incompetence, professional misconduct or substandard care, the action must be documented as such and is reportable to the NPDB after appropriate internal due process procedures are provided for reduction and revocation of privileges, pursuant to VHA Handbook 1100.19, Credentialing and Privileging. (See VHA Handbook 1100.17, National Practitioner Data Bank Reports, for additional information.)

NOTE: VA only reports to the NPDB adverse privileging actions against physicians and dentists. (See VHA Handbook 1100.17 and 38 CFR Part 46.)

NOTE: Material that is obtained as part of a protected performance improvement program (i.e., under 38 U.S.C. 5705), may not be disclosed in the course of any action to reduce or revoke privileges, nor may any reduction or revocation of privileges be based directly on such performance improvement data. If such information is necessary to support a change in privileges, it must be developed through mechanisms independent of the performance improvement program, such as administrative reviews and boards of investigation. In these instances, the performance improvement data may have triggered the review; however, the quality improvement information is confidential and privileged in accordance with 38 U.S.C. 5705, and therefore must be rediscovered through the administrative review or investigation process.

(4) When the Health System Director renders a final determination based on a clinical professional review, relating to possible incompetence or improper professional conduct, that adversely affects the clinical privileges of a physician or dentist by reducing, restricting, suspending, revoking, or failing to renew such privileges for a period longer than thirty (30) day, such action must be reported to the NPDB. Reports to the NPDB are to be submitted electronically using software provided by the NPDB. It is intended that the report be filed within fifteen (15) calendar days of the date the action is made final by signature of the Health System Director.

p. Reduction and Revocation of Privileges:

(1) Management officials are prohibited from taking or recommending personnel actions (e.g., resignation, retirement, reassignment, etc.) in return for an agreement not to initiate procedures to reduce or revoke clinical privileges where such action is indicated. In addition, reporting to the NPDB, including the submission of copies to SLBs, may not be the subject of negotiation in any settlement agreement, employee action, legal proceedings or any other negotiated settlement. Such agreements or negotiations are not binding on VA and may form the basis for administrative and/or disciplinary action against the officials entering into such agreement or negotiated settlements.

- (2) A reduction or revocation of privileges may not be used as a substitute for disciplinary or adverse personnel action. Where a disciplinary or adverse personnel action is warranted, the action against the privileges is to be incorporated into the due process procedures provided for the disciplinary or adverse personnel action.
- (3) Any situation that results in a practitioner being proctored where the proctor is assigned to do more than just observe--such as exercise control or impart knowledge, skill or attitudes to another practitioner ensuring that patient care is delivered in an appropriate, timely and effective manner--may constitute supervision. If this occurs after initial privileges have been granted, it is considered a restriction of the practitioner's privileges and as such is a reduction of privileges and is reportable to the NPDB if lasts longer than thirty (30) days from the date the privileges are reduced or the practitioner is placed in a proctored status.
- (4) These activities may be separate from the reappraisal and reprivileging process. Data gathered in conjunction with the healthcare system's performance improvement activity is an important tool for identifying potential deficiencies. Material that is obtained as part of a protected-performance improvement program, i.e., under 38 U.S.C. 5705, may not be used during the appraisal process, nor may any reduction or revocation of privileges action be based directly on such performance improvement data. If such information is necessary to support a change in privileges, it must be developed through mechanisms independent of the performance improvement program, such as administrative reviews and boards of investigation. In these instances, the performance improvement data may have triggered the review; however, the quality improvement information is confidential and privileged in accordance with 38 U.S.C. 5705 and must be rediscovered through the administrative review or investigation process.

Note: Actions taken against a practitioner's privileges that are not related to professional competence or professional conduct may not be subject to these provisions. Examples of actions that may be considered as not reportable include but are not limited to failure to maintain licensure and failure to meet obligations of Medical Staff membership.

- (5) A reduction of privileges may include restricting or prohibiting performance of selected specific procedures, including prescribing and/or dispensing controlled substances. Reduction of privileges may be time limited and/or have restoration contingent upon some condition, such as demonstration of recovery from a medically disabling condition or further training in a particular area. Revocation of privileges refers to the permanent loss of clinical privileges.
- (6) If it becomes necessary to formally reduce or revoke clinical privileges based on deficiencies in professional performance, the procedures indicated in this policy must be followed. Procedures for reduction and revocation of clinical privileges are identified in the following paragraphs and apply to all practitioners included within the scope of this policy.
- (7) A practitioner who surrenders clinical privileges, resigns, retires, etc., during an investigation related to possible professional incompetence or improper professional conduct must be reported to the NPDB in accordance with VA regulations 38 CFR Part 46 and VHA Handbook 1100.17, National Practitioner Data Bank Reports. This includes the failure of a practitioner to request renewal of privileges while under investigation for professional incompetence or improper professional conduct.

Note: Due process under these circumstances is limited to a hearing to determine whether the practitioner's surrender of clinical privileges, resignation, retirement, etc., occurred during such an investigation. If the practitioner does not request this limited hearing, the practitioner waives the right to further due process for the NPDB report and must be reported immediately.

(8) <u>Adverse Professional Review Action</u>: Any professional review action that adversely affects the clinical privileges of a practitioner for a period longer than thirty (30) days including the surrender of clinical privileges or any voluntary restriction of such privileges while the practitioner is under investigation is reportable to the NPDB pursuant to the provisions of the VHA policy regarding NPDB reporting.

(9) Summary Suspension:

- (a) Clinical privileges may be summarily suspended when failure to take such an action may result in imminent danger to the health of an individual. Summary suspension pending comprehensive review and due process as outlined in a prior paragraph of this policy is not reportable to the NPDB. However, the notice of summary suspension to the practitioner must include a notice that if a final action is taken based on professional competence or professional conduct grounds, both the summary suspension, if greater than thirty (30) days, and the final action will be reported to the NPDB. The notice of summary suspension must contain a notice to the individual of all due process rights.
- (b) When privileges are summarily suspended, the comprehensive review of the reason for summary suspension must be accomplished within thirty (30) calendar days of the suspension with recommendations to proceed with formal procedures for reduction or revocation of clinical privileges forwarded to the Health System Director for consideration and action. The Health System Director will make a decision within five (5) working days of receipt of the recommendations. This decision could be to exonerate the practitioner and return privileges to an active status, or to proceed with reduction or revocation of privileges if there is sufficient evidence of improper professional conduct or incompetence.
- (c) Proceeding to reduction or revocation of privileges requires appropriate due process. Guidance should be sought from Regional Counsel and Human Resources Management to ensure due process is afforded. Only after due process is completed, final action is taken by the Health System Director and all appeals are exhausted should the summary suspension and subsequent reduction or revocation of privileges of a physician or dentist be reported to the NPDB.
- (d) If the practitioner's clinical privileges are pending renewal and due to expire during a summary suspension or due process procedures for reduction or revocation, privileges must be denied pending outcome of the review and due process procedures. This denial is considered administrative until such time as a final decision is made in the summary suspension or due process procedures. This final decision determines whether an adverse action has occurred and the responsibility for reporting of the action. If the final action results in what would have been a reportable event, it must be reported in accordance with VHA Handbook 1100.17, National Practitioner Data Bank Reports.

(10) Independent Contractors and/or Subcontractors

- (a) Independent contractors and/or subcontractors acting on behalf of VA are subject to the provisions of VA policies on credentialing and privileging and NPDB reporting. In the following circumstances, VA must provide the contractor and/or subcontractor with appropriate internal VA Medical Center due process, pursuant to the provisions of VHA Credentialing and Privileging policy regarding reduction and revocation of privileges, prior to reporting the contractor and/or subcontractor to the NPDB, and filing a copy of the report with the SLB(s) in the state(s) in which the contractor and/or subcontractor is licensed and in which the facility is located;
- (b) Where VA terminates a contract for possible incompetence or improper professional conduct, thereby automatically revoking the medical staff appointment and associated clinical privileges of the contractor and/or subcontractor;
- (c) Where the contractor and/or subcontractor terminates the contract or subcontract, thereby surrendering medical staff appointment and associated privileges, either while under investigation relating to possible incompetence or improper professional conduct; and
- (d) Where VA terminates the services (and associated medical staff appointment and clinical privileges) of a subcontractor under a continuing contract for possible incompetence or improper professional conduct.
- (e) Where a contract naturally expires, both the medical staff appointment and associated clinical privileges of the contractor and/or subcontractor are automatically terminated. This is not reportable to the NPDB.
- (f) Where a contract is renewed or the period of performance extended, the contractor and/or subcontractor must be credentialed and privileged similar to the initial credentialing process, with the exception that non-time limited information, e.g., education and training, does not need to be re-verified.
- (11) <u>Automatic Suspension of Privileges</u>: Privileges will be automatically suspended for administrative reasons which may occur in instances where the provider is behind in dictation, or allowed a license to lapse and therefore does not have an active, current, unrestricted license. Such instances must be weighed against the potential for substandard care, professional misconduct, or professional incompetence. A thorough review of the circumstances must be documented with a determination of whether the cause for the automatic suspension does or does not meet the test of substandard care, professional misconduct or professional incompetence.
- (a) Under no circumstances should there be more than three automatic suspensions of privileges in 1 calendar year, and no more than twenty (20) days per calendar year. If there are more than three (3) automatic suspensions of privileges in one (1) calendar year, or more than twenty (20) days of automatic suspension in a calendar year, a thorough assessment of the need for the practitioner's services needs to be performed and documented and appropriate action taken. Any action is to be reviewed against all reporting requirements.
- (b) <u>Procedures Applicable to Administrative Heads.</u> Procedures to reduce and revoke clinical privileges identified within this Handbook are applicable to Directors, COSs, CMOs, and VISN Directors. All responsibilities normally assumed by the COS during the clinical privileging reduction or revocation process must be assigned to an appropriate practitioner who serves as

acting chair of the medical staff's Executive Committee. The COS may appeal the Director's decision, or the Director may appeal the Associate Director's decision, regarding the reduction of privileges decision to the VISN Director, just as all practitioners may appeal such a decision. A VISN Director whose clinical privileges to practice at a given facility are reduced or revoked may appeal to the Chief VISN Officer.

(12) Loss of a specific credential required for a specific privilege will result in the loss of that specific privilege with thirty (30) workdays to renew the credential. Failure to obtain the credential to perform that privilege after thirty (30) days will result in a loss of that privilege until the provider is re-credentialed for that privilege.

(13) Procedure for Reduction of Privileges

- (a) Initially, the practitioner receives a written notice of the proposed changes in privileges from the COS. The notice must include a discussion of the reason(s) for the change and must indicate that if a reduction or revocation is effected based on the outcome of the proceedings, a report must be filed with the NPDB, with a copy to the appropriate SLBs in all states in which the practitioner holds a license and in the state in which the facility is located. The notice must include a statement of the practitioner's right to be represented by an attorney or other representative of the practitioner's choice throughout the proceedings.
- (b) The practitioner must be allowed to review all evidence not restricted by regulation or statute upon which proposed changes are based. Following that review, the practitioner may respond in writing to the COS's written notice of intent. The practitioner must submit a response within ten (10) workdays of the COS's written notice. If requested by the practitioner, the COS may grant an extension for a brief period, normally not to exceed ten (10) additional workdays, except in extraordinary circumstances.

NOTE: Prior to releasing any information to the practitioner or any other individual associated with the review, consultation with the Privacy Officer or Regional Counsel is appropriate.

- (c) All information is forwarded to the Health System Director for decision. The Health System Director must make and document a decision on the basis of the record.
- (d) The practitioner may appeal the decision by requesting a hearing within five workdays of receipt of the decision. The Health System Director must appoint a review panel of three (3) professionals within five (5) workdays of receipt of the practitioner's request for hearing to conduct a review and hearing. At least two (2) members of the panel must be members of the same profession as the involved practitioner. If specialized knowledge is required, at least one (1) member of the panel must be a member of the same specialty. All panelists must be impartial. This review panel hearing is the only hearing process conducted in connection with the reduction of privileges; any other review processes must be conducted on the basis of the record. The practitioner must be notified in writing of the date, time and place of the hearing. The date of the hearing must not be less than twenty (20) workdays and not more than thirty (30) workdays from the date of the notification letter. The practitioner has the right to:
 - Be present throughout the evidentiary proceedings;

• Be represented by an attorney or other representative of the practitioner's choice;

Note: If the practitioner is represented, this individual is allowed to act on behalf of the practitioner including questioning and cross-examination of witnesses.

- Cross-examine witnesses;
- Purchase a copy of the transcript or tape of the hearing.
- (e) In cases involving reduction of privileges, a determination must be made as to whether disciplinary action should be initiated.
- (f) The panel must complete the review and submit the report, including findings and recommendations, to the Health System Director within fifteen (15) workdays from the close of the hearing. Additional time may be allowed by the Health System Director for extraordinary circumstances or cause.
- (g) The Health System Director has the authority to accept, reject, accept in part or modify the review panel's recommendations and must issue a written decision within ten (10) workdays of receipt of the panel's report. If the practitioner's privileges are reduced, the written decision must indicate the reason(s). The signature of the Health System Director constitutes a final action. A reduction of privileges is reportable to the NPDB.
- (h) The practitioner may submit a written appeal to the VISN Director within five (5) workdays of receipt of the Health System Director's decision. This appeal option will not delay the submission of the NPDB report. If the Health System Director's decision is overturned on appeal, the report to the NPDB must be withdrawn.
- (i) The VISN Director must provide a written decision, based on the record, within twenty (20) workdays of receipt of the practitioner's appeal. The decision of the VISN Director is not subject to further appeal.
 - (14) Procedure for Revocation of Privileges:
- (a) Recommendations to revoke a practitioner's privileges must be made to the Medical Executive Board through the Professional Standards Board based upon review and deliberation of clinical performance and professional conduct information.
- (b) A revocation of all privileges requires removal from both employment appointment and appointment to the Medical Staff unless there is a basis to reassign the practitioner to a position not requiring clinical privileges. Such an action may still result in reporting to the NPDB if the revocation and reassignment is for substandard care, professional incompetence or professional misconduct. An example would be the revocation of a surgeon's privileges for clinical practice issues when reassignment to a non-surgical area is beneficial to meeting other needs of the healthcare system.

- (c) When revocation of all privileges is proposed and combined with a proposed demotion or dismissal, the due process rights of the practitioner must be accommodated by the hearing provided under the dismissal process. Where removal is proposed, the due process procedures for removal and revocation of privileges must be combined. Dismissal constitutes a revocation of privileges whether or not there was a separate and distinct privileging action and must be reported without further review or due process to the NPDB.
- (d) Due process under all applicable policies and procedures must be afforded the practitioner. The Medical Staff Bylaws may not provide due process in addition to that established by VA. A coordination of all applicable due process procedures in advance will safeguard the healthcare system's obligations to the practitioner and the VA in a timely manner. An advance review by Regional Counsel is strongly recommended.
- (e) When revocation of privileges is proposed and not combined with a proposed demotion or dismissal, the due process procedures under reduction of privileges must pertain.
- (f) In instances where revocation of all privileges is proposed for permanent employees appointed under 38 U.S.C. 7401(1), the revocation proceedings must be combined with proposed action to discharge the employee under 38 U.S.C., Part V, Chapter 74, Subchapter V, or in accordance with current VA statutes, regulations and policy. In those instances where the permanent employee was appointed under 38 U.S.C. 7401(3), the revocation proceedings must be combined with proposed action to discharge the employee under VA Handbook 5021, Employee-Management Relations, or current VA statutes, regulations and policy.
- (g) Practitioners whose privileges are revoked for substandard care, professional incompetence or professional misconduct must be reported to the NPDB in accordance with the VHA policy on NPDB reporting. In addition, the practitioner's practice must be reviewed for reporting to SLB(s) consistent with VHA policy on SLB reporting.
- (h) For probationary employees appointed under 38 U.S.C. 7401(1), the proposed revocation requires probationary separation procedures contained in VA Handbook 5021. For employees appointed under 38 U.S.C. 7405, the proposed revocation requires actions to separate the employee under the provisions of VA Handbook 5021. Where proposed revocation is based on substandard care, professional misconduct, or professional incompetence, the probationary or temporary employee must be provided with the due process procedures that are provided for reduction of privileges, in addition to the procedures contained in VA Handbook 5021 for separation (i.e., the probationary procedures do not afford sufficient due process). When the proposed revocation is based on other grounds, the proposed revocation must be combined with the applicable separation procedures contained in VA Handbook 5021. Practitioners whose privileges are revoked based on substandard care, professional incompetence, or professional misconduct must be reported to the NPDB according to procedures identified in the VHA policy regarding NPDB reporting.
- (i) When the revocation of privileges is proposed for practitioners not covered under subparagraphs $6i(3)\underline{b}$ and $6i(3)\underline{c}$, consideration must be given to discharging or removing the practitioner, as applicable. It may be desirable to consider other alternatives, such as demotion or reassignment to a position that does not require privileges, where appropriate.

(j) Revocation procedures will be conducted in a timely fashion. Appropriate action must be taken to see that the practitioner whose privileges are ultimately revoked does not remain in the same position for which the privileges were originally required.

(15) Management Authority:

- (a) Nothing in these procedures restricts the authority of management to temporarily detail or reassign a practitioner to non-patient care areas or activities, thus in effect suspending privileges, while the proposed reduction of privileges or discharge, separation or termination is pending.
- (b) The Health System Director, acting in the position of Governing Body as defined in the Medical Staff Bylaws, is the final authority for all privileging decisions. This decision must be based on the recommendations of the appropriate service chief(s), COS and/or Medical Executive Board.
- (c) Furthermore, the Health System Director, on the recommendation of the COS, may summarily suspend privileges on a temporary basis when there is sufficient concern regarding patient safety or specific practice patterns.
- (d) Nothing precludes VA from terminating a practitioner in accordance with procedures found in VA Handbook 5021, Employee-Management Relations, when the separation is not for a professional reason. Healthcare professionals appointed under authority of 38 U.S.C. 7405 may be terminated in accordance with VA Handbook 5021 when this is determined to be in the best interests of VA.

q. Inactivation of Privileges:

- (1) Inactivation of privileges occurs when a practitioner is not an active member of the Medical Staff for an extended period of time. Although difficult to quantify, such periods of time may include time when no clinical practice occurs, when medical knowledge, skills and learning are not continued or when there is no formal clinical relationship between the healthcare system and the practitioner. Conditions that would be considered reasons for inactivation of privileges may include extended sick leave and sabbatical with or without clinical practice while on sabbatical. When providers return to the healthcare system following these circumstances, credentialing and privileging activities are similar to the initial credentialing process with the exception that non-time limited information, e.g., education and training, does not need to be re-verified.
- (2) Inactivation of privileges may not be used as a substitute for termination of Medical Staff appointment and/or revocation of privileges where such action is warranted.
- (3) At the time of inactivation of privileges, including separation from the Medical Staff, the Health System Director must ensure that within seven (7) calendar days of the date of separation information is received suggesting that the practitioner met generally accepted standards of clinical practice and there is no reasonable concern for the safety of patients, in accordance with VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards.
- (4) Medical Staff appointments and privileges will not be granted for a period longer than the formal relationship with the healthcare system. For example, if a contract has a finite end date,

privileges may not be granted past the end date of the contract regardless of intent to renew. If a contract is terminated prior to expiration of the contract, privileges must be terminated since there is no legal agreement for the practitioner to be providing care. Where the contract is terminated early based on substandard care, professional incompetence or professional misconduct, privileges must be revoked and a report made to the NPDB, following appropriate due process procedures. Where substandard care, professional incompetence or professional misconduct is not involved in the early termination of the contract, privileges must be terminated without regard to the due process requirements for privileging actions. This termination is not reportable to the NPDB.

- r. <u>Deployment and/or Activation Privilege Status</u>: When a provider is called to active military duty, the provider's privileges are to be placed in a deployment and/or activation status. The credential files continue to remain active with the privileges in this new status. If at all possible, this process for returning privileges to an active status must be communicated to providers before deployment.
- (1) Providers returning from active duty must be asked to communicate with the medical center staff as soon as possible upon returning to the area.

NOTE: This will hopefully occur with as much lead-time as possible.

- (2) The provider must update the electronic Credentials File after the file has been reopened for credentialing updating licensure information, health status, and professional activities while on active duty.
- (3) The credentials file must be brought to a verified status. If the provider performed clinical work while on active duty, an attempt must be made to confirm the type of duties, the provider's physical and mental ability to perform these duties, and the quality of the work; this information must be documented.
- (4) The verified credentials, the practitioner's request for returning the privileges to an active status, and the service chief's recommendation are to be presented to the medical staff's Executive Committee for review and recommendation. The decision of the medical staff's Executive Committee must be documented (the minutes must reflect the documents reviewed and the rationale for the stated conclusion) and forwarded to the Director for recommendation and approval of restoring the provider's privileges to Current and Active Status from Deployment and/or Activation Status.
- (5) In those instances when the practitioner's privileges did not expire during deployment, the expiration date of the original clinical privileges at the time of deployment continues to be the date of expiration of the restored clinical privileges.
- (6) In those instances where the privileges lapsed during the call to active duty, the provider needs to provide additional references for verification and the medical center staff needs to perform all verifications required for reappointment.
- (7) In those instances where the provider was not providing clinical care while on active duty, the provider in cooperation with the Service Chief, Medical Executive Board, and/or the

Governing Council must consider the privileges held prior to the call to active duty and whether a request for modification of these privileges needs to be initiated, on a short-term basis.

- (8) If the file cannot be brought to a verified status and the practitioner's privileges restored by the Director, the practitioner can be granted a Temporary Appointment to the Medical Staff not to exceed sixty (60) calendar days during which time the credentialing and privileging process must be completed. In order to qualify for this temporary appointment, when returning from active duty the following must be documented in VetPro:
- (a) Verification of all licenses that were current at the time of deployment and/or activation as current and unrestricted with no previous or pending adverse actions on the Temporary Enrollment Screen.
 - (b) Registration with the NPDB-HIPDB PDS with no match.
 - (c) A response from the FSMB with no match.
- (d) Marking of the Temporary Enrollment Screen as reinstatement from Deployment and/or Activation.
- (e) Documentation of the Temporary Appointment on the Appointment Screen not to exceed sixty (60) calendar days.

NOTE: No step in this process should be a barrier in preventing the provider from returning to the medical center in accordance with Uniformed Services Employment and Reemployment Rights Act of 1994.

7. DOCUMENTATION OF MEDICAL STAFF APPOINTMENT AND CLINICAL PRIVILEGES:

- a. Upon completion of the verification of credentials, recommendations by the appropriate service chief and committee(s) and approval by the Health System Director, the documentation of the appointment and granting of clinical privileges can be completed. Medical Staff appointments and the granting of clinical privileges are to be entered in VetPro for a period not exceeding two years. There is no provision for any extension of appointments or privileges.
- b. The appointment can be effective as of the date signed by the Health System Director, but may not become effective at a date later than thirty (30) calendar days from the date signed by the Health System Director or forty-five (45) calendar days after the recommendation of the Medical Executive Board, whichever is shorter. The timeframe for the appointment effective date must also comply with all other timeframes established in this policy.
- c. The type of employment appointment, i.e., full-time, part-time, WOC, consultant, contract, fee basis, sharing agreement or other must be specified, the date of the appointment, service, Director's name, the signature location of the approval document and any other appropriate comments are to be entered on the appropriate screens in VetPro including service chief's approval, committee minutes and appointment screens.

- d. When indicated, appropriate documentation is to be entered into the appointment screen of VetPro for less than full appointment, including temporary and expedited appointments.
- e. If at the time of initial evaluation it is determined that no Medical Staff appointment or clinical privileges will be granted, this action is to be documented in the appropriate supporting documentation, i.e., committee minutes screen and a do not appoint screen must be entered with appropriate comments. The electronic file then needs to be inactivated, transferring the file to VetPro VA Central Office.

f. Concurrent Appointments and Sharing of Files:

- (1) When a practitioner is providing care at more than one (1) facility, including via telemedicine services, Medical Staff appointments at all the facilities must be coordinated and concurrent.
- (2) When the file is reopened for credentialing, each facility at which the provider holds a medical staff appointment needs to start the re-privileging process.
 - (3) Instructions to the provider need to clearly state that:
 - (a) The re-privileging process is going to be done concurrently at all facilities,
 - (b) The provider only needs to submit the renewal application in VetPro once, and
 - (c) The provider must attest to each facility's Bylaws on the "Sign/Submit" screen.
- (4) Each facility needs to consider sharing the practitioner's responses to the Supplemental Questions and the references submitted as part of this coordinated credentials process. In coordinating this effort, the credentialers need to determine who is going to request documentation of any items identified on the Supplemental, the references, and/or peer appraisals.
- (5) A facility may not use any time-limited verifications that are obtained prior to the practitioner attesting to the facility's Medical Staff Bylaws. Non-time limited information, such as education or training verification, may be used.
- (6) Each facility needs to obtain the license verifications and document registration in the NPDB-HIPDB PDS.
- (7) If at any point during the time a practitioner is shared, any of the facilities suspend the practitioner's privileges, or takes an action that is considered to be an adverse personnel, medical staff appointment, or privileging action, the facility taking the action must notify all facilities that share the provider of the action. This notification needs to be made to the COS of each facility for appropriate review and action within the privileges granted at the shared facility.

g. Conversion of Appointment with No Change in Privileges:

- (1) When a provider has held a specific employment or Medical Staff appointment and is being converted to a different type of appointment, whether a Medical Staff appointment or a Title 38 appointment, the practitioner must apply for this conversion.
- (2) Prior to the conversion of the appointment, all time-limited information must be verified, regardless of the period of time since the previous verification.
 - (3) The NPDB-HIPDB must be queried.
- (4) The information obtained in this process will be evaluated and reviewed by the appropriate individuals in the same manner as at initial appointment or reappraisal. This review must be documented in the appropriate minutes as well as in the credentialing and privileging folder and VetPro. The appointment date remains the same as the previous appointment with the expiration date not to exceed two years from that date.
- h. <u>Appointment Expiration</u>: Upon receipt of information that a Medical Staff Member will be relinquishing their appointment at the Tennessee Valley Healthcare System, the Service Chief is responsible for notifying the provider that his/her privileges will also be terminated (Attachment D). Copies of this notification will be provided to Human Resources and the Medical Staff Office. In addition, the Service Chief will complete a review of the member's clinical activity within 7 days of leaving VA employment and will document this review on Attachment E. Completion of this form will serve as documentation of the initial review in accordance with VHA Handbook 1100.18, reporting to State Licensing Boards, and will be filed in the Credentialing and Privileging file of the provider.

8. REFERENCES:

Title 38 U.S.C. 5705

Title 38 U.S.C. 7304, 7401(1)(2)(3), 7402, 7405, 7409, and 7461 through 7464

Title 38 CFR Part 46

Title 45 CFR Part 60

Public Laws (Pub L) 99-166 and 99-660 and revisions

Pub L 100-177

Pub L 104-191, Section 221

Pub L 105-33, Section 4331(c)

Pub L 106-117, Section 209

Title 5 CFR Parts 315, 731 and 752

VA Handbook 5005, Staffing

VA Handbook 5007, Pay Administration

VA Handbook 5021, Employee-Management Relations

VHA Handbook 1100.17, National Practitioner Data Bank Reports

VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards

VHA Handbook 1100.19, Credentialing and Privileging

VHA Directive 2006-067, Credentialing of Health Care Professionals

The Joint Commission, Comprehensive Accreditation Manual for Hospitals

10. RESCISSION: Healthcare System Policy 626-07-00Q-15, Credentialing and Privileging, dated July 20, 2007

11. RESPONSIBILITY AND REVIEW DATE: The Administrative Assistant to the Chief of Staff, along with the Supervisor, Credentialing and Privileging, will review annually for revisions and reissue no later than January 31, 2015.

/s/ Juan A. Morales, RN, MSN 7/22/2011 Juan A. Morales, RN, MSN Health System Director

Attachments:

- A. Cmo Review Process And Form
- B. Standard (Six-Part) Credentialing And Privileging Folder
- C. Application For Clinical Privilege
- D. Notification Letter of Expiration of Privileges
- E. Provider Exit Review
- F. Index

ATTACHMENT A

CMO REVIEW PROCESS					
Credentials file is verified in accordance with VHA Handbook 1100.19 and local facility bylaws and policy.					
Service Chief's recommendation is completed addressing in detail provider competency and issues triggering a CMO review.					
Medical Executive Board (MEB) performs a preliminary review of the file, documenting discussion and recommendations in minutes and on the attached form.					
Attached form is completed and forwarded to VISN CMO for review and comment on facility's due diligence.					
CMO review is completed in VetPro.					
Entire file is presented to MEB for final review and recommendations, documenting discussion and recommendations in the minutes.					
Entire file and recommendations are forwarded to the Health System Director for final action.					

ATTACHMENT A, continued

Facility Name:

CMO CREDENTIALS REVIEW FORM

THIS DOCUMENT IS TO BE SENT TO THE VISN CMO USING PKI

Facility VetPro ID #:

Practitioner's Name:	First three digits of SSN:						
Chief of Staff:	CMO:						
Date sent to CMO: THE FOLLOWING IS TO BE COMPLETED BY THE MEDICAL CENTER STAFF AND							
	TTED TO THE CMO						
Was the application complete on submission of NOT, list the gaps and missing informations.	* -	No					
ii NO1, list the gaps and missing informati	tion.						
Did the practitioner submit additional infor	rmation upon request? Yes	No					
Date asked to enter information:	Date entered:						
Was the additional information completed?	? Yes	No					
Which trigger is met?	Primary Source o	btained?					
Three Paid Malpractice Claims:	Yes	No					
Two Paid Malpractice Claims totali	ng						
\$1,000,000 or more	Yes	No					
One Paid Malpractice Claim of							
\$550,000 or more	Yes	No					
History of licensure action	Yes	No					
All information is scanned into VetPro?	Yes	No					
Were any "red flags" identified during the							
credentialing process?	Yes	No					
Please comment and explain how these we	re addressed:						
Date of MEB/ECMS/PSB:							
Recommendation of MEB/ECMS/PSB:							
Chief of Staff comments:							

ATTACHMENT B

STANDARD (SIX-PART) CREDENTIALING AND PRIVILEGING FOLDER

1. GENERAL PROVISIONS

- a. The credentialing and privileging folder is the standard system for the establishment and maintenance of credentialing and privileging and related documents, regardless of the type of employment appointment (e.g., full-time, part-time, without compensation, consultant, contract, fee basis, sharing agreement, or other). Other information related to employment appointment is located in the employee's Official Personnel Folder, or for Title 38 employees who have personnel folders, in the Merged Records Personnel Folder (MRPF). The contents of the folder are based on requirements outlined in VHA Handbook 1100.19, Credentialing and Privileging.
- b. The COS is responsible for maintenance of the credentialing and privileging system. The folder must be kept active as long as the practitioner is employed by the healthcare system. If the practitioner transfers to another VA facility, the folder must transfer to the new location.

2. FORMAT AND/OR FILING SEQUENCE

- a. The model folder provided to all facilities by the Chief Medical Director (now the Under Secretary for Health) on April 9, 1991, represents a practitioner who has held appointment or been utilized to provide on-station patient care for more than two years. An appropriate credentialing and privileging folder is to be established for each practitioner regardless of the length of service. The specific sections of the standard folder are identified as:
 - (1) Section I. Application and Reappraisal Information
 - (2) Section II. Clinical Privileges
 - (3) Section III. Professional Education and Training
 - (4) Section IV. License(s)
 - (5) Section V. Professional Experience
 - (6) Section VI. Other Practice Information
- b. Sections I and II provide for a complete overview of the individual practitioner's qualifications, type of appointment and clinical privileges. Sections III through VI represent the support documents substantiating the information presented in Sections I and II. All documents are to be filed in the order specified.

ATTACHMENT C

VA TENNESSEE VALLEY HEALTHCARE SYSTEM SERVICE/SPECIALTY:

Revised

Reviewed and Approved by the PSB

		-to vio wou with 1-pp1 over	
Name of Physici			
	Last	First	Middle
Privileges Appr	oved	Priv	rileges Not Approved
From	То		
	ed by Credentialing Staff	only)	
		-	
Type of Request			
	Chec	ck Appropriate Box	
Initial			
Biennial Renewa			
Change in Privile			
Change in Categ	gory of Staff		
Membership			
	Category of Staff Member	orchin:	
	Category of Staff Member	Check Appropriate	Box
Full Time St	aff	Спеск турргорише	DOX
Part Time St			
Consultation			
	npensation (WOC)		
On-Station F			
Off-Station I			
On-Station C			
On-Station S	Sharing Agreement		
Settings for Priv	vileges:		
	(Check Appropriate Box	
Nashville	NASH (Inpt, Outpt, ED	, ICU,	
(NASH)	OR/Procedure Areas)		
York (ACY)	ACY (Inpt, Outpt, Ed.		
	OR/Procedure Areas, C	LC)	
Both	B (all areas)		
NASH/ACY			
CBOC	CB (outpt, ED, Pro	cedure	
	Areas)		

Eligibility Criteria: To be eligible to request clinical privileges, the applicant must meet the following minimum criteria (specialty specific):

1. Basic Education:

CC (Outpt)

Contract Clinic

ATTACHMENT C, continued

- 2. Minimum Formal Training:
- 3. Previous Experience:
- 4. **Board Certification**:

Please check the procedures for which you are requesting clinical privileges:

SUPPLEMENTA L PRIVILEGES	REQUESTED PRIVILEGES		SETTING OF PRIVILEG	RECOMMENDE D APPROVAL OF SECTION CHIEF		RECOMMEND ED APPROVAL SERVICE CHIEF		PSB APPROVAL		
	YE S	NO	ES	YES	NO	YES	NO	YE S	N O	DAT E

Add additional table rows as needed.

ATTACHMENT C, continued

Replicate signature block on every page.

Applicant's Signature	Date

STANDARDS FOR GRANTING AND RENEWING PRIVILEGES

1 -	cian comply with general requirements for continuing education, maintaining certification, num levels of activity (20 CMEs annually for physicians)?
YES	NO
including appropria	cian correctly perform procedures and processes that are his or her direct responsibility, at eselection of, compliance with, and departure from protocols (physician provides a list processes to the service chief)?
YES	NO
	sician achieve outcomes consistent with the expectations of the community, with due fferences in the population being treated?
YES	NO
4. Has the physicia	an respected the rights and safety of patients and colleagues?
YES	NO

ATTACHMENT C, continued

I ACKNOWLEDGE THAT I HAVE BEEN FURNISHED WITH A COPY OF THE CURRENT MEDICAL STAFF BYLAWS, AND I HEREBY AGREE TO ABIDE BY THEM. I ALSO AGREE TO PROVIDE CONTINUOUS CARE TO PATIENTS ASSIGNED TO ME AND ARRANGE FOR THE TRANSFER OF CARE AS APPROPRIATE. I CERTIFY THAT I HAVE HAD APPROPRIATE EXPERIENCE AND/OR TRAINING AND I AM PHYSICALLY AND MENTALLY COMPETENT TO PERFORM THE CLINICAL PRIVILEGES REQUESTED.

	☐ YES		□ NO
		/	
(Applicant's Signature)		/	Date
		/	
(Type/Print Name)		Date	
I recommend privileges requested ex	xcept as noted:		
/		/	
Section Chief/Supervisor	Date		Printed Name
/		/	
Service Chief	Date		Printed Name
/		/	
Chair, Professional Standards Board	Date		Printed Name
/		/	
Chief of Staff	Date		Printed Name
Approve/Disapprove of PSB Recomm	endation		
/		/	
Health System Director	Date		Printed Name

ATTACHMENT D



DEPARTMENT OF VETERANS AFFAIRS
TENNESSEE VALLEY HEALTHCARE SYSTEM
1310 24th Avenue South
Nashville, Tennessee 37212
Murfreesboro, TN 37129

DATE

PROVIDER ADDRESS

Dear Dr	•		,									
care to o	our pat luled to	ients; o prov	therefore, vide patient r privileges	your pr	ivileg our n	es are bo	eing tern enter. T	ninat This i	ed an	nd you wi	ill no	longer
			appreciate erm of your	-			•				our	veteran
If you	have	any	questions (nam				-			hesitate		
Sincerel	y your	s,										

NAME Service Chief

cc: Human Resources (05)
Medical Staff Office (11-MSO)

ATTACHMENT E Provider Exit Review

Provider's Name:	Service:
Date of Clearance from Facility:	
Reason:	Transferred to another VA
Transferred to another Service	Retired
Other	
	L STAFF OFFICE (11-MSO) WITHIN 7 DAYS OF G VA EMPLOYMENT
Care provided by this licensed health care I	professional: (CHECK ONE ITEM BELOW)
	f clinical practice, and there was no concern for the practice expected of competent professional, as well as carry out those responsibilities.)
additional training related to	clinical practice, however, may require proctoring or
	andards of practice as to raise reasonable concern for the cumstances, a reasonable person would be concerned for the dealth care professional.)
	dard actions that could provide basis for reasonable

The following are examples of substandard actions that could provide basis for reasonable concern for the safety of patients, and thus would warrant a **COMPREHENSIVE REVIEW** for the potential reporting in accordance with VHA Handbook 1100.18, Reporting State Licensing Board):

- 13) Significant deficiencies in clinical practice, for example, lack of diagnostic or treatment capability; multiple errors in transcribing, administering or documenting medications; inability to perform clinical procedures considered basic to the performance of one's occupation; or performing procedures not included in one's clinical privileges in other than emergency situations;
- 14) Patient neglect or abandonment;
- 15) Mental health impairment sufficient to cause the individual to make judgment errors affecting patient safety, to behave inappropriately in the patient care environment, or to provide unsafe patient care;
- 16) Physical health impairment sufficient to cause the individual to provide unsafe patient care;
- 17) Substance abuse when it affects the individual's ability to perform appropriately as a health care provider in the patient care environment.

ATTACHMENT E, continued

- 18) Falsification of credentials;
- 19) Falsification of medical records or prescriptions;
- 20) Theft of drugs;
- 21) Inappropriate dispending of drugs;
- 22) Unethical behavior or moral turpitude (such as sexual misconduct toward any patient involved in VA health care;
- 23) Patient abuse, including mental, physical, sexual, and verbal abuse, and including any action or behavior that conflicts with a patient's rights identified in the Title 38, Code of Federal Regulations (CFR); intentional omission of care; willful violations of a patient's privacy; willful physical injury or intimidation, harassment or ridicule of a patient; or
- 24) Falsification of research findings, regardless of where the research was carried out or the funding source as long as involved in some aspect of operations of the VA.

SERVICE CHIEF SIGNATURE	DATE

ATTACHMENT F

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PATIENT/RESIDENT RIGHTS AND RESPONSIBILITIES

- **1. PURPOSE:** To define the rights and responsibilities of patients/residents and their families receiving care throughout the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS). VA TVHS provides a mechanism to ensure the patient has a right to care that is free from discrimination. To provide a mechanism to insure patient rights are respected by all staff of the organization and there is an understanding of the patient's responsibilities.
- **2. POLICY:** VA TVHS employees will respect and support the rights of patients recognizing that we have been selected as a provider of care. It is the commitment of staff to make each patient's visit and/or stay as pleasant as possible working together in a partnership for health care. For the purposes of this policy, the term "patient" is inclusive of Veterans ("residents") residing in VA TVHS Community Living Centers (CLC) or other designated wards for long term care.

3. RESPONSIBILITIES:

- a. <u>VA TVHS Director</u>, <u>Associate Directors and Chief of Staff:</u> are responsible for the establishment of a strategic plan and vision that supports the principles in this document; controls to insure the rights of patients as set forth by this document are accomplished and maintained; and, assuring that the patients and staff of this organization are aware of elements of the patient rights and responsibilities.
- b. <u>Public Affairs Officer:</u> is responsible for the direction of a program that emphasizes patient rights, responsibilities, and patient satisfaction in the communication with staff, Veteran Service Organizations, and patients and their families.
- c. <u>Senior Staff Assistant to the Director:</u> is responsible for insuring that all issues brought to the attention of the Patient Advocate are addressed effectively and reported as part of the Patient Advocate reports and/or appropriate venue as determined by issue.
- d. <u>Service Chiefs:</u> are responsible to insure that members of their staff are made aware of the patient rights and responsibilities and effectively address any issues pertaining to this arena at the level closest to the patient's point of care or interaction.
- (1) <u>Supervisors</u> will emphasize the importance of patient rights to their employees and promote a proactive approach to elevate the quality of staff attitudes and responses to insure we meet and exceed patient/family expectations.
- (2) <u>Employees and Volunteers</u> are responsible at all times for their conduct in a manner that reflects the respect with which we hold our patients and the Veterans of this country and their families.

4. PROCEDURES:

- a. Upon admission and/or entry into the system, the patient or his/her representative shall be given a copy of the Department of Veterans Affairs brochure, *Patient Rights and Responsibilities* and organization specific information in their preferred language.
- b. A copy of the Patient Rights and Responsibilities will be posted in all major patient care areas and inpatient care units.
- c. Whenever possible, the staff member directly interacting with the patient will address any issue of patient rights, and if no resolution is identified, it will be brought to the attention of the supervisor, and ultimately to the Service Chief.
- d. Service-level resolution of matters involving Patient Rights and Responsibilities will be communicated to the Patient Advocate to ensure entry into the Patient Advocate Tracking System (PATS).
- e. The Patient Advocate is contacted when resolution requires the involvement of multiple services and/or the involved service needs assistance to provide an equitable resolution.
- f. The Integrated Ethics Committee or organizational leadership will be consulted by the Patient Advocate when indicated.
 - g. Patient Rights and Responsibilities are defined on the Attachment.
- h. Any printed materials such as handbooks should follow the guidance in this document and updated to be in concert with the VA Handbooks and Directives.

5. REFERENCES:

- a. The Joint Commission Comprehensive Accreditation Manuals for Hospitals (CAMH) and Long Term Care (CAMLTC), current editions
- b. Department of Veterans Affairs Brochure 10-88 *Patient and Nursing Home Resident Rights and Responsibilities*, dated September, 2006
- c. VHA Handbook 1605.03 Privacy Compliance Assurance Program and Privacy Compliance Monitoring, Dated April 13, 2009
 - d. VHA Handbook 1003.4 VHA Patient Advocacy Program, dated September 2, 2005
 - e. VHA Directive 1605 VHA Privacy Program, dated April 12, 2012

- **6. RESCISSION:** TVHS Memorandum 626-09-00Q-06 dated November 24, 2009.
- **7. RESPONSIBILITY AND REVIEW DATE:** The Patient Advocate Section will review annually and re-issue by January 31, 2015.

/s/ Juan A. Morales, RN, MSN 11/19/2012 Juan A. Morales, RN, MSN Health System Director

Attachment: A

ATTACHMENT A

PATIENT AND NURSING HOME RESIDENT RIGHTS AND RESPONSIBILITIES

The Veterans Health Administration (VHA) is pleased you have selected us to provide your healthcare. We want to improve your health and well-being. We will make your visit or stay as pleasant for you as possible. As part of our service to you, to other veterans and to the Nation, we are committed to improving healthcare quality. We also train future healthcare professionals, conduct research, and support our country in times of national emergency. In all of these activities, our employees will respect and support your rights as a patient. Your basic rights and responsibilities are outlined in this document. Please talk with VA treatment team members or a patient advocate if you have any questions or would like more information about your rights.

I. Respect and Nondiscrimination

- You will be treated with dignity, compassion, and respect as an individual. Your privacy will be protected. You will receive care in a safe environment. We will seek to honor your personal and religious values.
- You or someone you choose has the right to keep and spend your money. You have the right to receive an accounting of any VA held funds.
- Treatment will respect your personal freedoms. In rare cases, the use of medication and physical restraints may be used if all other efforts to keep you or others free from harm have not worked.
- As an inpatient or nursing home resident, you may wear your own clothes. You may keep personal items. This will depend on your medical condition.
- As an inpatient or nursing home resident, you have the right to social interaction and regular exercise. You will have the opportunity for religious worship and spiritual support. You may decide whether to participate in these activities. You may decide whether or not to perform tasks in or for the Medical Center.
- As an inpatient or nursing home resident, you have the right to communicate freely and privately. You may have or refuse visitors. You will have access to public telephones. You may participate in civic rights, such as voting and free speech.
- As a nursing home resident, you can organize and take part in resident groups in the facility. Your family also can meet with the families of other residents.
- In order to provide a safe treatment environment for all patients or residents and staff, you are expected to respect other patients, residents and staff and to follow the facility's rules. Avoid unsafe acts that place others at risk for accidents or injuries. Please immediately report any condition you believe to be unsafe.

II. Information Disclosure and Confidentiality

- You will be given information about the health benefits you can receive. The information will be provided in a way you can understand.
- You will receive information about the costs of your care, if any, before you are treated. You are responsible for paying your portion
 of any costs associated with your care.
- Your medical record will be kept confidential. Information about you will not be released without your consent unless authorized by law (an example of this is State public health reporting). You have the right to information in your medical record and may request a copy of your medical records. This will be provided except in rare situations when your VA physician feels the information will be harmful to you. In that case, you have the right to have this discussed with you by your VA provider.
- You will be informed of all outcomes of care, including any potential injuries. You will be informed about how to request compensation for any injuries.

III. Participation in Treatment Decisions

- You, and any persons you choose, will be involved in all decisions about your care. You will be given information you can understand about the benefits and risks of treatment. You will be given other options. You can agree to or refuse treatment. You will be told what is likely to happen to you if you refuse treatment. Refusing treatment will not affect your rights to future care but you take responsibility for the possible results to your health.
- Tell your provider about your current condition, medicines (including over-the-counter and herbals), and medical history. Also, share any other information that affects your health. You should ask questions when you do not understand something about your care. Being involved is very important for you to get the best possible results.
- You will be given, in writing, the name and title of the provider in charge of your care. As our partner in healthcare, you have the right to be involved in choosing your provider. You also have the right to know the names and titles of those who provide you care. This includes students, residents and trainees. Providers will properly introduce themselves when they take part in your care.
- You will be educated about your role and responsibilities as a patient or resident. This includes your participation in decision-making and care at the end of life.
- · If you believe you cannot follow the treatment plan, you have a responsibility to notify your provider or treatment team.
- You have the right to have your pain assessed and to receive treatment to manage your pain. You and your treatment team will develop a pain management plan together. You are expected to help the treatment team by telling them if you have pain and if the treatment is working.
- · As an inpatient or nursing home resident, you will be provided any transportation necessary for your treatment plan.
- You have the right to choose whether you will participate in any research project. Any research will be clearly identified. Potential risks of the research will be identified and there will be no pressure on you to participate.
- You will be included in resolving any ethical issues about your care. You may consult with the Medical Center's Ethics Consultation Service and/or other staff knowledgeable about healthcare ethics.
- If you or the Medical Center believes that you have been neglected, abused or exploited, you will receive help.

IV. Complaints

You are encouraged and expected to seek help from your treatment team or a patient advocate if you have problems or complaints.
 You will be given understandable information about the complaint process. You may complain verbally or in writing, without fear of retaliation.



PROCEDURE FOR REPORTING TEST RESULTS

- **1. PURPOSE:** Establish policy and procedures to ensure the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) measures, assesses and if appropriate, takes action to improve the timeliness of reporting and the timeliness of receipt of test results by the responsible licensed caregiver and by the patient.
- **2. POLICY:** This policy applies to attending physicians, residents, nurses, technologists, therapists and all other staff who orders, performs and/or reports diagnostic test results.
- a. Critical test results will be communicated to the ordering practitioner or surrogate by direct communication. All other test results will be communicated to the ordering practitioner or surrogate by direct communication or electronic communication.
- b. When a diagnostic practitioner identifies a critical test result, the result is reported by the diagnostic practitioner to the ordering practitioner or surrogate by direct communication within one hour to ensure that appropriate intervention is instituted. The hour begins at the time when the critical result is completed and available to the diagnostic practitioner and ends at the time the ordering practitioner documents having received the result. If the diagnostic practitioner has access to the Computerized Patient Record System (CPRS), then both the communication and the receipt of the result are documented in the CPRS Critical Values Note. If the diagnostic practitioner does not have access to CPRS, then the communication is documented in the permanent record available to the diagnostic practitioner and the receipt of the result is documented in the CPRS Critical Values Note.
- c. The individual who receives the critical test result will **write it down and read back** the information they have been given. In certain emergent or urgent situations in which it is not possible to write down the result, the individual who receives the critical test result will **repeat back** the information they have been given. **Read back** or **repeat back** will be done for all critical test results to ensure the results have been communicated clearly and accurately.
- d. Outpatient test results are communicated to patients no later than 14 calendar days from the date on which the results are available to the ordering practitioner. Significant abnormalities may require review and communication in shorter timeframes. Communication with patients may occur in person, by telephone or in writing. Communication of test results by licensed or certified health care staff to patients outside of an outpatient setting must be documented in the medical record. When a patient is notified in person or by phone, documentation must include that the communication was received and understood when the patient must take some kind of action, such as medication change or return for further evaluation.
- e. Tests ordered while the patient is an inpatient, but results reported after discharge are treated as outpatient tests. These tests are communicated by the ordering inpatient provider or their surrogate in accordance with this policy.

3. **DEFINITIONS**:

- a. <u>Ordering Practitioner:</u> An ordering practitioner is a practitioner authorized to enter and sign orders for diagnostic tests by privileges or acting under a scope of clinical practice.
- b. <u>Diagnostic Practitioner</u>: A diagnostic practitioner is a practitioner who performs or supervises the performance and interpretation of diagnostic tests by privileges or acting under a scope of practice.
- c. <u>Surrogate</u>: A surrogate is a health care practitioner who is authorized to act on behalf of another health care practitioner. For the purpose of this memorandum, this includes an RN who is caring for a patient in the inpatient or emergency department setting and who receives the report of a critical test result in order to relay it to the ordering practitioner who is temporarily unavailable.
- d. **Test Result:** Test results include the results of laboratory testing, diagnostic imaging, and diagnostic procedures.
- e. <u>Critical Test Result</u>: Any diagnostic finding/value/interpretation requiring immediate therapeutic intervention where a delay in reporting could result in serious adverse outcomes for the patient.
- f. <u>Abnormal Test Result</u>: An abnormal test result is a diagnostic finding that requires attention by the ordering practitioner, but not necessarily in an immediate time frame.
- g. <u>Direct Communication</u>: Direct communication is the transmission of test results by direct, non-electronic dialogue between the diagnostic practitioner and the ordering practitioner, or surrogate practitioner, by telephone or face-to-face conversation or hand-carried report.
- h. <u>Electronic Communication</u>: Electronic Communication is the transmission of test results by electronic means such as e-mail, fax, alert, etc.
- i. <u>Personal Representative</u>: A personal representative is a person who under applicable law has authority to act on behalf of the individual. This may include power of attorney, legal guardianship of an individual, the executor of the estate of a deceased individual, or someone under Federal, state, local or tribal law with such authority (e.g., parent of a minor). Personal representative is further defined in VHA Handbook 1605.1 "Privacy and Release of Information."
- j. **Read Back**: The term "read back" applies to how critical test results are communicated to all caregivers, including physicians. It means that the individual who receives the critical test result must write down the result and/or enter it into the critical values template in the computer, then read it back and receive confirmation from the individual who gave the result that it is correct.

- k. **Repeat Back**: The term "repeat back" means to repeat verbally the information the individual heard. In certain situations such as during a code blue or in the operating room, where a "read-back" of written results is not feasible due to the urgency of the situation, a verbal "repeat-back" of the critical test result is acceptable.
- 1. <u>Critical Value Note</u>: This is a template note in the CPRS with the title "Critical Values Note" (see Attachment A).

4. RESPONSIBILITIES:

- a. **The Chief of Staff** has overall responsibility and authority for this program.
- b. **The Medical Executive Board** is responsible for approving critical test results and for making the list of critical test results available to diagnostic and ordering practitioners in electronic format.
- c. <u>Clinical service chiefs</u> are responsible for establishing a chain of responsibility for the receipt of critical test results.
 - d. Ordering practitioners are responsible for:
 - (1) Placing the order in a manner which clearly identifies the ordering practitioner;
- (2) Initiating appropriate clinical action and following up on the results of any orders they have placed;
- (3) Documenting in the medical record treatment actions in response to critical and /or abnormal test results.
 - (4) Communicating outpatient test results to patients in accordance with this policy.
- e. <u>Diagnostic practitioners</u> are responsible for timely communication of critical test results to the ordering practitioner, the practitioner's surrogate, or other responsible caregiver as soon as results are obtained. Diagnostic practitioners must:
 - (1) Communicate critical test results;
- (2) Document the communication in the CPRS Critical Values Note. For those diagnostic practitioners who do not have access to CPRS, the communication is documented in the permanent record available to the diagnostic practitioner.
- f. <u>Registered Nurse (RN) Responsibility</u>: If the diagnostic practitioner cannot contact one of the listed providers as defined in paragraph 5 a. below, the inpatient or emergency department RN caring for the patient may be notified. The RN then is responsible for:
 - (1) Contacting the ordering practitioner or surrogate;

- (2) Documenting the time, the full name of the practitioner contacted and the means of such communication in the medical record.
- g. Periodic monitoring of timeliness of reporting critical values/results, communication of test results to veterans and adherence to TVHS policy will be utilized to identify opportunities for improvement.

5. PROCEDURES:

- a. A confirmed critical result from a diagnostic practitioner is to be verbally transmitted by direct communication to one of the following persons in this order:
 - (1) The ordering practitioner.
 - (2) The surrogate for the ordering practitioner to include the supervisor of the ordering practitioner as an alternate contact for critical results.
 - (3) The attending physician for the veteran.
- (4) For outpatient critical results arising at Bowling Green, Clarksville, Dover, Hopkinsville, Meharry Sharing Clinics, and Nashville, the emergency physician at Nashville campus is contacted. For outpatient critical results arising at Chattanooga, Cookeville, Home Based Primary Care, McMinnville, York, Tullahoma and any new sites added during the term of this memorandum, the emergency physician at York campus is contacted.
- b. The CPRS Critical Values Note is to be used by diagnostic practitioners with CPRS access to document communication of the critical test result and by ordering practitioners or their surrogates to document receipt of the critical test result. All fields of the template are to be completed. In the case of diagnostic practitioners without CPRS access, the documentation of communication of the critical test result is to be done in the permanent record available to the practitioner.
- c. Ordering practitioners on leave are to designate a surrogate in CPRS in order to facilitate timely communication of critical alerts to include the supervisor of the ordering practitioner as an alternate contact for critical results.
- d. Physicians ordering outpatient tests will track diagnostic orders until test results have been received and communicated to the veteran. The Patient Notification Letter of Test Results or Recent Test Results templates in CPRS will be utilized to document veteran notification of test results.

6. REFERENCES:

a. National Patient Safety Goal 02.03.01

b. Joint Commission National Patient Safety

Goals: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/

- c. VHA Directive 2009-019
- 7. **RESCISSION:** Memorandum 626-11-11-16, Procedure for Reporting Critical Test Values
- **8. RESPONSIBILITY AND REVIEW DATE:** The Chief of Medicine will review annually and update no later than January 31, 2014.

/s/ Juan A. Morales, RN, MSN 4/23/12 Juan A. Morales, RN, MSN Health System Director

Attachment A

ATTACHMENT A

🥨 Template: Critical Values Note				_ 🗆 ×
Critical Values Received				
	TS CALLED:Jun 13,2006@08: sults by:[] Telephone			
"read back" process and be written down and read	Service:* the recipient that the r need to back per medical center ,PATIENT ROOO-OO-7890and	policy.	the	
	*Indicates a Required Fi	OK Preview	pel	

PATIENT RECORD FLAGS TO IDENTIFY VETERANS AT HIGH RISK FOR SUICIDE

- 1. **PURPOSE:** Identification and tracking of Veterans at high risk for suicide is a key component of the Veterans Health Administration (VHA) national suicide prevention strategy. This policy will outline the proper use of the Category II Suicide Patient Record Flag.
- 2. **POLICY:** Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) will identify and track Veterans at high risk for suicide, using a Category II Local Patient Record Flag (PRF) at High Risk for Suicide.
- a. <u>Primary purpose of the High Risk for Suicide PRF</u> is to alert all Veterans Administration (VA) staff that a Veteran is at high risk for suicide and the presence of a flag should be considered when making treatment decisions. However, the PRF does not take the place of a proper warm hand-off of patient care from one treatment setting to another (Memorandum 626-11-118-30, Hand-Off Communication). The Patient Record Flag is not intended to be used as an exclusionary factor for referral to or inclusion in other mental health or VA programs.
- (1) The Mental Health Treatment Coordinator or Case Manager for the Veteran needs to ensure that the Veteran is evaluated weekly for the first 30 days after placement of the flag. After 30 days, placement on high risk list must be evaluated at least every 90 days, and the Veteran's status updated and documented. The clinician should consider involving significant others in care planning and limiting access to means of harming oneself when possible.
- (2) Front line staff need to be aware that if they are concerned about a Veteran's safety they are to contact the provider or the Suicide Prevention Coordinator (SPC). All staff should be aware that these patients may present for care for a variety of reasons in order to obtain safety and help. After regular business hours, or if the provider or SPC cannot be contacted, the Veteran should be taken to the hospital Emergency Department (ED) for evaluation or if on the telephone, the Veteran should be connected to the ED for immediate mental health consultation. The absence of a High Risk for Suicide PRF on a patient record does not indicate that the Veteran is not at risk for suicide. Many times warning signs and risk factors are not known by VA clinical staff.
- (3) All staff need to recognize that any Veteran may be at risk for suicide, regardless of the flag status on the Veteran's chart. In the event of concerns for suicide risk, referrals are to be made to the SPC.
- b. <u>Use of any PRF:</u> is restricted to addressing immediate clinical safety issues. It is important to ensure that usage of the PRF is limited to only those Veterans at high risk, and only for the duration of the increased risk for suicide. The PRF is removed as soon as it is clinically indicated to do so. This is especially important to minimize the risk of undue stigmatization for the Veteran, and to maintain the value of the PRF system as an

alert to an immediate clinical safety concern. Reporting of suicidal thoughts or a call to the national suicide hotline alone is not an automatic indication of high risk.

- c. <u>Veterans needing High Risk for Suicide PRFs:</u> must be assessed by a Mental Health Clinician and meet one of the following criteria:
 - (1) A current verified report or witnessed suicide attempt within the last 90 days;
- (2) Identification of current serious ideation that requires an immediate change in treatment plan, such as hospitalization; and,
 - (3) Presence of any of the following warning signs;
 - (a) Threatening to hurt or plan to kill oneself;
- (b) Looking for specific ways to kill oneself and seeking access to such means, as pills, weapons; and,
- (c) Talking or writing about death, dying, or suicide when these actions are out of the ordinary for the person.
- d. <u>Suicide Behavior Report (SBR):</u> The SBR is the documentation to be completed by a VA clinical staff member when they become aware that there has been a suicide attempt or significant suicidal behavior. (Attachment A). The SPC may complete this report when a referral from the VA National Suicide Hotline, or from another source, such as a community facility, is received indicating that a Veteran has made a suicide attempt.
 - (1) This report is used to:
- (a) Provide required information for the National Patient Safety reporting requirements on suicide and suicide attempts. The National Center for Patient Safety has approved the use of the SBR and use of its data reporting requirements from the field.
- (b) Populate a national suicide prevention database, established as part of VHA's national suicide prevention strategy.
- (2) The completion of this report may be an indication that a flag needs to be placed in the record, but it is not the sole criteria, nor is it necessary for placement of the PRF for suicide risk.

3. PROCEDURE:

a. <u>Identification of Veterans at high risk for suicide</u>: Veterans may be determined to be at high risk for suicide for a variety of reasons and this is always a clinical judgment made after an evaluation of risk factors, protective factors, and the presence or absence of

warning signs as listed on the VA Suicide Risk Assessment Pocket Card. The warning signs and high-risk criteria are described in the <u>Suicide Risk Assessment Guide</u> Reference Manual.

- b. The SPC must be alerted that a Veteran has been deemed high risk for suicide by being made an additional signer on the progress note, an e-mail, and/or telephone call from the Veteran's provider.
- c. A Suicide Prevention Safety Plan must be completed with the Veteran by the provider. If admitted, the Suicide Prevention Safety Plan will be in place by the time the Veteran leaves the hospital. If the Veteran is an outpatient, the Suicide Prevention Safety Plan will be in place at the first visit after the Veteran has been designated as high risk. (Attachment B). This is a Template Progress Note that reviews what the Veteran can do to keep themselves safe and what VA procedures will be followed.
- d. The SPC then places a flag on the chart which reviews the date and the circumstances that occurred to place the Veteran in the high risk category in Veterans Health Information Systems & Technology Architecture (VISTA). If the Veteran is hospitalized, the flag will be placed prior to discharge. If the Veteran is an outpatient, the flag will be placed at the first of the weekly required visits.
- e. A Computerized Patient Record System (CPRS) note titled PRF Category II-Suicide Risk will be entered and connected to the flag. (Attachment C). The information in this note will include the date the person was deemed at high risk for suicide and the reason for the high risk designation. Additional signers to this note will include the Primary Care Provider (PCP) and Mental Health (MH) providers.
- f. The Suicide Prevention Coordinators for the facility will coordinate and place PRF for Suicide High Risk.
- g. If a Veteran has had a suicide attempt or death, in the previous 90 days, that has not already been recorded then a CPRS note titled Suicide Behavior Report must be completed by clinical staff. This report is used to provide required information reporting requirements on suicides and suicide attempts.
- h. The SPC in conjunction with relevant staff providing care for the Veteran will review the flag every 90 days and make a determination regarding removal of the flag or continuation of the flag. If the flag is removed a CPRS note titled PRF Category II-Suicide Risk will be completed regarding removal of the flag and will be forwarded for additional signatures to the PCP and the MH team. The SPC is alerted through a VISTA e-mail that the flag removal date has expired.

4. RESPONSIBILITIES:

a. Facility Director:

- (1) Ensuring that the Category II High Risk for Suicide PRF is originated and accessible through CPRS.
- (2) Establish a process for requesting, assigning, reviewing, and evaluating Category II High Risk for Suicide PRFs and coordinating this with the existing processes for managing the PRF Program.
- (3) Ensuring training by the SPC of appropriate staff in determining when a Category II High Risk for Suicide PRF is to be entered, how PRFs are entered and how PRFs and PRF related documents are reviewed and maintained.
- (4) Evaluate the facility process to ensure the Category II High Risk for Suicide PRFs are assigned appropriately.
- (5) Ensuring that each Category II High Risk for Suicide PRF in a Veteran's record is accompanied by the appropriate CPRS note.
- (6) Ensuring the Category II PRF is used to local alert for Veterans at high risk of suicidal behavior. This use of the Category II flag enables staff to be aware of a Veteran in need of close follow up, including outreach efforts if the Veteran misses or cancels an appointment.
- (7) Ensuring when a High Risk for Suicide PRF is placed on a Veteran's chart it is reevaluated at least every 90 days to ensure that the PRF is promptly removed when the high risk status has resolved. This is based on clinical judgment of the conditions and behaviors involved.
 - (8) Ensuring that there is always an acting SPC when the Coordinator is absent.

b. Chief of Staff:

- (1) Instituting procedures to ensure that the utilization of a Category II PRF for High Risk for Suicide and the associated processes for recommending such a PRF are ethical, clinically appropriate, supported by adequate resources, and used in accordance with VHA Directive 2008-036 dated July 18, 2008.
- (2) Providing for a response to Veteran requests for deactivation of their Category II PRF for suicide risk.

c. Suicide Prevention Coordinator:

- (1) Managing the process of using Category II PRFs to identify Veterans at high risk for suicide.
- (2) Exclusively controlling all Category II suicide flags and limiting their use to Veterans who meet the criteria for being placed on the facility high risk list.

- (3) Coordinating with the facility committees and their processes which manage PRFs to incorporate the use of Category II PRFs into the overall process of utilization of PRFs at the facility.
- (4) Assessing the risk for suicide in individual Veterans in conjunction with their treating clinicians.
 - (5) Identify training needs relating to the prevention and management of suicide.
- (6) Ensuring that Veterans identified as being at high risk for suicide receive follow-up for any missed mental health and substance abuse appointments in conjunction with clinical treatment team, and that this follow-up is documented in the electronic medical record.
- (7) Working with clinicians, who refer potential high risk Veterans for flagging, to determine the advisability of the flag.
- (8) Maintaining communications with the facility-designated advisory groups or committee to keep them aware of the flag placements and outcomes of reviews.
- (9) Maintaining a list of Veterans who currently have a flag and establishing a system of reviewing the flags at least every 90 days.
- (10) Documenting when appropriate the nature of the follow-up and plans for continuing treatment in the electronic medical record.

5. REFERENCES:

- a. Department of Veterans Affairs of the Inspector General. Implementing VHA Mental Health Initiatives for Suicide Prevention; May 10, 2007.
- b. Mental Health Initiatives memo, Deputy Undersecretary for Health Operations and Management, June 1, 2007.
- c. <u>Suicide Risk Assessment Guide Reference Manual</u>, which can be found at :<u>http://vaww.mentalhealth.va.gov/files/suicideprevention/SuicideRiskGuide.doc</u>
 - d. VHA Directive 2008-036; July 18, 2008.
 - e. Memorandum 626-11-118-30, Hand-Off Communication
- **6. RESCISSION:** VA TVHS Memorandum 626-08-11M-09 Patient Record Flags to Identify Patients at High Risk for Suicide, dated August 31, 2008.

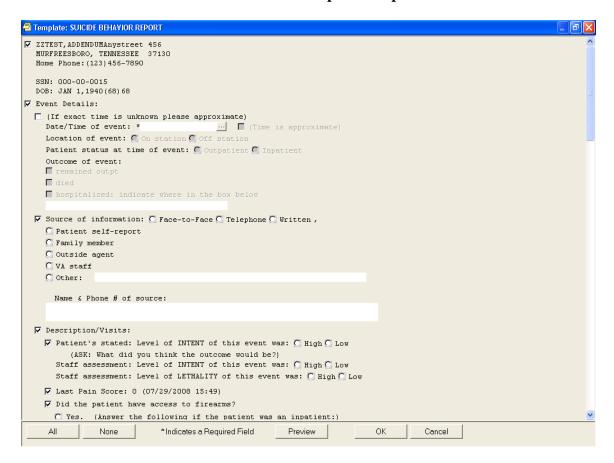
7. RESPONSIBILITY AND REVIEW DATE: Chief, Mental Health Care Line will review policy annually with updates by June 30, 2015.

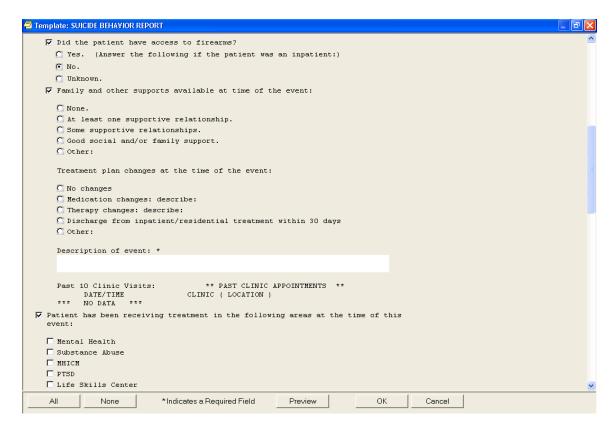
/s/ Juan A. Morales, RN, MSN 9/6/2012 Juan A. Morales, RN, MSN Health System Director

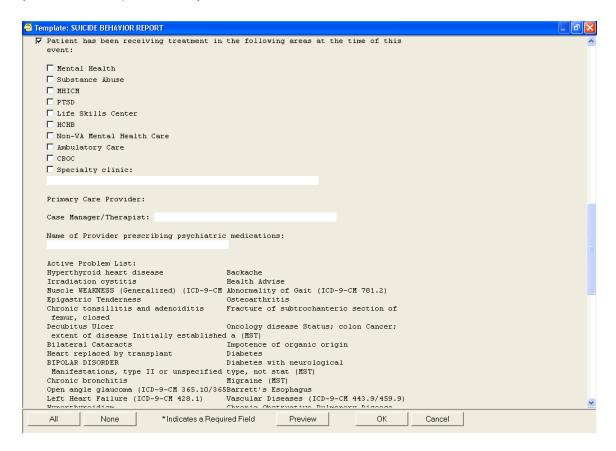
Attachments:

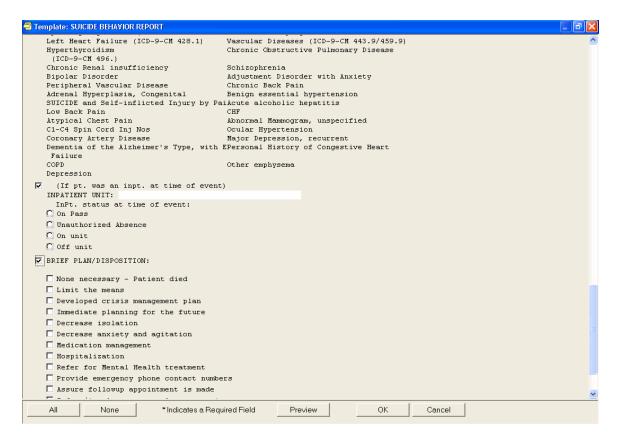
- A. Suicide Behavior Report Template
- B. TVHS Suicide Prevention Safety Plan
- C. PRF Category II Suicide Risk Template

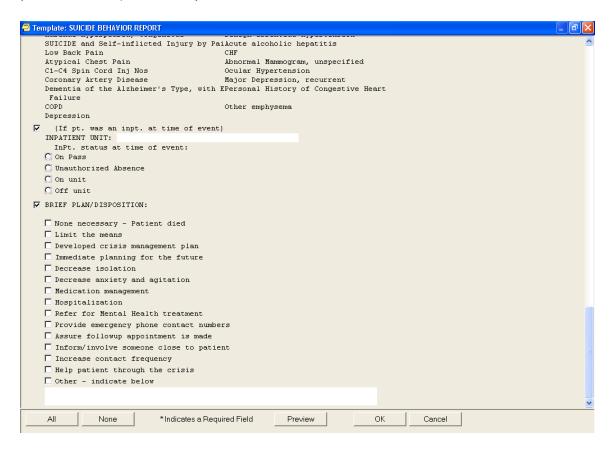
Attachment A Suicide Behavior Report Template











Attachment B TVHS Suicide Prevention Safety Plan

Suicide Prevention Safety Plan:

Step 1: Warning Signs	
1	
2	
3	
Step 2: Internal coping strategies -Thir problems without contacting another p	
1	
2	
3	
Step 3: People who can help support a	nd distract me:
1. Name:	Phone:
2. Name:	
3. Name:	
Step 4: People whom I can ask for help	n:
1. Name:	
2. Name:	Phone:
3. Name:	
Stan 5. Duefossionals on accusing I can	contact during a cuicie.
Step 5: Professionals or agencies I can	
1. Clinician Name:	Pnone:
Clinician Pager or Emergency Conta	
2. Clinician Name:	
Clinician Pager or Emergency Conta	
3. Local Urgent Care Services:	
Urgent Care Services Address:	
Urgent Care Services Phone:	
4. VA Suicide Prevention Coordinator	
VA Suicide Prevention Coordinator	
	ne: 1-800-273-TALK (8255), push 1 to rea
a VA mental health clinician.	
Step 6: Making the environment safe: 1	
2.	

Attachment C PRF Category II – Suicide Risk Template

Template: I	PATIENT RECOR	D FLAG CATEGORY II - SUICIDE RIS	K		_
□ PATIENT	RECORD FLAG	CATEGORY II - SUICIDE RISK			
Behav immed elect or re consi	ior due to r iate treatme: ronic record solved risk der continua:	added to the facility's High eported behaviors on Jul 30, nt plan change such as hospi s will be reviewed in 90 day factors, warning signs, and ; nce or removal from the High e for informational purposes	2008 requir talization. V s for evidence protective fac Risk list. C	ing an eteran's of continued tors to	
	_	reviewed for removal from th r Suicidal Behaviors.	e facility's		
▽ I	atient repor	ts medication compliance X 9	0 days.		
▽ I	atient atter	nded regularly schedule appoi	ntments X 90 o	days.	
✓ 1	here have be	en no reports of additional	suicidal behav	vors X 90 days	i -
V	No threa	ts to hurt or kill themselve	s or others X	90 days.	
F		ing for specific ways and me pills, weapons, etc.	ans to kill th	emselves, i.e	
·	Not talk	ing, writing, or researching	death, dying,	and suicide.	
	heck Appropr	riate Protective Factors:			
	Patient	has at least one positive so	cial support		
	Spiritua	lity			
□	Sense of	responsibility to family			
·	Children	in the home or pregnancy			
·	Life sat	isfaction			
□	Reality	testing ability			
□	Positive	coping skills			
·	Positive	problem-solving skills			
 	Positive	therapeutic relationship			
© Veteran, at this time, no longer meets criteria for inclusion on facility's High Risk List for Suicidal Behaviors. Veteran is currently at moderate to low risk and will be monitored by his/her Primary Care and Mental Health providers. Veteran can and will be reassess for inclusion on the High Risk List if and when clinically needed.					
All	None	* Indicates a Required Field	Preview	OK	Cancel

FEE BASIS CARE

- 1. PURPOSE: To establish Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) policies and procedures through which Veterans are authorized to receive clinically necessary procedures (diagnostic or therapeutic) at non-Department of Veterans Affairs (VA) institutions. Safeguarding scarce resources is an integral part of this process; both in designing in-house services and in determining the most cost effective way to out-source clinical care when VA resources are unavailable or do not meet timeliness standards. This policy outlines the process to ensure that oversight is performed routinely at the highest level.
- **2. POLICY:** The appropriate implementation and utilization of non-VA care policy and procedures is the responsibility of all VA staff associated with requesting, approving, and/or authorizing these services. Medical center management will actively review utilization of resources associated with this program and ensure that policy and process are adhered to. All referrals for non-VA care will be approved in advance by the Chief of Staff (COS) or designees. The COS may designate this responsibility to the Clinical Service Chiefs only. Consult requests for non-VA care will be directed to the Business Office (BO) for processing. Requests are to identify the specific clinical services required. The BO will identify and contact appropriate services' providers to ensure access and timeliness of service requirements can be met. The BO will maintain an active list of non-VA providers. In non-emergent situations, any referral that has not been approved, and an authorization is issued in advance of obtaining official approval, may not be paid. All requests for non-VA care will be carefully reviewed to determine if at a minimum:
 - a. There is a medical need for care utilizing evidenced based criteria;
 - b. Care can be provided within the facility in a timely manner;
 - c. Care can be provided timely by an existing contract service; and,
- d. When the non-VA provider is an affiliated institution, the COS or their designee will review the request to ensure that no conflict of interest issues exist.

3. RESPONSIBILITY:

- a. The COS, or their designee, is responsible for confirming that procedures are medically necessary and appropriate and that they cannot be feasibly performed within the timeliness and or geographic standards at another campus of VA TVHS.
- b. Requests for non-VA care from a VA provider are submitted utilizing a template consult containing the following mandatory justification fields:
 - VA facility does not provide the required service;
 - VA facility cannot timely provide the required service;
 - Veteran cannot safely travel to a VA facility due to medical reason (*specify medical reason*).

- c. Under special circumstances, the following justification fields will be utilized:
 - Veteran cannot travel to VA facility due to geographical inaccessibility;
 - Other (Please specify) (A free text field should also be available for the clinician to specify the indicated reason).
- d. Section Chiefs and Service Chiefs are responsible for knowing the procedures that can be performed at other campuses of VA TVHS. Service Chiefs are to submit a memorandum to Fee Basis of any changes of protocols outside the normal process with notification and approval by the Executive Leadership Team.
- e. Community Based Outpatient Clinic (CBOC) providers may enter and approve a Fee consult to a local medical facility for 911 emergencies only. All non-emergencies should be coordinated with the Transfer Coordinators for possible transfer to the Alvin C. York or Nashville Campus prior to requesting a Fee consult. Only the Service Chief / Chief of Staff or surrogate designee is authorized to approve a non-emergent Fee consult.
- f. Fee Basis is responsible for maintaining lists of facilities outside Veterans Health Administration (VHA) where these procedures can be performed.
- g. A consult is not required when justification for extending short-term fee-basis services and decisions to continue the use of Fee Basis is documented in the health record by the designated VA reviewing clinician. See VHA Handbook 1907.01, Section 5, paragraph "s".
- **4. PROCEDURES:** In order to obtain approval for services to be rendered by a non-VA health care institution or provider, the following processes must be followed:
- a. Providers are required to request in-house VA services prior to requesting non-VA care. Once it has been determined that the VA does not or cannot provide services in a timely manner then the requesting provider will submit a Computerized Patient Records System (CPRS) template Fee Basis consult containing the mandatory justification fields as listed in 3(b). This Fee consult must contain detailed information on the specific clinical evaluation that is being requested. This information is used to generate the fee authorization and instructions for the community provider. Non-emergent consults requested from the CBOCs must follow the same process as consults entered by the main campuses; however, CBOC consults entered for 911 emergencies may be approved by the requesting provider.
- b. Upon receipt of the Fee consult, the Fee Basis staff will conduct a review to assure that a VA in-house consult for care has been requested prior to entering a consult for Fee Basis care. The Fee Basis Staff will also review the Fee consult template for required elements. All consults for non-VA care and services that are received without prior VA consult request or Fee justification will be cancelled and returned to the requesting clinician as a view alert using the electronic consult process. Authorizations should not be entered by Fee staff until these requirements are complete.

- c. Once all required elements are provided, the Fee Staff will add a comment onto the CPRS consult requesting the Section Chief to conduct a clinical review. This will generate a CPRS View Alert to the designated Section Chief to review the consult for appropriateness. If the Section Chief determines that the Fee consult should be denied, the Section Chief will enter this decision as an added comment onto the CPRS consult. This will notify the Fee Basis staff that the consult has been denied. The Fee Basis staff will cancel the denied consult which will notify the original requestor of the decision.
- d. If approved by the Service Chief / COS or designated surrogate within CPRS, the Fee staff will process and schedule an "Evaluation Only" appointment with an appropriate provider in the community as soon as possible. If the surrogate is identified, they must indicate for which Service Chief they are approving the requested consult. Once the evaluation has been completed, the community provider will submit a mandatory "Treatment Plan" to the Fee Basis staff. This treatment plan will be scanned into CPRS and a View Alert sent to the requesting provider/service designee for review of continuity of care and appropriateness. Once the requesting provider/service designee enters recommended approval, a View Alert will be sent to the Service Chief/COS for review and final approval of the proposed treatment.

It is critical that this review be completed in a timely manner to avoid delay of patient treatment. If Fee staff have not received a response from the requesting provider/service designee within 48 hours, the request for approval will be sent directly to the Service Chief/COS for review and final approval of the proposed treatment. It is the requesting provider/service's responsibility to follow, act where appropriate, and monitor any care or recommendations presented by the Fee Basis provider.

- e. Once the Fee staff receives approval for the recommended treatment plan they will modify the Fee authorization documenting the approval and then notify the community provider to move forward with the proposed treatment.
- f. <u>Veteran Request for a Fee Basis Card:</u> Veterans with existing Fee Basis Cards that have not expired will be honored. Continuation and new requests for a Fee Basis Card will be disapproved. Fee Basis is no longer issuing Fee Basis Cards, and the Veteran may request to continue care through their VA TVHS Primary Care Provider.
- g. <u>Notification of Veterans in non-VA hospitals:</u> Fee Basis staff will notify the Transfer Coordinator via electronic Fee Basis Tracking Log System following notification of admission of a Veteran to a non-VA hospital. The Transfer Coordinator shall monitor progress of the Veteran for possible transfer back to VA. Any subsequent changes to the initial authorization should be promptly communicated to Fee Basis staff. Fee Basis staff will forward an authorization to the non-VA hospital for each episode of care that has met all criteria and received approval.
- h. **Payment:** Payment for authorized care will be made within 30 days of receipt of the invoice(s). When payments are made to providers on behalf of Veterans who have third-party health insurance, copies of the invoices are sent to the Mid-South Consolidated Patient Account Center (MS CPAC) for billing.
 - i. Requesting Fee Consults for Community Nursing Services:

- (1) The provider will enter a Geriatric Extended Care (GEC) consult for community health services, which include all community services except hospice and palliative care services.
- (2) For community hospice and palliative care services, the provider will enter a palliative care consult.
- (3) The Community Health Nurse or Hospice/Palliative Care Nurse will process the consult, identify the community vendor, and generate a Fee consult order for the community services. The Fee consult will be marked as "Hold for MD Signature" within CPRS.
- (4) Once the Community Health Nurse/Palliative Care Nurse marks the Fee consult as "Hold for MD Signature", this will automatically send a view alert to the requesting provider to sign off on the consult orders. This will release the Fee consult for processing.
- (5) The Business Office Fee staff will then process the Fee consult, waiving the additional approval signature by the Service Chief.
- (6) In the event the requesting provider does not answer the view alert within 24 hours, the view alert will be sent to the Medical Director for Community Health with a request to follow up with the requesting provider and to sign the orders if necessary to release the fee consult timely.

5. DENTAL FEE BASIS:

- a. Responsibility of Chief, Dental Service Outpatient Fee Dental Administration: The Chief, Dental Service, or designee, has the primary responsibility for administering the outpatient fee dental program. This includes review of all proposed treatment plans for approval/disapproval, and adjustment of submitted fees consistent with the Schedule of Maximum Allowances for Fee Dental Services. The Chief, Dental Service, or designee, is also responsible for review of the Schedule of Maximum Allowances for their area, at least annually.
- b. <u>Process for Fee Basis Authorization:</u> VA Form 2570-D or an equivalent electronic approved form will be used by the Chief, or designee, to authorize and approve fee basis treatment. Signature of the Chief, or designee, on the form will attest that the claim has been reviewed and validated.
- c. <u>Selection of Fee Basis Provider:</u> VA will not recommend a specific dental fee provider unless that provider has been properly credentialed and privileged by VA. It will be the Veteran's responsibility to select the provider of their choice once they have been approved for fee care. Definitive treatment should not begin without pre-authorization.

6. REFERENCES:

- a. 38 CFR Part 17.52 et seq
- b. M1, Part 1, Chapter 18, Outpatient Fee Services
- c. CBO Procedural Guide, Series 1601F: Fee Service

- d. VHA Handbook, 1660.3, September 22, 2008, Conflict of Interest Aspects of Contracting for Scarce Medical Specialists Services, Enhanced Use Leases, Healthcare Resource Sharing, Fee Basis, and Intergovernmental Personnel Act Agreements (IPAS)
 - e. VHA Directive, 2010-27, VHA Outpatient Scheduling Processes and Procedures
- 7. RESCISSION: TVHS Memorandum 626-10-136-09 dated March 2, 2010
- **8. RESPONSIBILITY AND REVIEW DATE:** The Chief, Business Office will review annually and update by February 28, 2015.

/s/ Juan A. Morales, RN, MSN 01/31/2012 Juan A. Morales, RN, MSN Health System Director

MEDICATION USE MANAGEMENT

- **1. PURPOSE:** The purpose of this memorandum is to establish policies and procedures in the management of medication use within the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS).
- **2. POLICY:** It is the policy of VA TVHS to follow federal laws, VA policy, and The Joint Commission standards for the procurement, storage, control, prescribing, dispensing, administration and monitoring of all drugs and drug products as an organized healthcare system.

3. RESPONSIBILITIES:

- a. The Chief, Pharmacy Service is a qualified and licensed pharmacist responsible for the administration of the Pharmacy Service and for all publication of medication policy. The Chief and all professional pharmacy staff will abide by an established code of ethics and are responsible for enforcing policy and procedure regarding medication in the best interest of all patients.
- b. The Pharmacy and Therapeutics Committee, in coordination with National and Veterans Integrated Services Network (VISN) Pharmacist Executives, pharmacy and other appropriate services, is responsible for all matters related to the use of drugs within TVHS.
- c. Compliance with the provisions of the drug policy is the responsibility of the authorized prescriber (licensed physician, podiatrist, dentist, or other appropriately licensed, credentialed, and privileged personnel operating under a scope of practice), pharmacy personnel filling and dispensing the order or prescription, and nursing/other personnel approved to administer medications.
- **4. PROCEDURES:** This policy is broken down into the following sections (controlled substances are additionally addressed in a separate VA TVHS policy.

NOTE: The headers below are hyperlinked to the specific section addressed in the policy:

Pharmacy Hours of Operation

Formulary Information

Sample Policy

Drug Storage, Handling & Security

Medication Labeling

Pneumatic Tube System

Prescribing/Profile Review/Allergy Review

Required Elements of a Prescription

Documentation of Diagnosis, Condition, or Indication for Use

Verbal/Telephone Orders

Resume Orders/Standing Orders

Medication-Related Devices and Supplies

Compounded Medications

Herbal Products/Dietary Supplements

Hold Policy

As Needed/PRN/Range Order Policy

Tapering Orders

Titrating Orders

Multiple Routes of Administration

Quick Orders/Order Sets/Preprinted Order Sheets

Discharge Prescriptions

Allergy Status/Documentation

Look Alike/Sound Alike Medications

Standardized Drug Concentrations

Abbreviations

Investigational Medications (see also Section k.)

Medication Sources

Emergent (up to 10 day) Prescriptions in Specified CBOCs

High Alert Medications

Dispensing

Administration/BCMA

IV Push Administration

Self-Administration

Monitoring of First-Doses

Outpatient Prescriptions

<u>Inpatient – Unit-Dose</u>

Tablet Crushing/Modifying/Splitting Policy

Inpatient – General IV Admixtures

Multi-Dose Vial (MDV) Policy

Concentrated Electrolytes

Inpatient – Ward Stock

Medication Inspections

Ready-To-Administer Form

Emergency Procurement of Medications

Investigational Medications

Return Drug Product Procedure

Patient's Personal Medications

Drug Recalls

Drug Shortages

IV Push List for Acute and Primary Care (Attachment A)

IV Push List for Long Term Care (Attachment B)

a. **PHARMACY HOURS OF OPERATION:**

- (1) Inpatient Pharmacy Services at the Alvin C. York (ACY) and Nashville Campuses are staffed 24 hours per day, 7 days per week, and 365 days per year. A pharmacist is on duty at all times at both locations.
- (2) Full Outpatient Pharmacy Services at Nashville and ACY are open and staffed from 8:30 a.m. to 5 p.m., Central Time, Monday through Friday (closed on weekends and holidays). Routine prescriptions and/or refills are not accepted at the pharmacy windows for immediate processing. Routine refills may be requested through the mail, dropped off at the window for mailing, called into the AudioFax system, or processed through the My HealtheVet Internet Refill processing function. After hours, *emergent only* prescriptions are handled through the Inpatient Pharmacy at the Nashville and ACY locations. Pharmacists will prioritize workload after hours by acuity level of the patient.

b. FORMULARY INFORMATION:

- (1) Pharmacy Service will provide and dispense drugs based upon a formulary of drugs approved at the national level. Categories of drugs will include formulary items (items for general hospital use) or formulary-restricted items (items that have specific criteria-for-use guidelines). Items not on the VA National Formulary (nonformulary) as well as the formulary-restricted medications will be made available as appropriate using the facility's nonformulary/Restricted Drug Consult Program. A Pharmacy & Therapeutic (P&T) designated Approving Official will review and either approve or disapprove the request based on specified guidelines. There is an opportunity for the provider to appeal the decision by entering a second consult that provides additional information for further review. The final appeal on nonformulary/restricted medication consults is the Chief of Staff. Emergency (STAT) consults will be processed within 24 hours and routine consults within 96 hours.
- (2) <u>Sample Policy</u>: Sample medications are not allowed in the Healthcare System under any circumstances.
- (3) No drug determined ineffective, (i.e., on the Food and Drug Administration's (FDA) Drug Efficacy Study & Implementation (DESI) list), by the FDA will be procured or dispensed by Pharmacy Service. Pharmacy procurement technicians will review the DESI list at least once yearly and report any problems to their supervisor.
- (4) Nonformulary and restricted formulary items are handled through the Computerized Patient Record System (CPRS) consult system and are guided by that specific policy.

c. **DRUG STORAGE, HANDLING AND SECURITY:**

(1) All medications located within the hospital and treatment areas must be placed in predefined medication storage areas, approved by Pharmacy Service, with security locks that

prevent unauthorized access by hospital personnel and/or patients. These predefined areas may include locked medication carts, cabinets, locked medication storage rooms, and secured automated dispensing equipment, such as Pyxis®. Pharmacy Service must approve these storage areas so that appropriate medication storage (e.g., proper temperature, humidity, protection from light, etc.) is assured for product stability and medications be properly inspected by Pharmacy personnel. Personnel removing medications from approved storage sites to be utilized in the care of patients are responsible for returning those medications to those approved areas preferably when done using them or maximally at the end of the individual's shift so that the medications may be properly stored and inspected. Storage appropriate to the specific medication between the receipt of a medication by an individual health care practitioner and medication administration will be assured by that health care practitioner removing the medication from its approved storage site, i.e., appropriate temperature, humidity, protection from light, etc. Appropriate handling of the medication, e.g., check for special handling procedures on toxins, biologicals, and cytotoxic medications, etc., is also the responsibility of the individual health care practitioner for the timeperiod of removal of the medication from the approved storage site to medication administration or return to the approved storage site. Prior to returning any medication to an approved medication storage site, the expiration date of medication will be checked by the person returning the medication, with appropriate disposition, if the medication is expired.

(2) Security of drugs will be established and maintained at all times, including during alarm drill procedures, rekeying procedures, and computer system contingency processes, defined in service policies. Security of the medications will be additionally maintained at all times between the receipt of a medication by an individual health care practitioner and when medication administration is complete.

NOTE: At no time should any medication be left unattended and/or unsecured. Medications will be under constant surveillance by the responsible health care practitioner while in an unsecured area.

- (3) <u>Medication Labeling:</u> All medications, whether stored within the Pharmacy or on the wards/clinics, as well as chemicals used to prepare medications, must be accurately labeled with the contents, expiration date, and warnings as applicable.
- (4) <u>Limited Access to Pharmacy Areas:</u> All pharmacy drug storage areas are secured environments with access permitted only by pharmacy personnel. Exceptions will be granted only with the explicit permission of the area pharmacy supervisor. Any non-pharmacy visitor admitted to the pharmacy is the responsibility of the pharmacy employee who let them into the pharmacy. If they can be left with another pharmacy employee, the employee allowing entry into the pharmacy is relieved of the responsibility and the responsibility for the visitor's activities while in the pharmacy becomes the responsibility of that pharmacy employee. Drug accountability, security of the pharmacy (including access by non-pharmacy employees), and the safety of pharmacy personnel are the responsibility of every pharmacy employee. Vault Inspectors will be allowed into the vault ONLY in the presence of another pharmacy employee.

Inspectors and any other non-vault approved personnel that have an approved need to be in that area must sign in and out of the vault using the "vault-access" log. *No one outside of approved vault personnel is to be left alone in the vault for any period of time under any circumstances.* The use of any object to prop open a vault door or hinder the locking mechanism is strictly prohibited. The vault day-gate must remain in a closed position at all times. Vault combination locks must be changed in accordance with Veterans Health Administration (VHA) Handbook 1108.1, Controlled Substances (Pharmacy Stock).

- (5) Pharmacy Service is responsible for the bulk storage and control of prescription pads (VA Form 10-2577F), Controlled Substance Order VA Form 10-2321, and the VISN prescription pads for use outside the VA. Issued prescription pads will be secured at all times by providers with prescriptive authority to which the forms were assigned. Prescription pads and order forms will be securely stored and accounted for in designated pharmacy vaults. *Any unused blank prescriptions are to be returned immediately to Outpatient Pharmacy when the individual leaves VA employment during the employee clearance process.* Further and more specific policies on this issue may be found in the policy entitled, Controls over Security Prescription Form (VA Form 10-2577F).
- (6) Medications delivered to the wards by way of the facility pneumatic tube system may be accessed by RNs, LPNs, nursing assistants, and ward clerks. These medications will be immediately placed in an approved medication storage area.

d. PRESCRIBING/PROFILE REVIEW/ALLERGY REVIEW:

- (1) <u>Required Elements of a Prescription:</u> Prior to dispatching any handwritten or Class II (**CII**) **Prescription Form**, VA Form 10-2577F, to the Pharmacy for dispensing, the following entries on the prescription form will be completed in a legible manner:
 - (a) Patient's full name, social security number, and current address.
- (b) Indicate the patient's status by circling or checking the appropriate patient program symbol.
- (c) Generic name of prescribed medication, concentration or strength (metric is preferred), quantity (both numeric and alphanumeric preferred for prevention of diversion), route of administration, dosage schedule or frequency, and number of refills. "As directed" or "as often as necessary (prn)" alone are not considered to be specific directions and are not acceptable. "With meals" alone is not considered to be specific information for a dosage schedule or frequency, i.e., some people may eat two meals a day.
- (d) Each prescription must have the prescriber's legible signature, name stamped, typed or printed in addition to the signature, complete Drug Enforcement Administration (DEA) number (if the drug is a controlled substance), and issue date (presigned and/or postdated prescriptions are not acceptable).

- (e) The prescription label for all outpatient prescriptions, including discharges will meet all of the legal labeling requirements.
- (2) Orders requiring signature must be signed by an authorized prescriber, using legal name and signature. Stamped (without accompanying signature) or pre-signed prescriptions are not permitted. **Date on the prescription must be the** *issue date* **of the prescription.** Any unsigned or incomplete prescription will be voided and filed in the vault along with other 10-2577F forms. The physician will be contacted, informed that the prescription has been voided with the reason for voiding, and requested to re-issue another prescription that is completed appropriately. *Prescriptions for CII controlled substances must bear the full name, address and social security number of the patient, issue date, as well as the DEA number of the provider*

NOTE: Physicians may use the VA assigned suffix where the physician is using the VA DEA number (the VA assigned suffix is the first letter of the last name and the last four digits of the provider's social security number). Mid-level practitioners may not utilize the VA DEA number, but instead must use their own DEA number provided to them by their state licensing board and the provider's name typed, printed, or stamped in addition to the provider's signature.

Note: All providers should immediately begin the personal DEA application process in preparation for the next version of CPRS will require the use of personal DEA numbers personal DEA numbers may be obtained with the fee waived for federal providers as long as they are functioning as a federal provider. Provider PIV cards should also be fully functional.

- (3) Electronic signatures may be used for prescribing controlled substances and all other pharmaceuticals for inpatient use.
- (4) Physicians and other authorized prescribers should prescribe drugs by the medications generic name (primarily applies to handwritten orders, as CPRS will only allow ordering by generic name). The generic name will be used in place of the trade or brand name for all labeling purposes.
- (5) <u>Documentation of Diagnosis</u>, <u>Condition</u>, <u>or Indication for Use:</u> Prior to the writing of any medication order or prescription, the patient's medical record must reflect a documented diagnosis, condition, or indication for use of all medications. The indication for use is highly encouraged, but not required, on all orders and prescriptions in order to aid in patient education and to decrease medication error potential (see section on PRN medication orders).
- (6) Physicians who see patients in the Emergency Department after normal duty hours will determine the kind and amount of medication to be issued in accordance with their professional judgment of the patient's need and with the intent of this policy as stated above. Patients who return during irregular hours for the express purpose of obtaining medication refills should be given only the medications needed to sustain their medical needs until the following workday. Controlled substance fills for any requirement other than an <u>acute</u> injury/illness through the Emergency Department after hours is to be avoided. The normal route of medication dispensing

should be the normal route of obtaining these medications. Narcotic pain and benzodiazepine contracts are required on all chronic use patients receiving these medications for a period longer than ninety days per policy entitled "Management of Opiates and Benzodiazepines for Chronic Use."

- (7) <u>Verbal or telephone orders</u> are limited to emergency situations, unavoidable absence of the authorized provider (e.g., home call), for pain control or sedation during procedures, or if CPRS is not available. Orders may be accepted by an RN, Pharmacist, or other practitioner granted a Scope of Practice to accept such an order. The order, either verbal or telephonic, is entered into the medical record and indicates the provider making the order.
- (a) To assure accurate transcription of verbal or telephone orders, the individual accepting such orders will utilize a process of "read-back" verification of the complete order to the authorized provider and require a confirmation of the read-back order before releasing or implementing the order. Verbal orders for the administration of pharmaceuticals require that a provider sign a verbal or telephone order within 24 hours.
- (b) Verbal orders for respiratory care services. Although direct entry by physicians of patient orders into the computerized medical record is desirable and strongly encouraged, it is within the Functional Statement of Respiratory Therapists (RT) to receive verbal orders from physicians regarding initial settings or changes in mechanical ventilator parameters and respiratory medications or other verbal orders to the physician for confirmation, and then enter the orders into the medical record.
 - (c) All non-verbal orders for treatment are entered into CPRS, dated and signed.
- (d) All orders for treatment will be administered only on the properly executed order of a member of the Medical Staff, medical or dental house staff with privileges to write orders, or other practitioners granted a Scope of Practice to enter such orders. Medical students cannot enter orders.
 - (e) Verbal orders via voicemail are not acceptable;
 - (f) Only approved abbreviations are used in the documentation of verbal/telephone orders;
- (g) Pharmacists may call non-VA providers to clarify/edit/change non-VA prescriptions for Fee Basis patients. These must be recorded, read back to the provider to assure accuracy of the order, and to avoid incorrect transcription. The verbal order function in CPRS may also be utilized to electronically send an order needing clarification to a provider for his/her electronic signature; and,
 - (h) Chemotherapy orders may NOT be given via telephone/verbal orders.

- (8) <u>Resume orders/standing orders</u>: A blanket reinstatement of previous orders (i.e., resume orders) and standing orders for medications is not acceptable.
- (9) <u>Medication-Related Devices and Supplies</u>: Logistics Service provides orders for expendable supplies (e.g., catheters, ostomy products, testing supplies) for all inpatients. Prosthetics Service provides medical devices. Pharmacy Service provides expendable medication-related supplies for outpatients.
- (10) <u>Compounded medications</u>: Orders for compounded drugs or drug mixtures not commercially available will be evaluated and approved on a case-by-case basis by the Pharmacy and Therapeutics (P&T) Committee, including initial literature review of the product and any commercially available and viable options. If approved by the P&T Committee, Pharmacy Service will compound if possible and appropriately label the product according to all United States Pharmacopoeia (USP) recommended guidelines. Any outsourcing based on a patient-specific prescription to a compounding pharmacy for Sterile Product Preparation will be through a State-Licensed and Pharmacy Compounding Accreditation Board (PCAB) accredited pharmacy. Any outsourcing based on batched sterile preparations (non-patient-specific IV's) will only be procured by an FDA-registered manufacturer after any and all FDA safety concerns with the company have been reviewed and resolved.
- (11) Herbal products and dietary supplements will not be normally provided to either inpatients or outpatients at the VA at present, but should be documented in the "Non-VA Med" package for all patients taking these for reference. Documentation of "Non-VA Meds" allows automatic order checks against orders for medications the patient will receive from the VA. Select dietary supplements (i.e., those that are sufficiently understood and prepared and labeled according to the same standards used for regular pharmaceuticals (e.g., certain vitamins, minerals, and nutraceuticals, but NOT herbal products) may be made available through TVHS on either a formulary or non-formulary basis at the discretion of formulary decision makers (i.e., National Formulary) via the standard formulary process. Any nutritional supplements approved by the National Formulary and provided by TVHS should have the USP seal to verify/validate good manufacturing practices.
- (12) <u>Hold policy</u>: Providers may place inpatient medication orders on hold for a specific number of days, doses, or dosing intervals. The pharmacist will discontinue the order and enter a new order to start at the appropriate time. If an order is written to hold a medication within certain clinical parameters (i.e., hold digoxin if pulse is <50), the nurse will mark the medication as "held" in Bar Code Medication Administration (BCMA). This medication can be "unheld" later and this action will not affect the next scheduled administration time. Orders written to be "on hold" for an unspecified time will be discontinued and sent back as a verbal order to the provider. Providers wishing to resume orders that were held due to a procedure will need to enter new orders. Providers may order outpatient medications with "Fill on Request" in the comments field. The pharmacist will process the order with a status of "HOLD." The patient or provider will need to contact Pharmacy to get the prescription changed to an ACTIVE status so

that it can be filled or refilled by Pharmacy. A HOLD order cannot be filled, refilled, renewed, or changed in CPRS. A HOLD order is also not visible to the patient in My HealtheVet.

(13) <u>As Needed/PRN/Range Order policy:</u> "As needed" or PRN orders and prescriptions for medications must have an indication for use to be present on the order or prescription in order to be considered a valid order in this healthcare system. PRN orders or prescriptions for medications that do not contain an indication for use will be discontinued by the pharmacist by way of "SERVICE REJECT". The provider will be required to enter a new medication order in CPRS with the required indication in order to be acted upon further.

In the inpatient setting, PRN pain medications should specify parameters for administration. Parameters should be based on VA TVHS approved pain rating scales as noted in the TVHS Memorandum on Pain Management. An appropriate pain rating scale can be determined by utilizing the Memorandum on Pain Management, Algorithm of Pain Assessment Techniques.

Range orders, e.g., 1-2 tablets q4-6 hours prn are not permitted on inpatient orders due to incompatibility with the BCMA program and nursing practice acts. Pharmacy will change the order to the lower dosage strength at the most frequent time interval prescribed for the order. The above example would be input as "take 1 tablet every four hours as needed."

- (14) <u>Tapering orders</u>: Inpatient tapering orders are created with separate orders that have unique start and stop date/times via order sets that we have such as "medrol dosepak" for each step of the taper. This is crucial to prevent different parts of the taper to be administered simultaneously. Outpatient tapering orders could generate one or multiple prescriptions, depending on the taper. For example, the terazosin taper would create two separate prescriptions, one for the 1mg qhs x 7 days then 2mg qhs for 7 days (based on the dispense drug terazosin 1mg) and a second prescription for 5mg qhs (based on the dispense drug terazosin 5mg). Outpatient tapering orders would generally have the same issue date, but the pharmacist may suspend one or more of the orders to be filled at a later date.
- (15) <u>Titrating orders:</u> Titrating dose orders are generally the same for inpatient and outpatient. An example of this would be "sliding scale insulin." Only one order is generated. The "comments section" for an inpatient order or the Sig for the outpatient order will list specific amounts of drug to be administered based upon a measurement outcome.
- (16) <u>Multiple routes of administration</u>: Orders for multiple routes of administration must be entered by the provider as separate medication orders, (e.g., By Mouth (PO)/Intramuscular (IM)/Per Rectum (PR)) must be entered as three separate medication orders, one for the PO route, one for the IM route, and one for the PR route of administration. These multiple routes of administration cannot be entered as comments in one medication order. If only one order is placed, the pharmacist will finish one medication order for one route of administration and notify the provider placing the order that two more orders will need to be placed.

- (17) <u>Quick orders/order sets/preprinted order sheets:</u> Providers authoring "personal" order sets/quick orders/preprinted order sheets should review these and update them as required to support clarity, accuracy, and safety.
- (18) <u>Discharge prescriptions:</u> Outpatient orders for patients being discharged will be written at least three hours prior to discharge and action taken on them, (e.g., renewed, edited, discontinued, etc.) as appropriate to the patient's required post-discharge medication needs.
- (19) Using standard drug information references, patients will be observed for an appropriate period of time for clinical effects and side effects if any medication is administered in the ambulatory care setting.
- (20) <u>Allergy status/documentation</u>: All clinical staff, prior to administering medications and when the patient is admitted to the hospital or reports to a clinic visit, will interview the patient (if possible, i.e., unless patient is unconscious or patient/caregiver is otherwise unable to respond) to obtain and enter any information pertaining to the patient's allergy history into the patient's electronic medical record. An alert in CPRS will display if a provider attempts to electronically sign medication orders when there has been no allergy assessment completed for that patient.
- (21) Pharmacists will assess the prescribed drug regimen for allergies before processing both inpatient and outpatient prescriptions.
- (22) It is the responsibility of every health care provider to document observed or reported allergies or adverse drug events in the allergy package. Medication orders will be assessed for allergies before provider order entry in CPRS, processing by the pharmacist, and administration at the unit or clinic level.
- (23) Prescriptions ordered at another VA facility must be assessed and reordered as deemed appropriate by a VA provider at TVHS.
- (24) Physicians, residents, and other authorized prescribers are required to clear station via pharmacy both for deactivation of their name in the Veterans Information System & Technology Architecture (VistA) provider file and to return unused prescription pads. The Pharmacy Service Administrative Office, Nashville campus, will be the clearing point. The provider will be deactivated in the provider file (VistA) and taken out of the automated dispensing devices immediately where applicable.
- (25) <u>Look Alike/Sound Alike (LASA) medications:</u> Medications, where there is potential for LASA medication errors as determined by the P&T Committee, have been entered into the computer in a form consistent with LittleMan Lettering to aid in prescribing. Pharmacy also marks shelves with this lettering, both in the Pharmacy itself and on the wards/clinics and physically separates these potentially dangerous medications (refer to list on CPRS Tools/BCMA Tools). The Pharmacy & Therapeutics Committee review this list annually.

- (26) In regards to Home Care, a list specifically applicable to the needs of patients in the home is likewise reviewed and approved by Home Based Primary Care (HBPC) and the P&T Committee. LASA medications are identified in the pharmacist's admission and quarterly reviews. They are also addressed during medication reconciliation with each visit to the Veteran's home. For LASA medications, if the patient is on both types' medications, they are as separated as possible and the patient and/or caregiver are educated.
- (27) <u>Standardized Drug Concentrations:</u> Intravenous (IV) drug concentrations will be reviewed by the P&T Committee and standardized throughout TVHS. The list of standardized concentrations will be posted on CPRS Tools/BCMA Tools for ready retrieval and use.
- (28) <u>Abbreviations</u>: Approved abbreviations for use in TVHS may be found in the Medical Center Memorandum on Symbols and Abbreviations Used in Medical Records. No abbreviations listed on the TVHS Unapproved Abbreviation List may be used in the medical record (refer to list found on CPRS Tools/BCMA Tools). If abbreviations listed in the facility's Unapproved Abbreviation List are used in medication orders or prescriptions, the pharmacist will call and request that the provider clarify the order.
- (a) The use of all abbreviations is discouraged. Write out instructions, (e.g., write "daily" rather than "q.d.," that could be misinterpreted as q.i.d. or as o.d.). Spell out the word "units" (e.g., 10 units regular insulin) rather than writing "u," which could be misinterpreted as a zero.

Using the abbreviation " μ g" instead of "mcg" has also been the source of errors because when handwritten, the symbol " μ " can look like an "m."

- (b) The use of trailing zeros (e.g., 2.0 vs. 2) or use of a leading decimal point without a leading zero (e.g. .2 instead of 0.2) are other dangerous order writing practices. A terminal zero should never be used (e.g., 5.0 ml), since failure to see the decimal could result in a tenfold overdose.
- (c) Do not use vague instructions, such as "take as directed," because specific instructions can help differentiate among intended drugs.
- (d) Specify exact dosage strengths (such as milligrams) rather than dosage form units (such as one tablet or one vial), with the exception of combination products, for which the number of dosage form units should be specified.
- (e) Avoid using locally coined names (e.g., Dr. Doe's syrup); chemical names (e.g., 6-mercaptopurine (instead of mercaptopurine) could result in a six fold overdose if misinterpreted); un-established abbreviated drug names (e.g., "AZT" could stand for zidovudine, azathioprine, or aztreonam); acronyms; and apothecary or chemical symbols.

- (29) Prescriptions will be prescribed for up to the maximum of 1 year except for those prescriptions limited by regulation, (e.g., 6 months for controlled substances CIII-V and 30 days for CII prescriptions or according to approved local or VISN 9 restrictions.)
- (30) <u>Investigational Medications</u>: Authorized providers may order investigational drugs using routine procedures for ordering other medications (see specific section in this policy on Investigational Medications). A copy of the order and a copy of a signed consent form must be in the possession of the pharmacist before the investigational drug will be dispensed. Investigational drugs will be stored and dispensed by TVHS pharmacy only.
- (31) <u>Medication Sources:</u> All medications for use in TVHS for the care of TVHS patients will be procured by the TVHS Pharmacy Service. Practitioners are not permitted to acquire medications from sources other than the TVHS Pharmacy Service for the care of patients at this facility.
- (32) <u>Emergent (up to 10 day) Prescriptions in Specified CBOCs</u>: Where contracts are in place with specific CBOCs for provision of emergent prescriptions, all prescriptions issued to patients to be dispensed by contracted private pharmacies will be input by the providers into the CPRS non-VA medication program for documentation and subsequent order checks.
- (33) <u>High Alert Medications</u>: A list of High Alert Medications (located in CPRS Tools/BCMA Tools, Medication Management Section) that will pose a risk of adverse effect if not prescribed, dispensed or administered with extreme care will be maintained by the P&T Committee. When a medication from this list is placed in the pharmacy stock, the container and storage shelf will be labeled with a HIGH ALERT medication auxiliary label. The label will be placed on the medication container, NOT on the box or carton containing the medication container. High Alert medications dispensed from the automated unit dose packing equipment will have each dose labeled as "high alert medication" by the automated equipment. A Clinical Drug Category warning will be placed on all High Alert medications in the Pyxis® system. High alert medications will undergo BCMA scanning, where available, and medication order verification. All health care providers administering high alert medications in-group 1 (Hospital list) will conduct an additional double verification on administration of the dose or infusion rate with documentation in the medication administration record.
- (34) In regards to **Home Care**, a list specifically applicable to the needs of patients in the home are reviewed and approved by the Home Based Primary Care (HBPC) and P&T Committee. High alert medications are identified in the pharmacist's admission and quarterly reviews. They are also addressed during medication reconciliation with each visit to the Veteran's home. In regards to high alert medications, the team is aware and monitors and the patient/family is educated about the medication and monitoring parameters.

e. **DISPENSING:**

(1) All medications in this institution will be dispensed by a licensed pharmacist or their by designee under the direct supervision of a licensed pharmacist. Licensure will be verified to be in good standing with the respective Board of Pharmacy. Each medication order is reviewed and verified by the dispensing pharmacist prior to dispensing, including orders for medication prepared by non-pharmacist personnel under the pharmacist's purview. Pharmacists, whenever there is need for clarification of an incomplete, illegible, or unclear medication order, will contact the provider for clarification prior to dispensing the medication. There are two allowable exceptions regarding the administration of medications prior to a pharmacist's review of the order. The first exception is in situations in which the licensed independent practitioner controls the ordering, preparation, and administration of the medication, such as in the operating room, endoscopy suite, and Emergency Department. The second situation is in urgent situations when the resulting delay would harm the patient. These include immediate (STAT) orders or those doses where the clinical status of the patient would be significantly compromised by the delay that would result from the pharmacist review (for example, new onset of nausea).

NOTE: Not all first doses meet this criteria and in no circumstance shall a medication nurse administer or prepare to administer (i.e., remove from automated dispensing units or floor stock) non-STAT medications to be administered prior to a pharmacist's review of the order.

NOTE: When a nurse is required to bypass the pharmacist review, a second nurse will verify the order and the medication prior to administration (unless a true emergency or "code" situation exists).

- (2) Only a licensed pharmacist or his/her designee under the direct supervision of a licensed pharmacist is authorized to prepare medication dosage forms, prescription and/or IV labels, labeling changes, or transfer medications to different containers. All labeling requirements will be observed in the transfer of medications to different containers.
- (3) In rare instances, and in concurrence with the Chief, Pharmacy Service, a physician credentialed as a member in good standing of TVHS's medical staff may dispense a medication in accordance with all hospital rules and regulations in addition to all Federal laws relating to the dispensing of medications.
- (4) It is the policy of Pharmacy Service to mail **all** prescriptions that can be mailed through the Consolidated Mail-Out Pharmacy (CMOP) system. Only those that are not available from CMOP or those that cannot be delayed for CMOP to mail, will be filled at the window. Refills should be requested **at least 14 days prior to running out of medication by:**
 - (a) Calling the "Dial-A-Refill" at 1-866-786-9367;
 - (b) Mailing in their signed refill slip(s);
 - (c) Dropping off the refill slip at the window for mailing of the prescription(s); or,

(d) Using the My HealtheVet Internet Refill option.

f. ADMINISTRATION/BARCODE MEDICATION ADMINISTRATION (BCMA):

- (1) The following employees are authorized to administer medications, IV admixtures, and IV fluids to patients:
 - (a) Physicians (Staff, Attending, Without Compensation (WOC), Residents);
 - (b) Dentists (Staff, Attending, WOC, Residents);
 - (c) Podiatrists (Staff, Attending, WOC, Residents);
 - (d) Respiratory Therapists (Inhalation Therapy only);
- (e) Students (Medical, Nursing, Radiology Technician (RT), etc. under the direct supervision of the respective professional);
 - (f) Code 500 Personnel (according to Advanced Cardiac Life Support (ACLS) protocol);
- (g) Technicians (X-Ray, X-Ray Technician (XRT), Nuclear Medicine, etc. under the direct supervision of the physician conducting the procedure); and,
- (h) Nurses (Registered Nurse (RN), Advanced Registered Nurse Practitioner (ARNP) all) (Licensed Practical Nurse (LPN), Graduate Nurse (GN), Graduate Practical Nurse (GPN) oral meds only) see nursing IV Therapy procedures for further information.
- (2) The BCMA package is to be utilized without fail in all applicable areas on all medication administration transactions unless the system is inoperable or in an immediate code situation. The patient's identification (ID) band should be scanned to bring up the patient's profile in BCMA and the medication scanned *immediately* prior to administration. Pharmacy should be immediately notified of any medication that is not scannable or issue surrounding an inability to properly scan a medication so that it may be addressed appropriately.
- (3) After successful competency validation medications approved for administration by IVP may be given by: acute medical, surgical, psychiatric inpatient units, specialty care clinic registered nurse staff, and long-term care registered nurse staff. Upon receipt of a complete order and when noted in Attachments A and B ordered within the parameters of approved dose ranges (consult drug references and manufacturer's guidelines for preparation, dilution, and administration information prior to administration). All other IVP medications will be administered by the physician in the acute medical, surgical, psychiatric inpatient units and areas, specialty care clinics, and long-term care areas. Exceptions to this policy include registered nurse staff in MCCU, Cardiac Cath Lab, GI Lab, ER, MICU, PACU, OR, Bone Marrow Transplant, and SICU (due to validated competency upon entry into critical care areas).

- (4) Medication and IV admixtures/IV fluids may be administered to patients pursuant to an existing provider's order and verification by a licensed pharmacist as above. This policy does not limit nor prohibit services from restricting individual service personnel from administering specific medication/types of medication dependent on personnel qualifications and/or resources.
- (5) When the BCMA program is unavailable and prior to administration of any medication, the person administering that medication will verify the order (or verified paper Continuing Medication/Treatment Record (CMT)) against two patient IDs: the patient's ID band and verbally asking the patient's name if the patient is conscious or verifying the patient's identify with a family member, another caregiver, or photo ID. Documentation of administration on the CMT by the nurse indicates that he/she has checked two patient ID's, medication administered, dose to be administered, time of dose to be administered, and route to be administered.
- (6) High alert medications will undergo BCMA scanning, where available, and medication order verification. All health care providers administering high alert medications in-group 1 (Hospital list) will conduct an additional double verification on administration of the dose or infusion rate with documentation in the medication administration record.
- (7) Before administering a medication, the Licensed Independent Practitioner (LIP) or appropriate health care professional administering the medication does the following:
- (a) Verifies that the medication selected for administration is the correct one based on the medication order and product label.
- (b) Verifies that the medication is stable based on visual examination for particulates or discoloration and that the medication has not expired.
 - (c) Verifies that there is no contraindication for administering the medication.
- (d) Verifies that the right medication is being administered to the right patient, at the right time, in the right dose, by the right route, and adhering to any special instructions pertaining to administration such as crushing tablets or giving with applesauce, etc.
- (e) Advises the patient, or if appropriate the patient's family, about any potential clinically significant adverse reaction, or other concerns about administering a new medication.
- (f) Discusses any unresolved, significant concerns about the medication with the patient's provider and/or relevant staff involved with the patient's care, treatment, and services.
- (8) Self-Administration of Medications: patients in the hospital and residents in long term care areas have the right to *self administer* medications when ordered by an LIP. When patients and/or residents request to self-administer medications, the treatment team evaluates their request, determines their ability to do so safely, and provides training and appropriate information about the following:

- (a) The nature of the medication to be administered;
- (b) How to administer medications, such as the appropriate frequency, route of administration; and dose.
 - (c) The expected actions and side effects of the medications to be administered; and,
 - (d) How to monitor the effects of the medications on the patient.
- (9) Self-administered medications will be kept in the medication cart and controlled by nursing personnel, as are all medications. These medications, even though self-administered by the patient, will still have administration documented in BCMA by the nurse overseeing the self-administration process.
- (10) <u>Monitoring of Medication First-Dose Administration</u>: Persons authorized to administer medications will monitor a patient's vital signs and any sign of adverse reaction following the first dose of any medication new to a patient for the first hour and during the infusion of said drug or blood product. Monitoring a medication's effect on a patient includes the following:
- (a) Gathering the patient's own perceptions about side effects, and when appropriate, perceived efficacy;
- (b) Referring to information from the patient's medical record, relevant laboratory results, clinical response, and medication profile, in particular actual or potential medication-related problems.
- (11) A patient's response to medications is documented in the physician's progress note, nurse's notes, lab results, vital sign sheets, Intake & Output (I&O) sheets, and/or BCMA records.

g. OUTPATIENT PRESCRIPTIONS:

- (1) The Outpatient Pharmacy prescription label will include:
- (a) Name, city, and phone number of the facility;
- (b) Full name of the patient and patient identifier number;
- (c) Prescription number assigned to the prescription;
- (d) Date that the prescription was filled or refilled;
- (e) Generic drug name;

- (f) Quantity of drug dispensed;
- (g) Drug strength and dosage form;
- (h) Directions for use;
- (i) Provider's name;
- (j) Code number of the pharmacist who finished the prescription;
- (k) Beyond-use date; and,
- (l) Any warning or other auxiliary labels as required by law or by currently accepted standards of practice.
- (2) If a prescription requires multiple units of issue to be dispensed, (e.g., more than one prescription vial, box, bottle, etc.) each unit to be dispensed will have a label appropriately affixed. For example, a patient receiving a prescription for a quantity of two albuterol Metered Dose Inhalers (MDI) will receive the two boxes both labeled with a prescription label.
- (3) Discharge prescriptions, (i.e., electronic order(s)), must be in outpatient pharmacy at least three hours prior to time of patient discharge, to allow pharmacy sufficient processing time.
- (4) On non-controlled substances, medication quantities will not exceed a 90-day supply, no more than 12 months of refills will be authorized, and no prescriptions over 12 months old will be filled/refilled, regardless of the number of refills authorized or remaining refills unused. Controlled substances (CIII-V) may not exceed six months of fills and will only be filled in 30 days or less increments, i.e., no 90-day supplies will be issued on controlled substances (CIII-V). CII controlled substances will have zero refills and must be rewritten on every fill. Quantities will not exceed a 30-day supply on CII prescriptions.
- (5) All prescriber actions for outpatient prescriptions must be entered electronically using the CPRS system. EXCEPTIONS: Prescriptions may be handwritten on the prescription form, VA Form 10-2577F or on the Outpatient Action Profile only in cases where; 1) CPRS is not functional or 2) VA Form 10-2577F is required for all CII prescriptions. CII prescriptions may be electronically entered by the provider but will *not* be processed or dispensed by the Pharmacy Service without the accompanying hard copy. Authorized Fee Basis patients will be processed by way of hard copy private prescription forms. Outpatient prescriptions will be entered for any new medication order and any changes in dosage, direction, or quantity.
- (6) Pharmacists will participate in a multidisciplinary approach to assist with patient medication education. Pharmacists will offer to counsel on all new outpatient prescriptions. Verbal counseling will be utilized when possible and each new prescription will also have a printed information sheet included with the medication at the time of dispensing. Information

provided to the patient, at minimum, will include indication, proper use, and possible side effects of the medication. Upon patient counseling, pharmacists will request a patient history on all herbal products, dietary supplements, medications received from a source other than the VA, home remedies, and over-the-counter (OTC) medications taken by the patient, but not provided by the VA. If the patient is taking these products, the pharmacist will enter these in the "Non-VA Med" section of CPRS. Pharmacists may place a medication on hold at the patient's request.

- (7) Only patients or their caregiver may pick up medications. The VA ID card or other photo ID must be presented by the patient or caregiver to pharmacy personnel. When available, the Veteran's VA ID card **must** be scanned into the ScriptPro Checkpoint for verification of the medications (if not available, patient should be advised to obtain one prior to next medication pickup). Pharmacy personnel **must** also ask the patient or caregiver to recite the patient's name and address (date of birth may also be checked) at **minimum** prior to medications being given to patient or caregiver. Name and address recited will be checked against **all** medication bags before dispensing these to the patient. They may additionally ask for other patient information where required in order to verify accurate dispensing of medication. Pharmacy personnel should utilize open-ended questioning techniques in verifying identification, i.e., do not state the name and address to have the patient confirm, rather ask the patient to state this information so as to prevent incorrect dispensing of medication at the pick-up window.
- (8) Copayments and e-Pharmacy: A copayment will be charged for each 30 day (or less) supply on all non-service connected outpatient prescriptions and all service connected conditions less than 50 percent, which are not prescribed to treat a service connected condition, as required by law. Service connected patients in the 50 percent or greater category will be exempt from copay. However, all non-service connected prescriptions will be marked as non-service-connected and will be charged to the private prescription insurance of the service-connected patients. Any charge for non-service connected medications not covered by private prescription insurance will be billed by VA to the non-service-connected and service-connected less than 50 percent Veteran.
- (9) No home intravenous therapy may be dispensed by TVHS Pharmacy to an outpatient. A contract with a Joint Commission-accredited home infusion company must be in place.
- (10) ScripTalk® labels: Patients, who have been approved on consult as vision-impaired and meeting specific criteria, will have the ScripTalk® key activated and be provided ScripTalk® prescription labels on all original and refill prescriptions. A pharmacy technician will first label the prescription vial with the label from the ScriptPro® system, generated from the SP200 or from the workstations. The pharmacy technician will then obtain the ScripTalk® label and place it with the prescription for pharmacist checking. The pharmacist will then scan the ScripTalk® label with the reader to verify that the verbal information agrees with the label printed information. The pharmacist will then place the ScripTalk® label over the ScriptPro® label. It is important that reader verification be done before the ScripTalk® label is affixed. This is to ensure that the label will be able to be read by the patient's reader at home. (Refer to Memorandum on Audible Prescription Reading Device (ScripTalk®) for additional information.)

h. <u>INPATIENT – UNIT-DOSE/BCMA:</u>

- (1) Active outpatient prescriptions will not be automatically cancelled in the VistA system following an admission. It shall be the responsibility of the discharging prescriber to order, renew, and discontinue outpatient medications per individual patient needs.
- (2) Medications will NOT be dispensed to patients, employees, or visitors from medication stock on wards or in the clinics.
- (3) All medication orders for individual patients will be entered electronically via CPRS (primary and required route when available), on VA Form 10-1158, (Doctor's Orders) when CPRS is unavailable, or by using approved overprints and are a permanent part of the patient's record. Orders will be written in indelible ink or signed electronically.

NOTE: Medication orders may NOT be placed in the Nursing Text Order section, Progress Notes, or the Consult section of CPRS. Orders placed in these areas of the medical record will NOT be accepted by Pharmacy or Nursing Service as medication orders.

- (4) Each medication order/medical record should contain the following information and the pharmacist will review the following where applicable for accuracy:
 - (a) Patient Identification and location;
 - (b) Drug Name (generic);
 - (c) Strength or Concentration;
 - (d) Dose (use of metric units is encouraged);
 - (e) Route of Administration;
 - (f) Dosage Schedule or Frequency;
 - (g) Provider comments (where applicable);
 - (h) Date/time each set of orders is written; and,
 - (i) Prescriber's electronic or legal signature.
- (5) Additional review of doctor's orders by the pharmacist will include the following as applicable (problems uncovered in the review process will be addressed to the individual prescriber with appropriate alternatives in mind; any discrepancies in order entry, incomplete, illegible or unclear orders will be clarified with the prescriber and corrected before any drug is dispensed).

Service corrections will be done by licensed pharmacists wherever a change is required and the intent of the order is not compromised:

- (a) Therapy indications;
- (b) Allergy status and past sensitivities;
- (c) Sex of the patient;
- (d) Weight and height as appropriate;
- (e) Age-specific considerations;
- (f) Pertinent laboratory tests;
- (g) Diagnoses, comorbidities and concurrently occurring conditions;
- (h) Current medications;
- (i) Drug appropriateness;
- (j) Dose and scheduling appropriateness;
- (k) Drug contraindications;
- (l) Potential drug interactions between the medication and other medications, food and relevant lab values;
 - (m) Drug incompatibilities or duplications;
 - (n) Cost containment factors;
 - (o) Drug's formulary status and if proper approvals have been received;
 - (p) Duplication of therapy;
 - (q) Potential misuse of medications;
 - (r) Pregnancy and lactation status where appropriate; and,
 - (s) Other considerations that are required for safe medication management.

NOTE: This information is available to all health care professionals that provide for the care of the particular patient in question.

- (6) Specific drugs, due to their pharmacokinetic properties, should be dosed at evenly spaced intervals throughout a 24-hour period. These specific drugs will be dosed at evenly spaced intervals regardless of how the order may be written. Drugs that require evenly spaced intervals will be administered every 12 hours versus twice a day, every 8 hours versus three times a day, every 6 hours versus four times a day, etc.
- **NOTE:** The pharmacist will change all Twice Daily (BID), Three Times Daily (TID), Four Times Daily (QID), etc., orders for antibiotics, antiarrhythmics, antihypertensives, antianginal (except nitrates), anticonvulsants, and bronchodilators to every 12 hours, every 8 hours, every 6 hours, etc. If the provider wants to make an exception to this policy, he/she must state so in the order. Exceptions to this will be the pre- and post-op antibiotics that will be given exactly as prescribed by the provider in the comments section such that appropriate discontinuation times will be observed.
- (7) Patients on phenytoin suspension, because its bioavailability is decreased in patients receiving concomitant enteral feedings, should have their enteral feedings interrupted two hours <u>before</u> and <u>after</u> the dose of the suspension, if their nutritional status allows. The feeding tube should be irrigated with 60 ml of saline before and after the phenytoin dose is given to improve absorption; nevertheless, the patient may still require an increase in phenytoin dosage. If the feedings are discontinued after the phenytoin dosage is increased, the dosage must be adjusted to prevent toxic plasma levels from occurring.
- (8) Where paper Medication Administration Records (MARs) must be in use, as in when BCMA is unavailable, no corrections will be made by crossing through orders or by inserting items after the order has been transcribed by ward personnel or pharmacy.
- (9) All medication or pharmacy items may be administered to the patient only after an order is written by an authorized prescriber and verified by pharmacy before dispensing (see exceptions to this in E(1) above). Qualified and licensed personnel will use the BCMA computerized electronic medication administration record to chart each dose of drug given to a patient. During instances where BCMA is unavailable, a paper MAR is required for each patient. The paper MAR is a permanent part of the patient's record. In no instance will a placebo, medication treatment, pain medication, etc.; be given without the knowledge and approval of an authorized prescriber.
- (10) Orders for patients transferred from ward to ward or facility to facility will not be automatically cancelled, but will be reviewed and re-authored as required by the treating provider. Medications are transferred with the patient to the receiving ward by the transferring nurse (this includes all by mouth (PO) or specialty medications IV medications will be sent back to the Pharmacy for relabeling).
- (11) Automatic stop orders exist on specific medications ordered at this medical center, as approved through the Pharmacy and Therapeutics Committee. Providers will be notified of all automatic stop orders by way of a computerized alert in CPRS. For areas, using automated

MARs and databases; stop order notices will be used and may be generated by each ward. Time limits are imposed on the following items:

- (a) Orders for Schedule II and Schedule III narcotic substances to be administered to patients from unit dose or ward stock will be written for periods not to exceed seven days. Exceptions may be made if the responsible staff practitioner has evaluated the patient's condition and determined there is a need for a longer duration of therapy. In such cases, the practitioner may prescribe for a period not to exceed 14 days if the practitioner indicates a specific length of therapy or number of doses in the individual patient's order.
- (b) Clozapine: 14-day stop date. (Clozapine can now be prescribed up to 28 days depending on if Veteran meets requirements (7, 14, 28 days are the options).
 - (c) Enoxaparin/Dalteparin/Tinzaparin/Fondaparinux: 14-day stop date;
 - (d) Ketorolac: 5-day stop date;
 - (e) Medrol® dosepak: 18 doses;
 - (f) Vaccines: one dose;
 - (g) Sildenafil/vardenafil (unless pulmonary HTN): four doses/30 days;
 - (h) Neuromuscular blocking agents: 1 day;
 - (i) Acetylcysteine contrast pre-op: four doses;
 - (i) Acetylcysteine: 3 days;
 - (k) Linezolid: 10 days;
 - (1) Dronabinol: 3 days;
 - (m) Phytonadione: 3 days;
 - (n) Norepinephrine: eight doses;
 - (o) Skin tests: one dose;
 - (p) Respiratory agents: Three days;
 - (q) Digoxin immune FAB: one dose;
 - (r) Lomustine: one dose;

- (s) All other orders will expire in 28-days. An evaluation and a reorder are required to continue therapy. All orders must be renewed electronically in CPRS by a provider. Writing only "renew orders" or "continue previous medication" is <u>NOT</u> permissible.
- (t) Orders for residents of Nursing Home Care Unit (NHCU) will expire after 28 days, except as noted above. There will be documented reviews of orders each month by provider (i.e., physician, Advanced Practical Nurse (APN), or Physician Assistant (PA)), staff nurse, and pharmacist.
- (u) All antibiotic and albumin orders, when written, must have the number of doses or days of therapy before pharmacy acceptance.
- (12) Orders for STAT/Now should be called/referred to the pharmacist at extension 67660 (Nashville) or extensions 24600 (York) for processing. The pharmacist must be notified by phone or pager of STAT/NOW orders. Orders prescribed as "STAT" will be delivered in 30 minutes or less from receipt of order by pharmacy and must be a legitimate "STAT" order. "Now" orders will be delivered in one hour or less from receipt of order, and must be a legitimate "now" order.

The following items are generally **not** considered STAT drugs and will automatically be handled as regular orders unless specific direct communication between the provider and pharmacist occurs:

- (a) Suppositories;
- (b) TPN orders;
- (c) oral medications;
- (d) Irrigation solutions; and,
- (e) Chemotherapy.

NOTE: Legitimacy will be determined by the pharmacist, and if needed, provider interaction. All other orders will begin at the scheduled administration time following receipt of order by pharmacy appropriate for that drug.

- (13) Orders prescribed, as "on call" will be medications given per schedule or series of schedules only before going to surgery or procedure. All other orders will be cancelled and must be rewritten upon return to a ward. If a patient is given a pre-op or prescribed an "on-call" medication and does not go to surgery for some reason and returns to room, then orders must be rewritten.
- (14) Standardized Medication Administration Times are as follows (all inpatient orders will be administered in accordance with the standard administration times unless otherwise specified

by the prescriber when a medication is ordered). Inpatient units may have their specific unit set up to default to other administration times if their meal times, etc. vary considerably from the above 'universal' listing.

5X-DAILY	0500-0900-1300-1700-2100
AC	0600-1100-1600
AC+HS	0600-1100-1600-2100
BID	0900-2100
BID-(RESPIRATORY)	0900-2100
BID-AC	0600-1600
BID-HYPOGLY/DIURETIC	0630-1630
BID-MEDROL	0600-2200
BID-NITRATE (8A-2P)	0800-1400
BID-PC	0700-1700
BID-WITH-MEALS	0630-1630
DAILY AT NOON	1200
DAILY AT SUPPER	1630
DAILY BEFORE BRKFST	0600
DAILY DIURETIC	0630
DAILY MEDROL	0600
DAILY NITROPATCH	0900
DAILY WARFARIN	2100
DAILY-(RESPIRATORY)	1800
DAY-1-MEDROL	ONE TIME
DAY-2-MEDROL QHS	2200
DAY-2-MEDROL TID	0600-1300-1800
DAY-3-MEDROL QID	0600-1300-1800-2200
DAY-4-MEDROL TID	0600-1300-2200
DAY-5-MEDROL BID	0600-2200
DAY-6-MEDROL DAILY	0600
EVERY OTHER DAY	0900
EACH NIGHT	2100
EVERY NIGHT	2100
EVERY OTHER BEDTIME	2100
HS	2100
HS-MEDROL	2200
NIGHTLY	2100
PC	0700-1200-1700
PC+HS	0700-1200-1700-2100
PID (5-TIMES-DAILY)	0500-0900-1300-1700-2300
Q4H	0400-0800-1200-1600-2000-2400
Q8H	0600-1400-2200
Q12H	0900-2100
Q12H TACROLIMUS	0700-1900
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Q12H-(RESPIRATORY)	0900-2100
Q1H	01-02-03-04-05-06-07-08-09-10-
Q24H	0900
Q2H	0100-0300-0500-0700-0900-1100-
Q2H-(RESPIRATORY)	0100-0300-0500-0700-0900-1100-
Q3H `	0300-0600-0900-1200-1500-1800-
Q48H	0900
Q4H	0100-0500-0900-1300-1700-2100
Q4H-(RESPIRATORY)	0200-0600-1000-1400-1800-2200
Q6H	0500-1100-1700-2300
Q6H-(RESPIRATORY)	0300-0900-1500-2100
Q6WEEKS	0900
Q8H	0500-1300-2100
Q8H-(RESPIRATORY)	0500-1300-2100
QAM	0900
QAM BREAKFAST	0630
QAM-HYPOGLYCEMIC	0630
QDAILY	0900
QHS	2100
QID	0900-1300-1700-2100
QID-(RESPIRATORY)	1000-1400-1800-2200
QID-(REST IKATOKT) QID-MEDROL	0600-1300-1800-2200
QOAM-EVERY OTHER AM	0900
QOHS-EVERY OTHER HS	2100
OPM	2100
QPM SUPPER	1630
QPM-HYPOGLYCEMIC	1630
OWEEK	0630
Q-10-DAYS	0900
Q-12-DAYS	0900
Q-14-DAYS	0900
Q-21-DAYS	0900
Q-28-DAYS	0900
Q-20-DATS Q-30-DAYS	0900
Q-3-DAYS	0900
Q-4-DAYS	0900
Q-5-DAYS	0900
Q-72H	0900
Q-7-DAYS	0900
Q-90-DAYS	0900
•	0500-0900-1300-1700-2100-2300
SID (6-TIMES-DAILY) TID	0900-1300-2100
TID-(RESPIRATORY)	1000-1400-1800
TID-MEDROL	0600-1300-2200

TID-NITRA (8A-1P-6P)	0800-1300-1800
TID-WITH-MEALS	0630-1130-1630
WM TID	0630-1130-1630

NOTE: There are, however, other schedules that are used that do not have an administration time associated with the schedule. For instance, the schedule MO-WE-FR can be selected with the provider selecting to administer at 0900 and 2100. This would build a schedule that appears as MO-WE-FR@0900-2100.

- (15) <u>Tablet Crushing/Modifying/Splitting Policy</u>: All medications that need to be and can be crushed will have an accompanying order for a tablet crusher placed in CPRS by the patient's provider. Pharmacy will dispense one patient-specific tablet crusher per patient per admission upon receipt of this order. For patient safety reasons, the patient-specific tablet crusher will remain at all times in the patient's individual medication drawer where applicable, or labeled and kept securely for the individual patient on cartless wards. Tablet crushers will no longer be utilized on multiple patients [Ref: VISN 9 Directive 10N9-126-10]. The following are general rules on which medications should *not* be crushed, modified or split [refer also to specific list located on CPRS/BCMA Tools, Medication Management Section]. If there are any questions about a specific product, contact a pharmacist. In general, these include:
 - (a) Enteric-coated preparations;
 - (b) Controlled release preparations;
 - (c) Medications designed for sublingual or buccal administration; and,
 - (d) Medications that:
 - 1. Produce oral mucosal irritation, (i.e., isotretinoin, valproic acid, and piroxicam);
- <u>2.</u> Produce extremely bitter or otherwise unacceptable taste (may be appropriate for nasal gastric (NG) route) (i.e., ibuprofen, promethazine); and,
 - 3. Contain dyes or substances that could stain teeth or oral mucosa.
- (16) Labeling: All drugs used in the inpatient section will follow unit dose procedures. An internal lot number is assigned to each drug bearing a manufacturer's lot/expiration for prepacking to shorten information put on a label. Prepack cards are maintained to identify those drugs that are repackaged. The unit dose label will include:
 - (a) Generic name of drug;
 - (b) Strength or concentration;

- (d) Expiration date; and,
- (e) Barcode.
- (17) All inpatient drugs, including nonformulary items, are dispensed in unit dose form where available from the manufacturer.

i. <u>INPATIENT – IV ADMIXTURES:</u>

- (1) Only the Pharmacy Service will compound or admix all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (e.g., when the product's stability is short). For specifics regarding IV admixture preparation, refer to current Compounding Sterile Products Policy and Procedures. For the list of standardized drip concentrations, please refer to the list posted on CPRS Tools.
- (2) <u>Labeling</u>: All compounded IV admixtures and parenteral nutrition solutions will be labeled with the following information:
 - (a) Patient name and location;
 - (b) Generic name of drug;
 - (c) Strength or concentration;
 - (d) Diluent as applicable;
 - (e) Date prepared;
 - (f) Technician/Pharmacist's initials;
 - (g) Expiration date;
 - (h) Barcode; and,
- (i) Directions for use and any applicable cautionary statements either on the label or attached as an accessory label.
- (3) Hyperalimentation will be compounded during regular IV tours. No order will be initiated before 7 a.m., after 3:30 p.m., or on weekends or holidays without consultation from the Nutrition Support Team (NST). Exceptions may occur with justification from NST physician, Chief of Service, or attending physician.

- (4) Chemotherapy drugs must be preordered by 1600 for next day administration. Chemotherapy drug preparation will be coordinated based on scheduled administration times. Exceptions may occur with justification from the oncology physician.
 - (5) Multi-Dose Vial policy:
 - (a) Open vial;
- (b) Calculate 28 days from day vial opened (e.g., today = 4/23/07; 28 days = 5/21/07) [Tool to help with this calculation is available on CPRS/BCMA Tools, Medication Management Section];
 - (c) Label vial as follows:



Date (28 days) from day vial opened & initial;

- (d) Discard 28 days after opening, NOT to exceed manufacturer's expiration date;
- (e) Example: 5/21/07 DAK;
- (f) Aseptic technique must be used to access multidose vials. Discard if sterility is compromised or questionable;
 - (g) Nursing will have primary responsibility for discarding vials; and,
 - (h) Pharmacy Service will check monthly.

NOTE: SINGLE USE VIALS – Use ONCE only.

NOTE exception: Vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to assure integrity of the vaccine. The CDC has excellent resources regarding the use, storage and handling of vaccines at: http://www.cdc.gov/vaccines/recs/storage/default.htm

(6) <u>Concentrated Electrolytes:</u> concentrated potassium chloride for injection, concentrated sodium chloride for injection and concentrated potassium phosphate for injection will NOT be maintained and/or stocked on wards, clinics and similar sites except where authorized and properly secured and labeled. Currently, the Pharmacy IV rooms at the York and Nashville

campuses are the only approved locations where these items are currently stored. Normal or routine VA practice is for IV solutions to be centrally mixed (i.e. Pharmacy IV room), and prepared to proper dilution for administration with appropriate labeling.

- (7) Upon receipt and verification of a provider order for a pharmacy stocked blood product, pharmacy staff must complete a drug specific electronic log sheet/book before dispensing the blood product. The following information is to be maintained: date dispensed, patient name & social security number (SSN), lot #, expiration date, initials of person dispensing. Blood products may be ward stocked in selected areas. When ward stocked, the pharmacy log sheet is to indicate the patient receiving, last four SSN, date dispensed, lot #, and expiration date. Blood products dispensed by Pharmacy Service include: albumin; Coagulation Factor VIII-SD; Factor IX Complex, Human injection; Monoclate injection; Koate HT; and Immune Globulin.
- (8) No intravenous therapy may be dispensed to an outpatient. A contract with a Joint Commission-accredited home infusion company must be in place.
 - (9) Use of Immune Globulin Intravenous (IGIV) products.
- (a) Pharmacy is permitted to substitute a non-sucrose containing IGIV product for a sucrose-containing product.
- (b) Pharmacy will preferentially procure the non-sucrose containing IGIV product; however, if the sucrose-containing product must be used due to availability issues, CPRS ordering be altered to reflect the actual product being dispensed to the patient so that the provider and nursing will be alerted that the patient is receiving a sucrose-containing IGIV product.
- (c) Providers should evaluate patients scheduled to receive any IGIV product based upon the FDA recommendations outlined below:
 - 1. Ensure adequate hydration in patients receiving IGIV prior to the initial infusion.
- $\underline{2}$. Consider risks and benefits of IGIV preparations containing sucrose, especially in patients with risk factors for developing ARF, such as:
 - a. Any degree of pre-existing renal insufficiency;
 - **b.** Diabetes mellitus;
 - c. Age greater than 65;
 - d. Volume depletion;
 - e. Sepsis;

- f. Paraproteinemia; and,
- g. Concomitant nephrotoxic drugs.
- 3. Do not exceed the recommended dose. Reduce dose, concentration, and/or rate of administration in at-risk patients.
- 4. Monitor renal function tests (urine output, blood urea nitrogen, serum creatinine), especially in patients at risk for nephrotoxicity, before starting infusion with IGIV and at periodic intervals after initiation.
 - 5. Discontinue IGIV infusion if renal function declines.
- 6. Instruct patients and/or caregivers to immediately report to their physician(s) any symptoms of decreased urine output, fluid retention/edema leading to sudden weight gain, and/or shortness of breath (possibly indicative of kidney damage) associated with any IGIV infusion.

j. <u>INPATIENT – WARD STOCK:</u>

(1) Ward stock (automatic replenishment) medication will be used on wards and in certain clinic areas, but will be kept to a minimum. Levels of stock will be established per area and replenished weekly by pharmacy personnel per an established schedule in non-automated areas or in accordance with the Pyxis® replenishment report in automated areas. Usage will be monitored and items not used frequently will be removed. Levels of stocked medication may be adjusted by each area, if appropriate, by contacting the pharmacy supervisor. *Nonformulary* items are not routinely stocked on the wards and in the clinics, but may be stocked if prior approval has been received from the pharmacy supervisor for specific patients or for a specific department's use. Ward stock will be maintained in an economical and efficient manner by ward personnel. The Nurse Manager on each ward/area will assure maintenance and proper security of medication. Medications will be maintained under proper storage conditions. Internal medications will be separated from external medications in all Pyxis® systems, ward stock areas and in Pharmacy Service stock. Antidote charts, equivalents, and poison control number will be posted on each ward. Refrigerators will be equipped with a thermometer and maintained between 2°-8° C (36°-46° F). A daily temperature log (twice daily for areas storing vaccines) will be maintained by Nursing Service on all wards and medication treatment area with a medication storage refrigerator. Areas that are not open 24/7 will utilize either a "Min/Max" thermometer or document through Remote Temperature Monitoring data to assure appropriate medication storage temperatures during times the area is not open. Any temperature checks that fall outside the recommended range will have the action taken notated on the refrigerator monitor log. All drugs and biologicals will be stored under proper conditions of temperature, light, and security. A proper storage place (medication room) will provide privacy for drug preparation. Medications will be stocked in a well-illuminated, locked storage device, cabinet, or room, accessible only to authorized personnel. Proper security for controlled substances and alcohols requires a double lock system or employee-specific access code/combination code to an

automated dispensing device anchored either to the wall/floor or behind locked doors. Unit dose carts are to be kept locked at all times when not in use.

- (2) <u>Medication Inspections:</u> medicine rooms/storage sites will be kept neat, clean, orderly, and locked when not in use. Inspections will be completed monthly by pharmacy personnel on all approved medication storage sites. *Medications placed outside the approved drug storage areas will be the responsibility of the ward staff.* A copy of the inspection report will be maintained in pharmacy. The pharmacy staff member will discuss deficiencies with the Nurse Manager or designee for each area to ensure proper storage and control of medication. These will be noted on the inspection form for correction. *Drugs due to expire will be removed from each area prior to the expiration date by pharmacy personnel.* All medications stored on the ward/clinic will be made available to the inspecting pharmacy personnel at the time of inspection or by mutual arrangement for a later time that same month. Controlled substances expiration monitoring will be performed by and be the responsibility of the Controlled Substances Pharmacy Technicians or designated pharmacist.
- (3) <u>Ready-To-Administer Form:</u> bulk liquids used for ward stock will only be used when the item is not commercially available in unit dose packaging. Medications stored in patient care areas must be maintained in the most ready-to-administer form available from the manufacturer (e.g., unit dose, pre-filled syringes, premixed bags, etc.).
- (4) <u>Poison Antidote Cabinet:</u> A poison cabinet is located in the triage area in a locked environment. Contents are determined by the Intensive Care Committee. Changes/updates are made and approved via the Pharmacy and Therapeutics Committee. Contents are inspected monthly by pharmacy via the area medication inspection. Triage personnel will notify pharmacy when items are depleted on a case-by-case basis.
- (5) Emergency Procurement of Medication: all transactions involving the borrowing or procurement of drug products must be handled through the Pharmacy Service. Medications that are "borrowed" for emergency needs will be borrowed in unit dose or commercially manufactured containers where identification and lot numbers are known. The Pharmacist-In-Charge or the procurement technician will contact other area pharmacies, manufacturers, and/or the Prime Vendor as appropriate to locate and acquire the required medication within the timeframe needed. Once located, arrangements will be made to borrow and transport the medication to the VA pharmacy. The most acceptable means of transportation (contracted courier service, cab, VA staff, etc.) will be used. All pertinent information about the drug and the loaning facility will be documented and made available to the procurement technician and area supervisor. This information will be used by the supervisor or the procurement technician on the next administrative day to arrange for replacement/ repayment. If unable to locate any drug, the provider will be notified and offered suggestions for alternate drug and dose. In disaster situations, the Pharmacist-In-Charge will refer to the TVHS Disaster Policies.

k. <u>INVESTIGATIONAL MEDICATIONS:</u>

- (1) It is the policy of TVHS to conform to all laws and regulations governing the control and dispensing of investigational medications, as well as provide safeguards to protect the patient, staff, facility, and quality of the drug study.
- (2) Investigational medications are drugs in clinical stages of evaluation that have not been approved by the Food and Drug Administration (FDA) for General Use and are not available for distribution through regular channels of interstate commerce.
- (3) An approved drug being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an Investigational New Drug (IND) application, in a controlled, randomized, or blinded clinical trial is also considered an investigational medication.

(4) <u>CUSTODY AND DISPENSING:</u>

- (a) The Research Pharmacist will be responsible for the receipt, custody, and appropriate storage and dispensing of all drugs involved in protocols approved for use by the TVHS Institutional Review Board (IRB) and the Research and Development Committee, including both inpatients and outpatients of TVHS, as well as drugs used within laboratories for animal research.
- (b) Investigational drugs will be maintained in a controlled-access area within the pharmacy, separate from other stock medications. Items that must be refrigerated will be maintained in a separate investigational refrigerator. Frozen medications will be maintained in a separate, locked section of the pharmacy freezer.
- (c) A copy of the patient's signed agreement to participate in research (Consent Form, VAF 10-1086) must be received before an investigational drug may be dispensed.
- (d) A completed VAF Trailer document or form specific to the research protocol is required for each dispensing of investigational drug. The completed form signed by an authorized prescriber must be received before an investigational drug may be dispensed.
- (e) Each initial dispensing of an investigational drug must be accompanied by an Investigational Drug Information Record sheet (VAF 10-9012), for use by personnel preparing and administering the drug. The form will include a thorough but brief summary of all pertinent information regarding the drug including toxicities, adverse reactions, and food or drug interactions. The completed VAF 10-9012 must be made available to the pharmacy and must be in the patient's medical record by written or electronic media.

NOTE: Names of authorized prescribers for the study are located at the bottom of the VAF 10-9012. Contact numbers for the study investigator and coordinator will be listed in the electronic study note referenced as a Patient Record Flag (PRF) on the cover sheet of the Computerized Patient Record System (CPRS).

- (f) A special investigational drug label, in addition to information required by law on prescription labels will include the following legend, "FOR INVESTIGATIONAL USE ONLY", and other auxiliary, caution, or warning labels as indicated. NO investigational drug shall be administered in the TVHS that has not been inspected by Pharmacy Service and the container affixed with an appropriate TVHS prescription label. Investigational drugs brought into the TVHS from a patient or investigator MUST be sent to the Pharmacy Service for appropriate storage, dispensing, labeling, and distribution.
- (g) Drug accountability will be recorded on forms provided by the study sponsor and/or the pharmacy "Investigational Drug Dispensing Log." Drug accountability will include the following information:
 - 1. Name of drug;
 - 2. Manufacturer or Sponsor information;
 - 3. Amount, date, and quantity received;
 - 4. Lot/Control number and expiration or retest date;

NOTE: Pharmacy will contact the study sponsor for retest date if expiration date is not provided on package or shipment records. If the sponsor is unable to provide the information pursuant to their policies, then the Research Pharmacist will request a statement to be filed in the dispensing record from a representative of the sponsor stating that the expiration or retest dates are monitored centrally and dispensing sites will be notified prior to any drugs that are approaching an expiration date being assigned or dispensed to patients.

- <u>5.</u> Prescription number and date of prescription dispensing;
- 6. Patient's name and/or subject number;
- 7. Amount and date dispensed and balance remaining;
- 8. Date of protocol approval by IRB;
- 9. Name of authorized prescriber; and,
- 10. Initials of dispensing pharmacist.
- (h) Use of an investigational drug from an outside source for a hospitalized patient may be permitted to ensure the patient's well-being.
- <u>1.</u> The pharmacy must obtain the drug and dispense in accordance with FDA guidelines (21 CFR 312.34).

- 2. The Principal Investigator (PI) of the study must be contacted prior to dispensing.
- <u>3.</u> The PI must provide a copy of the signed Informed Consent Form, information on the protocol, and all drug-related information prior to any dispensing.
- (i) A file containing the approved protocol with amendments, the approved Investigational Drug Information Record(s) (VAF 10-9012), the Investigator Brochure and copies of all subjects signed Consent Forms (VAF 10-1086) will be maintained for all active drug protocols.
- (j) The final entry in each study file will be the date of disposition of any remaining drug after the completion of the study. Required records must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1). Contact with the study sponsor will be made to determine disposition of unused study drugs. Drugs authorized by the sponsor to be destroyed will be sent to a contracted vendor for destruction of drugs by methods in compliance with hazardous waste handling.
- (k) The primary Research Pharmacist should dispense investigational drugs, when feasible. Other designated pharmacists who have completed training on Investigational Drug policies and procedures may perform this function in the absence of the primary Research Pharmacist. Drugs that require special handling (example: chemotherapy) will be prepared by the Chemotherapy Pharmacist after all of the required documentation has been received by the Research Pharmacist and the necessary information relayed to the Chemotherapy Pharmacist.
- (1) Study drugs to be administered to patients that are admitted to the TVHS will be labeled with the patient's name and the study drug name as well as a barcode for BarCode Medication Administration (BCMA) documentation. An authorized order for the study medication will be entered in the patient's electronic record, as well as any applicable progress notes. The investigator or designee will ensure that a copy of the patient's signed informed consent and the VAF 10-9012 is filed in the patient's electronic medical chart.
- (m) Satellite investigational pharmacies may be established within TVHS to handle the storage and dispensing of investigational drugs: Distribution of investigational agents to approved satellite locations occurs from the Inpatient Pharmacy, Nashville Campus. The pharmacist designated at the satellite sites will have sole responsibility for storing and dispensing investigational drugs according to the following policies and procedures:
- <u>1.</u> Ensure that the Investigation Review Board (IRB) and the Research and Development Committee have approved all protocols prior to dispensing any drugs.
- <u>2.</u> Maintain a file for each protocol containing current protocol with all amendments, Investigator Brochure with all updates, approved VAF 10-9012 bearing the approval signatures of the IRB and the R&D Committee chairperson, and copies of signed Consent Forms for

patients who received any drug associated with the protocol. Also, maintain a file of written prescriptions signed by authorized prescribers for all study drugs dispensed.

- <u>3.</u> Ensure adequate storage of all study drugs separate from other drugs stored on site. Minimum security requirements consist of a double-locked storage closet or cabinet accessible only by the pharmacist. Temperature will be controlled and a daily log maintained. All drugs will remain under the control and in the custody of the pharmacist until dispensing.
- <u>4.</u> Maintain a log of all transactions involving receipt, dispensing, and disposition of used and unused study drugs.
- <u>5.</u> Input all orders into the patient's electronic medical record for all drugs dispensed pursuant to the protocol as well as ensuring that all electronic study notes have been posted.
- <u>6</u>. Satellite investigational pharmacies will be visited regularly by the TVHS Research Pharmacist to monitor compliance.

1. <u>RETURN DRUG PRODUCT PROCEDURE FOR OUTDATED AND UNUSABLE</u> PRODUCTS:

- (1) All unused, expired, or returned medications will be *immediately* delivered to Pharmacy Service for disposition. Pharmacy Service will determine whether these medications should be used or destroyed as applicable to the known storage and handling of the medication while out of Pharmacy control. If the storage and handling of a medication while not under Pharmacy's control is unknown, the medication will be destroyed through the contracted Returns Company or in accordance with State and Federal pharmaceutical waste regulations. If the Pharmacy is able to verify that the medication has been stored under all legal storage and handling requirements, i.e., dispensed to a patient care area meeting all facility policies, and remains sealed and intact, then the Pharmacy may reuse the medication if within the manufacturer's dating. All expired, damaged, and/or contaminated medications will be segregated from working medication stock, placed in a locked cabinet, logged appropriately and destroyed through the contracted Returns Company. At no time will any controlled substance be maintained outside of Pharmacy Service unless in full compliance with the policy on Controlled Substances Management. Medications brought in by patients will follow the policy addressed below in order that potential diversion primarily of controlled substances may be averted. All controlled substances are carefully tracked and monitored through the Controlled Substances package and the Narcotic Inspection Program.
- (2) <u>Patient's Personal Medications (Meds Dispensed to Patients)</u>: Patients are requested to *not* bring their personal medications into the facility or turn them in to the Pharmacy. (There are three *exceptions*: 1) pharmacy dispensing error, 2) medication recall where the Pharmacy requests the patient to return the medication to the Pharmacy and 3) investigational medications that the patient *must* remain on during his/her admission must be redispensed after identification and visual evaluation of the medication's integrity by Pharmacy Service and secured as per investigational policy). Patients being admitted to the Medical Center must surrender all

personal medications, including over-the-counter medications and herbal products to their caregiver/family member for return to their place of residence during the admission process. If no caregiver is present, the patient's medications will immediately be placed in a mailing envelope by the patient and a TVHS employee acting as a witness, addressed to the patient's home address by the patient if capable or second health care personnel if patient is unable, and sealed. This facility will not take possession of a patient's personal medications. This procedure, in addition to notification of the provider and the patient, will be the responsibility of nursing personnel for medications brought to Triage and Nursing wards (direct admission). The Admitting Office will be responsible for patients who are admitted through the exam suite. The sealed addressed envelope will be brought to Outpatient Pharmacy (Inpatient Pharmacy during hours where Outpatient Pharmacy is closed). Once pharmacy has received the package, a mailing label will be generated if necessary, placed on the package, and the package mailed. Pharmacy will send all packages regular mail delivery only. A progress note will be entered in CPRS by Nursing Service or the Admitting Office, as applicable, to include the medications placed in the sealed package and mailed to the patient. Pharmacy will complete an addendum to the progress note stating the date the package was mailed by Pharmacy Service. The facility Pharmacy Service will dispense all medications administered to the patient during inpatient admissions, with the exceptions previously noted under the Dispensing Section of this policy.

(3) Non-Controlled Substances:

- (a) All expired, damaged and/or contaminated pharmacy products, *except* controlled substances (discussed separately below and in Controlled Substances Management policy) and designated p-, u-, and d-listed hazardous waste items (disposition of these discussed in Hazardous Waste Management policy), are segregated from working stock and *secured* in the designated locked cabinet within the Pharmacy Service, labeled "EXPIRED MEDICATIONS ONLY" or in a secure manner as stated in the Hazardous Waste Policy and acceptable to State and Federal hazardous waste regulatory agencies.
- (b) Each Pharmacy Procurement Technician or designee will scan, input or log all items being held in the outdated medications cabinet into the EXP Pharmaceutical internet Web Portal for log documentation of what is being held for destruction prior to the service call date, which allows the pharmacy procurement staff to maintain and print an easily retrievable running list of medications being held for return for credit (contents of opened units or bottles may be estimated), which is then compared to the EXP Pharmaceutical Service Report that is generated by the EXP Pharmaceutical customer service representative at the time of service call for proper medication credit reconciliation. They will call the Returns Company and set up the appointment times with the Returns Company preferably for the first working day of each month.
- (c) The Returns Company personnel will inventory and box-up all inventory being held for return to the various manufacturers along with medical waste for appropriate disposition (p-, u-, and d-listed hazardous waste will not be handled by this process; rather through the process referred to in the Hazardous Waste Management Policy).

- (d) The Returns Company personnel will provide a copy of the products for return to the Pharmacy Procurement Technician before departure.
- (e) Each Pharmacy Procurement Technician will reconcile the medication listing of what was being held for destruction in the McKesson Physical Inventory package against what the Returns Company Manifest listed as being returned/destroyed. Discrepancies will be immediately brought to the attention of Pharmacy Management. Reconciliation of items being held for destruction against what was destroyed by the Returns Company will be documented for future retrieval, with discrepancies documented.
- (f) Each Pharmacy Procurement Technician will regularly test whether the amount of credits received for returned drugs is correct and submit this report to the Lead Item Manager for summarization to the Chief, Pharmacy Service.
- (g) The Lead Item Manager will ensure the overall facility monitoring of credits received for returned medications. In order to maximize credits for returned medications, the Lead Item Manager must review the vendor reports and:
 - (1) Reconcile credits received against drugs returned;
 - (2) Take corrective action on any identified discrepancy; and,
 - (3) Identify any opportunities for improvements.
- (h) The Lead Item Manager will, on a quarterly basis, analyze information regarding drugs returned to manufacturers to identify potential improvements that may increase the amount of credit received, submit findings on this analysis to the Chief, Pharmacy Service, who will communicate findings further with the VISN 9 Pharmacist Executive.

(4) Controlled Substances:

- (a) The Pharmacy Service Controlled Substances Technician/Pharmacist will *immediately* write up for destruction any expired, damaged, and/or contaminated controlled substance and maintain them in a locked tote within the vault. The Controlled Substances Technician/Pharmacist will use the "Hold for Destruction" option in VistA to prepare the list of controlled substances to be returned. For more specific procedures, please refer to the Controlled Substances Management Memorandum.
- (b) On a monthly basis, the Controlled Substances Technician/Pharmacist will prepare all the controlled substances for return through the Returns Company.
 - (b) Each month, the Controlled Substances Technician and the Returns Company representative will verify the holding drug numbers with the holding report. The Returns

Company will generate the Drug Enforcement Administration (DEA) 222 Form during the verification process.

- (d) All controlled substances are boxed up and sealed by the Controlled Substances Technician/Pharmacist and the Returns Company representative to be picked up later by United Parcel Service. They will remain locked inside the vault until released directly to the United Parcel Service for return.
- (e) The Returns Company will provide a printed invoice of all controlled substances they returned.
- (f) The Controlled Substances Technician then mails the DEA Form 222 to the Nashville Branch of the Drug Enforcement Administration.
 - (5) All returned products (controlled and non-controlled):
- (a) The Returns Company will return all "returnable" products to the respective manufacturers for credit.
 - (b) The Returns Company will destroy all "non-returnable" products.
- (c) The Returns Company will send pharmacy service an itemized list of all products that have been returned to manufacturers for credit.
- (d) Credit for all returnable products will be issued through the Pharmaceutical Prime Vendor whenever possible.
- (e) Credit Memos from the Pharmaceutical Prime Vendor will be documented by the procurement technicians in the Returns Company log book maintained in their respective areas and the return paperwork matched up for proper record keeping.
- (f) All Returns Company paperwork will be retained in the procurement folder and the controlled substances folder for a period of three years.

m. **DRUG RECALLS:**

- (1) **Class I** recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, food with undeclared allergens, a label mix-up on a life saving drug, or a defective artificial heart valve.
- (a) In a Class I recall, the company notifies their customers (i.e. distributors or vendors), and directs them to notify the intended recipients of the device (i.e. other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients). The notification usually

contains the name of the device being recalled, identifying lot or serial numbers, the reason for the recall, and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall and issues a press release to notify the public, if appropriate to minimize health consequences.

- (b) FDA may also issue its own press release or public health notice.
- (c) FDA posts consumer information about all Class I recalls on its <u>Medical Device Recalls</u> website.
- (2) **Class II** recalls are for products that might cause a temporary or reversible health problem, or pose only a slight threat of a serious nature, usually a less serious risk than a Class I recall. One example is a drug that is under-strength but that is not used to treat life-threatening situations. In a Class II recall, the company notifies their customers (i.e. distributors or vendors) and sometimes asks them to notify the intended recipients of the device. FDA generally does not issue a press release or expect the company to issue a press release for Class II recalls, unless there is a specific need to do so (for example, if the device could affect the health of a large number of people, if patients need more information, or if the recalling company could not reach every intended recipient).
- (3) **Class III** recalls are for products that are unlikely to cause any adverse health reaction, but violate FDA labeling or manufacturing regulations. A Class III recall represents a less serious risk than a Class II recall. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food. In a Class III recall, the company notifies their customers (i.e. distributors or vendors). FDA would not issue a press release, and it would not expect the company to issue a press release.
- (1) The Pharmacy Service will be notified of drug recall notices by the following: FDA Bulletins; correspondence from pharmaceutical manufacturers; Outlook messages from the Pharmacy Benefits Management Strategic Health Group, Hines; professional journals; forum announcements; bulletins; and newsletters.
- (2) All drug recalls will be evaluated and promptly acted upon by the Pharmacy Procurement Officials, under the direction and immediate oversight of the Pharmacy Drug Control Program Manager. The nature, cause for, and level (retail or consumer) of recall will be immediately investigated by the Drug Control Program Manager and/or the Inventory Management Specialist, who will ensure that appropriate and timely action, is taken. Results of the local recall review in all medication storage areas will be posted on the VA Hazardous Recalls/Alerts Website, located at http://vaww.nbc.med.va.gov/visn/recalls/.
 - (3) If a danger to health exists (Class I):

- (a) All supplies of the drug will be immediately removed from pharmacy stock and quarantined.
- (b) All supplies from all patient care areas will be immediately removed from stock and quarantined.
- (c) Outpatient prescriptions will not be refilled with recalled product. Notification of all patients receiving the medication will be attempted by:
- <u>1</u>. Using the computer to generate a list of all prescriptions dispensed in the timeframe specified by the recall (by patient name and social security number)
- <u>2.</u> Notifying each patient by phone or mail as recommended. If unable to contact by phone when recommended, sending registered letter explaining the drug recall and asking the patient to contact the Pharmacy Service.
- <u>3.</u> Advertising in the newspaper, on the radio and television, if necessary, due to the severity of the situation as determined by the Chief of Staff and Chief, Pharmacy Service with approval of the Medical Center Director.
- <u>4.</u> Retrieval of medical records and referral to provider or clinic for review and appropriate action, where appropriate.
 - (4) If potential danger to patient health exists, but is remote (Class II):
- (a) All supplies of the drug will be immediately removed from pharmacy stock and quarantined.
- (b) All supplies of the drug will be immediately removed from all patient care areas and quarantined.
- (c) Outpatient prescriptions will not be refilled with recalled product. Determine specific level of recall, as to whether it is retail level or consumer/patient level recall. Send patient written instructions and information as warranted by recommended level of recall.
 - (5) If potential danger to patient health does not exist (Class III):
- (a) All supplies of the drug will be immediately removed from pharmacy stock and quarantined.
- (b) All supplies of the drug will be immediately removed from all patient care areas and quarantined.

- (c) Outpatient prescriptions will not be refilled with recalled product. Patient-level notification not undertaken unless specifically recommended by the company or the FDA.
- (6) Recall items are subject to disposal instructions promulgated by the FDA or manufacturer. Where appropriate, recalled items will be sent back to the Prime Vendor for replacement or credit.
- (7) The Pharmacy Drug Control Program Manager or the Inventory Management Specialist will initiate prompt action to procure emergency replacement medications from available sources of supply not affected by the drug recall. If the recall is of such a nature that replacement medication is not available, the following action will be taken:
- (a) A discussion in a Pharmacy Newsletter *or* an e-mail will be sent to all authorized providers, Pharmacy, and Nursing staffs informing them that a discontinued drug or recalled drug is not available for issue and that an alternative therapeutic agent should be prescribed on all new orders where applicable.
- (b) On all refill requests, the prescribing provider will be contacted for authority to dispense another therapeutic agent, unless a therapeutic alternative is named by the Pharmacy & Therapeutics Committee and automatic substitution is authorized by the Pharmacy Service.

n. **DRUG SHORTAGES**:

(1) Surveillance:

- (a) Review of Food and Drug Administration (FDA), American Society of Health-System Pharmacists (ASHP), Veterans Affairs (VA) Pharmacy Benefits Management (PBM), PBM "Top 10" reports from Consolidated Mail-Out Pharmacy (CMOP) data, drug recalls, and Prime Vendor reports will be the responsibility of the Inventory Management Specialist. The following web sites may be used: http://www.fda.gov/cder/drug/shortages/, and/or http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/DrugShortages.aspx.
- (b) Investigation of CMOP returns due to manufacturer shortages will be the responsibility of the Inventory Management Specialist and the CMOP Program Manager.
- (c) The Inventory Management Specialist will identify drug shortages. Section supervisors will also report shortages to the Inventory Management Specialist when a shortage is identified.
- (2) Verification, assessment and notification: initial verification, assessment, and notification of the shortage to the appropriate Pharmacy section supervisor, Clinical Pharmacy Manager and the Chief of Pharmacy is the responsibility of the Inventory Management Specialist. Potential

shortages that may impact TVHS facilities will be verified with the manufacturer or distributor. In the event of a drug shortage or backorder, the Inventory Management Specialist will:

- (a) Identify location and quantity of drug remaining in stock.
- (b) Prioritize which Services/indications should have availability of remaining supplies.
- (c) Contact manufacturers to determine release dates, availability of emergency supplies, and reason for the shortage/backorder.
 - (d) Order any product available from regular and/or alternate sources.
- (e) In cooperation with the Clinical Pharmacy Manager or designee, determine availability of therapeutic equivalent once identified for products in short supply or on back order.
- (f) Oversee ordering of therapeutic equivalent when drug product or generic equivalent cannot be obtained.
- (3) The clinical impact expected from the shortage will be assessed by the Clinical Pharmacy Manager, including but not limited to, the following:
 - (a) Nature of medication:
 - (b) Expected duration of shortage;
 - (c) Available stock on hand;
 - (d) Utilization of medication;
 - (e) Availability of product from alternate source;
 - (f) Availability, equivalence and cost of substitute; and,
 - (g) Availability of National or VISN guidelines for dealing with shortage.

NOTE: Notification of the Chair, Pharmacy PT Committee, Chief Specialty Service (as needed for consult) is the responsibility of the Clinical Pharmacy Manager.

(4) <u>Decision:</u> The Clinical Pharmacy Manager, in conjunction with other Pharmacy section supervisors and the Inventory Management Specialist, will be responsible for forming an action plan, consulting appropriate provider(s) and notifying the Chair, P&T Committee and/or Chief of Staff (COS), and other providers as needed, of the shortage and the plan. The decision for the appropriate action plan will include at least the following:

- (a) The product(s) that can be used as a substitute including dosage conversions or equidosing algorithms;
 - (b) Restrictions, if necessary, for remaining stock;
- (c) Strategies to avoid errors with substitutes (i.e., staff education, repackaging, warning labels, computer alerts);
 - (d) Estimated duration of the shortage;
- (e) How and when the patient will be notified (i.e., via phone call, a letter sent to all patients or with the new prescription) including drafting a patient letter if needed, and responsibility for communication to the patient;
- (f) Method for notification of providers (i.e., email, alerts, printed flyers, or verbal correspondence); and,
- (g) Plan for additional monitoring required (i.e., adverse events, status of shortage, clinical impact, evaluation of patient).

Actions may include, but are not limited to:

- 1. No action, shortage will resolve without intervention with little or no clinical impact;
- <u>2.</u> Temporary substitution;
- 3. Permanent conversion; or,
- 4. No substitution is available, contact providers to evaluate alternative treatments;
- (5) <u>Communication/Education:</u> The Clinical Pharmacy Manager is responsible for assuring communication with and education of medical, nursing, and pharmacy staffs, in addition to P&T Committee and Leadership (COS, Director) to ensure seamless patient care during the shortage. Responsibility of communication to the patient will be determined in the action plan.
- (6) The Clinical Pharmacy Manager will ensure notification and education of appropriate hospital personnel (nursing, medical, respiratory therapy, pharmacy) on:
 - (a) Reason for shortage
 - (b) Anticipated release date
 - (c) Available alternative products

- (d) Comparison of alternative agent to the standard agent
- 1. Dosing/scheduling/administration differences;
- 2. Possible adverse effects: common and severe;
- 3. Cautions/contraindication;
- <u>4.</u> Identify strategies to avoid errors related to the use of alternative products (prescribing/dispensing/administration); and,
 - <u>5.</u> Proactively monitor for adverse effects.
- (7) The Inventory Management Specialist is responsible for reporting any updates pertaining to the medication shortage to Clinical Pharmacy Manager and Section Supervisors.

5. REFERENCES:

- a. M-2, Part VII, various Chapters
- b. Code of Federal Regulations, PART 1300 TO END, and current year
- c. United States Pharmacopoeia
- d. Joint Commission on Accreditation of Healthcare Organizations Accreditation Manuals, current year
- e. VHA Handbook 1108.01; VHA Handbook 1108.02; VHA Handbook 1108.05; VHA Handbook 1108.06; VHA Handbook 1108.07; VHA Directive 2008-021.
- **6. RESCISSION:** TVHS Memorandum 626-12-119-07 dated March 9, 2012.
- **7. RESPONSIBILITY AND REVIEW DATE:** Chief, Pharmacy Service will review annually and update no later than March 31, 2016.

/s/ Juan A. Morales, RN, MSN 3/19/2013 Juan A. Morales, RN, MSN Health System Director

ATTACHMENT A

Administration of Intravenous Push Medications by Registered Nurses in Acute Medical/Surgical/Psychiatric and Primary Care Areas: Approved Medication List

DRUG	APPROVED ADULT DOSE RANGE	RATE OF ADMINISTRATION/COMMENTS	DILUTION/ADMINISTRATION GUIDELINES
Bumetanide (e.g., Bumex®)	0.5 - 1 mg	Over two minutes	Undiluted
Bortezomib (e.g., Velcade®) Chemotherapy- Certified RNs only	1.3mg/m2	Over 5 seconds	
Dexamethasone (e.g., Decadron®)	Up to 20 mg	Over one minute	Undiluted
Dextrose 50%	Up to 50 ml	Each 10 ml over one minute (Monitor glucose levels closely)	Undiluted
Diazepam (e.g., Valium®)	Up to 10 mg	Each 5 mg dose over one minute (Monitor respirations frequently/PRN; keep emergency resuscitation equipment readily available). Into a large vein, do not administer intra-arterial	Undiluted, not compatible with any IV solution, do not administer intraarterial ONSET: 1-5 min PEAK: 30 min DURATION: 15-60 min
Digoxin (e.g., Lanoxin®) Monitored patients only. A Licensed Practitioner must be present at the patient's bedside with portable telemetry monitoring present.	0.5 mg	Over five minutes (Monitored patients only) (Monitor apical pulse before and after administration)	Undiluted or Diluted four-fold in NS, D5W, or SW. Less than 4-fold dilution may cause precipitation
Diphenhydramine (e.g., Benadryl®)	Up to 50 mg	Over one minute Max 25 mg over one minute	Undiluted
Famotidine (e.g., Pepcid®)	10 – 20 mg	Over two minutes	Each 20 mg must be diluted with 5- 10ml NS

	T		
Flumazenil	Max dose is	0.2 mg IV q min x1-5 doses	Undiluted or diluted in NS, D5W,
	3mg unless pt	Administer only into tubing of a free-	or LR
	partially	flowing compatible IV infusion into a	
	responds to	large vein	
	3mg, then it		
	increases to		
	5mg		
Fluorouracil (5-	400mg/m2	Over 5 minutes	
FU)	(dose varies)		
Chemotherapy-			
Certified RNs			
only			
Furosemide (e.g.,	Up to 40 mg	Over two minutes	Undiluted
Lasix®)		Each 40 mg over 2 minutes	
Hydromorphone	1 – 4 mg	Each 2 mg over three minutes	Undiluted or may be diluted with
(e.g., Dilaudid®)	5	=8	5ml of NS or D5W
(5., 2			ONSET: 10-15 min
			PEAK: 15-30 min
			DURATION: 2-3 hours
Ketorolac (e.g.,	15 – 30 mg	Over two minutes	Undiluted
Toradol®)	13 – 30 mg	(Minimum of 15 seconds)	Chanaca
Lorazepam (e.g.,	0.5 - 4 mg	2 mg over one minute	Dilute with equal volume NS,
	0.5 – 4 mg	2 mg over one minute	<u> </u>
Ativan®)			D5W, or Sterile water for injection
			ONSET: 1-5 min
			PEAK: 10-15 min
3.6 .1. (10 50	0 6	DURATION: 12-24 hours
Meperidine (e.g.,	10 - 50 mg	Over four minutes	Undiluted or may be diluted with at
Demerol®)		Recommended max use for 48 hours	least 5 mL of NS, D5W, or sterile
		and in doses no greater than 600 mg/	water for injection
		day	ONSET: 1 min
		WARNING: Meperidine produces a	PEAK: 5-7 min
		metabolite called normeperidine that	DURATION: 2-3 hours
		is not excreted very well by kidneys	
		that are compromised .As it builds up	
		it crosses the blood-brain barrier and	
		can produce seizure activity. Not a	
		good first-line pain management	
		agent.	
Metoclopramide	Up to 20 mg	Each 10 mg over two minutes	Undiluted
(e.g., Reglan®)			
Morphine sulfate	Up to 15 mg	Each dose over five minutes	Undiluted or dilute with 5 mL of
r	1 1 1 1 1 1 1 1 1 1 1 1		NS or sterile water for injection
			ONSET: 5 min
			PEAK: 20 min
			DURATION: 2-4 hours
		<u> </u>	DUMITION, 2-7 HUUIS

Naloxone (e.g., Narcan®) Anticipate transferring patient to higher level of monitoring, A Licensed Practitioner must be present at the patient's bedside with portable telemetry monitoring present. Ondansetron Ondansetron Ondansetron Orborholoride (e.g., Zofran®) Prochlorperazine (e.g., Compazine®) Vinoristine sulfate Chemotherapy- Certified RNs only Over 30 seconds IV q 2-3 IV q 2-6 IV q to 2mg IV q 2-7 IV p to 2mg IV q 2-7 IV p to 2mg IV q 2-8 IV q 2-9 IV q 2	N-1	0.1.00	01-	TT., 4914 - 4
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ATTACHMENT B

Administration of Intravenous Push Medications by Registered Nurses in Long-Term Care Inpatient Units

DRUG	APPROVE D ADULT DOSE RANGE	RATE OF ADMINISTRATION/COMME NTS	DILUTION/ADMINISTRAT ION GUIDELINES
Dextrose 50%	0.5-1mg	Over two minutes	Undiluted
Diphenhydramin e (e.g., Benadryl®)	Up to 50mg	Over one minute	Undiluted
Furosemide (e.g., Lasix®)	Up to 40mg	Over two minutes	Undiluted
Hydrocortisone (e.g., Solu- Cortef®)	100-500mg	Over one minute	Diluted per manufacturer's instructions
Prochlorperazine (e.g., Compazine®)	2.5-10mg	Each 5mg over one minute	Undiluted or diluted in normal saline
Hydromorphone (e.g., Dilaudid®) - Only Hospice RN may administer to hospice Residents/patien ts.	1-4 mg	Each 2mg over three minutes	Undiluted or may be diluted with 5ml of NS or D5W ONSET: 10-15 min PEAK: 15-30 min DURATION: 2-3 hours
Morphine sulfate - Only Hospice RN may administer to hospice Residents/patien ts.	2.5 – 15mg	Given over 4 to 5 minutes. May be given q 4 hrs. May be diluted with 4 - 5cc of sterile water for injection	Undiluted or may be diluted with at least 5 mL of NS or sterile water for injection ONSET: 5 min PEAK: 20 min DURATION: 2-4 hours

ADVERSE DRUG EVENTS/ADVERSE DRUG REACTIONS

- **1. PURPOSE:** To establish a policy and procedure for defining, identifying, reviewing, and evaluating adverse drug events (ADEs)/adverse drug reactions (ADRs) for the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) including both main campuses as well as all Community Based Outpatient Clinics (CBOCs).
- **2. POLICY:** It is the policy of this facility to improve reporting of ADEs/ADRs and to increase patient safety in medication therapy. Reporting of ADEs/ADRs through the Medication Safety Subcommittee and discussion of the significant ADEs/ADRs in Pharmacy & Therapeutics (P&T) Committee as well as reporting to the VA Adverse Drug Event Reporting System (VA ADERS) and the Federal Drug Administration (FDA) MedWatch system are all critical components of this program.

3. **DEFINITIONS**:

- a. <u>Adverse Drug Event (ADE):</u> Is an injury resulting from the use of a drug. For the purposes of this policy, this definition includes harm caused by the drug as a result of adverse drug reactions, drug-drug interactions, product quality problems or drug overdoses (whether accidental or intentional). Severity levels are:
- (1) <u>Mild ADE</u>: Is an event that requires no intervention or minimal therapeutic intervention such as discontinuation of drug(s);
- (2) <u>Moderate ADE:</u> Is an event that requires active treatment of adverse reaction, or further testing or evaluation to assess extent of non-serious outcome;
- (3) <u>Serious ADE:</u> Is serious when the patient outcome is: death, life-threatening, hospitalization-initial, prolonged disability, permanent damage, congenital anomaly, or birth defect, required intervention to prevent permanent impairment, damage, or other serious important medical events.
- b. <u>Adverse Drug Reaction (ADR):</u> Is a response to a drug which is noxious and unintended and which occurs at doses normally used in men for prophylaxis, diagnosis, therapy of disease, or for the modification of physiologic function.
- **NOTE:** There should be a causal or suspected link between a drug and adverse drug reaction. However, a causality assessment or association of the drug to the adverse drug reaction does not have to be established in order to report an adverse drug reaction or adverse drug event.
- (1) <u>Historical ADR:</u> Is a past event (i.e., more than three months old) or an event that reportedly occurred in the past at another healthcare setting. It is defined in the Computerized Patient Record System (CPRS) as "reported by the patient as occurring in the past; no longer requires intervention."

- (2) Observed ADR: Is defined in CPRS as a reaction that is "directly observed or occurring while the patient was on the suspected causative agent."
- **NOTE:** Observed refers to a newly noted adverse outcome, typically within the past three months. Although the term implies that the provider of record made the diagnosis, the fact that a provider may not have visually "observed" an adverse drug reaction does not preclude reporting as "Observed."
 - c. ADE/ADR Program Manager: Coordinates the ADE/ADR reporting process at TVHS.
 - d. Allergy: Is an ADR mediated by an immune response (e.g., rash, hives).
- e. <u>Causality Assessment:</u> Is a determination whether there is a reasonable possibility that the drug caused or contributed to an adverse event. It includes assessing temporal relationships, de-challenge or re-challenge information, association (or lack of association) with underlying disease and the presence (or absence) of a more likely cause.
- f. **Reporter:** Are any health care personnel suspecting an ADE/ADR and reports that suspicion to the ADE/ADR Program manager.
- g. <u>Side Effect:</u> Is an expected and known effect of a drug that is not the intended therapeutic outcome. Since the term "side effect" tends to nominalize the concept of injury from drug, it is recommended that this term be avoided and be reported and monitored as an ADR.
- h. <u>Suspect Drug:</u> Is a drug product administered before the ADE began and is believed by the reporter, manufacturer, or the health care agency to have contributed to its occurrence. It is "suspected" of being the cause of the ADE and this suspicion makes the ADE an ADR for reporting purposes. Types of suspect drugs include: drug products or products of biologic origin (vaccines, blood products); non-prescription drugs; replacement drugs (hormones, vitamins, minerals, electrolytes, and fluids); non-active ingredients (excipients); or medical, surgical, and dental devices and their interactions with drugs.
- i. <u>VA ADERS Reporter:</u> Is the ADE/ADR Program Manager or designee and is responsible for entering ADE/ADR reports in VA ADERS.
- j. <u>VA Adverse Drug Event Reporting System (VA ADERS)</u>: Is the VHA intranet spontaneous ADE reporting system that standardizes reporting at the facility level, centralizes ADE data analysis, and improves efficiency of ADE report coding used to categorize and classify symptoms associated with the event. VA ADERS is able to:
- (1) Report, track, and electronically submit serious adverse drug events to the FDA's MedWatch system;

- (2) Assess information on adverse drug events that are potentially preventable and reports to the personnel involved in ADE monitoring;
 - (3) Trend ADE data at local, regional and national levels;
- (4) Track ADEs associated with newer drugs (e.g., drugs that have been on the market in the United States for three years or less).

4. RESPONSIBILITIES:

- a. Any clinical personnel suspecting an ADE/ADR shall immediately relay such suspicion to the patient's responsible provider *and* report it for investigation to the ADE/ADR Program Manager or designee *via one of the following routes*:
- (1) Make a notation of the suspected ADR in the patient's electronic record and document electronically the suspected ADR in the allergy-tracking package.
- (2) By sending an e-mail describing the event to *TVH Adverse Drug Reactions* in Outlook with encryption where patient information is involved or to *G.ADR* in Veterans Health Information Systems and Technology Architecture (VISTA) (do not put patient identifiers in the Subject: line on VISTA).
- (3) By filling out an electronic FDA MedWatch form and forwarding to the ADR Program Manager on Outlook's TVH ADR mail group with encryption.
- b. The ADE/ADR Program Manager or designee will enter all reports into the VA ADERS and provide monthly reports at the Medication Safety Subcommittee and the P&T Committee. The P&T Committee minutes will be reviewed by the Medical Executive Board (MEB).

5. PROCEDURES:

- a. The ADE/ADR Program Manager or designee, when made aware of possible ADE/ADR occurring anywhere across VA TVHS, will investigate and record the information in the VHA VA ADERS program for further review and data collection.
- b. The ADE/ADR Program Manager or designee will then provide a monthly summary to the Medication Safety Subcommittee and P&T Committee of all events reported to VA ADERS.
- c. The ADE/ADR Program Manager or designee will conduct an annual ADE/ADR summary review. Any trends noted over the previous year will be presented and discussed at the Medication Safety Subcommittee and Pharmacy and Therapeutics Committee. Any action that is required and/or prescribing tips identified will be made available to all professional staff.

6. REFERENCES:

- a. Joint Commission Comprehensive Accreditation Manual for Hospitals: The Official Handbook, Oakbrook Terrace, IL, Joint Commission
 - b. VHA Directive 2008-059, dated September 29, 2008
- c. Nebeker JR, et.al. Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation and Reporting, Annals Int Med, 2004; 140:795-801
- 7. RESCISSION: VA TVHS Memorandum 626-10-119-08 dated March 26, 2010.
- **8. RESPONSIBILITY AND REVIEW DATE:** The Chief, Pharmacy Service will review annually and update no later than August 31, 2016.

/s/ Juan A. Morales, RN, MSN 4/12/13 Juan A. Morales, RN, MSN Health System Director

CONTROLLED SUBSTANCES MANAGEMENT

- **1. PURPOSE:** The purpose of this memorandum is to update established policy and procedures for the handling of all controlled substances for the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS).
- **2. POLICY:** Pharmacy Service shall maintain strict accountability of all controlled substances. VA TVHS employees will follow all policies dealing with controlled substances accountability.
- **3. RESPONSIBILITY:** These procedures will be adhered to by all VA TVHS employees. It is the responsibility of all personnel, including but not limited to, physicians, physician assistants, dentists, nurses, nurse practitioners, nurse anesthetists, and pharmacists to adhere to the procedures written in this memorandum that pertain to their areas. This memorandum should not be construed to be the *only* procedures governing controlled substances applicable to VA TVHS employees.

4. GENERAL PROCEDURES:

- a. Controlled substances consist of medications and other substances listed in Title 21 Code of Federal Regulations (CFR) Part 1300. Controlled substances approved for use in this Healthcare System are categorized into Schedule II, III, IV, or V. The policies identified herein should pertain to all schedules of controlled substances approved for use in this healthcare system unless specifically stated otherwise.
- b. These substances are inventoried according to Drug Enforcement Agency (DEA) and VA regulations. Procedure is primarily taken from 21 CFR 1300 to end and Veterans Health Administration (VHA) Handbook 1108.1 and 1108.2.
- c. Controlled Substance prescriptions will routinely be entered by authorized prescribers electronically for Schedule II-V medications. Each authorized prescriber will be verified by credentialing for appropriate licensure and personal DEA number. Entering Schedule II-V controlled substance medication orders will also require the use of a facility issued PIV (Personal Identity Verification) card and PIN (Personal Identification Number). Prescription Forms (VA Form 10-2577f) that have previously been used solely for Schedule II prescribing prior to ePrescribing, will still be retained and securely stored by Pharmacy Service in the vault until dispensed. These forms will be available to all providers authorized to prescribe Schedule II-V controlled substances for outpatients, *only* during computer downtimes as the contingency system or in cases where an authorized prescriber, validated by credentialing with appropriate licensure and personal DEA number has *temporary* issue with his/her PIV (Personal Identity Verification) card that would impede electronic order entry. All provider PIV issues are expected to be resolved immediately and *proactively*, such that paper prescriptions will essentially be restricted to computer downtime only. Names of providers/services writing controlled substances prescriptions on VA Form 10-2577f during non-computer contingency times will be forwarded to the Chief of Pharmacy and then on to the Chief of Staff for further review. At their request, an authorized provider (verified by review of credentials and current licensure information documented in the Veterans Health Information Systems and Technology

Architecture (VistA), must sign out 100 forms (one pad) which are recorded and accounted for by serial number. No partial pads in increments less than 100 will be issued. These forms are to be securely stored by providers who have signed these out from the Pharmacy Service at all times while they are in the provider's possession. Any loss of these prescription forms must be reported immediately to the Chief, Pharmacy Service and the Chief, Police Service. Disposal is in accordance with Department of Medicine and Surgery (DM&S) Records Control Schedule 10-1. If Prescription Form (VA Form 10-2577f) is returned to the pharmacy for any reason (i.e., the provider leaves employment or transfers), then the prescription forms that he/she turns into the Pharmacy will be destroyed by voiding and then placing in a secured and approved bin for shredding and documented with a witness as to the disposition and the serial numbers recorded.

- d. Hospital DEA registration covers the entire institution. Licensed independent practitioners whose position may require prescribing of Schedule II-V medications are required to obtain a personal DEA registration and prescriptive authority on this class of medications will be provided in accordance with DEA authority in regard to classes that may be prescribed. Residents will be assigned by Pharmacy Service an internal code number/DEA suffix, unless they work in the facility in a Contractual or Fee Basis role as a physician practitioner, in which case they must also obtain a personal DEA to use. The Pharmacy-assigned DEA suffix permits a resident physician to carry out functions within the confines of the healthcare system with respect to controlled substances during their training program without being personally registered with the DEA. VA Physicians may apply for their own DEA number free of charge and use that within the VA Healthcare System. The Chief of Staff's office will be asked to supply Pharmacy Service with an updated list of credentialed prescribers with current DEA numbers as staff changes. Mid-level practitioners (i.e., physician assistants (PAs) and nurse practitioners (NPs)) must also have applied for and received a personal DEA number, have licensure allowing specific prescribing of controlled substances prior to being given this prescribing capability and have an approved Scope of Practice authorizing this level of prescribing. Mid-level practitioners must abide by all the legal requirements of their state licensure as well as all VA regulations and requirements. All controlled substances Schedule II-V will be electronically entered. This will require all practitioners authorized to prescribe controlled substances to have a valid Federal DEA number, an active PIV card, and know their PIN number in order to electronically enter controlled substances orders in the Computerized Patient Record System (CPRS). Residents that do not moonlight as VA providers may still use the VA DEA number, but will still need an active PIV card and to know their PIN number.
- e. All transactions dealing with controlled substances will be completed in black or blue ink or typewritten. All controlled substance records must be maintained for three years.

5. PROCEDURES:

a. <u>Ordering Controlled Substances:</u> Schedule II controlled substances are ordered electronically through the Controlled Substance Ordering System (CSOS) utilizing an electronically signed digitally encrypted DEA Form 222 authorized by the facility's designated power of attorney sent to the Prime Vendor for fulfillment. Schedule II narcotics are ordered separately from all other schedules. Each order for controlled substances will not contain any

non-controlled substances. Items are ordered from the Prime Vendor or direct from the manufacturer. The only time that a hard copy DEA Form 222 would be used would be if the vendor or manufacturer is not equipped to accept an electronically generated order, or if there was an emergency to where electronic ordering was not available or operational.

b. **Receiving Controlled Substances:** All controlled substances will be delivered directly to Pharmacy Service in unopened, sealed containers and immediately placed in the designated Pharmacy vault. The controlled substances technician, assigned/authorized pharmacy technician, or designated pharmacist and designated Accountable Officer from Logistics will check, verify, sign, and date the invoice for all received controlled substances. Per VHA Handbook 1108.1, Controlled Substances Pharmacy Stock, all controlled substance documents of receipt, reconciliation, distribution, or destruction will be signed by a licensed pharmacist overseeing this process. Therefore, all invoiced items received in the vault will be evaluated and ultimately signed by a licensed pharmacist. The procurement technician processes the signed and completed invoice into the Drug Accountability package in Veterans Health Information Systems and Technology Architecture (VistA). It is then verified again by the controlled substances technician or assigned/authorized pharmacy technician electronically, or licensed pharmacist and witnessed by the Accountable Officer from Logistics which upon verification, updates the narcotic inventory balance in the Controlled Substances package to reflect what has been ordered and received. A stamp has been created stating that upon signature, the Logistics Accountable Officer and the controlled substances technician, assigned/authorized pharmacy technician, or licensed pharmacist have witnessed the receipt and the verification of the incremented updated balances in the controlled substance package of VistA. A copy of all signed invoices and DEA Forms 222 electronically generated via the controlled substance ordering system (CSOS) where applicable will be maintained by the procurement technician in the pharmacy, in the vault by the controlled substances technician, and kept on file at Logistics.

The person processing the invoice into the Drug Accountability package cannot be the same person that verifies the invoice into that package, (i.e., the computer package will not allow these two processes to be completed by the same person). A designated Accountable Officer from Logistics will also be responsible for verifying the receipt of all CII controlled substances by reconciling, signing, and dating the DEA 222 form electronically generated from the controlled substance ordering system (CSOS), retained by the Controlled Substances Technician or designated pharmacist as verification of receipt of all CII narcotics. All reconciled DEA 222 forms electronically generated will be sent to the Pharmacy Item Manager at the Alvin C. York Campus for final disposition and future retrieval by the DEA as required.

c. Storage and Security:

(1) All controlled substances are stored in the vault until they are distributed to other authorized areas in the pharmacy or to the wards/clinics. The combination to the outer steel door will be limited to the Chief, Site Managers, Clinical Manager, and supervisors of Pharmacy Service. The inner day-gate is equipped with encrypted BioID fingerprint technology, which when used in combination with the scanning of the employee's name badge will permit entry into the vault. This will be limited to pharmacists other than those having access to the outer vault

door and be limited to no more than ten persons at any one point in time. Access to the vault will be monitored by a computerized security system to assure compliance with VHA Handbook 1108.1. Routine reports will be viewed weekly for vault access during evening hours and off tours, as well as overall reader access to all Pharmacy doors and vaults, with recorded documentation logged for dates of review. The security system also employs the use of cameras installed in the vault of which activity can be recalled by time or date. Any supervisor who has the combination to the outer steel door will not also be given a combination to the inner day-gate, therefore requiring two people for entry.

- (2) All access to the pharmacy vault by personnel who do not have electronic lock access will be logged onto a sign-in/sign-out sheet *and accompanied by authorized pharmacy personnel at all times while in the vault area.* The log sheet will be maintained and filed monthly by the controlled substances technician or designated pharmacist. The sheet will identify time-in/time-out of personnel and their reason for being there. Access to the vault will be limited only to vault business and routinely will not be more than two persons.
- (3) All controlled substances issued to wards, clinics and anesthesia service as a stock supply will be stored in a Pyxis Medstation accessible to nurses or nurse anesthetists, or other authorized licensed personnel (i.e. Dentist, Physician) working in that area only. The only exception to this would be the ordering and compounding of controlled substances requested by the Research area of VA TVHS. The Research area orders controlled substance stock electronically in VistA from the Pharmacy Service by approved licensed personnel and is issued from the pharmacy on a computer-generated and numbered green sheet. All controlled substance stock will be checked for expiration dates monthly by assigned pharmacy personnel and routinely on a daily basis via Pyxis report.
- (4) <u>Prepacking:</u> controlled substances and alcohols in unit-dose for inpatients or unit-of-use for outpatients will be done by the controlled substances technician. The controlled substances technician will be responsible for planning and maintaining an adequate number of prepacks. Prepacking will be kept to a minimum.

d. Inpatient Dispensing:

(1) <u>Dispensing:</u> all controlled substances and authorized alcoholic beverages will be dispensed from the vault primarily by the controlled substances technician or designated pharmacist to all Pyxis Medstations located on wards or clinics, Anesthesia, and outpatients. When delivering to all Pyxis Medstations, the controlled substances technician, designated pharmacist, or assigned pharmacy technician will replenish the cabinets and complete all electronic transactions in the VistA Controlled Substance package. The automated dispensing units have been programmed with appropriate par levels of stock adequate for usage at each particular location. A "pick and delivery" report is queued to generate automatically on a daily basis to inform the controlled substances technician of the areas that need restocking as well as a suggested restock report that can be generated from the Pyxis CII Safe Medstation located in the vault. These reports are compared on a daily basis to help determine usage and if any adjustments need to be made regarding par levels. Once it is determined what controlled

substance items are needed at each site, a pharmacist will check each order for correctness before delivery. Upon delivery and subsequent loading into the automated dispensing unit by an authorized technician or pharmacist, a licensed staff [i.e., Registered Nurse (R.N)., Licensed Practical Nurse (LPN)] will witness the restock and sign a receipt verifying the addition to stock and initial the quantities of each medication listed of which they are accepting custody. In addition to this wet signature and initialing of each quantity by licensed personnel accepting custody of this stock addition, it will also be necessary for them to perform an electronic verification at the Pyxis Medstation known as Rx Check. The electronic verification will serve to verify not only the quantity of the controlled substances being added to the inventory, but also the correctness of the medication being dispensed. Therefore, there are two checks in place in the dispensing and receiving of controlled substances to automated dispensing units. When the implementation/upgrade to Pyxis Medstation 4000 occurs, there will also be software enabling the user to scan the barcode on the drug and pocket for correctness as the items are being loaded and/or refilled into each medstation. Once all controlled substance medications have been delivered to their respective area of assignment, a Pharmacist will "reconcile" that the medication assignments met their intended destination. This reconciliation is accomplished but not limited to VistA and/or CII Safe generated reports (i.e., Pyxis vs. CII Safe, Review Send Report, Pharmacy Dispensing Report, and Destructions Holding Report). A signature by the reconciling Pharmacist will serve as verification that all medications released or returned from the vault met their intended destination.

- (2) Controlled substances and authorized alcoholic beverages to be stocked on the wards/clinic including Anesthesia and Research will be dispensed by the controlled substances technician, assigned/authorized pharmacy technician or designated pharmacist according to VHA Handbook 1108.1.
- (3) Controlled substances stocked in the Pyxis Medstation units will be replenished by the controlled substances technician, designated pharmacist, or assigned/authorized pharmacy technician as required and the controlled substances technician, designated pharmacist, or assigned/authorized pharmacy technician will complete all electronic inventory adjustments through the controlled substances package.
- (4) All inpatient orders will be entered by the provider using the CPRS. Written orders shall only be accepted when CPRS is inaccessible due to a power outage or emergency and the facility is in a contingency situation. Written orders shall include the name of the drug, dosage form, dose, route of administration, and instructions for administration. All written orders will also include the patient's name, social security number, ward, physician's signature, handwritten name, and pager number. Written orders will be checked and entered into the computer by a pharmacist.
- (5) Any patient medication order, documentation of administration, or record of waste may be charted in either volume or strength (i.e., ml, mcg or mg) in the patient record; however, the chosen nomenclature must be consistently used throughout the entire document and not include any unapproved abbreviations.

- (6) All electronically entered CPRS inpatient orders for Schedule II, III, IV, and V controlled substances will be verified electronically by a pharmacist.
- (7) Inpatient orders for Schedule II & III narcotics will be honored for a maximum of seven days. Orders for Schedule III non-narcotics through Schedule V and alcohol will be honored for a maximum of 28 days. Exceptions may be made on Schedule II and III narcotics if the responsible practitioner has evaluated the patient's condition and determined there is a need for a longer duration of therapy. In such cases, the provider may prescribe for a period not to exceed 14 days if the practitioner indicates a specific length of therapy or number of doses in the individual patient's order.

NOTE: This is usually for long-term care, oncology, and Hospice patients. Self-medication status will not include any controlled substances.

- e. <u>Outpatient Dispensing:</u> outpatient dispensing will be conducted in accordance with VHA Handbook 1108.1. Additional guidelines are as follows:
- (1) Schedule II-V controlled substance orders for outpatient dispensing will be entered electronically using CPRS. Each authorized prescriber will utilize his/her facility-issued PIV card and PIN to digitally sign all controlled substance prescription orders.
- (2) During computer downtime/contingency *only*, the physicians and dentists must use VA Form 10-2577F for all controlled substance prescriptions (Schedule II-V) and are responsible for complying with the following procedures. The form must be dated and signed on the day when issued (i.e., issue date only, no pre-signing allowed) and must bear the following information:
 - (a) Full name, address and social security number of the patient as well as his/her status;
 - (b) Name and DEA registration number of the practitioner stamped, typed, or hand printed;
 - (c) Practitioner's signature in blue or black ink;
 - (d) Generic name of controlled substance, one drug per prescription;
 - (e) Dosage form;
 - (f) Strength;
 - (g) Quantity (written out and numeric preferred to prevent diversion);
 - (h) Complete directions for use; and,
 - (i) No unapproved abbreviations used.

NOTE: Prescriptions will not be filled if they are more than 30 days old when presented.

A maximum of five refills will be permitted on Schedule III, IV, and V substances. These refills will be honored up to six months from the date the original prescription was written. Schedule II substances are not refillable and may be electronically issued for an amount not to exceed a 30 day supply. Physicians Assistants, Nurse Practitioners, and Clinical Pharmacy Specialists practicing under Scope of Practice must have the cosignature of the managing physician on all controlled substance prescriptions unless they have a personal DEA number, their state licensure permits such prescriptive authority, and they have an approved Scope of Practice authorizing such prescribing. Mid-level practitioners are to abide by all their State Licensure requirements on the prescribing of controlled substances at all times. Electronically edited changes or alterations are permitted on the prescription only if they do not change the original content or intention of the provider (i.e. strength and quantity changed but changes are equivalent in dose and frequency to what the provider originally prescribed) or break the integrity of the provider's digital signature. If editing of certain fields of the prescription becomes necessary such that the provider's digital signature will be broken, then the pharmacist must reject the prescription back to the provider so that he/she may reissue appropriately with their digital signature intact. At any point if a digital signature is compromised, then a "hard copy" prescription must be obtained to account for failure to receive a digital signature as indicated. Pharmacists will also screen all received hard copy controlled substance prescriptions when there is a computer downtime/ contingency or temporary provider issue with electronic prescribing, for the VA-required information and for the use of unapproved abbreviations cited by the facility which could lead to possible confusion in processing or dispensing of the prescription and return incomplete prescriptions to the prescriber for completion.

- (3) Controlled substances with refills will not be refilled early or a new prescription honored early unless the dosage has changed. No partial prescriptions are allowed on controlled substances. Alcohol will not be dispensed to outpatients.
- (4) Controlled substance prescriptions will be input into CPRS by the prescriber and processed by the pharmacist using VistA. The computer entry and label generated hard copy shall be considered a verified prescription. This entry and printout will serve as the prescription in dispensing controlled substances.
- (5) The inventory for each controlled substance dispensed, including the Pharmacy Drug Cache, for all schedules of controlled substances, will be completed on VA Form 10-2320 or electronic equivalent every 72 hours or as required in VHA Handbook 1108.2. Each page of the inventory record is to be signed by the person(s) completing the inventory. Pharmacy staff will verify the resulting balance (i.e., back counts on the remaining balances) each time a controlled substance is dispensed. Pharmacy will also keep a running list of each quantity dispensed and the date dispensed on the side of the stock bottle in order to track any discrepancies. Empty stock bottles with recorded prescription numbers and dispensed quantities will be kept inside the vault from one inventory until the next inventory is complete to assist in resolution if a discrepancy is discovered during this 72 hour timeframe.
 - (6) Positive *photo identification (ID)* will be obtained for each patient prior to dispensing a

controlled substance prescription. In addition to a photo ID, the Veteran's VA ID (VIC) card will be scanned in the ScriptPro® system against the batch label on the bagged controlled substance. If the patient does not have a VIC card that is scannable, the patient should be directed to obtain one prior to his/her next medication window pickup and positive identification shall include verification of at least two patient identifiers from this list in addition to the photo ID: full name, address, full date of birth, and full social security number by way of open-ended questions. For example, Pharmacy staff will not state the address and ask the patient if that is correct. The patient will need to recite this information for verification. If the patient does not have a photo ID, additional verification will be required. The patient's photo may be in CPRS (under Tools, then VistA Imaging Display) if the patient has had a VIC card done previously and this should be checked when no photo ID is available. The accepting party will sign the ScriptPro® electronic signature device, thus acknowledging receipt for the correct amounts of all scheduled drug prescriptions. Only the patient or his authorized caregiver is allowed to accept a controlled substance prescription with valid ID and signature. The authorized caregiver picking up a controlled substance prescription will be required to sign for receipt of the medication and to also write down their relationship to the patient before the medication is released to them.

NOTE: No VA TVHS employee will be permitted to take custody of a patient's controlled substance prescription at any time.

- (7) While awaiting pick-up, all controlled substance prescriptions will be kept in an electronically locked cabinet or vault in accordance with VHA Handbook 1108.1, such that person and time entry may be monitored. Any controlled substances that are not picked up the same day of issue will be sent to the Veteran at the beginning of the following week via the VA approved mail carrier in which a signature will be required as receipt of delivery. Any controlled substance sent via the VA approved mail carrier that originated as a window fill will be noted as such in the computer.
- (8) The controlled substances technician, designated pharmacist, or assigned/authorized pharmacy technician will complete all preparation functions on all controlled substances and a staff pharmacist will check all completed prescriptions within the confines of the vault. Vault personnel or other authorized/assigned personnel will move controlled substances awaiting dispensing directly from the vault into the approved secured cabinet with an electronic lock documenting person/time entry into the system. All Schedule II-V controlled substances will be sent via VA approved mail carrier requiring signature confirmation of receipt. Overnight mailing with Signature Required may be utilized where required for appropriate delivery.
- (9) "Hard copy" prescriptions for Schedule II-V controlled substances *must* be matched *daily* with the computer generated VistA EPCS Inspection Report which lists all controlled substance prescriptions that have been issued from the vault without the digital signature of the provider. This report is run daily in addition to the Pharmacy Daily Dispensing Activity Report that lists *all* controlled substance prescriptions released. This "hard copy" audit will be performed on a daily basis utilizing the computer-generated VistA EPCS Inspection Report verifying documentation of C-II-V prescription activity without provider electronic digital signature and will also be kept on file in the vault as well as signed and dated by the individual doing the audit and a licensed

pharmacist. The Pharmacy Daily Dispensing Activity Report will also be run daily as well and signed and dated by a licensed pharmacist. No controlled substance will be dispensed from a faxed copy, (i.e., the hard copy must be in-hand in order for dispensing to occur).

- (10) Prescriptions written for controlled substances cannot be mailed outside the United States.
- (11) The label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act must, when dispensed to or for a patient, contain the following warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."
- f. The controlled substances technician or designated pharmacist will be responsible for the preparation of the required Biennial DEA Controlled Substances Inventory according to DEA regulations as found in 21 CFR 1304.

g. **Inspections and Audits:**

- (1) An actual count of the perpetual inventory of all pharmacy controlled substance stock will be performed by the controlled substances technician, assigned/authorized pharmacy technician, or pharmacist at a minimum of every 72 hours in accordance with VHA Handbook 1108.1 for vault areas open seven days a week and 24 hours per day. All TVHS pharmacy controlled substance vaults are open continuously and fall into this category. Every 72 hours, the inpatient controlled substances technician and the outpatient controlled substances technician will switch roles and perform the 72 hour inventory of the alternate controlled substance stock previously performed on the last inventory, (i.e., no two inventories will ever be conducted by the same individual). Any discrepancies not associated with simple math or paperwork errors will be reported immediately to the area supervisor, the Chief of Pharmacy, the VA Police for documentation and preliminary investigation, and Controlled Substance Coordinator for reporting to the Facility Director, who will notify the Office of Inspector General (OIG) and other agencies as required.
- (2) An unannounced monthly inspection of all controlled substances will be completed in accordance with VHA Handbook 1108.2. All areas where controlled substances are stored will be inspected including pharmacy, wards, clinics, anesthesia, research, and Pyxis. Controlled substances inspectors will randomly check controlled substances signed out of stock (e.g., Pyxis, etc) for at least five actual active patient orders but not less than two active patient orders and documented administration. The Controlled Substances Coordinator will monthly certify by memorandum to the Director the accuracy of the records and inventory in the areas inspected. Each assigned inspector will complete an approved checklist of mandatory items to be reviewed per controlled substance area as required in VHA Handbook 1102.2, The Inspection of Controlled Substances. The Controlled Substances Inspectors will also perform either a full inventory of all controlled substances found in the area(s) of assignment quarterly, or an inventory of at least ten percent of the controlled substance stock found in the assigned narcotic inspection area on all months that a full inventory is not performed.

(3) The controlled substances technician or designated pharmacist will be responsible for unscheduled audits of controlled substances stored on wards/clinics. Discrepancies will be immediately communicated to the Chief, Pharmacy Service. Also, pharmacy supervisors and/or the Drug Control Officer may conduct unscheduled audits of all controlled substances stored in Pharmacy Service with the assistance of the Control Substance Officer (CSO). All unresolved Pyxis discrepancies will be reported to the Chief, Pharmacy Service, the Chief, Police Service, the Controlled Substance Coordinator, and the Director of the Facility who will ultimately report to investigative offices such as the OIG and DEA if not resolved within 72 hours of occurrence.

h. Returns:

- (1) All completed Controlled Substance Administration Records, VA Form 10-2638, will be returned to Pharmacy Service in accordance with VHA Handbook 1108.1. These completed forms can be returned after the ward/clinic has been inspected and before the first day of the following month by appropriate personnel. These completed forms will be reviewed by pharmacy for mathematical accuracy, signatures, and proper documentation of wasted medications. All wasted medications will be documented by two licensed personnel and as instructed in VHA Handbook 1108.1. After review, all completed forms will be returned in VistA and filed in the pharmacy vault for a minimum of three years before destruction.
- (2) Expired or excess controlled substances must be returned to pharmacy from the wards/clinics after the ward/clinic has been inspected and before the first day of the following month. Procedures for turn-in, storage, and destruction or reissue will be in accordance with VHA Handbook 1108.1 and all applicable Waste Management policies.
- (3) Returns from Pyxis will be determined for suitability of reissue or destruction by review of usage/storage and expiration dating upon request from the ward/clinic. Upon removal from the automated system by a pharmacy employee, reusable controlled substances will be returned to pharmacy and prepared for reissue. Controlled substance items that will expire soon, or are damaged or deemed unusable, will be placed in a tamper resistant evidence bag at the site of removal or discovery and signed by both the pharmacy technician and the nursing staff or other licensed personnel witnessing the removal and quantity sealed for destruction preparation.
- (4) Controlled substances returned by mail and determined not suitable for reissue will be prepared for destruction in accordance with VHA Handbook 1108.1.
- (5) Controlled substances returned by mail as undeliverable and those not picked up by patients at the pharmacy window and determined suitable for reissue will be returned to pharmacy stock in accordance with VHA Handbook 1108.1.
- (6) Returned controlled substance prescriptions as undeliverable are tracked electronically on the VA approved mail carrier website via a tracking number. Upon documentation via the website that a package has not been delivered, that information is recorded onto a spreadsheet with the patient name, date sent, tracking number, and prescription number. It is then the

responsibility of the vault personnel receiving the returned package(s) to supply information on the spreadsheet as to the disposition of each package (i.e., resent with new tracking number and date, patient picked up with signature log, or destroyed with documentation of a destruction holding number).

- (7) Controlled substances, along with all other medications, surrendered by a patient upon admission to the hospital will be returned to the patient's home by mail if there is no caregiver available to take the patient's medications back to the patient's home. Padded mailing envelopes will be provided by pharmacy to areas most likely for a patient to enter the hospital as an admission (e.g., triage, admissions, nursing wards). Documentation of medications brought in by the patient and mailed to the patient's home must be made in CPRS by the staff receiving the medication as well as securing the use of a witness to verify the integrity of the medication as it is sealed and prepared for mailing to the patient's home. Preferably this witness would be the patient if they are physically able to participate in this procedure. The envelopes are addressed and delivered to Outpatient Pharmacy in a sealed status for prompt mail delivery.
- i. <u>Accidental Breakage or Loss in the Pharmacy:</u> Accidental breakage/loss of small quantities of controlled substances will be documented in accordance with VHA Handbook 1108.1.
- j. Loss in the Mail: The pharmacist handling the patient's complaint that his/her medication was not received should evaluate the situation to determine the validity of the complaint and take appropriate action to research the package information and subsequently notify the provider of the findings. A notation will be made on the narrative in the computer to the effect that a loss has occurred and document what action was taken by pharmacy and the provider. Each TVHS outpatient pharmacy employee preparing controlled substance prescriptions for delivery via the VA approved mail carrier will perform a daily reconciliation of the prescriptions dispensed/ released from the vault from the Pharmacy Dispensing Report, with all prescriptions prepared for mail delivery and window pickup to insure that there is accountability for each prescription released.

Notification of any complaint involving the loss of a controlled substance during mail transit will be forwarded to the Consolidated Mail Outpatient Pharmacy (CMOP) Program Manager (York ext. 23723/23710) who will in turn notify the Inspector General's Office, the CMOP and other agencies/personnel where applicable and in accordance with loss procedures outlined in VHA Handbook 1108.1.

k. Nursing Administration of Controlled Substances:

(1) Administration of controlled substances, as with all inpatient medications, dispensed from Pyxis will be documented by using the electronic BarCode Medication Administration (BCMA) system. Documentation of the administration of controlled substances on the Pro Re Nata (PRN) and One Time Administration Record or the Medication Administration Record will only be permitted in an instance where BCMA is not available due to a computer contingency situation. Administration of controlled substances not stored in an automated system will be

documented using the same method described and, in addition, will be documented on VA Form 10-2638.

- (2) The setup and usage of a Patient Controlled Analgesia (PCA) pump is restricted to fully trained medication nurses who are familiar with all operations of the PCA pump. Narcotics used via a PCA pump must be documented through the BCMA software package and only either on a paper Medical Administration Record (MAR) or as a PRN when the BCMA is unavailable due to a computer contingency situation. The medication nurse responsible for a patient using a PCA pump will document at the end of each shift the remaining balance of narcotic. In the event that a quantity of narcotic administered via a PCA pump is remaining following the discontinuance of therapy, the destruction of the remaining balance of medication will be documented electronically in the Pyxis Med station with a second licensed witness as instructed in VHA Handbook 1108.1. If a patient expires while receiving narcotic analgesia via a PCA pump, the responsible medication nurse, along with a second licensed witness, will document the remaining quantity of medication, waste appropriately at the Pyxis Med station, and make certain that the remaining balance of narcotic is discarded/destroyed appropriately in accordance with VHA standards of handling pharmaceutical waste. When warranted, the PCA pump will also be tested to insure proper function.
- (3) All used fentanyl patches and intravenous (IV) bags will be wasted immediately by cutting the fentanyl patch or bag and placing the patch, after folding in half in a sharps container and the contents of the IV bag down a sink drain, with that wastage witnessed by a second licensed person and documented in the automated medication dispensing system (Pyxis), regardless of duration of use on the patient. Appropriate waste documentation is expected on every discard. Even when a patient enters the facility wearing a fentanyl patch, a waste of this patch must still be performed at the Pyxis Medstation by entering "waste", selecting the correct patient's name from the census, and then touching the "all meds" bar at the bottom of the screen. The appropriate selection for the fentanyl patch to be wasted is then selected. This selection shall be named "Discarded/Used Fentanyl Patch". Once selected, the "remove" quantity will default to "1". The user then shall select "waste now", "accept", and then have his/her witness enter their user identification into the system. The "amount given" on the following screen shall be entered as zero since this documentation is for discarding a used patch and the amount "wasted" entered as one. Once recorded, the patch will then be immediately folded in half and discarded/destroyed appropriately by acceptable VHA and The Joint Commission (TJC) standards. This method will also be employed in the disposal of a testosterone patch.
- (4) In cases where a controlled substance is dispensed from Pharmacy on a green sheet, which is limited to the Research area of TVHS, the designated and authorized person will inventory the stocked controlled substances at the beginning of the tour and at the end of the tour, but only on the days where the double-locked cabinet is entered. VA Form 10-1043, Alcoholics and Narcotics Inventory and Certification Record will be used to document the agent's signatures. Any discrepancy will be immediately reported to the Chief, Pharmacy Service and the Chief, Police Service.

- (5) All wards/clinics will stock and maintain enough controlled substances to avoid shortages after hours and over weekends and holidays. The controlled substances technician, assigned back-up controlled substances technician, or designated pharmacist will stock and maintain enough controlled substances in all Pyxis units to avoid shortages after hours and over weekends and holidays.
- (6) In the event there is an after hours need for a controlled substance, the pharmacy will be notified and will replenish as necessary to accommodate the shortage. Inpatient pharmacy narcotic vaults are open to access 24 hours a day/seven days a week to supply patient needs. Due to the continual access of obtaining controlled substances to replenish Pyxis and meet the needs of patient care, there is no circumstance where the transferring or borrowing of controlled substances or any other medication is required.
- 1. Automated System Back-up Plan: In the event of complete Pyxis failure, VA Form 10-2638 will be issued on all wards for the documentation and record keeping of all ward stocked controlled substances until such time the automated system can be repaired or replaced. Inventories of all stock will be conducted by nursing staff at each shift change and all other policies pertaining to the use of VA Form 10-2638 will apply. Provided that the interruption in Pyxis service is not detrimental to the actual use of the medstation(s) during computer or system downtime, the devices will be set to enter a phase of "critical override" to where controlled substance medications may be removed emergently until interface data can be restored. If there is a Pyxis failure on an isolated medstation only, arrangements may be made for a few nursing staff to gain access to the nearest functioning Pyxis Medstation such that when entering their patient in this alternate medstation location, they will be able to remove medications from his/her profile.
- m. Destruction of Controlled Substances: Controlled substances that are determined to be unsuitable for reissue will be removed from pharmacy stock and destroyed in accordance with the procedures outlined in VHA Handbook 1108.1 and the VA TVHS policy on Hazardous Waste Management. At a minimum, the turn in for destroyed controlled substances will be performed monthly. All controlled substances identified for destruction will be immediately secured in an approved evidence bag with a tamper evident seal, signed and dated across the seal by two personnel. If expired/damaged controlled substance medications are removed from a ward area to be brought back to the pharmacy vault for destruction, then a licensed hospital employee (i.e., RN, LPN, DDS, MD, CRNA) must sign the generated paperwork at the automated device as well as the evidence bag itself which will relinquish custody back to the pharmacy to hold until destruction by a Reverse Distributor ensues. These evidence bags will then be placed in a sealed tote within the vault. The tote will be secured with numbered tags that will be recorded onto a Destruction Log as to date, contents and any reason that the seal was broken and new numbered tags applied. The corresponding numbers on the tags will be recorded on each 72 hour inventory sheet and inspected at the time of each inventory. All controlled substances marked for destruction will be electronically entered as a Hold for Destruction in the Controlled Substances VistA package and subsequently turned over to a certified reverse distributor giving a receipt of documentation that all identified items have been destroyed. The acceptance of controlled substance numbered items being held for destruction by the reverse

distributor will be witnessed, reviewed, and reconciled by an Accountable Officer from Logistics Service and signed by a licensed pharmacist as required in VHA Handbook 1108.1. The reverse distributor will then subsequently mail back a manifest of the controlled substance items removed from the narcotic vault that have been destroyed. The controlled substances technician assigned backup pharmacy technician or designated pharmacist shall then reconcile these manifests with the records in the vault for what was indeed identified and sent to be destroyed. This manifest reconciliation will then be reviewed and signed by a Pharmacist for validity and correctness.

n. Controlled Substances in Research Areas:

- (1) All controlled substances for use in research (animal or human) must be ordered through Pharmacy. All controlled substances must be ordered separately from non-controlled substances. The drugs are to be charged to the appropriate research cost control point. Pharmacy vault staff will assure that an approved protocol involving the ordered medication is on file in the vault prior to dispensing.
- (2) On receipt, Pharmacy Service must issue the drug to the appropriate research area. The drugs are to be charged to the appropriate research cost control point.

o. Accountability:

- (1) Risk management indicators will be reviewed by pharmacy managers and Healthcare System management regularly. Identification of items at risk will be accomplished by Chief, Pharmacy Service. Chief, Police Service and Chief, Pharmacy Service will meet with local police, state police (Tennessee Federal Bureau of Investigations (TBI)), OIG, and DEA regional staff as required to determine current diversion products.
- (2) Any suspected theft, diversion, or suspicious loss will be reported immediately to the Chief, Pharmacy Service, the Chief, Police Service, the Health System Director, and the OIG Criminal Division and to the DEA within 24 hours of the loss. The loss, theft, or diversion will be reported in accordance with procedures listed in VHA Handbook 1108.1.
- **6. REFERENCES:** VHA Handbook 1108.1 and 1108.2; 21 CFR 1300 to end
- **7. RESCISSION:** TVHS Memorandum 626-10-119-09 dated June 4, 2010.
- **8. RESPONSIBILITY AND REVIEW:** Chief, Pharmacy Service will review annually and updated no later than September 30, 2016.

/s/ Juan A. Morales, RN MSN 11/21/2013

Juan A. Morales, RN, MSN Health System Director

SCANNING POLICY

1. PURPOSE: To define policies, objectives, and responsibility for scanning of Department of Veterans Affairs (VA) and non- VA documents related to patient care into the Computerized Patient Record System (CPRS) for Department of Veterans Affairs Tennessee Valley Health Care System (VA TVHS).

2. POLICY:

- a. Only documents that cannot be created or interfaced with CPRS will be scanned. Scanned documents will be made available to all clinical and support staff who currently have access to CPRS. All scanned documents will be handled as any other paper document was handled prior to scanning. Scanning of older documents is available on a case-by-case basis, by Health Information Management (HIM) or the appropriate decentralized service.
- b. Documents that originate within the clinic or from inpatient care, and cannot be entered within CPRS, will be scanned by HIMs and/or by the appropriate decentralized service. Documents originating at the Community Based Outpatient Clinics (CBOCs) will be scanned at those sites, when staffing allows. Otherwise, they will be forwarded to the HIMs Scanning Unit for scanning via secure method.
- c. The Medical Record Forms Committee (MRC) will approve the documents to be scanned into CPRS. Only those approved will be allowed to be scanned. All forms and documents standard to the VA will be reviewed by members of the Forms committee for standardized naming conventions for note titles. Administrative documents/images and other documents as determined might be captured more appropriately by attaching to the patients imaging record instead of a progress note using standard categories in Veterans Integrated System Technology Application (VISTA) Imaging.
- d. Originals (hardcopy) of scanned documents will be recycled once quality assurance checks have been performed. VISTA Imaging Display will be accessed to check the accuracy of the patient information entered, date of procedure and correct note title used to index the document into CPRS. Once that has been completed, the electronic copy becomes the original copy.
- e. Quality controls must be completed by all services scanning/capturing documents/images. Scanning quality controls must include the following: integrity of the data captured, accuracy of linking to correct patient and note title, accuracy of indexing document type, specialty, event/procedure, and visit.

3. RESPONSIBILITIES:

a. <u>The Chief Health Information Management Section (HIMS) or designee is</u> responsible for:

- (1) Ensuring that all requests for scanned documents are approved by the Medical Record Forms committee:
- (2) Ensuring that staffs performing scanning duties are provided with training and certifying competency of the staff designated to scan documents;
- (3) The Chief, HIMS or Privacy Officers will correct all errors involving scanned images and will be the only staff with the functionality to delete a scanned image.

b. The Medical Records Forms Committee is responsible for:

(1) Approval of the types of documents and images scanned/imported into CPRS. Only those VA and non-VA documents and images approved will be scanned/imported into the electronic record.

c. The File/Scanning supervisor(s), or their designees are responsible for:

- (1) Providing training to staff on scanning procedures and proper selection of note titles;
- (2) Performing quality control monitoring for importing images or document scanning within their service/section. Audits will be performed on 100% of imported images/photos until no error.
- d. Scanning staff will be responsible for accurately scanning the documents into VistA imaging according to established policies and procedures.
- e. Fee Staff will be responsible for scanning all non-VA Purchase Care (Fee) documentation into the Fee Basis Claims System (FBCS) Doc Manager using the appropriate title. The FBCS Doc Manager will transfer clinical documentation automatically into VISTA Imaging.
- f. The VISTA Imaging Manager will grant appropriate VISTA Imaging access to employees who will be performing document-scanning duties.

4. PROCEDURES:

a. Staff responsible for scanning duties will ensure that each document contains at least two patient identifiers. This will include full name, full social security number, or full name plus last four of social security number and/or date of birth (DOB). When this information is missing, the staff member will research CPRS and other sources to determine the accuracy of the patient identification information as appropriate. When an accurate determination cannot be made by scanning staff, the document will be returned to the originating service for further identification.

- b. Staff performing scanning duties will perform 100% review of each scanned document during the scanning process for quality control purposes to ensure it is readable and retrievable for health record retention.
- c. Errors involving scanned documents will be reported to the Chief, HIMS or designee, Privacy or TVH Privacy. The Chief HIMS or designee will review the record and report error. If the image is scanned incorrectly (wrong patient, wrong image, etc.) and needs to be deleted from the record, the Chief HIMS or designee will follow this procedure:
- (1) Staff will send an email to g. Privacy in VISTA or encrypted email to the TVH Privacy mail group in Outlook, and use 'Correction Request' in subject line. Include the following information in the email: the document or image to be deleted; full patient name and last four of SSN; date of document; image document title; image I.D. number; and reason for deletion.
- (2) Scanning staff will add an addendum to any progress note with a linked image for removal. For example, image entered on wrong patient or wrong image scanned.
- d. Errors involving iMed Consents that are created on the wrong patient, signed and sent to the electronic record should be sent to g.Privacy in VISTA or encrypted email TVH Privacy mail group in Outlook.
- (1) If the error was discovered before the treatment /procedure, a new form should be signed by the patient.
- (2) If the error was discovered after the treatment/procedure, the members of the Privacy mail group will print the image, make a pen/ink correction to the document, and have the iMed Consent re-scanned into the correct patient's record. The clinician should write a note in the correct patient's record explaining why correction was done.
- e. Scanning staff will stamp or write in 'scanned' on each scanned document, initial, and date as verification that the document has been processed. This will allow for staff performing the quality monitor to know that the scanning staff has performed their own quality monitor check prior to completion of the capture of the scanned document.
- (1) Scanning staff will stamp or write 'POOR QUALITY' on any document that is of poor quality prior to scanning, after it has been reviewed by the supervisor.
- (2) Scanning staff will stamp or write 'BLANK PAGE' on any page intentionally left blank prior to scanning.
- (3) Source documents will be placed in a container for shredding following the completion of quality checks of scanned documents as outlined in VHA Handbook 1907.01. Original source documents may be destroyed after scanning as long as record retention and quality control measures have been completed. Image records must be retained to satisfy the 75 year after the last episode of care retention requirement.

f. Non-VA Purchased Care (FEE) documents approved for scanning/importing must be in compliance with VHA Handbook 1907.01. Only those non-VA documents that are authenticated may be maintained as part of the patient's permanent health record. Clinical providers must

indicate which documents including images need to be included, and this should be limited to pertinent, present, or continued care. A summary progress note written by the clinician may be used instead. This will eliminate the need to scan the non-VA documents. Clinicians who want external source documents scanned must complete Attachment A and forward to scanning. Documents that need further clarification will be sent back to clinician for additional information.

- g. When non-VA clinical documents are received on compact disc (CD), the clinician can enter a summary progress note of the reviewed CD or submit a hard copy of the documentation that should be included in the electronic record along with Attachment A.
- h. All non-VA clinical documents <u>not</u> approved for scanning by the clinician will be returned to the patient or properly disposed of in the shred bin.
- i. Copyrighted documents must be approved by the originator of the document before scanning into the electronic record. Evidence of permission must be on file and submitted for review by the Forms Committee.
- j. For periods of CPRS/VISTA Imaging unavailability for more than four hours, documentation completed during the time that CPRS was not available will be scanned into the electronic medical record.

5. REFERENCES:

- a. VHA Handbook 1907.01, Health Information Management and Health Records dated September 19, 2012
 - b. The Joint Commission Manual Information Management Standards
 - c. VHA Records Control Schedule (RCS-10-1)
- d. Health Information Management Office of Health Data and Informatics, Scanning FAQ's, November 2012
- e. Fact Sheet Non-VA Purchased Care VISTA Imaging Capture Indexing Reference Guide for Internal and External Documents, January 2013
 - f. VISTA Imaging System Technical Manual, December 2012, Revision 38

- g. Patient Care Support During Hospital Computer System Non-Availability, August 29, 2012
- **6. RESCISSION:** TVHS Memorandum 626-10-136-27, dated February 16, 2010.
- **7. RESPONSIBILITY AND REVIEW DATE:** The Chief, Health Information Management Section (Business Office) will review by February 28, 2016.

/s/ Juan A. Morales, RN, MSN 07/15/13

Juan A. Morales, RN, MSN Health System Director

Attachments: A thru C

FOR HIM STAFF USE ONLY--

Record Prep Performed

Date/Initials

Supervisor's Name

QUALITY REVIEW SCANNING CHECKLIST

ATTACHMENT A

Tennessee Valley HealthCare System	_	TO SCAN NON-Varmation Managemen	A DOCUMENTS FORM nt Section	
NOTE: The following options are availa	ble when presen	nted with Non-VA pa	per records. Please review and	
proceed as noted:				
Available Options		·	hould proceed	
Outside records returned to patient		to patient	ot required – return all paper records	
Records to be destroyed per preference of the patient		Form completion not required – Discard records in approved shred container		
Summary Progress note written in lieu of scanning Non-VA Documents		Form completion not required – Either return records to patient or discard records in approved shred container		
Request that some or all of the Non-VA records be scanned in CPRS		The completion and mailing of this form is mandatory – Review all required elements below.		
FORM REQUIREMENTS FOR ALL	-			
NOTE: Please attach the documents you				
patient and check the appropriate boxes below. Only those documents approved for scanning will be scanned				
without further justification. Only Legible and Authenticated documents are allowed to be scanned. Please initial				
the documents/pages you wish to have scanned.				
FROM: (Name of Hospital, HMO, or Do	octor where care	was provided)		
**To Be Completed By Reviewing Clinician: Date Records Reviewed:				
Patient Name:	La	sst 4 #	DOB:	
Clinician's Name	Clinician's Sign	ature	Date	

Route FORM TO: ATTN: Scanning Section, Nashville, 1st floor, room G129 or ACY-Bldg. 5B, Rm. 243

Record Scanned

Date/Initials

Date

NOTE: HIMS employees must complete this section with date performed and initials

-- RANDOM QUALITY REVIEW BY HIMS SUPERVISOR --

Record Indexed

Supervisor's Signature

Date/Initials

ATTACHMENT B

QUALITY ASSURANCE PROCEDURES

1. PURPOSE: All document images will be monitored to insure documents scanned into the patient's computerized medical record are accurate for clinical and administrative use. This process will also ensure compliance and adherence to the medical center Document Scanning Policy.

2. RESPONSIBILITIES:

a. File/Scanning Supervisor is responsible for:

- (1) Performing quality assurance monitors on documents scanned by the HIM scanning staff; and.
- (2) Insuring the HIM scanning staff are properly trained to capture document images in CPRS.

b. <u>Services involved in decentralized scanning of documents originating in their departments are responsible for:</u>

- (1) Performing quality monitor, using Attachment C, on documents scanned by the staff of their service;
- (2) Insuring staff are properly trained by the File/Scanning supervisor or the VISTA Imaging Manager to capture document images in CPRS; and,
- (3) Forwarding results of monthly quality monitors to the Chief, Health Information Management Section or designee.

3. PROCEDURES:

- a. The supervisors will identify 50 documents per month for each individual who scans. The images will be reviewed using the Image Quality Assurance Monitor (Attachment C). The documents will be screened for proper and timely entry into CPRS and legibility of the scanned document. Audits will be performed on a weekly basis.
 - b. All discrepancies will be followed up with the individual who scanned the document.
- c. If a document is entered into an incorrect patient record, the Health Information Manager/Record Officer, or designee, will be notified to delete the document from the wrong patient's record and enter into the proper record.

- d. If the document is entered into the wrong progress note title, the Health Information Manager/Record Officer, or designee, will be notified for proper action.
- e. If the document is illegible, the Chief, Health Information Manager, or designee, will be notified to delete the scanned document and re-scan the document.
 - f. Results of the QA audits will be sent to Chief, HIMS, or designee, on a monthly basis.
- g. If problems are identified, focused reviews will be conducted to look at a higher volume of cases. The errors will be investigated to determine the cause, scope and seriousness.

Scanner: _____

ATTACHMENT C

IMAGING QUALITY ASSURANCE MONITOR

Records	1	2	3	4	5	6	7	8	9	10
Last Name										
Last Four SSN										
Document										
Type										
Correct Document										
Date Entered #pages										
Correct										
Name Entered										
Correct										
Title Entered										
Document Positioned										
Correctly										
Document Legible										
(Note if record is not										
legible)Also note on										
document										
Date Received										
Comments:										

MANAGEMENT OF PATIENTS AT RISK FOR A PSYCHIATRIC EMERGENCY

- **1. PURPOSE:** To outline and update the policy and provide guidance for the assessment and management of Veterans with suicidality or other psychiatric emergencies. This includes guidance for proper assessment, management, observation, and transfer of Veterans with suicidality or with any psychiatric emergency to prevent elopement and/or destructive behavior directed at self and/or others.
- **2. POLICY:** It is the policy of the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) to ensure the safety of all personnel and Veterans throughout the facility and Community Based Outpatient Clinics (CBOCs) when dealing with Veterans with suicidality or who are at risk for or currently undergoing a psychiatric emergency. VA TVHS will specify the policy, procedure and management strategies of Veterans with suicidality or other psychiatric emergency which addresses the following: implementation of strategies to identify Veterans with suicidality or other psychiatry emergency through the proper assessment, treatment, and management of these Veterans; processes for evaluation and consultation by mental health (MH) staff for appropriate and timely communication from other services to MH service, and timely reciprocal communication from MH to other services; use of suicide precautions; observation strategies which will ensure safety during transfer while using a one-to-one (1:1) observation level for any psychiatric emergency; guidance regarding the documentation of relevant information within the Computerized Patient Record System (CPRS); and staff training.

These policies and procedures are in place to provide treatment guidelines for Veterans with suicidality or other psychiatric emergencies. It is important to note that serious mental illnesses are associated with an increased risk of death due to suicide in spite of ready access to the best medical and mental health care. Efforts are directed at reducing suicidal behaviors, with the full recognition that all suicides cannot be prevented.

- **3. RESPONSIBILITIES:** This directive applies to all medical centers and CBOCs in VA TVHS.
- a. <u>VA TVHS Health System Director</u>. The Director, or designee, is responsible for assuring VA TVHS compliance with this policy. The Director is responsible for providing the VISN 9 Network Office (including Network Director, Chief Medical Officer, and MH Services Manager) with copies of all locally developed suicide prevention policies and procedures. Changes to this policy or procedures involving the management of suicidality and other psychiatric emergencies must be directly communicated to the Network Office.
- b. <u>Service Chiefs.</u> Service Chiefs, or designees, are responsible for ensuring that clinicians accurately comply with this policy.
- c. <u>Clinicians</u>. Clinicians are responsible for assuring that all Veterans presenting to them with behavioral health issues are assessed for suicide risk as established in this policy.
- d. <u>Staff Members.</u> Any staff member who encounters a Veteran with suicidality or other psychiatric emergency will accurately comply with this policy.
- e. <u>Facility Suicide Prevention Coordinators.</u> Facility Suicide Prevention Coordinators (SPC) are responsible for overseeing the overall suicide prevention efforts at the medical center, as well as,

establishing and monitoring Patient Record Flags (PRF) for Veterans identified as being at risk for suicide. SPCs are responsible for coordinating and providing the training of all staff on suicide prevention principles and on implementation of any suicide-related policies and templates (See TVHS Policy 626-YY-11M-09 Patient Record Flags to Identify Patients at High Risk for Suicide).

f. <u>VA Police</u>. VA Police are responsible for directly assisting MH clinicians in bridging communications between the VA facilities and community law enforcement officials to obtain welfare checks. This assistance includes contacting the appropriate law enforcement agency to conduct the welfare check. The VA Police are also responsible for obtaining information from public law enforcement officials and communicating back to the MH clinician(s) the results of their efforts the same day they obtain information on welfare checks.

4. **DEFINITIONS**

- a. <u>High Risk for Suicide</u>. Veterans may be determined to be at high risk for suicide for a variety of reasons. Determination of "high risk for suicide" will be finalized by the facility's Suicide Prevention Team and will be signified by the placement of a high risk for suicide patient record flag on the individual's medical record. This determination is always a clinical judgment made after an evaluation of risk factors (e.g., history of past suicide attempts, recent discharge from an inpatient mental health unit), protective factors and the presence or absence of warning signs as listed on the Suicide Risk Assessment (**See Attachment B**). The following list, although not exclusive, contains indicators that Veterans may be considered at high risk:
 - (1) A current verified report or witnessed suicide attempt;
- (2) Identification of current serious ideation that requires an immediate change in treatment plan such as hospitalization;
 - (3) Presence of any of the following warning signs:
 - (a) Threatening to hurt or plan to kill themselves;
- (b) Looking for specific ways to kill themselves and seeking access to such means as pills or weapons;
- (c) Talking or writing about death, dying, or suicide when these actions are out of the ordinary for the individuals.
- b. <u>Self-Directed Violence Classification System Definitions</u>. Suicidal behavior will be defined using the Self-Directed Violence Classification System found in VISN 9 Directive 10N9-100-10 **Attachment A: CDC/VA/DOD Definitions**.
- c. <u>Clinician.</u> A clinician is an appropriate health care provider who has had specific training and clinical experience in a mental health discipline and who is responsible for providing mental health services.

d. <u>Psychiatric Emergency.</u> A Psychiatric Emergency is a situation when the Veteran has active suicidal, homicidal, and/or assaultive tendencies with the potential to cause danger to self or others AND in which timely intervention is of the essence.

e. Different levels of observation

- (1) 1:1 Observation. Veteran will be **WITHIN ARMS' REACH** of the staff member at <u>all</u> times. Paper gown, sheets, etc. are optional and often not merited due to the close proximity of staff and Veteran. Physician's order required for 1:1, to include justification and time limits not to exceed 48 hours. Veterans on 1:1 (within arms' reach) will be evaluated on weekends to determine if clinically appropriate to continue.
- (2) Eye Sight Observation. Veteran will be OUT of arms reach <u>but within eyesight at all times</u>. Paper gown, sheets, etc. would generally not be indicated in this situation.
- (3) <u>Close Observation.</u> The patient will be <u>seen</u> every 15 minutes. Paper gown, sheets, etc. could be utilized during this intervention as the Veteran <u>would not</u> be in constant eyesight.
- (4) <u>Seclusion</u>. For the veteran who is in a locked room where exit is prohibited, the observation level will be, IN PERSON, the first hour. After the first hour, the Veteran may be <u>watched by a staff member via VIDEO AND AUDIO</u> for the remainder of the seclusion episode, if the risk for self-harm has decreased substantially. Paper gown, sheets, etc. could be utilized during this intervention as the Veteran would be out of arms' reach of staff as they are monitored via video/audio.
- f. <u>Physical Behavioral Restraints.</u> For any Veteran in cuff and belt restraint for behavioral reasons, the observation level is 1:1 (see above for the definition of 1:1). Paper gown, sheets, etc. would generally not be indicated in this situation (See TVHS Policy 626-YY-118-12 Physical Restraints and Seclusion).

5. PROCEDURES

a. Face-to-Face Patient Evaluation

- (1) Veterans who are identified as having clinically significant warning signs for current suicidality during a face-to-face evaluation at any VA facility will be referred to a mental health clinician for an immediate detailed suicide assessment and initiation of a plan of care. CBOCs will initiate emergency services when a mental health clinician is not on site.
- (2) A "warm handoff" will occur between the referring staff member(s) and the mental health clinician. This requires a direct, in-person handoff of Veterans between referring staff members and mental health clinicians, as well as verbal communication to the receiving clinician and written documentation in the Computerized Patient Record System (CPRS) (e.g., level of suicidal or homicidal risk, specific care instructions, etc., if the communication is between clinicians). All Veterans expressing or displaying current suicidal behavior must be attended by a staff person (1:1 observation) until given clearance to discontinue this level of care by a mental health clinician (See TVHS Handoff Communication Policy 626-YY-118-30).

- (3) Once Veterans with clinically significant warning signs for suicide are identified, a mental health clinician will then conduct a detailed suicide assessment and document relevant factors in the medical record (See Attachment B- Suicide Risk Assessment).
- (4) If the assessment indicates the Veteran is actively suicidal and requires inpatient hospitalization, the Veteran must remain on 1:1 observation until a psychiatrist has re-evaluated the Veteran and discontinues the order for 1:1 observation. If the assessment and recommendation for inpatient psychiatric hospitalization of an actively suicidal Veteran occurs outside the Emergency Department (ED), 1:1 observation must be provided continuously through the transfer process to the ED, while in the ED, during transfer to the inpatient unit, and on the unit until ordered otherwise by a psychiatrist.
- (5) In the event that actively suicidal Veterans elope from staff while under observation, staff will immediately contact the VA Police, or local police when calling from CBOCs, and will document the elopement in CPRS. The VA Police will follow their own standard operating procedures for patient elopement. Staff will attempt to reach the Veteran through telephone contacts and/or welfare checks when necessary. Attempts to reach the Veteran should be documented in CPRS and should continue until the Veteran is physically located and assessed or until all reasonable efforts have been made to locate the Veteran.

b. Telephone Contacts

- (1) Veterans who call a VAMC or CBOC and express suicidality will be referred to a MH clinician, or other designated clinical staff, for immediate consultation. Afterhours procedures will be identified at all facilities to manage Veterans expressing suicidality after normal hours of operation (See Attachment C Suicide Call Flow Sheet).
 - (2) Recipients of suicidal calls will follow these steps:
 - (a) Keep callers on the phone;
 - (b) Ask for their name, phone number, location, and last four of social security number;
- (c) Inform callers that you will connect them with a clinician, and tell them that you will stay on the phone until the clinician answers;
 - (d) Stay on the phone until you are sure the clinician is involved with the caller; and
 - (e) If you cannot connect with a clinician, ask another staff member to call VA Police.
- (3) In the event that a suicidal call is lost or dropped, the VA staff involved in the call will contact the VA Police for assistance;
- (4) Callers will be provided information on 911, local suicide prevention hotlines, and/or the Veterans Crisis Line (1-800-273-8255) where they can be connected with a local or regional resource. All medical center staff will have access to these telephone numbers and will be trained on the appropriate suicide prevention procedures for their particular medical center or CBOC.

Procedures for calls that occur during both administrative and non-administrative hours will be established and communicated to all staff.

- (5) If Veterans are determined to be at imminent risk for suicidal behavior through incoming telephone calls, but are unwilling to come in for a face-to-face evaluation, the Suicide Prevention Coordinator and/or other involved clinicians will inform VA Police. VA Police will assist in obtaining welfare checks through local law enforcement where Veterans reside.
- (6) When VA Police are engaged to assist in the management of suicidal Veterans, the VA Police will provide written and/or verbal communication to the MH clinicians or other involved clinicians regarding the results of their intervention. The clinician will enter a summary of the police intervention in CPRS to assist in the plan of care for Veterans.

c. Documentation

- (1) When it is determined that a suicide risk assessment is to be completed, the TVHS Suicide Risk Assessment Template is mandatory for use. (Use Attachment B Suicide Risk Assessment)
 - (2) General Guidance for documentation regarding specific observation levels:
- (a) 1:1 Observation Documentation will be done hourly on the nursing check sheet and noted on every shift in CPRS (noting the level of observation and specific Suicidal, Homicidal and/or Assaultive behaviors exhibited). Physician's order required for 1:1, to include justification and time limits not to exceed 48 hours.
- (b) Eye Sight Observation Documentation will be done hourly on the nursing check sheet and noted on every shift in CPRS (noting the level of observation and specific Suicidal, Homicidal, and/or Assaultive behaviors exhibited).
- (c) Close Observation Documented hourly on the nursing check sheet and noted in CPRS every shift (noting the level of observation and specific Suicidal, Homicidal and/or Assaultive behaviors exhibited).
- (d) Seclusion Documentation is on a flow sheet every 15 minutes (special flow sheet specific for seclusion and restraint), with every 4 hour notation in CPRS (initiation note, continuation note and/or discontinue note). Notation in the comment section, of each template, should reflect the behaviors that lead to initiation, continuation, or discontinuation of the restraints and debriefing after the episode.
- (e) Physical Behavioral Restraints Documentation is on the restraint/seclusion flow sheet every 15 minutes, with every 4 hour notation in CPRS (initiation, continuation, and or discontinuation notes). Notation in the comment section, of each template, should reflect the behaviors that lead to initiation, continuation, or discontinuation of the restraints and debriefing after the episode.
- (3) The Suicide Risk Assessment (SRA) (**Attachment B**) is a standardized suicide risk assessment that will be used to assist in the assessment process as follows:

- (a) <u>In Mental Health Individual Outpatient visits</u>. The MH clinician will consider suicide risk and protective indicators including factors such as Veteran's history, current presentation, individual strengths and weaknesses, psychosocial and environmental stressors and variables, psychiatric illness and symptoms, and medical conditions and pain at each visit. Based on the clinician's consideration of all of these variables the Veteran will be determined as:
- <u>1.</u> Being at individual baseline and presenting no imminent risk for suicide or need for follow-up;
- <u>2.</u> Being at potentially elevated risk that requires completion of the full Suicide Risk Assessment. This determination will be documented in the medical record.
- (b) <u>In Mental Health Group visits.</u> Any communication of suicidality or behavior that suggests the possibility of suicidality will be addressed by initiating a Suicide Risk Assessment to be completed by an appropriate mental health clinician and documented in the medical record.
- (c) <u>In Inpatient Psychiatric Setting.</u> A brief suicide risk assessment will be done as a part of the general admission process. If positive, the SRA will be completed by a MH clinician. Veteran will be assessed prior to discharge by the Treatment Team under the direction of the Psychiatrist, who will assess and consider suicide risk and protective indicators including factors such as Veteran's history, current presentation, individual strengths and weaknesses, psychosocial and environmental stressors and variables, psychiatric illness and symptoms, and medical conditions and pain. Based on the consideration of all of these variables, the Psychiatrist will determine if Veteran is at individual baseline and presents no imminent risk for suicide, or if full SRA needs to be completed. This determination will be documented in the medical record.
- (d) <u>In Residential Setting.</u> A brief suicide risk assessment will be done as a part of the screening and general admission process and as clinically indicated. If the brief risk assessment is positive, the SRA will be completed by a MH clinician. Veteran will be assessed prior to passes and prior to discharge by the Treatment Team, who will assess and consider suicide risk and protective indicators including factors such as Veteran's history, current presentation, individual strengths and weaknesses, psychosocial and environmental stressors and variables, psychiatric illness and symptoms, and medical conditions and pain. Based on the consideration of all of these variables, an appropriately licensed or credentialed Mental Health Clinician will determine if the Veteran is:
 - 1. At individual baseline and presents no imminent risk for suicide or need for follow-up or;
- <u>2.</u> Being at potentially elevated risk that requires completion of the full SRA. This determination will be documented in the medical record.
- (4) Veterans determined by the facility's Suicide Prevention Team to be at high risk for suicide will have a Category I High Risk for Suicide PRF placed in CPRS. This PRF is to communicate to staff that a Veteran is at high risk for suicide, and the presence of this flag should be considered when making treatment decisions.
- (5) A Suicide Behavior Report (SBR) is to be completed by a clinical staff member, SPC, or designee when they become aware that there has been a suicide completion, suicide attempt, or

significant suicidal behavior. The SBR replaces the Patient Incident Report (PIR) (See Attachment D – Suicide Behavior Report).

(a) The SBR is used to

- <u>1.</u> Provide required information for the National Patient Safety reporting requirements on suicide completions and suicide attempts. The National Center for Patient Safety has approved the use of the SBR and use of its data reporting requirements from the field.
- <u>2.</u> Populate a national suicide prevention database, established as part of VHA's national suicide prevention strategy.
- b. The completion of this report may be an indication that a flag needs to be placed in the record, but it is not the sole criteria, nor is it necessary for placement of the PRF for suicide risk.
- d. <u>Initial Clinical Management.</u> Initial therapeutic interventions should be instituted for Veterans with suicidal thoughts, plans, or behaviors. This includes the following:
- (1) Immediately attending to patient safety. **All** patients who are considered to be in a situation defined as a psychiatric emergency should immediately be considered as a <u>1:1 level observation</u> until assessed by a mental health provider. Specifically, all patients expressing imminent suicidal ideation must be attended by a staff person (1:1 observation) until given clearance to discontinue this level of care by a mental health clinician. Clinicians should ensure that patients do not have access to implements or objects or be in a physical location that would increase the likelihood of self-injurious behavior.
- (2) Determining the least restrictive setting for treatment while maintaining patient safety and an efficacious treatment approach. If necessary for patient safety, involuntary holds or commitments may be initiated following local laws and statutes as required. Each facility will address specific procedures, allowed by the state, to detain Veterans for emergency evaluation and/or commitment procedures.
- (3) Establishing a cooperative and collaborative clinician-Veteran relationship. Clinicians working with suicidal Veterans will encourage compliance with treatment to improve functioning and reduce immediate risk.
- (4) Providing education to Veterans and to family and significant others, when indicated. This education includes providing VA telephone numbers and suicide hotline numbers.
- (5) For patients who are outside of the Emergency room area (clinics, etc.) when this crisis need is identified, the clinician must ensure that the patient is under 1:1 observation with elopement precautions until the arrival of VA Police, or local police when at a CBOC, and/or adequate staff in order to escort the patient to the Emergency Department (ED).
- (6) While staff is not expected to physically prevent the patient from eloping, if the patient does leave the area, the observer must immediately contact VA Police and his/her immediate supervisor.

- (7) Employees should utilize Prevention and Management (PMDB) of Disruptive Behavior techniques when dealing with a Veteran undergoing a psychiatric emergency as outlined in TVHS policy 626-YY-00-09 "Workplace Violence Prevention Program."
- (8) If the patient is disruptive, threatening, or has a weapon, a Code Purple should be initiated as per the Code Purple policy 626-YY-11M-02 while utilizing the Workplace Violence Prevention Program policy for PMDB, guidance (626-YY-00-09).

e. Patient Transfer

- (1) The patient will be escorted to ED/Triage or the Psychiatric Inpatient Unit; with the assistance of VA Police; if necessary. If VA Police assistance is necessary, they should be informed of the patient's name and identification number, the diagnosis and situation, and how the clinician would like the Police to be involved. Police Service can be reached at extension 67740 in Nashville and extension 26600 in Murfreesboro. CBOCs should follow their routine emergency protocols.
- (2) Always ensure proper **hand-off communication** procedures are followed per medical center policy: 626-YY-118-30, *Hand Off Communication*. Remember the acronym *I-SBAR*: Identification, Situation, Background, Assessment, and Recommendation. This is used to standardize communication of critical patient information to decrease the likelihood of adverse patient events and outcomes; therefore, ensuring patient safety.
- (3) Immediately attend to Veteran's safety. Specifically, all Veterans expressing or displaying imminent risk for suicidal behavior must be attended by a staff person (1:1 observation) until given clearance to discontinue this level of care by a mental health clinician. Clinicians should ensure that Veterans do not have access to items that could pose a danger or be in a physical location that would increase the likelihood of self-injurious behavior.
- f. Ongoing Interventions and Treatment. Veterans may benefit from different treatment settings such as involuntary inpatient hospitalization, residential treatment, intensive outpatient programs, and ambulatory care clinics. Many factors are taken into consideration for determination of appropriate treatment settings including severity and acuteness of suicidal ideation and primarily, patient safety. The benefits of intensive interventions (e.g., hospitalization) also must be weighed against their possible negative effects, such as loss of autonomy, disruption of employment, financial and other psychosocial stress, and social stigma. Variables that influence the intensity of interventions include, but are not limited to:
 - (1) Assessment of Veteran's current suicide risk and/or potential danger to others;
 - (2) Medical and psychiatric comorbidity;
 - (3) Availability of a psychosocial support network outside the treatment setting, and
- (4) Ability of Veteran to provide adequate self-care, to give reliable self-report, and to cooperate with treatment.

- g. <u>Treatment Planning.</u> The treatment plan should identify interventions made to increase patient safety to include specific steps taken to alleviate modifiable risk factors or factors creating acute stress, as well as Veteran's response to treatment plan interventions.
- (1) Clinicians with responsibility for treating Veterans following an inpatient admission must have timely access to Veterans' discharge summaries in CPRS. If high-risk Veterans are hospitalized as part of their care, the discharge summaries must be completed and signed in a timely manner to ensure availability to all VA clinical staff who will engage in follow-up care.
- (2) The arrangement of timely follow-up appointments, increased frequency of sessions (as clinically indicated), and various environmental interventions will be specified. Treatment documentation in any follow-up treatment planning will address risk factors identified in the detailed suicide risk assessment.
- (3) Veterans should be provided with outpatient follow-up appointments in an appropriate time frame that takes into account individual clinical needs and minimizes risk. Follow-up appointments will be scheduled at a frequency determined by the treating clinician and may include face-to-face individual or group visits, telemental health visits, telephone visits, or in-home visits by specialty staff such as Mental Health Intensive Case Management (MHICM), Community Residential Care (CRC), Homeless Program Outreach, Home-Based Primary Care (HBPC), and other staff as appropriate. If Veteran has a Category I High Risk for Suicide PRF, follow-up appointments will be scheduled on a weekly basis for the first 30 days following flag initiation.
- (4) Veterans identified as high risk for suicide will develop Safety Plans in collaboration with clinicians who will utilize the VA Safety Plan Form (See Attachment E Suicide Prevention Safety Plan). Written copies of their Safety Plans will be provided to Veterans prior to discharge from inpatient care and prior to leaving the facility if in outpatient settings. Safety Plans will include recognizing warning signs, identifying internal coping strategies, identifying social supports, contact information for helping professionals including the Veterans Crisis Line, and steps taken to make environments safer.
- (5) If a Veteran with a high risk for suicide PRF no-shows to an appointment, a qualified mental health provider will attempt to contact the patient. At least three attempts should be made to reach the patient and this must be documented in the patient's medical record. If contact is unsuccessful for high-risk patients after three attempts, the suicide prevention coordinator will collaborate with the treatment provider(s) to determine the next appropriate action by utilizing clinical judgment and the pre-developed Safety Plan, if possible. Contacting local law enforcement for assistance is recommended when risk of harm is deemed to be imminent. Additionally, the Clinician will complete the High Risk Mental Health No-Show Follow-up Clinical Reminder and add the Suicide Prevention Team as additional signers to the progress note template. (See attachment F-High Risk MH No-Show Follow-up Clinical Reminder template).

h. Ongoing Evaluation of Suicidal Risk

(1) <u>Inpatient and Residential Care.</u> Clinicians should reassess suicide risk prior to approving a pass or discharge from inpatient or residential treatment. The decision to grant a pass or discharge should include a risk-benefit analysis to support the clinical decision. A simple denial of suicidal ideation is insufficient evidence to determine an absence of suicide risk.

- (2) <u>Use of No-Harm Contracts.</u> Research data does not support the effectiveness of a suicide prevention contract or "no-harm contract" as a guarantee that the Veteran will not engage in self-injurious acts. Therefore, "no-harm contracts" will not be used at any time. The VA Safety Plan can be used to help Veterans recognize warning signs and develop plans to utilize internal coping strategies, social supports, and assistance from helping professionals.
- (3) <u>Support Systems.</u> When family members or significant others are asked to assist in the monitoring of risk, both Veterans and family or significant others should be given education and instructions regarding suicide prevention. Instructions should include how to access the treating physician or clinician regarding questions, observations, or concerns during and after normal working hours and includes any limitations on staff availability.
- (4) <u>Chronic Suicidality.</u> Some Veterans have repeated contacts with the health care system for the treatment of self-injurious behavior. Each event should be assessed in the context of the current situation. Although such behaviors may occur without evidence of suicidal intent, all attempts at self-harm should be taken at face value and assessed appropriately.
- (5) <u>Suicide Risk Reassessment</u>. Reassessment of suicide risk for Veterans flagged as high risk will be completed by mental health clinicians on an ongoing basis throughout the flagged period, when there are changes in Veterans' conditions and prior to the flag review dates to determine the need for continuance or removal of the PRFs.
- i. <u>Risk Management.</u> Medical Center Directors will establish local procedures for notifying the facility SPC about suicidal Veterans. The SPC will initiate a PRF in CPRS for individuals identified as high risk and will review flags within the designated time periods to determine the need for continuance or removal of flags. Once the PRF is in place, the facility SPC will place an electronic note in the medical record documenting reasons for flag placement. An electronic progress note MUST accompany each flag. The SPC will be responsible for tracking and establishing the process for follow-up contacts with all Veterans who have been assessed as high risk for suicide.

j. Training

(1) All medical center staff will be offered annual Suicide Prevention Guide training that provides a basic foundation in suicide prevention, periodically throughout each year. Training will also be available to staff upon request. New employees will receive Suicide Prevention Guide training as part of new employee orientation and will complete an annual refresher course as outlined by individual facilities. New employees who are Health Care Providers, (Physicians, Psychologists, Registered Nurses, Social Workers, Physician Assistants, Pharmacists, Dentists, and any employee serving in the capacity as Case Manager or Vet Center Team Leader or Counselor) are required to complete additional training titled "Suicide Risk Management Training for Clinicians" in the Learning Management System within 90 days of hire and an annual refresher course as outlined by individual facilities. Medical Center Directors or designees will develop and utilize an appropriate tracking system to ensure training compliance.

(2) Medical Center Directors will ensure that all mental health clinical staff has documented competencies in comprehensive suicide risk assessment and ongoing management of individuals with suicidality.

6. REFERENCES

- a. VISN 9 Directive 10N9-100-14 Management of Veterans with Suicidality Dated 1/31/2014
- b. VA TVHS Code Purple Policy 626-12-11M-02 Dated 7/2/2012
- c. VA TVHS Workplace Violence Prevention Policy 626-14-00-09 Dated 2/27/2014
- d. VA TVHS Physical Constraints and Seclusion Policy 626-13-118-12 Dated 02/28/2013
- e. VA TVHS Handoff Communication Policy 626-11-118-30 Amended 7/14/2011
- f. JC 2010 National Patient Safety Goal (15.01.01)
- g. VA TVHS Disruptive Patient Behavior Committee (Patient Record Flag) Policy 626-12-11M-15, dated 1/23/2013
- h. TVHS Mandatory Training for Suicidal Veterans
- i. TVHS Training for Hand-Off Communication
- j. VA TVHS Patient Record Flags to Identify Patients at High Risk for Suicide, 626-12-11M-09 Dated 9/6/2012
- k. On-line Self-Directed Violence (SDV) Classification Tool: (http://www.mirecc.va.gov/visn19/education/sdvtree/sdv_tree.asp)
- **7. RECISSIONS**: TVHS Memorandum 626-11-11M-08 Management of Patients at Risk for a Psychiatric Emergency Dated 7/28/2011, Amended 3/4/2014
- **8. FOLLOW-UP RESPONSIBILITY**: The Chief, Mental Health Care Line (11M) will review annually and revise no later than June 30, 2017.

/s/ Juan A. Morales, RN, MSN 08/11/2014 Juan A. Morales, RN, MSN Health System Director

Attachments: A through D

ATTACHMENT A CDC/VA/DoD Definitions

Self-Directed Violence Classification System

Key Terms

Self-Directed Violence:

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

Suicidal Intent:

There is past or present evidence (implicit or explicit) that an individual wishes to die, means to kill him/herself, and understands the probable consequences of his/her actions or potential actions. Suicidal intent can be determined retrospectively and in the absence of suicidal behavior.

Preparatory Behavior:

Acts or preparation towards engaging in Self-Directed Violence, but before potential for injury has begun. This can include anything beyond a verbalization or thought, such as assembling a method (e.g., buying a gun, collecting pills) or preparing for one's death by suicide (e.g., writing a suicide note, giving things away).

Physical Injury (paraphrased):

A bodily lesion resulting from acute overexposure to energy (this can be mechanical, thermal, electrical, chemical, or radiant) interacting with the body in amounts or rates that exceed the threshold of physiological tolerance (e.g., bodily harm due to suffocation, poisoning or overdoses, lacerations, gunshot wounds, etc.). Refer to the Classification System for the Centers for Disease Control and Prevention definition.

Interrupted By Self or Other:

A person takes steps to injure self but is stopped by self/another person prior to fatal injury. The interruption may occur at any point.

Suicide Attempt:

A non-fatal self-inflicted potentially injurious behavior with any intent to die as a result of the behavior.

Suicide:

Death caused by self-inflicted injurious behavior with any intent to die as a result of the behavior.

ATTACHMENT B SUICIDE RISK ASSESSMENT

Template: Suicide Risk Assessment	
Suicide Risk Assessment	_
Are you feeling hopeless about the present/future? Yes O No	
Are you having thoughts about taking your life? O Yes O No	
When did you have these thoughts?	
Do you have a plan to take your life/kill yourself? Yes C No	
Have you ever attempted to kill yourself?C Yes C No	
Does clinical presentation indicate need for completion of full risk assessment	?
O Yes O No	
If no, please explain:	
	T
*Indicates a Required Field Preview O	K 🗘

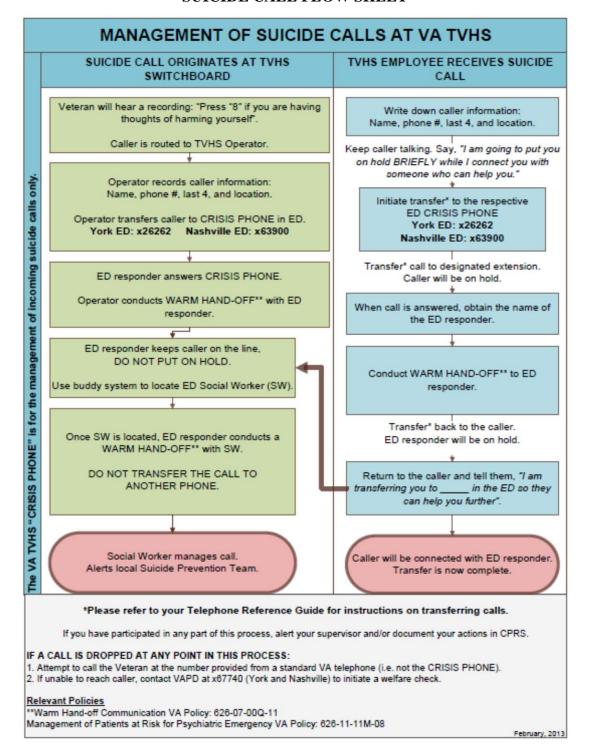
ATTACHMENT B, SUICIDE RISK ASSESSMENT CONT'D

Template: Suicide Risk Assessment	_
Do you have access to firearms?C Yes C No	_
Check present suicide warning signs: 	
[] Hopelessness	
[] Rage, anger, seeking revenge	
Acting reckless or engaging in risky activities without thinking	
[] Feeling trapped, like there is no way out	
[] Increased alcohol and/or drug use	
[] Withdrawing from friends, family and society [] Anxiety or agitation	
[] Dramatic changes in mood	
[] No reason for living or sense of purpose in life	
[] Other:	
Check present factors that may increase risk:	
Current ideation, plan, intent, access to means	
[] Previous attempts	
[] Family history of suicide	
Recent discharge from inpatient treatment	
[] Recent losses	
[] Acute life stressors/distress [] Living alone	
[] Homelessness	
[] Minimal social support	▾
[] Impulsivity and poor impulse control	_
[] Psychiatric diagnosis/previous history of psychiatric diagnosis	
[] Alcohol or drug use	
[] Chronic pain	
[] Chronic or terminal medical problems	
[] Gender (male)	
[] Age (young adult or elderly)	
[] Race (Caucasian) [] Sexual orientation (gay, transgendered)	
[] Sleep disturbance	
[] Other	
Check present factors that may decrease risk:	
[] Positive social support	
[] Spirituality	
Sense of responsibility to family	
[] Children in the home/pregnancy	
[] Life satisfaction [] Positive coping skills	
[] Positive coping skills	
[] Positive therapeutic relationship	
[] Reality testing ability	
[] Active participation in treatment planning/program	
Plans for the future	
*Indicates a Required Field Preview	ок 🗦
1) //.

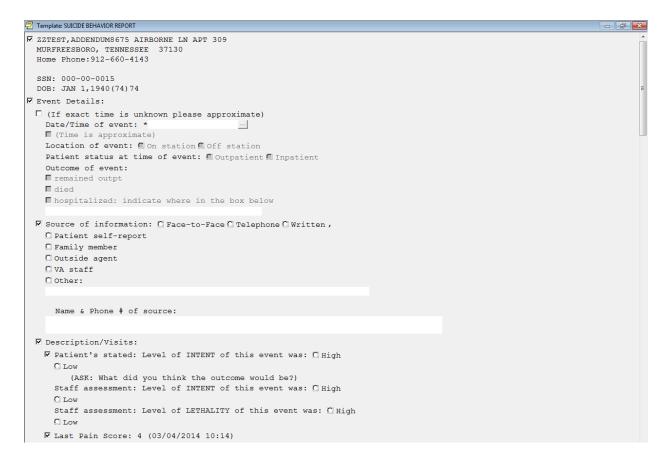
ATTACHMENT B, SUICIDE RISK ASSESSMENT CONT'D

Template: Suicide Risk Assessment	_
[] Restricted access to means	_
[] Other	
Assessed Level of Suicide Risk:	
abbebbea Bever of Satorac Kibk.	
[] Imminent - Lethal or potentially lethal suicide attempt or severe	
suicidal ideations with plan and intent requiring immediate psychiatric hospitalization	
[] High - Psychiatric diagnosis with severe symptoms or acute	
precipitating event, protective factors not relevant, potentially lethal suicide	
attempt or persistent ideation with strong intent or suicide rehearsal	
[] Wadawata Wultiple wiel festage for protesting festage quisidel	
[] Moderate - Multiple risk factors, few protective factors, suicidal ideation with a plan, no intent or behavior	
Dow - Modifiable risk factors, strong protective factors, thoughts of death, no plan or behavior	
of death, no plan of senavior	
Describe:	
Imminent and High Risk requires notification to Suicide Prevention Coordinato:	r
Treatment Recommendations/Interventions:	
	▼
[] Inpatient admission	
[] Outpatient referral [] Emergency Department referral	
[] 1:1 initiated [] Discussion on means reduction	
[] Safety Planning	
[] Medication adjustment [] 911 called	
[] Welfare check initiated	
[] No INTERVENTION indicated as veteran has been assessed as low risk for suicidal behavior at this time.	
[] Other:	
Veteran's response to intervention/recommendations (including Veteran's choice	e
of	
treatment setting):	
Verbal and/or Written information provided on:	
[] National Suicide Hotline 1-800-273-8255	
[] Other numbers provided by SPC	
Additional comments:	
*Indicates a Required Field Preview	ok 🗦
*Indicates a Required Field Preview	1

ATTACHMENT C SUICIDE CALL FLOW SHEET



ATTACHMENT D SUICIDE BEHAVIOR REPORT



ATTACHMENT D, SUICIDE BEHAVIOR REPORT CONT'D

```
\overline{\mathbf{W}} Did the patient have access to firearms?
    \overline{\mathsf{W}} What action was taken to notify VA police?
   Unknown.
  \overline{\mbox{\ensuremath{\ensuremath{\wp}}}} Family and other supports available at time of the event:
    \ensuremath{\mathbb{C}} 
 At least one supportive relationship.
    ☐ Good social and/or family support.
    Other:
    Treatment plan changes at the time of the event:
    No changes
    \hfill\square Medication changes: describe:
    ☐ Therapy changes: describe:
    \square Discharge from inpatient/residential treatment within 30 days
    Other:
    Description of event: *
    Past 10 Clinic Visits: ** PAST CLINIC ADATE/TIME CLINIC ( LOCATION )

*** NO DATA ***
                                   ** PAST CLINIC APPOINTMENTS **
\overline{\mathbf{v}} Patient has been receiving treatment in the following areas at
   the time of this
  ☐ Mental Health
  ☐ Substance Abuse
  □ MHICM
  □ Life Skills Center
□ нснв
```

ATTACHMENT D, SUICIDE BEHAVIOR REPORT CONT'D

```
☑ Patient has been receiving treatment in the following areas at
   the time of this
  □ Mental Health
 ☐ Substance Abuse
  □ MHICM
  □ PTSD
  □ Life Skills Center
  □ нснв
  \hfill\square Non-VA Mental Health Care
  ☐ Ambulatory Care
  □ свос
  □ Specialty clinic:
  Primary Care Provider:
  Case Manager/Therapist:
  Name of Provider prescribing psychiatric medications:
  Active Problem List:
  Health maintenance alteration (SCT 24441roi (ICD-9-CM 799.9)
                                       Abscess (ICD-9-CM 682.9)
Long Term (current) use
  cabg (ICD-9-CM 799.9)
  Unspecified Fall (ICD-9-CM E888.9)
   of Medications (ICD-9-CM V58.69)
  Stomatitis and Mucositis, unspecified (IMigraine, unspecified,
   without mention of Intractable Migraine without mention o
   (ICD-9-CM 346.90)
  Coronary Atherosclerosis of Native CoronChronic hepatitis C
   without mention of hepatic coma (ICD-9-CM 070.54)
  Observation for other specified suspecteHypertension (ICD-9-CM
   401.9)
  Hearing Impairment (ICD-9-CM 799.9) Candidiasis, Oral (ICD-9-CM 112.0)
  Obesity (ICD-9-CM 278.00)
   (ICD-9-CM 799.9)
  Posttraumatic Stress Disorder (ICD-9-CM Schizophrenia, paranoid
  type (ICD-9-CM 295.30)
```

ATTACHMENT D, SUICIDE BEHAVIOR REPORT CONT'D

```
oral cancer (ICD-9-CM 799.9)
                                        Other chest pain
                                                                                                                              .
   (ICD-9-CM 786.59)
  Gout (ICD-9-CM 274.9)
                                          Low Tension Glaucoma
   (ICD-9-CM 365.12)
  Diabetes Mellitus Type II or unspecifiedDepressive Disorder NOS
   (ICD-9-CM 311.)
  Observation of other Suspected Mental CoHyperthyroid heart
   disease (ICD-9-CM 429.9)
  Backache (ICD-9-CM 724.5)
                                          Irradiation cystitis
   (ICD-9-CM 595.82)
  Health Advise (ICD-9-CM V65.49)
                                        Muscle WEAKNESS
   (Generalized) (ICD-9-CM 728.87)
  Abnormality of Gait (ICD-9-CM 781.2) Epigastric Tenderness
   (ICD-9-CM 789.66)
  Osteoarthritis (ICD-9-CM 715.90)
                                        Chronic tonsillitis and
   adenoiditis (ICD-9-CM 474.02)
  Fracture of subtrochanteric section of fDecubitus Ulcer
   (ICD-9-CM 799.9)
  Oncology disease Status; colon Cancer; eBilateral Cataracts
   (ICD-9-CM 366.8)
  Impotence of organic origin (ICD-9-CM 60Heart replaced by
   transplant (ICD-9-CM V42.1)
  Diabetes (ICD-9-CM 250.00)
                                          BIPOLAR DISORDER
   (ICD-9-CM 799.9)
  Diabetes with neurological ManifestationChronic bronchitis
   (ICD-9-CM 491.9)
  Migraine (MST) (ICD-9-CM 346.90)
(ICD-9-CM 365.10)
                                        Open angle glaucoma
  Barrett's Esophagus (ICD-9-CM 530.85) Left Heart Failure
   (ICD-9-CM 428.1)
  Vascular Diseases (ICD-9-CM 443.9)
                                        Hyperthyroidism
   (ICD-9-CM 242.90)
  Chronic Obstructive Pulmonary Disease (IChronic Renal
   insufficiency (ICD-9-CM 585.9)
  Schizophrenia (ICD-9-CM 295.90)
                                          Bipolar Disorder
   (ICD-9-CM 799.9)
  Adjustment Disorder with Anxiety (ICD-9-Peripheral Vascular
   Disease (ICD-9-CM 443.9)
  Chronic Back Pain (ICD-9-CM 724.5)
                                          Adrenal Hyperplasia,
   Congenital (ICD-9-CM 255.2)
  SUICIDE and Self-inflicted Injury by PaiAcute alcoholic
   hepatitis (ICD-9-CM 571.1)
  Low Back Pain (ICD-9-CM 724.2)
                                          CHF (ICD-9-CM 428.0)
  Atypical Chest Pain (ICD-9-CM 786.59) Abnormal Mammogram,
  unspecified (ICD-9-CM 793.80)
  C1-C4 Spin Cord Inj Nos (ICD-9-CM 952.000cular Hypertension
   (ICD-9-CM 365.04)
  Coronary Artery Disease (ICD-9-CM 414.9) Major Depression,
   recurrent (ICD-9-CM 296.30)
  Dementia of the Alzheimer's Type, with ECOPD (ICD-9-CM 496.)
  Schizophrenia, paranoid type (ICD-9-CM 2

☑ (If pt. was an inpt. at time of event)

  INPATIENT UNIT:
   InPt. status at time of event:
  On Pass
  C Unauthorized Absence
  On unit
 Off unit
▼BRIEF PLAN/DISPOSITION:
  □ None necessary - Patient died
 \hfill\square Limit the means
 Developed crisis management plan
 \hfill\square 
 Immediate planning for the future
 \square Decrease isolation
 □ Decrease anxiety and agitation
 ☐ Medication management
 ☐ Hospitalization
 □ Refer for Mental Health treatment
 \square Provide emergency phone contact numbers
 \square Assure followup appointment is made
 \square Inform/involve someone close to patient
 □ Increase contact frequency
  □ Help patient through the crisis
 □ Other - indicate below
```

ATTACHMENT E SUICIDE SAFETY PLAN

		WARNING SIGNS hay be starting to get suicidal:	
1. 2. 3. 4. 5.			
		L COPING STRATEGIES e distract myself from thoughts	about suicide:
1. 2. 3. 4.			
		CTS WHO MAY DISTRACT eople may help me distract my	FROM THE CRISIS self from thinking about suicide:
1. 2. 3. 4. 5.	•		
		ENDS WHO MAY OFFER HE	ELP y thoughts of suicide in order to help m
NA 1. 2. 3. 4. 5.	ME	PHONE NUMBER	

STEP 5: PROFESSIONALS AND AGENCIES TO CONTACT FOR HELP

Therapist:

Primary care physician or psychiatrist:

24-hour emergency treatment:

Call 911

Go to local Emergency Room

24-hour emergency VA Hotline: 1(800)273-TALK (8255)

STEP 6: MAKING THE ENVIRONMENT SAFE

These are steps I will take to limit access to means to kill myself:

- 1.
- 2.
- 3.
- 4.
- 5.

Veteran has been given a copy of this safety plan.

Comment:

PLAN REVIEW

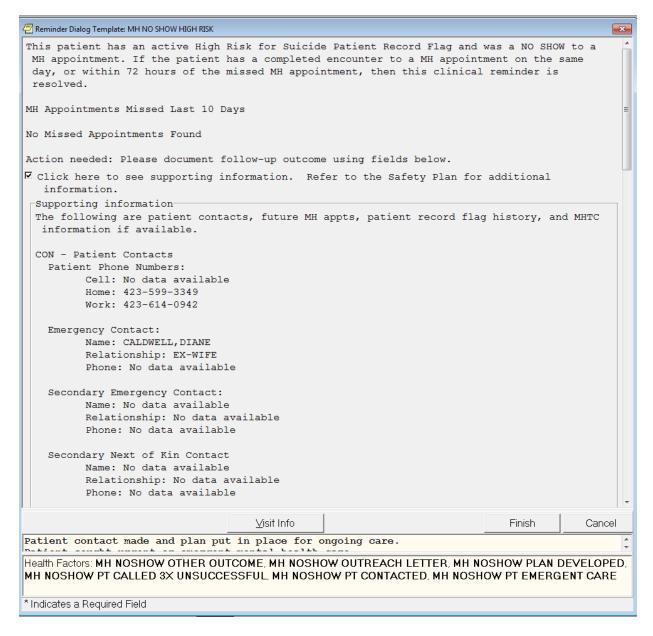
Suicide High Risk Treatment Plan will be reviewed:

Monthly Weekly Planned date of next review:

Provider to notify Suicide Prevention Coordinator of any: status change, session, emergency, no show, PRN, of any Veteran on the facility High Risk for Suicide list.

Veteran will be reevaluated for High Risk for Suicide list a minimum of every 90 days.

ATTACHMENT F MH NO SHOW FOLLOW UP CLINICAL REMINDER TEMPLATE



INITIAL MANAGEMENT OF MENTAL HEALTH REQUESTS

- **1. PURPOSE:** To outline the policy and process of provision of an initial mental health evaluation within 24 hours for Veterans who request, or require such an evaluation at the Veterans Affairs Tennessee Valley Healthcare System (VA TVHS). This Policy's intent is to ensure full compliance with the April 28, 2014 Memorandum "Identification and Management of Mental Health Conditions" and the June 1, 2007 Memorandum "Mental Health Initiatives."
- **2. POLICY:** It is the policy of VA TVHS to meet all requirements of the April 28, 2014 Memorandum "Identification and Management of Mental Health Conditions" and the June 1, 2007 Memorandum "Mental Health Initiatives." All patients physically present at the medical centers, CBOCs, and clinics of VA TVHS who request mental health evaluation or require such an evaluation will be seen for an initial evaluation within 24 hours. In general:
- a. Suicidal ideation or psychiatric emergencies are treated as per VA TVHS memorandum 626-YY-11M-08, *Management of Patients at Risk for a Psychiatric Emergency*, and memorandum 626-YY-11M-02, *Psychiatric Emergency/Code Purple*. The processes established in these memorandums meet all requirements of national memorandums.
- b. Patients in the Emergency room having a mental health need or making a mental health care request are seen by the ER social worker, Mental Health Officer of the Day, or Psychiatric Officer of the Day. The two TVHS emergency rooms provide 24 hour a day consultative coverage that meets the requirements of the national memoranda.
- c. Patients at Primary Care Clinics, PACT clinics, CBOCs, and specialty clinics may be seen by any licensed independent provider (LIP) for initial evaluation of mental health needs. LIPs for this memo include Physicians, Nurse Practitioners, Physician Assistants, Psychologists, and Licensed Clinical Social Workers all who may work in a PACT team, specialty clinics, Emergency Rooms, or other clinical care settings.
- d. Initial Management for patients who do not present physically to TVHS is outlined in TVHS Memorandum 626-YY-11M-08, *Management of Patients at Risk for a Psychiatric Emergency*.
- **3. DEFINITIONS:** <u>Initial Mental Health Evaluation.</u> An "initial mental health evaluation" is a basic examination of a patient that is physically present in the clinic and meets the following requirements:
- a. The patient requests a mental health and/or substance abuse assessment or the patient is otherwise identified as someone who could benefit from a mental health assessment. Identification may be completed by any healthcare clinician, positive clinical reminder screen, or other method generally accepted as identifying a medical concern.
 - b. A LIP performs the evaluation.

- c. Evaluations are performed the same day but not more than 24 hours after the time of the request or of the identification of need.
- d. The patient agrees to the evaluation. Evaluations that are required or involuntary such as suicidal risk assessment are covered in the memorandum *Management of Patients at Risk for Psychiatric Emergency*.
 - e. The provider:
 - (1) Performs an adequate history and examination to:
 - (a) Determine the urgency of the need for care
 - (b) Identify the appropriate setting for subsequent evaluation and treatment
 - (c) Answer the patient's questions to facilitate engagement in care.
 - (2) Arranges for treatment, if needed.
- (3) Provides the Veteran with contact information for mental health care and instruction about accessing emergency services.
- **4. RESPONSIBITIES:** This policy applies to all medical centers, CBOCs, and clinics at VA TVHS.
- a. <u>Heath System Director</u>. The Health System Director, or designee, is responsible for assuring VA TVHS is in compliance with this policy.
- b. **Service Chiefs.** Service Chiefs are responsible for ensuring that clinicians understand and comply with this policy.
- c. <u>Clinicians</u>. Clinicians are responsible for assuring that all Veterans presenting with a mental health evaluation request or need are assessed as established by this policy.
- d. <u>Any Staff member.</u> Any staff member who encounters a Veteran with a request for mental health evaluation ensures that the patient is referred to a clinician.

5. PROCEDURES

- a. Any patient that in person requests a mental health evaluation or is identified as having a mental health need should receive an Initial Mental Health Evaluation as defined above.
 - b. The "Initial Mental Health Evaluation" is completed by:
- (1) Referral to a higher level of care as per the memorandum *Management of Patients at Risk for a Psychiatric Emergency*.

- (2) Direct referral to a PC-MHI provider.
- (3) Referral via consult to substance abuse treatment.
- (4) Referral via consult to mental health care.
- (5) Judgment of no mental health problem by a provider and no further action taken other than documentation of the evaluation.
 - c. Follow-up in ensured by:
 - (1) Direct "warm hand-off" to the PC-MHI provider.
- (2) Direct "warm hand-off" to the ER staff per the memorandum *Management of Patients at Risk for a Psychiatric Emergency*.
- (3) Seen by the mental health consult provider or the mental health provider places a no-show note and completes the TVSH Mental Health no-show process.
 - (4) No follow up action is needed if the Veteran cancels the appointment.
- **6. COMPLIANCE:** Compliance with the policy is ensured by:
 - a. Yearly education of all staff by dissemination of this memorandum to staff.
 - b. Yearly education of all supervisors by dissemination of this memorandum.
- c. Bi-annual audits of not less than ten charts to ensure that "mental health consult" referrals follow the process identified in his memo.

7. REFERENCES

- a. Identification and Management of Mental Health Conditions, Memorandum dated April 28, 2014 from Acting Deputy Under Secretary for Health for Operations and Management Thomas G. Lynch, MD
- b. Mental Health Initiatives Memorandum dated June 1, 2007 from Deputy Under Secretary of Health for Operations and Management William F. Feeley, MSW, FACHE.
 - c. TVHS Memorandum 626-YY-11M-02, Psychiatric Emergency/Code Purple.
- d. TVHS Memorandum 626-YY-11M-08, Management of Patients at Risk for a Psychiatric Emergency.

8. RECISSONS: None

9. FOLLOW-UP RESPONSIBILTY: The Chief, Mental Health Care Line, will review annually and revise no later than June 30, 2017.

/s/ Juan A. Morales, RN, MSN 07/23/2014 Juan A. Morales, RN, MSN Health System Director

MEDICATION RECONCILIATION

- **1. PURPOSE:** To ensure quality patient care by establishing policy and procedure that guides the provider to accurately and completely reconcile medications across the continuum of patient care.
- **2. POLICY:** Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS) has established a standardized process for completing medication reconciliation across the continuum of care to ensure well coordinated, safe, appropriate, and patient-centered medical care as it pertains to the management of patient medication information.

3. DEFINITIONS

- a. <u>Medication Reconciliation.</u> The process of comparing a patient's medication orders to all of the medications that the patient has been taking in order to avoid medication errors such as omissions, duplications, transcriptions, dosing errors, drug interactions, or drug-disease interactions. The goal is to ensure maintenance of accurate, safe, effective, and patient centered medication information by:
- (1) Obtaining a current comprehensive list of medications from the patient, caregiver, or family members that he/she has been taking at home including dosing, route and frequency.
- (2) Comparing the information obtained from the patient, caregiver, or family member to the medication information available in the VA electronic medical record, including active medications, recently expired medications, medications given at other VA facilities (via remote data view), and non-VA medications, in order to identify and address discrepancies.
- (3) Assembling and documenting the medication information in the VA electronic medical record.
- (4) Communicating with and providing an updated list of medications and education to the patient, caregiver, or family members regarding updated medication information.
- (5) Communicating relevant medication information to and between the appropriate members of the VA and non-VA health care team.
- b. <u>Medications.</u> prescription medications; sample medications; vitamins/minerals/herbals or other over-the-counter products; nutraceuticals/natural products; vaccines; diagnostic and contrast agents; radioactive agents; respiratory therapy agents; parenteral nutrition; blood derivatives; intravenous solutions (plain or with additives); and any product designated by the Federal Drug Administration (FDA) as a drug. *NOTE: Supply items are not considered in this definition, and therefore, are not specifically reviewed during the medication reconciliation process.*
- c. <u>Minimal Medications</u>. There are some situations that would seem to carry little risk of duplication, omission or drug interaction e.g., topical fluoride in dentistry, local infiltration anesthesia for dental work or suturing lacerations, wound care check, enteric barium for imaging studies. These situations typically occur as brief outpatient encounters, not involving medication

use, discharge prescription of medications or any other changes in medications that the patient has been taking.

d. Points of Care in the Medication Reconciliation process

- (1) Outpatient settings where action may be taken on medication therapy, e.g., Emergency Department (ED), Patient Aligned Care Team (PACT) clinics, specialty clinics
- (2) Patient admission to the hospital, Community Living Center (CLC), Residential Rehabilitation Treatment Program (RRTP), or outpatient procedural area where medications are utilized
 - (3) Patient transfers of service, setting, or level of care
 - (4) Patient discharge
- e. <u>Providers.</u> attending or staff physicians, resident physicians, specialty fellows, dentists, optometrists, podiatrists, clinical pharmacy specialists, nurse anesthetists, nurse practitioners, clinical nurse specialists and other advanced practice nurses, and physician assistants.

4. RESPONSIBILITIES

- a. <u>The Health System Director.</u> The Health System Director is responsible for appointing the TVHS Medication Reconciliation Point-of-Contact (POC), for ensuring that veterans under his/her care are provided the highest level of safe patient care, and for ensuring that the organization complies with The Joint Commission National Patient Safety Goals (NPSG) for medication reconciliation as a mechanism to ensure safe patient care.
- b. The multidisciplinary Medication Reconciliation Subcommittee. The multidisciplinary Medication Reconciliation Subcommittee reports to the Pharmacy and Therapeutics (P&T) Committee and is responsible for developing and revising the medication reconciliation policy and procedures as required to meet The Joint Commission NPSG 03.06.01. The Subcommittee will identify opportunities for improvement and make improvement recommendations as necessary.
- c. <u>The TVHS Medication Reconciliation POC.</u> The TVHS Medication Reconciliation POC is responsible for receiving information and helping disseminate new knowledge of Medication Reconciliation from the VISN Medication Reconciliation POC as it is made available.
- d. <u>The Chief of Staff.</u> The Chief of Staff is responsible for the overall implementation and enforcement of this policy, including ensuring:
- (1) VA providers are adequately trained and educated on the medication reconciliation process and understand its importance in the scope of quality patient care and safety.
- (2) VA providers are knowledgeable about their lead role and responsibilities with respect to medication reconciliation.

- (3) VA providers have been provided sufficient resources for inter-provider, inter-departmental, inter-facility, and inter-system communication that conforms to all relevant VA and VHA privacy policies and Federal law.
- e. <u>Clinical Service Chiefs.</u> Clinical Service Chiefs are responsible for compliance with this policy as it pertains to their service and the appointment of a medication reconciliation champion to represent their service or service line.
- f. <u>The HIMS Operations Manager</u>. The HIMS Operations Manager is responsible for the oversight of inpatient medication reconciliation monitoring and reporting processes to ensure compliance with the medication reconciliation process and for reporting findings through the multidisciplinary Medication Reconciliation Subcommittee to the P&T Committee.
- g. <u>The Chief, Quality, Safety, and Value.</u> The Chief, Quality, Safety, and Value is responsible for the oversight of outpatient and post-discharge medication reconciliation monitoring and reporting processes to ensure compliance with the medication reconciliation process and for reporting findings through the multidisciplinary Medication Reconciliation Subcommittee to the P&T Committee.
- h. <u>The Chief of Education</u>. The Chief of Education is responsible for providing educational programs and guidance related to this policy and the procedures associated with it.
- i. <u>Attending physicians.</u> Attending physicians are responsible for appropriate resident supervision in medication management, including the medication reconciliation process described in this policy.
- j. <u>The Inpatient Provider.</u> The Inpatient Provider is responsible for completing an assessment of each patient's medication regimen. This includes obtaining an accurate list of the medications the patient is currently taking, documenting the list in the medical record, and reconciling the list against the medications the organization provides at each transition of care.
 - k. **All Providers** (see 3.e.) are responsible for
 - (1) Completing medication reconciliation in accordance with local policy.
- (2) Documenting a plan to address medication discrepancies that is commensurate with the severity of the discrepancy and the risk of patient harm. (Note: this does not always require managing a medication or changing the medication order.)
 - (3) Educating dual care patients as per VHA's National Dual Care Policy.
 - (4) Documenting and reporting adverse events and close calls.
- (5) Assisting the Veteran patient, caregiver, or family member to maintain, update, and take ownership of the patient's medication information.

- 1. <u>Registered Nurses.</u> Registered Nurses on the inpatient units are responsible for conducting a medication history during completion of the Nursing Admission Intake (NAI), instructing patients on discharge orders, providing the patient a printed list of medications at discharge, and documenting these interactions in the patient's medical record.
- m. <u>Clinical Pharmacists.</u> Clinical Pharmacists are responsible for assisting with medication reconciliation as available during scheduled work hours.
- n. <u>Physicians Performing Procedures.</u> Physicians Performing Procedures (e.g., cardiac cath, interventional radiological procedures, endoscopy) are responsible for reviewing the medication list prior to any procedures in which medications will be administered or when current medications may affect the outcome of the procedure and reconciling the list against the medications the organization provides.

5. PROCEDURES

- a. Sources from which a medication history may be obtained include the following: patient and/or family/caregiver when appropriate, remote VA medications, Computerized Patient Records System (CPRS) outpatient progress notes, and Outpatient and Non-VA medication lists in CPRS.
- b. In all areas of TVHS, the patient is expected and encouraged to be an active participant in his/her healthcare. The patient is instructed on the importance of maintaining an accurate list of all outpatient medications and communicating his/her medication list with VA and non-VA providers. Patients followed by Non-VA providers(s) will be given the opportunity to complete a Release of Information (ROI) form which will allow TVHS to send a copy of his/her medication list to the Non-VA provider(s) of his/her choice.
- c. For medications managed by other providers, or when medications are outside the scope of practice of the health care team member performing medication reconciliation, patient instructions may include referral to his/her primary provider or prescribing specialist for evaluation of medication appropriateness.
- d. For "minimal use" scenarios, a list of the patient's current medications and a history of the patient's allergies must be obtained. Further, if all of the following conditions apply, communication of the list of the patient's current medications is not necessary at completion of the encounter.
 - (1) The "minimal medication use" is in the context of a brief outpatient encounter
 - (2) The medications in question act locally with negligible systemic effect
 - (3) No other medications are used during the encounter
 - (4) No new medications are prescribed for or provided to the patient
 - (5) There are no changes to the patient's "current medications"

(6) Any provider of care to whom the patient is being referred, already has the patient's current medication information.

e. Inpatient Admission, including NHCU/TCU

- (1) Upon patient admission, the Registered Nurse conducts a medication history and lists any variances in the NAI.
- (2) Clinical Pharmacists assist with medication reconciliation as available during scheduled work hours and communicate information to the Inpatient Provider as appropriate.
- (3) The Inpatient Provider reviews the NAI and information provided by the Pharmacist-as available and also conducts a medication history to compare and reconcile against the newly created inpatient medication list. The reconciled list is documented by the provider during completion of the History and Physical (H&P) in CPRS.
- f. <u>Inpatient Transfer/Post-Op Surgery.</u> All orders are rewritten when a patient is transferred to another inpatient unit within the facility due to change in level of care (e.g., MICU to telemetry bed). The receiving Inpatient Provider will compare the active inpatient medication list against the outpatient medication list to determine the need for drug therapy adjustments due to a change in patient's medical status or transition of care.
- g. <u>Change of Provider/Team (NOT involving a change in level of care).</u> Reconciliation will take place between providers/teams as part of the hand-off process.

h. Inpatient Discharge

NOTE: when the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications.

- (1) The Inpatient Provider will reconcile and write for all discharge medications in a timely manner so that all medications and dose changes will be accurate on the list of medications he/she or designee provides to the patient and/or family/caregiver upon discharge. The reconciled discharge medication list will be documented in the medical record and be consistent with discharge instructions provided to the patient and/or family/caregiver. In cases where a patient is discharged to another facility (e.g., Nursing Home), a copy of the discharge medication list and/or discharge summary containing the reconciled medication list will be provided to the receiving facility.
- (2) Clinical Pharmacists provide medication reconciliation services as available during scheduled work hours. Upon patient discharge, the Pharmacist assists the ordering Provider with medication reconciliation as necessary, educates the patient on medications he/she should be taking when discharged (for example, name, dose, route, frequency, purpose, side-effects), provides an updated medication list, explains the importance of managing medication information, and documents these actions in the medical record as appropriate.
- (3) Nursing staff will provide patient education on all discharge orders, ensure the patient receives an updated list of the medications when discharged (for example, name, dose, route,

frequency, purpose), explain the importance of managing medication information, and document these actions in the medical record.

- i. <u>Outpatient Service.</u> For the purpose of this document, this means Emergency Departments and Ambulatory Care.
- (1) The provider obtains an updated list of medications from the patient and/or family member/caregiver and reconciles the patient's home medication list with the active outpatient prescription list in CPRS to identify and address discrepancies.
- (2) Any changes to medication therapy should be entered into the outpatient VA or non-VA prescription profile. At the end of the clinic visit, the provider or designee reviews the medication list with the patient and/or family member/caregiver, provides the patient a copy of the list, explains the importance of managing medication information, and documents these actions in the medical record. When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications.
- j. <u>Procedural Areas.</u> As part of the pre-procedural review of the patient, the provider in these areas will review the current medication list in CPRS with the patient, and note any discrepancies. The purpose of this review is to determine if any contraindications exist in performance of the procedure, and to identify any potential drug interactions that could develop with drugs commonly given during the procedure.
- (1) A complete, documented medication reconciliation process will be used when a new medication is prescribed or another change to the medication regimen is made. In these instances, the provider or designee reviews the updated medication list with the patient and/or family member/caregiver, provides the patient a copy of the new list, explains the importance of managing medication information, and documents these actions in the medical record. When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications.
- (2) For brief outpatient encounters with "minimal medication use" (e.g., like topical fluoride in dentistry, local infiltration anesthesia for dental work or suturing lacerations, wound care check, enteric barium for imaging studies), an updated list of the patient's medications and allergies will be obtained from the patient and/or family member/caregiver prior to the procedure. If all criteria as listed for "Minimal Medications" are met (see Procedures. d.), then communication of the list of the patient's current medications following the brief outpatient encounter is not necessary.
- **6. MONITORING:** Monitoring of medication reconciliation will be completed by Health Information Section for inpatient and Quality Management for outpatient on a monthly basis. This will be performed in an ongoing manner utilizing medical records reviews. Reports will be provided to the Medication Reconciliation Subcommittee, Medical Records Committee, P&T Committee, and Medical Executive Board (MEB).

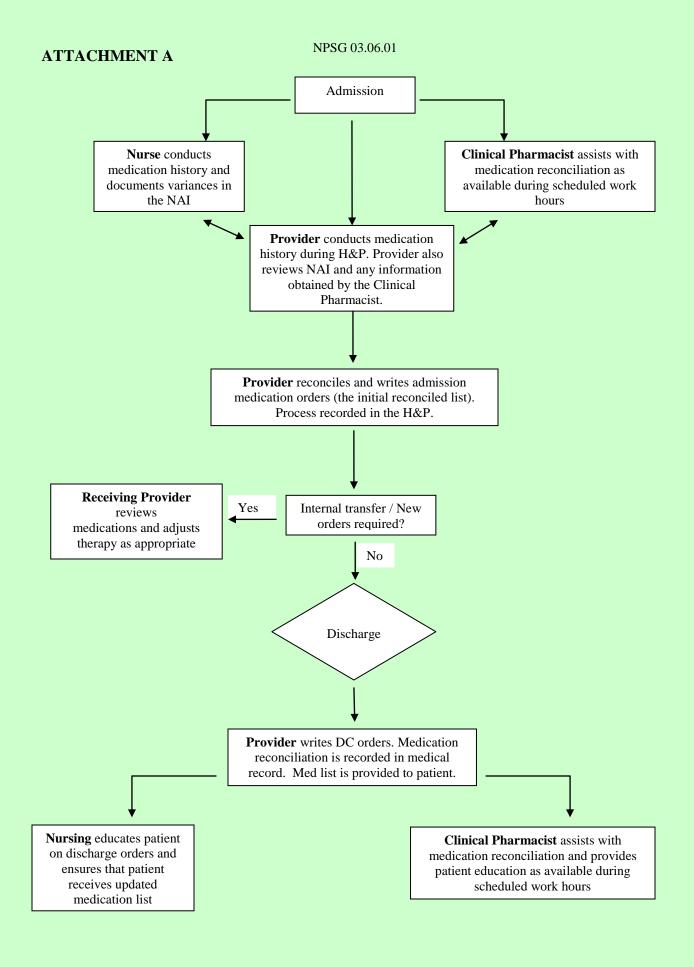
7. REFERENCES

a. The Joint Commission Comprehensive Accreditation Manual.

- b. National Patient Safety Goals (NPSG 03.06.01), MM 1.10.
- c. VHA Medication Reconciliation Directive 2011-012.
- **8. RESCISSION:** VA TVHS Memorandum 626-11-119-16, dated November 2, 2011.
- **9. REVIEW DATE AND RESPONSIBILITY**: The Chief of Pharmacy will review as required and update no later than August 30, 2017.

/s/ Juan A. Morales, RN, MSN 08/04/2014 Juan A. Morales, RN, MSN Health System Director

Attachment A



RECORDS MANAGEMENT

- **1. PURPOSE:** This document establishes the policy for records management within the Department of Veterans Affairs Tennessee Valley Healthcare System (VA TVHS).
- **2. POLICY:** Each organizational entity shall establish and maintain an active, continuing records management program that effectively and efficiently manages records throughout their life cycle.

3. GLOSSARY

- a. <u>Audiovisual Records</u>. Records in pictorial or aural form which include motion pictures, still pictures, sound recordings, video recordings, graphic materials such as posters and original art, audio and video recordings, and combinations of media such as slide tape productions.
- b. <u>Disposal.</u> Removal of records from VA control and authority by their sale, donation, or assignment of legal custody or title to others (Federal or non-Federal entities), or by their physical destruction, sale as waste material, or other forms of salvage or transfer; includes erasure of information captured or maintained on electronic media.
- c. <u>Disposal Authority.</u> The legal authorization obtained only from the Archivist of the United States, National Archives and Records Administration (NARA), for the disposal of records and recorded information.
- d. <u>Electronic Records.</u> A category of computer processed records in which the information is represented by electronic impulses on a magnetic medium; such as magnetic tape, disk, and optical disk, and which requires the use of specialized equipment to convert the information to human-readable form.
- e. <u>File Plan.</u> A file plan contains identifying numbers, titles, or descriptions, disposition authority, and retention periods of all files held in an office or program. The file plan also contains the location of all records, including paper, electronic, and special media and how the records are to be arranged. A file plan allows for consistent filing practices which is critical for an effective and efficient record program.
- f. General Records Schedule. The NARA General Records Schedule (GRS) contains the retention and disposition requirements for records and information that are common to two or more Federal agencies. The disposition requirements of the GRS, including record retention periods, are mandatory VA-wide unless an exception is obtained from NARA. The GRS does not cover all VA/VHA records. Citations from the GRS will be used in VHA records control schedules as the authority for disposition of VHA records whenever applicable.
- g. <u>Information System.</u> The aggregate of all records, information, information handling functions, and systematic processes necessary for operating a program; the organized collection,

processing, transmission, and dissemination of information in accordance with defined procedures, whether automated or manual.

- h. <u>Life Cycle of Records.</u> The management concept that records pass through three stages: creation, maintenance and use, and disposition.
- (1) <u>Creation.</u> The records life cycle is initiated by the creation, collection, and receipt of records in the form of data or documents; in any medium (i.e., paper, film, disk, or electronic file) and format (i.e., electronic, audiovisual, microfilm, architectural, engineering, or printed) in the course of carrying out administrative, programmatic, and clinical responsibilities and needs of the facility. Records disposition must be part of the architecture of any new record development or updates/corrections or modifications to existing records.
- (2) <u>Maintenance and Use.</u> Records life cycle continues through the maintenance and use of the record which includes filing, retrieving, use, duplication, printing, dissemination, release, and exchange of the records. The facility will maintain and preserve records necessary to protect the legal and financial rights of the government and of persons directly affected by its activities. Reasonable efforts will be made to maintain records in appropriate format or media for reproduction under the Freedom of Information Act (FOIA). Duplicate records will be prepared only in amounts required for the efficient operations of the medical center or as required by Federal regulations.
- (3) <u>Disposition</u>. The final stage in the life cycle is disposition, which means records are no longer needed for current facility business. Disposition includes storage, transfer, preservation, and destruction of the records. Disposition of records will be made in a timely manner and in accordance with the VHA Records Control Schedule (RCS) 10-1. Safeguarding measures will be applied to all records through all stages of their lifecycle.
- i. <u>Non-record Material.</u> Federally owned informational materials that do not meet the statutory definition of records (44 U.S.C 3301) or that have been excluded from coverage by definition. Excluded materials are extra copies of documents that are kept only for reference, stocks of publications and processed documents, and library or museum materials included solely for reference or exhibit (36 CFR 1220.14).
- j. <u>Permanent Records and Information.</u> In U.S. Government usage, records and information appraised by VA and approved by NARA as having enduring value because they document the organization and functions of the agency that created or received them and/or because they contain significant information on persons, things, problems, and conditions with which VA dealt, and for which there is no plan for destruction.
- k. <u>Records.</u> All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate

successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them (44 U.S.C. Chapter 33, Sec. 3301).

- 1. **Records Appraisal.** The process of determining the value and, thus, the final disposition of records and information based upon their administrative, financial, and other uses, their evidential, legal, and informational or research value, their arrangement and relationship to other records, and their historic value to VA, other agencies of the Federal Government, or to the general public.
- m. <u>Records Control Schedule (RCS) 10-1.</u> RCS 10-1 contains the VHA-specific schedules covering records and record series that are unique to the VHA; it supplements the GRS. RCS 10-1 applies to records maintained in the Veterans Health Administration (VHA) field facilities and Central Office VHA program offices.
- n. <u>Records Inventory.</u> The record inventory will include the date prepared, department or program creating the inventory, person conducting the inventory, record location, record series, description of the record, inclusive dates of information in the series, disposition, and type of medium (paper, electronic, audiovisual, etc.). Both electronic and non-electronic records should be included in the record inventory.
- o. <u>Records Liaison Officer</u>. Service line representative who works in conjunction with the Records Officer to ensure proper management of records created and maintained by the service line.
- p. <u>Records Management</u>. The managerial activities involved with respect to records creation, maintenance and use, and disposition of records to achieve adequate and proper documentation of the policies and transactions of the Federal Government and effective and economical management of VA operations.
- q. **Records Officer (Facility, VISN, VACO Service/Department).** Person assigned responsibility by the TVHS Director for managing and coordinating the TVHS-wide records management program.
- r. **Records Officer (VA).** Person assigned responsibility by the agency head for overseeing an agency-wide records management program.
- s. **Records Officer (VHA).** Person assigned responsibility for overseeing the VHA records management program.
- t. **Records Series.** File units or documents arranged according to a filing system or kept together because they relate to a particular subject or function, result from the same activity, document a specific kind of transaction, take a particular physical form, or have some other relationship arising out of their creation, receipt, or use, such as restrictions on access and use.

Each series of records should have a file plan which promotes ease of access to the information as appropriate.

- u. <u>Shadow Records.</u> Shadow health records are defined as duplicate health records that are kept for the convenience of a department or health care provider.
- v. **SharePoint.** SharePoint is a tool that allows people to collaborate on current active documents that may be Federal records. SharePoint does not meet DOD Standard 5015-2 and should not be considered an electronic recordkeeping system. Official records must be maintained on the network drive or in accordance with the department's file plan.
- w. <u>Temporary (non-permanent) Records.</u> Records approved by NARA for disposal, either immediately or after a specified retention period.
- x. <u>Unscheduled Records.</u> Records whose final disposition has not been approved by NARA.
- y. <u>Vital Records.</u> Records essential for maintaining the continuity of activities during and following a national or regional emergency (36 CFR Part 1236).

4. ROLES AND RESPONSIBILITIES

a. The Medical Center, VISN or VHA Central Office Director

- (1) Designates a Records Officer as appropriate to their level of authority.
- (2) Ensures that the records management program is compliant with agency requirements.
- (3) Provides the necessary resources (funding and personnel) to support the Record Management Program.
- (4) Ensures that all record management requirements mandated by VA policy, VHA policy, and other Federal legislation are met.
- (5) Ensures that Product/Service Line Records Liaison Officer (s) are designated to support the records management program.

b. Service Chiefs, Product/Service Line Managers, Program Supervisors/Managers

- (1) Appoints a Record Liaison Officer(s) to support the records management program.
- (2) Ensures the Record Liaison Officer collaborates with the Records Officer on all projects concerning the creation, maintenance and use, and disposition of all records.
 - (3) Ensures all service/program employees are aware of and abide by this policy.

(4) Ensures that employees, volunteers, contractors, including those departing, do not remove Federal records from VHA custody.

c. <u>Chief Information Officer (CIO)/Chief Office Information and Technology (OIT), or designee</u>

- (1) Establishes, coordinates, and maintains an automated information systems to support the Records Management program in accordance with all applicable VA and VHA regulations.
- (2) Implements a program for managing electronic and audiovisual records and microfilm media in accordance with current Federal regulations.
- (3) Ensures all electronic records are migrated to existing current software to ensure records are readable and usable throughout their life cycle.
- (4) Coordinates with the Records Officer to provide technical advice and other assistance relative to the record management requirements for implementation of IT systems, policies, and procedures.

d. Contracting Officer Representative (COR)

- (1) Collaborates with the Records Officer to ensure that records and information created, received, or maintained by contractors are maintained in accordance with all VA and VHA policy and procedure.
- (2) Ensures that contractors are aware of, and abide by, records management procedures as stated in the contract.
- (3) Ensures that current records requirements criteria are stated in the Performance Work Statement.
- (4) Ensures that contract performance meets record management requirements and appropriate actions are taken to terminate the contract if such requirements are not being met as noted in the current Performance Work Statement.

e. Records Officer

- (1) Implements and manages the record management program at the appropriate organizational assignment.
- (2) Implements policy and procedures for administering the records management program that assures the creation, maintenance and use, and disposition of Federal records in accordance with all applicable statutory and regulatory requirements.

- (3) Completes, upon appointment and annually thereafter, the current VA Talent Management System (TMS) Records Management Course, or alternative course approved by the VHA Records Officer as required by VHA Directive 6300, Records Management. Note: The "Role Based Records Management Training for VA Personnel" in TMS has been suspended pending update. The My VeHU Campus course in TMS "VA 16863 HIM: The Ins and Outs of Records Management for VA" will meet the requirement for training.
- (4) In collaboration with Record Liaison Officers, assures completion of the Records Management Facility Self-Assessment on a quarterly basis in accordance with VHA Handbook 1605.03, Privacy Compliance Assurance Program and Privacy Compliance Monitoring.
- (5) Communicates and collaborates with all entities within scope to ensure that the records management program is carried out in accordance with this policy.
- (6) Conducts regular internal records management reviews to assist in implementing appropriate records management procedures.
- (7) Works with the Privacy Officer or, depending on facility designation, the responsible staff member, to ensure compliance with the current annual NARA training requirement for all employees to complete the VA Talent Management System (TMS) course: "VA Privacy and Information Security Awareness and Rules of Behavior" (VA10176).
- (8) Develops standardized file plans and indexing approaches where appropriate to simplify the use, access, and integration of information within the facility.
- (9) Systematically reviews and updates file plans and procedures to ensure they are accurate and current on an annual basis at a minimum.
 - (10) Maintains the facility master record inventory.
- (11) Implements approved records dispositions, to ensure that records are dispositioned as specified in the Federal Records Act.
- (12) Collaborates with the VHA Records Officer to schedule records when new records are created and when existing records are found to be unscheduled.
- (13) Coordinates with PO and CIO to plan and implement new or newly discovered electronic or manual information systems and/or data bases to ensure that records or information created and/or generated are properly scheduled and placed in the organization's records control schedule or if necessary, a System of Records is created.
- (14) Implements a vital records program in accordance with the VA-wide program as described in VA Handbook 6300.2, Management of the Vital Records Program.

- (15) Ensures the identification and availability of vital records is addressed in the facility Emergency Preparedness Plan (also known as the Continuity of Operations Plan (COOP)).
 - (16) Apprises leadership and managers on matters relating to records management activities.
- (17) Provides technical advice and training to Records Liaisons and facility staff on maintaining an effective records management program.
- (18) Ensures that employees, including departing employees, do not remove Federal records from VA custody.
- (19) Reviews facility contracts that create, use, store, and disposition Federal records to ensure compliance with 36 CFR 1220.30(c) (1).
- (20) Ensures on-site and off-site storage locations for Federal Records meet the requirements of 36 CFR 1234, Subpart B, Facility Standards for Records Storage Facilities.
- (21) In conjunction with the Privacy Officer and Regional Counsel, implements a process to research, document, and implement Litigation Hold requirements, to ensure records are safeguarded for possible use in litigation.
- f. <u>Records Liaisons Officer.</u> Records Liaisons Officers are responsible to their manager for the full implementation of the records program at their service level. Responsibilities include:
 - (1) Maintains a complete and accurate inventory of records created and stored.
- (2) Collaborates with the Records Officer to identify records not scheduled for disposition, completes the VA Form 7468, Request for Disposition of Records, for records no longer needed for TVHS business and forwards the form to the Records Officer for submission to the VHA Records Officer to be scheduled.
 - (3) Provides annual records management staff training.
- (4) Conducts internal records reviews to ensure an effective records management program within their scope is maintained on, at a minimum, an annual basis. The review will comprise their department's inventory, file plan, charge-out system, and records to determine the adequacy of the filing system and its effectiveness in providing the records and information in a timely manner. The review will assess issues such as duplication of material, misclassification, misfiles, and check-out process. The findings and corrective action, if required, will be provided to the Records Officer upon completion.
- (5) Ensures that employees, volunteers and contractors, including those departing, do not remove Federal records from VHA custody.

- (6) Ensures that vital records are maintained in accordance with VA Handbook 6300.2, Management of the Vital Records Program.
- (7) Ensures records are stored in accordance with 36 CFR 1234, Subpart B, Facility Standards for Records Storage Facilities.
- (8) Completes, upon appointment and annually thereafter, the current VA Talent Management System (TMS) Records Management Course, or alternative course approved by the VHA Records Officer, as required by VHA Directive 6300, Records Management. Note: the "Role Based Records Management Training for VA Personnel" in TMS has been suspended pending update. The My VeHU Campus course in TMS "VA 16863 HIM: The Ins and Outs of Records Management for VA" will meet the requirement for training.
- g. **Employees.** In coordination with their service/department Records Liaison Officer, employees:
- (1) Create, maintain, protect, and disposition (only as authorized) records within their area of responsibility in accordance with Directive 6300, Records Management.
- (2) Ensure that all records within their scope are listed in the department and/or program inventory and file plan.
 - (3) Prepare eligible records for transfer to NARA approved record storage centers.
- (4) Ensure records are not removed from the department or facility without approved authorization.
- (5) Report to the Records Officer or Records Liaison Officer any unlawful destruction or mutilation of records.
 - (6) Certify upon separation from the facility that records under VA custody are not removed.
- (7) Complete "VA Privacy and Information Security Awareness and Rules of Behavior" (VA 10176) in order to fulfill the annual NARA training requirement of 36 CFR 1220.34(f).

5. PROCEDURES

a. Creating Federal Records

(1) The creation of Federal records shall be limited to records that are essential for administrative, legal, or fiscal purposes to include patient care functions. Examples of records include but are not limited to: health records; medical device records; accounting records; dietary records; supply orders and invoices; medical center and program policies, decisions, and procedures; human resource records; contracts; project files, etc.

- (2) Records shall be created in a medium and format that meets the administrative and clinical needs of the facility. Consideration must be given to the length of time the records will be maintained to ensure that the information will be accessible throughout its expected lifecycle.
- (3) The records and information collected and created by personnel in the conduct of official business belong to the Federal Government and not to the employee(s) who initiated their collection or creation. Records or information collected or created by VA in any form, manual or automated, may not be disposed of (destroyed, erased, loaned, or otherwise removed from VA custody) without authorization from NARA. Until a request for disposition is approved by NARA, the records are unscheduled and shall be maintained indefinitely.
- b. <u>Identifying Federal Records.</u> Federal records are categorized into distinct types: temporary, permanent, unscheduled, and vital records.
- (1) <u>Temporary Records</u>. Temporary records are approved for destruction after a specific retention period. Temporary records will not be retained beyond their authorized retention period; nor will they be destroyed or otherwise disposed of prior to the end of their authorized retention period. Temporary records are to be inventoried and their location and disposition identified in a file plan.
- (2) <u>Permanent Records.</u> Permanent records have been determined to have enduring historical or other value to warrant the continued preservation by the Federal Government. Permanent records will not be destroyed and will be transferred to the National Archives at the time they are no longer needed for administrative, legal, or fiscal purposes. Permanent records are to be inventoried and their location and disposition identified in a file plan.
- (3) <u>Unscheduled Records.</u> Unscheduled records do not have disposition established by NARA. The Records Officer must be notified when unscheduled records are identified.
- (4) <u>Vital Records.</u> Vital records are essential to the continued function or reconstruction of an organization during and after an emergency. Vital records are categorized as either Emergency Operating Records (Category A Vital Records) or Legal and Financial Rights Records (Category B Vital Records).
- (a) <u>Category A Vital Records.</u> Category A Vital Records are defined within VA Handbook 0320, Comprehensive Emergency Management Program, and include emergency plans and directives, order of succession, delegation of authority, staffing assignments, records of a policy or procedural nature that provide agency staff with guidance, and information resources necessary for conducting operations during an emergency and for resuming formal operations at its conclusion.
- (b) <u>Category B Vital Records</u>. Category B Vital Records are defined within VA Handbook 6300.2, Management of the Vital Records Program, and include Construction Contract Records

(Basic Files), Construction Contract Records (New Files, Additions, Changes), Patients' and Members' Account (Active or Inactive During the Year), Patient Data Card Listing File (Active), Daily Gains and Losses Sheets File (maintained electronically).

- c. <u>Identifying non-Federal records</u>. The two categories of non-Federal records are non-records and personal papers.
- (1) Non-records. Non-records are informational documents excluded from the definition of a record or not meeting the requirements of that definition. Examples of non-records include, but are not limited to, extra copies of documents kept only for convenience or reference, routing slips, catalogs, trade journals, stocks of publications, e-mails from list serves, etc. However, in some cases non-records, such as transmittals or routing slips, may acquire record status because they clarify a matter being documented. Similarly, carbons or reproduced copies that duplicate record material in other files may acquire record status if they constitute a collection of material on a single subject or for a particular function, and the original record material is dispersed throughout many files.
- (2) <u>Personal papers</u>. Personal papers consist of documents that relate only to an individual's personal affairs and do not affect the conduct of government business. Examples of personal papers are diaries, journals or other personal notes that are not created in the process of transacting government business. Personal papers may be disposed of in accordance with the owner's preference. However, personal record information and data created and maintained on VA equipment may be considered VA property. Calendars are not considered personal papers since they document agency business.

d. Maintenance and Use of Federal Records

- (1) The maintenance and use of the record includes functions such as filing, retrieving, use, duplication, printing, dissemination, release, and exchange of the records. Record filing, indexing and storage systems should be designed and documented to the extent appropriate and necessary to maximize the usefulness of the records and allow for ready retrieval throughout the record's life cycle.
- (2) Each series of records should have a file plan which promotes ease of access to the information as appropriate.
- (3) The facility will maintain and preserve records necessary to protect the legal and financial rights of the government and of persons directly affected by its activities. Reasonable efforts will be made to maintain records in formats or media that are reproducible for purposes of the Freedom of Information Act (FOIA). Duplicate records will be prepared only in amounts required for the efficient operations of the medical center or as required by Federal regulations.

- (4) Within their department and/or program, each Records Liaison Officer will assist in developing and implementing a standardized procedure for filing, retrieving, charging-out, and re-filing the records.
- (5) Non-record material and personal papers are not to be interfiled with Federal records. Personal papers shall be clearly designated as nonofficial and shall at all times be filed separately from the official records of the office. In cases where matters requiring the transaction of official business are received in private personal correspondence, the portion of such correspondence that pertains to official business shall be extracted and made a part of the official files.
 - (6) Permanent records are to be filed separately from temporary records.
- (7) Temporary records will be clearly identified through labeling and indexing, and will not be interfiled with permanent records or non-record material. Temporary records eligible for disposition will be removed from active files at least annually. If disposition is destruction, the destruction will be documented.
- (8) Working files, such as preliminary drafts and rough notes, and other similar materials shall be maintained for purposes of adequate and proper documentation if:
- (a) They were circulated or made available to employees, other than the creator, for official purposes such as approval, comment, action, recommendation, follow-up, or to communicate with agency staff about agency business.
- (b) They contain unique information, such as substantive annotations or comments included therein, that adds understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.
- (9) Electronic Mail (e-mail) can be a Federal Record. Personal e-mail must be kept separate from official e-mails. E-mail records must be maintained in a recordkeeping system, either printed out and filed, or saved in an electronic records management application.
- (10) Records or information obtained from other Government agencies will be maintained in accordance with VA and VHA records management policies.
- (11) Shadow records must be limited or non-existent. The need for shadow records should be documented in the appropriate committee minutes. There should be a process to track the location of all shadow records and a policy to address the privacy, security, and disposition of shadow records.

e. Disposition of Federal Records

(1) Record disposition means the records are no longer needed for current facility business. Disposition includes storage, transfer, preservation, and disposition/destruction in accordance

with RCS 10-1 and the General Records Schedule (GRS). Annually, the Records Liaison Officers will review RCS 10-1 and disposition records that meet the retention timelines.

- (2) The Record Liaison Officer is required to contact the Records Officer when records are improperly disposed of or damaged. The Records Officer will send a memo to the VHA Records Officer that includes record description, volume, date of incident, etc. The VHA Records Officer will submit the report to NARA.
 - (a) Non-records should be destroyed after their purpose has been served.
 - (b) Personal papers may be disposed of at any time.
 - (c) Working files may be destroyed when the finalized document is published.

f. Safeguarding of Records

- (1) All Federal records and information, regardless of format or medium, must be safeguarded in accordance with applicable Federal laws and regulations, throughout their lifecycle. Information on Veterans, beneficiaries, employees, and others having dealings with VHA, including proprietary information, will be collected only when legally authorized and will be protected from unauthorized disclosure.
- (2) The laws, regulations, and policies that apply to records and information maintained and used by the facility also apply to records and information maintained and used on behalf of the facility by contractors and those covered by a Business Associate Agreement (BAA) or Memorandum of Understanding (MOU).
 - (3) Federal records will only be removed in accordance with facility policy.

6. REFERENCES

- a. 36 C.F.R. Chapter XII, Subchapter B Electronic Records Management
- b. 44 U.S.C. Chapter 31 and Chapter 33 Federal Records Act of 1950, as amended
- c. M-12-18, Managing Government Records Directive
- d. OMB Circular A-123 Management's Responsibility for Internal Control
- e. OMB Circular A-130 Management of Federal Information Resources
- f. VA Handbook 0320, Comprehensive Emergency Management Program
- g. VA Handbook 6300.1, Records Management Procedures

- h. VA Handbook 6300.2, Management of the Vital Records Program
- i. VA Handbook 6300.3, Procedures for Implementation of the Freedom of Information Act
- j. VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act
- k. VA Handbook 6300.5, Procedures for Establishing and Managing Privacy Act Systems of Records
- 1. VA Handbook 6300.6, Procedures for Releasing Lists of Veterans and Dependents Names and Addresses
 - m. VA Handbook 6300.7, Procedures for Computer Matching Programs
- n. VA Handbook 6300.8, Procedures for Shipment of Records to the VA Records Center & Vault in Neosho, Missouri
- o. VHA Handbook 1605.03, Privacy Compliance Assurance Program and Privacy Compliance Monitoring
 - p. VHA Directive 6300, Records Management
 - q. Records Management Service http://www.rms.oit.va.gov/Records.asp
- r. VHA Health Information Management (HIM) Records Management Webpage http://vaww.vhaco.va.gov/him/recordsmanagement.html
- 7. RESCISSION: TVHS Memorandum 626-11-136-32 dated October 20, 2011
- **8. RESPONSIBILITY AND REVIEW DATE:** The Chief, Health Information Management will review annually and update no later than February 28, 2017.

/s/ Juan A. Morales, RN, MSN 09/19/2014 Juan A. Morales, RN, MSN Health System Director

Attachments: A through C

Attachment A

Current Roster on File with Records Manager/Alternate Records Manager

Records Liaison Officer Roster for TVHS

RL Name	Date Designated	Phone #	email	Dept Program	Supervisor	Alternate RL Name
				ACOS/Education		
				Anesthesiology		
				Audiology Service		
				Business Office		
				HIMS (Business Office)		
				Canteen Service		
				Cardiology		
				Chaplain Service		
				Chattanooga Outpatient Clinic		
				Chief of Staff's Office Clarksville Outpatient Clinic		
				Dental Service		
				Director's Office		
				Engineering Service Environmental Management Service		
				Fiscal Service		
				GEC (ACY)		
				GRECC		
				Human Resources Management Service		
				Information Resource Management (IRM)		
				Library Service/Education		
				Logistics		
				Medicine		
				Primary Care (ACY) Resident/Student Education Program (ACY)		
				Medical Imaging		
				Medical Service		
				Mental Health Care Line		
				Neurology Service		
				Nuclear Medicine		
				Nursing Service		
				Nutrition & Food Service (Nash)		
				Nutrition & Food Service		

(ACY)
Pathology & Laboratory
Service
Pharmacy Service
Physical Medicine &
Rehab. Service
Police Service
Prosthetics & Sensory
Aids
Quality Management
Radiology Service
Research & Development
Social Work Service
Surgical Service
Transplant Service
Voluntary Service
Meharry Sharing
Clinics(Charlotte
Avenue/Women Vet.
Clinic/Meharry
Clinic@Albion)

ATTACHMENT B

Disaster Contingency Plan For Records

- **1. PRIORITY RECORDS:** For the purpose of evacuation, the following records are designated as priority records. This contingency plan is to establish disaster procedures for the Tennessee Valley Healthcare System (VA TVHS). Medical record documents will have top priority in recovery efforts in case of flooding, fire or water damage.
 - a. Inactive clinical records and correspondence folders.
 - b. Personnel folders.
 - c. Time and Attendance Reports, VAF 4-5631 (active and inactive).
 - d. Earnings and Leave Statements, VAF 4-5632.
 - e. Patients' and Members' Accounts, VAF 10-1083 Series (active and inactive).
 - f. Active correspondence folders.
 - g. Construction Contract Records.
 - h. Deed and Property Files Engineering Service.
 - i. Emergency Room Books Emergency Service.
 - j. Gains and Losses Sheets Medical Administration Service.
- **2. POLICY:** It is Health Informations Management (HIMS) policy to provide departmental support to protect the medical center's documentation process from unexpected events; through rapid emergency response.
- **3. RESPONSIBILITITY:** It is the responsibility of the Chief of Health Information Management to identify and ship damaged medical documents for reclamation for health records.
- **4. PROCEDURES:** A Records Salvage and Removal Team, as established by the Chief, Business Officer /or designee, is responsible for coordination of all activities involving evacuation of vital records. In the event of a situation requiring the evacuation of records, the following procedure will be followed:

- a. All records listed in paragraph 1, above, will be housed in metal cabinets, metal shelving, or safes, and marked "Fire Priority". The marking will be accomplished under the direction of the Records Manager through Service Record Liaisons. All health records (including records to scanned) loose sheets will be boxed/labeled and stored in the ACY file room on pallets.
- b. If patients are being transferred to another facility because of a disaster, HIMS staff will print30-day Health Summaries, place each in a manila folder, and provide for transport with patients. HIMS will start print Heath Summaries two days (if time permits) before patient evacuation.
- c. These records, whenever possible, will be replaced in their respective file storage receptacle at the close of each business day.
- d. Inactive clinical records and correspondence folders will be properly aligned on their shelves so as to prevent water damage in case of fire or emergency.
- e. In the event of fire or other emergency, the records will be housed in their proper file receptacle, time permitting, to prevent their destruction from fire or water damage. Records Salvage and Removal Team, have responsibility to assure that records are removed to designated areas of safety.
- f. HIMS will notify transcription contractor that all Discharge and Transfer Summaries are to be transcribed STAT (2 hour turnaround time or less than 2hrs turnaround, if possible).
- **5. RECORDS SALVAGE AND REMOVAL:** The following procedures will be followed in the event of water damage due to flooding or fire after a disaster.
- a. The Chief, Health Information Management Section (HIMS) will contact a vendor (GSA contract) in the event that paper medical record documents are water damaged.
- b. All water damaged records will be prepared and shipped to vendor according to the following preparation procedures for damaged documents:
 - (1) Use cardboard "banker's box" 15'x12"x10" for packing.
 - (2) Handle wet materials carefully to avoid additional damage.
 - (3) If necessary, rinse off heavy mud and dirt using clean water.
 - (4) Pack books spine down and documents upright in the box.
 - (5) Books must be packed in the box only one widths high.
 - (6) Write station name and contents on the side of the box.

- (7) When palletizing boxes, stack them only three high to prevent crashing the bottom layer during transport.
- (8) If at all possible freeze wet books and documents within 48 hours to prevent mold growth. Low temperature blast freezers give smaller ice crystals and better end results.
 - (9) If at all possible freeze coated papers within 8 hours to avoid blocking of pages.
 - c. Records sent to vendor for reclamation will be logged on a spreadsheet.
- d. Records that may have been completely destroyed will be recreated by utilizing all available options in CPRS and VISTA, i.e. Release of Information Health Summary, or other record sources.

CEDVICE

ATTACHMENT C

RECORDS MANAGEMENT PROGRAM SURVEY

The Records Manager or designee will meet with the appointed Records Management Liaison of each Service for the purpose of conducting a review of their records management program as scheduled below:

MONTH

SERVICE	MONTH
Radiology Service Medical Service Radiation Therapy Service	January
Office of the Medical Center Director Police and Security Service Nursing Service	February
Office of the Chief of Staff Ambulatory Care Service ACOS/Education	March
Pharmacy Service Canteen Service Physical Medicine & Rehabilitation Medicine Service	April
Business Office Medical Media Service Psychiatry Service	May
Chaplain Service Social Work Service Information Resource Management Service	June
Pathology and Laboratory Medicine Service Research Service Audiology and Speech Pathology Service	July
Acquisition and Materiel Management Service Fiscal Service	August
Nutrition and Food Service Psychology Service Nuclear Medicine Service	September

ATTACHMENT C, continued

Human Resources Management Service

Dental Service

October

Engineering Service Voluntary Service

Prosthetics and Sensory Aids Service

November

Environmental Management Service Surgical Service

Neurology Service

December