

CLOZAPINE PATIENT MANAGEMENT PROTOCOL (CPMP)

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides updated procedures regarding the use of the atypical antipsychotic drug Clozapine within VHA.

2. SUMMARY OF CONTENTS. This is a new Handbook which:

a. Establishes a Department of Veterans Affairs (VA) policy that all VA patients with schizophrenia or schizo-affective disorder who have experienced failures on two or more antipsychotic medications must be given the option of treatment with Clozapine.

b. Changes requirements to make signature consent necessary for all VA patients prior to initiation of clozapine treatment in accordance with VHA Handbook 1004.1, Informed Consent for Clinical Treatments and Procedures.

c. Updates the Clozapine Patient Management Protocol (CPMP) to reflect changes in Food and Drug Administration (FDA) labeling.

d. Adds guidelines allowing blood monitoring every 4 weeks in select patients, including the requirement for monitoring and reporting absolute neutrophil count (ANC).

e. Clarifies the lines of authority and modifies the registration process for patients, providers, and facilities.

f. Provides an explicit mechanism for shared responsibility by a psychiatrist or neurologist, and another clinician in the care of patients on clozapine.

3. RELATED DIRECTIVE. VHA Directive 1160 (to be published).

4. RESPONSIBLE OFFICE. The Office of Patient Care Services Officer, Mental Health (116), is responsible for the content of this VHA Handbook. Questions may be addressed to 202-461-7350.

5. RESCISSION. VHA Directive 99-035 is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working date of December 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 12/29/08
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 12/29/08

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CLOZAPINE PATIENT MANAGEMENT PROTOCOL (CPMP)

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides updated procedures regarding the use of the atypical antipsychotic drug clozapine within VHA by: establishing Department of Veterans Affairs (VA) procedures to offer a trial of Clozapine to any veteran who fails two or more trials of other antipsychotic medication, with associated change in informed consent; updating the Clozapine Patient Management Protocol (CPMP) to reflect changes in the Food and Drug Administration (FDA) labeling; adding guidelines allowing blood monitoring every 4 weeks in select patients, including a requirement for monitoring and reporting absolute neutrophil count (ANC); clarifying the lines of authority; modifying the registration process for patients, providers, and facilities; and providing an explicit mechanism for shared responsibility by a psychiatrist or neurologist, and another clinician in the care of patients on clozapine.

2. BACKGROUND

a. In 1989, the FDA approved clozapine (Clozaril® by Novartis), an atypical antipsychotic medication, for the treatment of schizophrenia. Clozapine has been associated with the potential life-threatening side effect of agranulocytosis, a severe and often life-threatening decrease in infection-fighting white blood cells. Because of this problem:

- (1) The FDA placed clozapine under control of a manufacturer-operated medical registry,
- (2) Registration is required by physicians and pharmacists using clozapine, and
- (3) Verification of specific blood test parameters is required before dispensing the medication.

b. VA already had an integrated, cost-effective system to monitor laboratory values, control dispensing, and communicate data electronically. VA petitioned the FDA, and ultimately received approval, to establish the VA National Clozapine Coordinating Center (NCCC), guided by VHA CPMP and a Clozapine National Registry.

c. VA continues to maintain the internal registry and protocol to ensure the safe use of clozapine in VA. The NCCC performs internal medical registry functions with six independent FDA medical registries, including medical review and consulting services, and is the primary liaison for all VA facilities. All VA facilities route communication and data to the FDA registries through the NCCC, significantly reducing the administrative burden and the operating costs of maintaining independent communication lines.

3. SCOPE

a. Through the collaboration of the Office of Mental Health Services (OMHS), the Mental Health Quality Enhancement Research Initiative (QUERI), the Pharmacy Benefits Management (PBM)-Medical Advisory Panel (MAP), and the Employee Education System (EES), all VHA facilities prescribing clozapine must implement the use and monitoring of the clozapine program

and an educational program (as outlined in subpar. 5c), to inform staff regarding the use of clozapine, the new CPMP, and strategies to enhance the efficiency and effectiveness of clozapine use.

b. The scope of protocol contained in this Handbook, and enforced by VHA policy:

(1) Creates a process and procedures at each VA facility to monitor the safe and effective use of the atypical antipsychotic drug clozapine by veterans receiving care within VHA.

(2) Ensures that VA physicians prescribing clozapine are properly trained as required by the FDA and by VA contract with the Clozapine National Registry.

(3) Establishes a communication system between the VA's NCCC and the individual VA facilities where clozapine is prescribed.

4. RESPONSIBILITIES OF THE FACILITY CHIEF, MENTAL HEALTH SERVICE

The Chief, Mental Health Service, at each facility, is responsible for overseeing the implementation and maintenance of CPMP. If a psychiatrist, this individual may function as the Clozapine Treatment Manager, or may delegate this role to a qualified psychiatrist. If the Chief, Mental Health Service, is not a psychiatrist, a qualified psychiatrist must be selected to serve in this role. *NOTE: Although a Clozapine Treatment Team (CTT) is no longer required, CTTs may be continued or established, based on local considerations.*

5. RESPONSIBILITIES OF THE CLOZAPINE TREATMENT MANAGER

The Clozapine Treatment Manager at each facility must be a psychiatrist and is responsible for:

a. Implementing the CPMP and ensuring the safe and appropriate use of clozapine within VA and FDA requirements and regulations.

b. Identifying and ensuring that clozapine is offered as an option to any VA patient diagnosed with schizophrenia or schizo-affective disorder, who has experienced two antipsychotic medication failures. Documentation by the clozapine specialist is required (see par. 6).

c. Approving physicians to prescribe clozapine and submitting VHA Form 10-0363F, Clozapine Treatment Team (CTT) Documentation (see App. G). Additions or deletions from this list need to be submitted in writing or by e-mail to the NCCC. At a minimum, all physicians including clinicians with Shared Care Responsibility (see par. 7), approved to prescribe clozapine must have met the educational requirements, including reading the latest Clozapine package enclosure, VA's CPMP, VHA Handbook 1160.01, and other reading as determined by the Clozapine Treatment Manager (see App. B).

NOTE: At the parent facility level, Mental Health controls clozapine prescribing privileges using the Vista YSCL AUTHORIZED Security key. This computer key must be issued to all approved clozapine specialists in order to prescribe (see par. 19).

d. Coordinating with the facility's Laboratory Service to ensure that Clozapine-related data are appropriately entered into the Veterans Health Information System Technology Architecture (VistA).

e. Overseeing quality management, together with individual prescribers, the medical center's Drug Use Evaluation (DUE) Committee, and the NCCC.

f. Maintaining and using valid NCCC-assigned patient clozapine authorization numbers on written and computer transmissions.

g. Collecting and submitting the following information and documents to the NCCC:

(1) A list of physicians who are approved to prescribe clozapine.

(2) The initial patient application, VA Form 10-0363, Application for VA Clozapine Treatment (see App. A).

(3) A weekly report of clozapine laboratory and prescription data by facsimile to comply with FDA mandatory requirements. This report must contain:

(a) Patient's clozapine authorization number.

(b) Social Security Number (SSN).

(c) Date of the blood test (WBC and ANC) test.

(d) WBC and ANC count results.

(e) Date the prescription was dispensed.

(f) Dose per day prescribed, based on the WBC and ANC test results.

(g) Drug Enforcement Agency (DEA) number of the prescriber. If the prescriber has no DEA number, the NCCC must provide identification suitable for FDA registration based on agreements with the clozapine registries.

(h) VA facility number.

NOTE: *The NCCC pursues alternative methods of data transmission, including web-based File Transfer Protocol (FTP) sites, and must provide these if they become available. If automatic data transmission methods prove reliable, the NCCC informs the facility in writing that facsimile transmission of data is not necessary, using VA Form 10-0363E, Weekly Tracking Information, National Clozapine Coordinating Center (see App. F).*

h. In case of an abnormal blood event, reporting the specific information to the NCCC.

NOTE: *An "abnormal blood event" is defined as a WBC count less than 3500 per millimeter*

(/mm)³ or an ANC of less than 2000 /mm³. Abnormal blood events dictate changes in the required frequency of blood monitoring. Information to be reported to the NCCC includes:

- (1) All physical and mental diagnoses,
- (2) Most recent WBC and ANC counts,
- (3) Concomitant medications, and
- (4) The lot number and expiration date of the clozapine medication.
 - i. Completing VA Form 10-0363B, Termination of Clozapine Treatment (see App. C.), when clozapine therapy has been stopped or has been interrupted for more than 4 days.
 - j. Preparing, in case of death, a Progress Note in the patient's medical record documenting the death, including cause and circumstances, of any VA-registered clozapine patient, especially if clozapine was either directly or indirectly involved.
 - k. Providing a copy of this Progress Note to the NCCC with a Notification of the Death, including cause and circumstances of any VA-registered clozapine patient. **NOTE:** *The NCCC must perform the data reporting required by the FDA and the Clozapine National Registry, including termination notification.*

6. RESPONSIBILITIES OF THE CLOZAPINE SPECIALIST, i.e., Attending Psychiatrist or Neurologist

A Clozapine specialist must be a psychiatrist or neurologist, Board-certified by the American Board of Psychiatry and Neurology, or Board Eligible in Psychiatry, and must be approved by the facility Chief, Mental Health Service, or designated Clozapine Treatment Manager (see par. 4) to prescribe clozapine.

- a. The responsibility for each clozapine patient rests with the individual clozapine specialist and the medical center's Mental Health Service. **NOTE:** *Procedures and information outlined in this Handbook provide a system and structure for supporting the safe use of clozapine in VA patients; however, this protocol is not to be considered a substitute for clinical judgment and expertise.*
- b. VA Mental Health Policy requires a clozapine specialist to evaluate any patient diagnosed with schizophrenia or schizo-affective disorder, with two failures of antipsychotic medication for the option of treatment with clozapine.
 - (1) If the clozapine specialist determines the patient should not be given the option, the reasons, including any applicable medical contraindications, must be documented in a Progress Note in the patient's chart. **NOTE:** *For some factors that should be considered when determining whether to offer clozapine as a treatment option, see subparagraphs 12f and 12g.*
 - (2) If the Clozapine specialist determines the patient should be given the option:

(a) Signature consent for clozapine treatment must be obtained in accordance with VHA Handbook 1004.1, Informed Consent for Treatments and Procedures. Consent forms are available in the “Mental Health” category of iMedConsent.

(b) If a patient declines treatment with Clozapine, the stated reasons (if any) must be recorded by the clozapine specialist in a Progress Note in the patient chart.

7. RESPONSIBILITIES OF THE CLINICIAN WITH SHARED CARE RESPONSIBILITY (SCR)

For select patients, a clozapine specialist may share some patient treatment and monitoring responsibilities, on- or off-site, with another VA or non-VA clinician.

a. The Chief, Mental Health or Clozapine Treatment Manager, is responsible for approving clinicians to participate in SCR and must provide education and training to the SCR clinician.

b. The Clozapine Treatment Manager must transmit written approval, including a statement signed by the clozapine specialist and the SCR clinician, indicating agreement with shared responsibility to the NCCC.

c. The SCR may be implemented with two different categories of clinician, which are:

(1) VA or non-VA physicians who could monitor the patient’s clinical status and WBC and ANC results and consult with the clozapine specialist. This physician may be fee-based, must be registered with an FDA clozapine registry, and be authorized to prescribe Clozapine.

(2) VA or non-VA nurse clinicians, physician assistants, and supervisory pharmacists who can monitor the patient’s clinical status and the WBC and ANC results, and recommend dose changes to the clozapine specialist. This clinician may be fee-based and is not authorized to prescribe clozapine.

8. RESPONSIBILITIES OF INFORMATION RESOURCE MANAGEMENT (IRM)

Information Resource Management (IRM) at each facility is responsible for:

a. Installing the latest version of the VistA Outpatient Pharmacy Package, VistA Inpatient Pharmacy Package, VistA Mental Health Package, and the latest version of Computerized Patient Record System (CPRS). *NOTE: Installation is mandatory at all VA facilities.*

b. Assisting with questions regarding the local pharmacy computer program.

c. Assisting if problems develop during the electronic data transfer of subsets of patient information (the patient’s registration number, clozapine doses, and WBC and ANC results) from the medical center computer to the national data bank. This data is used to partially fulfill national contract obligations for reporting data to the manufacturer, and by the NCCC for post-marketing surveillance and national quality assurance purposes. The information transmitted weekly to the NCCC by facsimile, supplements computer and electronic transmissions to meet the manufacturers’ information requirements.

9. RESPONSIBILITIES OF THE MEDICAL CENTER DRUG USE EVALUATION (DUE) COMMITTEE

At the medical center level, data on the use of clozapine is collected and summarized for review by the medical center's DUE Committee as part of the facility's Quality Assurance plan. Data collection is assisted by special clozapine lock-out software reports on patients taking clozapine and their WBC and ANC values, and by reports of lock-out overrides. **NOTE:** *Incorporation of clozapine data monitoring into the facility's DUE plan is consistent with The Joint Commission (TJC) requirements for monitoring a high-risk and problem-prone drug.*

10. RESPONSIBILITIES OF PHARMACY SERVICE

The Pharmacy Service has responsibility for dispensing outpatient and inpatient medication supplies after verification that the clozapine patient's WBC count and ANC are within acceptable limits. They also provide additional patient education on aspects of clozapine treatment (see subpar.13c).

11. RESPONSIBILITIES OF THE NATIONAL CLOZAPINE COORDINATING CENTER (NCCC)

NCCC activities are guided by an expert panel of VA clinicians (the VA Clozapine Task Force) representing the Chief Officer, Mental Health Services; VA Central Office, or designee; and the Chief of Clinical Pharmacy for Quality Management, VA Central Office. At the national level, the NCCC is responsible for:

- a. Serving as primary liaison for information and data between the VA clozapine sites and the Clozapine National Registry.
- b. Monitoring the medical center's compliance with CPMP.
- c. Documenting those mandated structures and procedures instituted at each site to ensure safe and appropriate use of clozapine.
- d. Refining the risks and benefits of clozapine in VA patients through post-marketing surveillance.
- e. Serving as a consultation resource on difficult cases.
- f. Maintaining a NCCC national database:
 - (1) On VA patients receiving clozapine to prevent any unauthorized re-challenge of clozapine at a different VA site, and to prevent simultaneous clozapine treatment of the same patient at two or more facilities.
 - (2) Of demographic information on VA clozapine patients that can be used for data analysis and research.

g. Conducting quality improvement studies based on data electronically gathered by the pooling of patient information into the NCCC central VA data bank.

12. PRESCRIBING CLOZAPINE TO A VA PATIENT

a. **Application for VA Clozapine Treatment.** The VA application to prescribe Clozapine for a patient, VA Form 10-0363, establishes a monitoring structure within VA that adheres to FDA requirements, and institutes safety procedures that protect the health and well-being of a VA patient receiving Clozapine. VA Form 10-0363 needs to be completed following the self-explanatory directions. It must be installed by the facility as a template in CPRS so that it may be submitted as a Remote Consult in the CPRS,. The Remote Consult needs to be filled out according to local instructions and sent to the NCCC, which must respond to the consult within CPRS when the authorization number is available.

(1) Before starting a patient on clozapine, the clozapine specialist must first verify that the patient meets VA criteria for clozapine use, then prepare VA Form 10-0363 to be submitted to the NCCC for authorization. VA criteria for use of clozapine can be found on VA Form 10-0363A, Selection Criteria for Clozapine Treatment, and the FDA-approved Clozapine package insert. The Clozapine specialist (see par. 6):

(a) Ensures that the patient meets VA criteria for the use of clozapine.

(b) Obtains signature consent for clozapine treatment from the patient or duly authorized surrogate in accordance VHA Handbook 1004.1, Informed Consent for Treatments and Procedures. *NOTE: Consent forms are available in the “Mental Health” category of iMedConsent.*

(c) Prepares a treatment plan that considers issues related to clozapine treatment, including follow-up plans. The treatment plan for each patient must be documented by the clozapine specialist and made available to the NCCC upon request.

(d) Reviews and signs the forms (if submitting by facsimile or mail).

(2) The clozapine specialist transmits the application form(s) to the NCCC by Remote Consult in CPRS, facsimile, or mail. If the submitted forms comply with the requirements of the CPMP, the NCCC secures a new patient clozapine authorization code from the manufacturer for drug initiation and reporting purposes. To initiate clozapine treatment, the NCCC provides the medical center’s Clozapine Treatment Manager and clozapine specialist with its endorsement of the patient’s application, together with a clozapine authorization code for the patient. This review process is usually accomplished within 24 hours, but may be delayed if the application materials are incomplete.

b. **Physical Examination.** A baseline examination must be performed within 30 days prior to initiating clozapine treatment. *NOTE: Any abnormal result must be evaluated thoroughly.*

(1) The physical must include baseline measures of:

(a) Height and weight,

- (b) Waist circumference,
 - (c) Pulse,
 - (d) Temperature, and
 - (e) Blood pressure.
- (2) The required baseline laboratory testing must include:
- (a) A complete blood count (CBC) and differential,
 - (b) Fasting plasma glucose,
 - (c) Fasting lipid profile,
 - (d) Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) liver function tests,
 - (e) Blood urea nitrogen (BUN),
 - (f) Creatinine, and
 - (g) A pregnancy test (in fertile women).
- (3) An electrocardiogram (EKG) must also be obtained at baseline.

c. **Patient Status and Authorization Number.** The patient must be registered and have an NCCC-assigned authorization number to receive services in the medical center facility. The FDA requires that all patients receiving clozapine be registered with the Clozapine National Registry. The NCCC arranges for this registration; however, certain rules must be followed. VA agreements with the Clozapine National Registry require a new authorization number to be assigned when a clozapine patient changes to the jurisdiction of another facility. Therefore, one VA facility cannot, under any circumstances, use the authorization number to dispense clozapine to a patient when clozapine was assigned while at another facility.

- (1) A new clozapine authorization number is needed when:
- (a) The patient is starting clozapine.
 - (b) Clozapine is not started within 30 days after initial registration.
 - (c) Clozapine treatment is administratively or medically interrupted for more than 30 days.
 - (d) The patient is transferred to another VA facility, including transfer for short-term medical or vacation care.

- (e) The patient has temporarily left VA care and has received clozapine from another source.
- (2) A new authorization number is not needed when clozapine treatment is interrupted, but reinitiated within 30 days of interruption.
- (3) Each time a new Clozapine authorization number is needed, the Clozapine specialist must prepare VA Form 10-0363, and record any changes in patient information. **NOTE:** *This form may be submitted as a Remote Consult in CPRS.*

d. **Limitations of Clozapine Use.** The FDA and VA recommend clozapine trials for patients with severe schizophrenia (treatment-resistant or treatment-intolerant) and in schizophrenic or schizoaffective patients with emergent suicidality. Although Clozapine may be superior to traditional antipsychotics in certain situations, the potential side effects preclude its use as first-line therapy in most patients.

e. **Off-label Use of Clozapine.** Some research studies support the use of Clozapine for other purposes. With special documentation, Clozapine may be used in VA for unlabeled reasons, such as to treat Schizoaffective Disorder, Bipolar Affective Disorder, the tremor and/or psychosis of Parkinson's disease, or the negative symptoms of schizophrenia. In these cases, the clozapine specialist must complete the VA Form 10-0363. The patient or duly-authorized surrogate must sign a consent form specifically designed for off-label use of Clozapine (available in the "Mental Health" category of iMedConsent).

f. **Patient Variables to Consider.** The treating Clozapine specialist needs to consider multiple variables in deciding whether Clozapine treatment is feasible and whether benefits are likely to outweigh risks. Clozapine needs to be avoided, or used with caution, if weekly monitoring and ethical treatment (i.e., benefits of treatment outweigh risks) could be jeopardized because of factors documented by the Clozapine specialist. **NOTE:** *The clozapine prescriber needs to refer to the most recent Clozapine package insert, available from the NCCC for full information on warnings, contraindications, precautions, and adverse effects. The package insert for Clozapine may also be obtained online at <http://www.pharma.us.novartis.com/product/pi/pdf/Clozaril.pdf>.*

- (1) These factors include Administrative variables, such as:
 - (a) Geographic distance from the facility or clinic.
 - (b) Social situation,
 - (c) Substance abuse,
 - (d) Non-compliance, and
 - (e) Lack of follow-up care.
- (2) These factors also include Medical variables, such as:
 - (a) Metabolic disorders,

- (b) Seizure disorders,
- (c) Cardiac disorders, and
- (d) Hematologic disorders (i.e., chronic benign leucopenia).

g. **Access to Care or Extended Service Area Arrangements.** Clozapine is not available through the fee-basis program, the Civilian Health and Medical Program of VA (CHAMPVA), or any other paid service provider procedure, except as directed and monitored by the Chief, Mental Health Service. However, if appropriate, the Chief, Mental Health Service, can administer patient-specific plans to provide Clozapine treatment through the SCR mechanism for veterans who cannot reasonably (because of medical condition or distance) visit VA on a weekly basis. Clinical and laboratory monitoring may be performed at Community-based Outpatient Clinics (CBOCs) provided that the CPMP is followed. **NOTE:** *Patient-specific plans may include use of telehealth technologies.*

(1) **Qualifications for Extended Service Area Use.** Use of Clozapine in an extended service area must be approved by the Chief, Mental Health Service. This approval needs to take into consideration the clinical needs and safety of the individual patient. Specific factors to consider include:

- (a) Duration and stability of Clozapine treatment.
- (b) Clinical stability, i.e., whether psychosis is in at least partial remission.
- (c) Stability of WBC results more than ($>$) 4,500 per mm^3 , and ANC results $>$ 2,500 per mm^3 .
- (d) Need for close monitoring of Clozapine side effects.
- (e) Required history of blood disorders, lymphatic system disorders, or seizure disorders while on clozapine.
- (f) Clinical support availability at the distant site. If the distant site is a CBOC, it needs to be part of the parent facility's computer network so that the WBC and ANC can be transmitted electronically to the NCCC from the parent facility. In an emergency situation, data could be reviewed for safety at the parent site and a physician at that site would be able to write a prescription remotely for Clozapine, if needed.
- (g) Family or social service support availability at the distant site.
- (h) Inability, documented by the Clozapine specialist, to return to the medical center for weekly monitoring.
- (i) Eligibility for fee-basis medical care, if applicable.

(j) Availability to return to the VA medical center or clinic immediately, if the psychiatrist determines that concerns have arisen about the patient's physical or mental condition.

(k) Training regarding the clinical and administrative aspects of Clozapine use provided to staff at the remote site.

(2) Contracting with a Distant Physician (SCR Clinician) for Certain Monitoring

(a) If the VA facility and closest affiliated clinic cannot feasibly and safely provide Clozapine treatment and monitoring for a veteran, the facility Mental Health Service may enter into special contractual arrangements with a distant physician for WBC and ANC and side-effect monitoring. Such agreements between the Mental Health Service and distant physicians or facilities require Mental Health Service certification that:

1. The treating physician meets the same standard required for VA Clozapine prescribing psychiatrists (except psychiatrist status). This practitioner may be paid with fee-basis funds.

2. The distant laboratory monitoring WBC and ANC meets the standards of the Clinical Laboratory Improvement Act of 1988, specifically a United States (U.S.) Department of Health and Human Services (HHS) laboratory registration certificate for moderate-to-high complexity tests. This laboratory testing may also be paid with fee-basis funds.

***NOTE:** All Clozapine used by VA patients must be dispensed by a VA pharmacy. The expenditure of fee-basis funds for pharmacy and medication is not allowed.*

(b) The fee-basis, Mental Health Service-approved local care practitioner is responsible for evaluating the patient's current condition, performing the weekly phlebotomy, and arranging for the WBC and ANC counts and side-effect evaluation information to be faxed to the Chief, Mental Health Service.

(c) The facility Chief, Mental Health Service, or designee, is responsible for:

1. Reviewing the information, and entering the WBC and ANC counts into the VA laboratory computer.

2. Entering the prescription into the VA pharmacy computer.

3. Dispensing by mail a 7-day supply of Clozapine, or 14 or 28 days if patient is qualified for less frequent monitoring, with an optional one-time, 4-day supply for emergency backup.

4. Reporting the data to the NCCC.

5. Evaluating, for verification of effectiveness, at least once each 6-month period, the management of patients being treated under this arrangement.

h. Accepting Patient Transfers

(1) A patient from another Clozapine treatment system can be accepted for treatment at a VA medical facility without interrupting medication. However, VA agreements with the Clozapine National Registry require a new authorization number when a Clozapine patient changes to the jurisdiction of another facility. When a patient transfers, VA Form 10-0363 must be completed and forwarded to the NCCC, which issues a new patient authorization number. NOTE: Using the Clozapine authorization number from another facility to dispense Clozapine is prohibited.

(2) All Clozapine patient transfers require:

(a) A new VA Form 10-0363 prepared and submitted to the NCCC by the accepting facility.

(b) A valid consent form for Clozapine treatment (see par. 13) must be completed in CPRS before the NCCC can provide authorization to dispense Clozapine. A new signature consent form for Clozapine treatment must be completed at the facility to which the patient is transferring.

13. INFORMED CONSENT FOR CLOZAPINE TREATMENT

a. Informed Consent procedures must be performed in accordance with VHA Handbook 1004.1, Informed Consent for Clinical Treatments and Procedures.

b. A valid consent form for Clozapine treatment must be completed at each major (parent) VA facility treating the patient before dispensing Clozapine to the patient. The consent form can be found in the Mental Health section of iMedConsent.

c. The informed consent discussion must be repeated and a new consent obtained if there has been a change in the patient's condition that could reasonably be expected to alter the diagnosis or therapeutic decision making or if there is a significant deviation from the treatment plan to which the patient originally consented (see VHA Handbook 1004.1).

d. **Informed Consent for Approved Use of Clozapine.** Signature consent is required prior to the initiation of Clozapine treatment (see VHA Handbook 1004.1). *NOTE: Specific disclosures required by the FDA are included in the consent forms available in the Mental Health section of iMedConsent.*

e. Informed Consent for Unlabeled Use of Clozapine

(1) Specific signature consent must be documented for unlabeled use of Clozapine (consent form titled "Clozapine Treatment for Unlabeled Use" in the Mental Health section of iMedConsent):

(a) To prescribe Clozapine to treat illnesses not listed on the FDA product labeling (the Clozapine package insert is available from the NCCC or online at <http://www.pharma.us.novartis.com/product/pi/pdf/Clozaril.pdf>).

(b) To prescribe clozapine in dosages exceeding 900 mg per day to patients who are not responding to lower doses (see subpar. 14b(2)(b)), and

(2) If the WBC or ANC of a patient currently being treated with clozapine reaches the FDA definition of “non-rechallengeable” (WBC less than (<) 2000/mm³ or ANC <1000/ mm³). Consult the NCCC for instructions.

(3) A copy of the consent form titled “Clozapine Treatment for Unlabeled Use” and VA Form 10-0363A, Special VA Application to Use Clozapine for Unlabeled Treatment, must be submitted to the NCCC for approval prior to off-label use. A special use approval from the NCCC is valid for 3-months trial period, unless a longer period is requested from the facility. If the patient has documented improvement that warrants continuation past the 3 month trial period, the NCCC must be so informed. If the target criteria for improvements established by facility clinicians have not been met, sufficient time must be allowed to taper the patient off clozapine.

f. **Patient Education by a Pharmacist.** While the clozapine specialist is responsible for primary patient education about clozapine, the pharmacist must also speak with the patient and:

- (1) Describe common side effects, and provide practical advice for relieving the distress;
- (2) Describe the signs of neutropenia, including sustained temperature elevation with flu-like symptoms or sore throat;
- (3) Explain the importance of strict compliance with laboratory tests;
- (4) Explain the importance of notifying the clozapine prescriber and the Pharmacy Service if problems are suspected; and
- (5) Document the discussion with the patient in the medical record.

14. INITIATION AND TERMINATION OF CLOZAPINE TREATMENT

a. **Dose Titration.** To minimize the likelihood of side effects, Clozapine treatment needs to be initiated at very low doses and titrated gradually over at least 2 weeks. NOTE: See the latest FDA Clozapine package insert from the NCCC or online at <http://www.pharma.us.novartis.com/product/pi/pdf/Clozaril.pdf>.

b. **Non-response**

(1) An initial trial of Clozapine for at least 8 weeks is generally recommended to determine whether to continue clozapine therapy or not. An adequate Clozapine trial may take up to 6 months.

(2) The VHA-Department of Defense (DOD) Clinical Practice Guideline for the Management of Persons with Psychoses recommends a dose range of 150-600 milligrams per day (mg/day). According to the package insert, the maximum Clozapine dose per day is 900 mg. If the patient does not appear to respond, a daily dose above 900 mg could be approved if:

(a) The patient's Clozapine plasma level is below 350 nanograms (ng) per milliliter (ml), and

(b) The patient, or the duly authorized surrogate, provides signature consent for the dosage above 900 mg per day and is specifically informed that the high dosage has not been approved by the FDA and may result in unknown side effects. The consent must be documented on the Consent for Unlabeled Use of Clozapine described in subparagraph 13e(1)(b).

c. **Termination of Clozapine Treatment.** If the patient does not respond, clozapine is to be tapered off over 1 to 2 weeks to avoid potential withdrawal reactions consisting of confusion, emotional withdrawal, or an intensified resurgence of psychotic symptoms. The treating physician needs to continue to monitor and report the patient's WBC and ANC counts for 4 weeks after discontinuing clozapine.

15. AGRANULOCYTOSIS AND GRANULOCYTOPENIA

a. **Incidence.** Clozapine has a clear association with leukopenia, granulocytopenia, neutropenia, and agranulocytosis (less than 500/mm³ ANC). Therefore, Clozapine is contraindicated in patients who have pre-existing leukopenia, a history of hematologic reactions to drugs, or lymphoproliferative disorders. The cumulative incidence of agranulocytosis associated with 1 year of Clozapine use has been estimated to be approximately 1.3 percent. The incidence of agranulocytosis based upon a weekly monitoring schedule rises steeply during the first 2 months of therapy, peaking in the third month. Most of the cases occur within 4 to 10 weeks of initial exposure. After 6 months of continuous Clozapine treatment, the incidence of agranulocytosis declines almost completely; however, it never reaches zero. Some cases have been reported in the 165th week of Clozapine treatment. NOTE: Neither dose nor duration is a reliable predictor of agranulocytosis.

b. **Patient Groups at Increased Risk of Agranulocytosis.** No patient characteristics have been clearly linked to the development of agranulocytosis in association with Clozapine use, but data reported to the FDA show a greater frequency of agranulocytosis in women. Agranulocytosis induced by Clozapine increases with age, with significant increase in risk above age 40 and the highest risk in patients over 65 years old. Risk of agranulocytosis increased in patients who are cachectic or who have a serious underlying medical illness. NOTE: Such patients may also be at particular risk with clozapine.

c. **Drug Interactions.** Clinicians need to carefully weigh the risks and benefits of administering Clozapine to patients who also take drugs that potentially suppress bone marrow function. Such drugs include: carbamazepine, penicillamine, antineoplastics, antiretrovirals, protease inhibitors, and some antifungatives. Because Clozapine is known to cause respiratory depression or apnea in some patients, it needs to be used with caution in combination with benzodiazepines and other potential respiratory depressants, especially in the first 72 hours of Clozapine treatment. Caution is also advised when combining Clozapine with medications that cause sedation or hypotension, or have anticholinergic effects. *NOTE: The most recent package insert contains an updated listing of drug interactions.*

16. MONITORING FOR AGRANULOCYTOSIS

Because of a Clozapine patient's risk of developing agranulocytosis, VA has strict procedures for frequent monitoring and reporting of the patient's WBC and ANC counts to comply with FDA regulations. The protocol for required monitoring, including eligibility criteria for WBC and ANC monitoring every 14 days and every 28 days, is detailed in the Clozapine package insert. Regardless of the frequency of monitoring, the WBC and ANC counts for a patient on Clozapine must be monitored, with laboratory values obtained within 7 days prior to the date of dispense, and reported to the NCCC. Monitoring and reporting must continue until 4 weeks following cessation of Clozapine treatment.

17. DOCUMENTATION OF CLINICAL MONITORING

a. Documentation of General Aspects of Clozapine Treatment and Monitoring Efficacy

(1) Treatment of a Clozapine patient must be fully documented, from initial application to termination of treatment. **NOTE:** *The numbered VA Clozapine forms referenced in this Handbook may be placed into the patient's medical record; however, documentation can also include locally-developed forms to trace information deemed specifically relevant to the individual patient. This might include record of weight gain, blood pressure, or blood glucose, all of which may be altered by use of Clozapine and may be considered essential information by the prescribing physician.*

(2) At a minimum, the following data must be placed in the patient's hard copy chart and CPRS:

(a) VA Form 10-0363, with back-up documentation.

(b) Evidence of 7 day, 14 day, or 28 day blood testing for WBC and ANC, the review of these laboratory values for safety, and side-effect monitoring.

(c) Reason for terminating Clozapine therapy.

b. **Effectiveness.** Improvement in the patient's condition, if any, must be carefully documented in the medical record at least monthly during the first 3 months of treatment, and at least semi-annually thereafter. Use of VA Form 10-0363C, Brief Psychiatric Rating Scale-Anchored (BPRS-A), and VA Form 10-0363D, Abnormal Involuntary Movement Scale (AIMS), National Clozapine Treatment is strongly recommended to document improvement. **NOTE:** *VA Form 10-0363D may also be administered through the Clinical Reminder package.*

18. MONITORING OTHER ADVERSE OUTCOMES OR SIDE EFFECTS

To assess whether the patient can tolerate Clozapine therapy, patients, especially during titration, need to be monitored closely for the following adverse outcomes or side effects:

a. Cardiac problems or tachycardia.

- b. Pulmonary embolism.
- c. Hepatitis.
- d. Hyperglycemia.
- e. Anticholinergic toxicity.
- f. Seizures or seizure disorder.
- g. Sleep apnea.
- h. Renal impairment.
- i. Sedation.
- j. Sialorrhea.
- k. Hypotension.
- l. Fever.
- m. EKG repolarization.
- n. Unexpected death.

NOTE: *These side effects are risks of treatment that should be included in the informed consent discussion and that are documented on the consent forms available in the “Mental Health” category of iMedConsent. For comprehensive, up-to-date information on Clozapine side effects, the package insert is available by e-mail from the NCCC or online at <http://www.pharma.us.novartis.com/product/pi/pdf/Clozaril.pdf>.*

19. PHARMACY DISPENSING OF CLOZAPINE AND MONITORING

a. **Dispensing of Medication.** All cCClozapine, whether for inpatient and outpatient veterans, must be dispensed through the VistA Outpatient Pharmacy Package until scheduled improvements to VistA Inpatient Pharmacy Package are instituted. All Clozapine providers must have a DEA number in either the DEA field or the VA DEA field of the pharmacy provider list and must have the YSCL Authorized Key, issued by Mental Health. **NOTE:** *If DEA or VA DEA number is not available, contact the NCCC at 214-857-0068 for help in obtaining a fee-exempt DEA number.* All patients must be registered and authorized by the NCCC before Clozapine can be dispensed. The following rules apply to dispensing Clozapine:

(1) A blood count must be performed before a prescription is written; only one prescription may be filled for a given. A prescription for Clozapine, either written or entered in CPRS, is required for a visit (7 days, 14 days, or every 28 days).

(2) The number of tablets dispensed cannot exceed the amount used in 7 days, 14 days, or 28 days, according to the patient's blood monitoring schedule

(3) Prescriptions with refill orders are permitted within the 7, 14, or 28 day limits of the patient's blood monitoring schedule.

(4) Clozapine orders are subject to an automatic 7-day stop-order policy. The pharmacist may fill a Clozapine prescription only after verification of the WBC and ANC count from blood samples drawn on the day of dispensing or within the previous 6 days.

(5) A 4-day supply of Clozapine may be provided to an outpatient veteran as an emergency backup in the case of anticipated severe weather or delays in receiving clozapine by mail from the VA pharmacy. Each time this 4-day supply is dispensed, the pharmacist must document it in the patient's CPRS. *NOTE: This supply is to be used for emergencies only, and never to circumvent the timing between the blood counts.*

b. **Outpatient Monitoring.** For safety reasons, the blood sample needs to be drawn, tested, and reviewed immediately (on the same day) before Pharmacy Service dispenses the medication. A valid Clozapine evaluation must include both WBC and ANC (from the same sample) drawn within 7 days prior to the date of dispense, regardless of monitoring frequency. Outpatient treatment of patients on Clozapine needs to be synchronized with the laboratory and pharmacy so that all laboratory tests, any mental health evaluations, and pharmacy distributions are performed on the same day of the week. *NOTE: The weekly WBC and ANC count and corresponding face-to-face evaluation of side effects and effectiveness by the Clozapine specialist, or approved SCR clinician, are highly-recommended for at least the first 20 weeks of clozapine treatment, especially given the risk of agranulocytosis.*

(1) Optionally, the patient's blood may be sampled several days prior to the weekly clinic visit so the results are available for the clinician to review before the prescription is written.

(2) Dispensing Clozapine by mail is permitted for a clozapine patient who has completed 20 weeks without significant hematological problems, after review of the WBC and ANC count by the prescribing physician.

c. **Inpatient Monitoring.** To ensure proper hematologic monitoring, dispensing of Clozapine to inpatients must be entered into the VistA Outpatient Pharmacy Package until improvements to VistA Inpatient Pharmacy Package are complete

(1) Continuation of inpatient orders is the decision of the treating facility. However, at a minimum, the clozapine specialist or SCR clinician must write a progress note for each week of Clozapine treatment, specifically showing a review of the blood count and the Clozapine dose for that week, an estimate of efficacy, and any signs of side effects.

(2) If only inpatient orders are written, the WBC and ANC values and daily dosage for each week of treatment must be reported to the NCCC.

20. CLOZAPINE PROCUREMENT AND DISTRIBUTION

a. **VA Sites Registered with the NCCC.** VA sites registered with the NCCC are permitted to purchase and dispense clozapine. Consolidated Mail Outpatient Pharmacies (CMOPs) may purchase clozapine for supply to a VA-registered clozapine site; however, CMOPs are not authorized to dispense cClozapine directly to VA patients.

b. **Drug Procurement.** Clozapine for VA patients may be purchased through the current appropriate Federal contract, either directly from the manufacturer or from any acceptable drug wholesaler. VA contracts with the Clozapine supplier and the FDA require the VA NCCC to provide certain types of patient data to the Clozapine National Registry on a weekly basis. Failure of the VA site to report to the NCCC on a weekly basis jeopardizes VA agreements and policy.

c. **Services Procurement.** Optionally, a VA medical center may seek a contract for an external blood monitoring system. Contracting officials must ensure that the data collection and forwarding specified as part of the contract are consistent with the requirements established by VHA policy. Contracts must specify a requirement for data transmittal to the NCCC.

d. **Pharmacy Service.** The Pharmacy Service dispenses outpatient or inpatient cClozapine medication supplies after verification that the WBC count and the ANC results are within acceptable limits. All orders are entered into the VistA Pharmacy Outpatient Package as outpatient orders after the computer and pharmacist verify that a proper, acceptable blood test was performed. *NOTE: The number of tablets dispensed cannot exceed the total needed for the interval between required blood tests.*

(1) For inpatients, actual drug distribution may be through the regular unit dose or ward stock systems. When the ward stock system is employed, the patient's Clozapine is dispensed to the ward in patient-specific containers with 7 days of medication.

(2) For outpatients, the pharmacist entering the outpatient physician's order must verify the patient's current address and telephone number on each Clozapine prescription so that the patient may be contacted in case problems arise. The facility Chief, Pharmacy Service, is responsible for entering a note in the message field of the drug file to cue pharmacists to verify the patient's address and telephone number.

(3) When the pharmacist enters the physician's order into the computer, a software program must verify that the patient's WBC and ANC data from the last 6 days has been entered into the computer system and that the blood counts are within acceptable limits and that the WBC and ANC sample dates and times match. If these conditions are true, the computer allows the entry of the physician's order. Otherwise, to prevent the patient from receiving Clozapine, the computer automatically locks out any entry of the physician's order.

NOTE: Local procedures which permit delay, particularly delays of more than 6 days between the Clozapine specialist writing the prescription and the pharmacist dispensing the medicine, are strongly discouraged. Best safety practice encourages blood testing, review of results, prescription of medication, and dispense of Clozapine in the same day.

(4) The NCCC may override a computer lock out and permit the pharmacy to dispense Clozapine under most lockout condition. The NCCC cannot perform the override unless the facility has submitted traceable documentation requesting the procedure.

(a) Administrative Lockouts. If lockout results from any of these conditions, notify the Chief of Mental Health of the designated Clozapine Treatment Manager (see subpar. 5d), and provide the NCCC with fax documentation of the current WBC, ANC, and date of blood test and request override in writing. **NOTE:** *Repetitive requests for overrides of these correctable errors are referred by the NCCC to the Chief of Mental Health at the facility for resolution.* These correctable errors most frequently result from failure to:

1. Manually enter lab values tested at other facilities.
2. Properly link the correct lab tests and units of measure (YSCL MultiTest Link).
3. Enter only numeric values (no text) into linked lab fields.
4. Match the test time of the WBC with the test time of the ANC.

(b) Patient Safety Lockouts. If lockout results from these conditions, the provider must write a Progress Note in the patient's local file showing the latest WBC, ANC, and date of blood test and request override to allow dispense. Unofficial telephone, e-mail, or faxed documentation are not acceptable. At a minimum, this Progress Note must include clinical justification for continuing clozapine when the WBC or ANC is not current or outside FDA parameters and acknowledgment of the provider that continuation is contrary to FDA and VA safety protocols for clozapine. Fax a SIGNED copy of this Progress Note to the NCCC at 214-857-0339 for review along with the provider's contact phone number or pager number. The Director, NCCC, must review the Progress Note to determine if override is clinically indicated (i.e., benefits of override outweigh risks), or if additional justification is needed. If approved by the Director, the NCCC will provide override codes to the local facility computer to permit a single dispense for a specific date and will contact the provider with authorization. A patient safety lockout can result when :

1. WBC or ANC is not current (within 7 days of dispense), or
2. WBC or ANC are not within FDA safety limits.

(5) The pharmacist with Clozapine Manager Key (PSOLOCKCLOZ) completes the override code as instructed by the NCCC. The pharmacist will maintain a permanent record of all lock out overrides of the clozapine safety software and print a weekly report for the Clozapine Treatment Manager, who reviews the circumstances of each override to ensure that it was justified and properly documented in the medical record.

(6) The pharmacist needs to generate a report 24 hours after entry of the physician's order, listing the patient who received clozapine, date of the visit, and results of the WBC and ANC count. After review, the pharmacist forwards the report to the Clozapine Treatment Manager.

(7) The VA or non-VA Laboratory and/or VA Pharmacy is responsible for notifying the clozapine prescriber and Clozapine Treatment Manager when the patient's WBC count is $< 5000/\text{mm}^3$ or ANC is below $3500/\text{mm}^3$

21. PATIENTS ENROLLED IN RESEARCH STUDIES

Individual arrangements must be made between clinical investigators and research sponsors for protocols, approvals through appropriate committees, and drug procurement. However, VA patients enrolled in a clozapine research protocol must be monitored using the processes and procedures outlined in this Handbook, including the participation of the facility Chief, Mental Health Service, or designee, and the data transmittal to the NCCC.

22. COMPLIANCE WITH THE CLOZAPINE PATIENT MANAGEMENT PROTOCOL

a. **Failure to Comply.** Individual prescribers who fail to comply with the CPMP jeopardize safe and effective care for this difficult to treat patient population, a major objective of the national VA clozapine initiative. Individual physician compliance failures are reportable to the chief of the relevant service (Mental Health, Neurology) and may lead to a decision to revoke privileges for clozapine prescribing.

b. **Notification of Compliance Failure.** When major compliance failures or patient management and safety concerns are identified and cannot be resolved through communication with the Chief of the relevant Service:

(1) The NCCC notifies the Veterans Integrated Service Network (VISN) Clinical Manager and the facility Chief of Staff (COS) of the specific problem, and withholds authorization of new patients at the site.

(2) The VISN Clinical Manager and medical center COS must assume full responsibility for clozapine patient safety and proper risk management procedures until the problem is resolved. They must investigate the problem and institute corrective actions, as warranted, informing the NCCC of the investigation results.

23. COMMUNICATION OF PROTECTED HEALTH INFORMATION (PHI)

a. **Protected Health Information (PHI).** PHI is individually identifiable health information in any written or electronic communication which contains individual patient identifiers (SSN, Date of Birth (DOB), Zip Code, Clozapine Authorization Number, or any other information points that can be used or combined to differentiate one person from another. PHI must be properly secured before transmitting. *NOTE: The VA Clozapine system relies heavily on the free exchange of this type of PHI.*

(1) Authority for release of PHI to the FDA registries, excluding 38 U.S.C. §7332 information, is provided by VHA Handbook 1605.1.Paragraph 27 b (1) Food and Drug Administration (FDA) Routine Reporting.

(2) Authority to provide PHI, excluding 38 U.S.C. §7332 information, without specific patient consent or authorization is contained in 45 Code of Federal Regulations §164.512.

b. Responsibilities of the VA NCCC for Secure Communication of PHI

(1) **Outgoing.** All documents must be reviewed before transmission for the presence of PHI.

(a) The NCCC will not transmit PHI through MS Exchange (Outlook) unless the information is secured using Public Key Interface (PKI). *NOTE: VA employees may obtain PKI capability by contacting their local Information Security Officer (ISO).*

(b) The NCCC will not transmit PHI by facsimile to a facility without confirmation of the telephone number. The machine must be located in a non-public area with access limited to password or badged personnel. The recipient must confirm receipt of the transmittal.

NOTE: NCCC fax transmittals must only be in the continuous data stream form. The NCCC will not prepare facsimiles using computer fax programs.

(c) The NCCC is responsible for the security of manual and automatic PHI transmissions between Vista servers.

(d) The NCCC is responsible for the security of data transmission of PHI to the FDA clozapine registries. *NOTE: The NCCC has established protected and highly secure data links with Novartis (Clozaril) and Mylan (clozapine). The other four brands of clozapine, Alamo, Caraco, IVAX (TEV), are non-formulary and offer no secure data links to VA.*

(2) Incoming

(a) NCCC's facsimile at 214-857-0339 must be fully tended between 8:00 AM and 4:30 PM (Central Time Zone) Monday through Friday. In addition and at all other times, the facsimile machine is secured in a non-public area that requires a staff-limited double-keypad password and double-keyed entry. Printing is not to be visible until it is removed from the machine. Fax data sheets are retained only as long as needed to transfer and verify the information. These sheets are destroyed by shredding.

(b) The NCCC staff will maintain a PKI license which permits secure transmission of PHI over Microsoft (MS) Exchange (Outlook).

c. **Responsibilities of the Local VA Facility for Secure Transmission of PHI.** Incoming and outgoing electronic transmission of information containing PHI, particularly Outlook e-mail and facsimile, must be secured locally. VA has mandated that each site must develop policies and procedures to secure all incoming and outgoing communications containing PHI. These procedures need to be reviewed and approved by the local Information Security Officer (ISO) in compliance with Information Security Directive and Handbook 6500 and any subsequent directives and handbooks. *NOTE: Some guidelines for these procedures, such as the Information Security Policy and/or Procedure Template, are published by the VA Office of Cyber and Information Security at <https://vaww.ocis.va.gov/portal/server.pt?/>*

VA FORM 10-0363, APPLICATION FOR VA CLOZAPINE TREATMENT

Department of Veterans Affairs (VA) Form 10-0363, Application for VA Clozapine Treatment, can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.

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APPENDIX B

**VA FORM 10-0363A, SPECIAL VA APPLICATION TO USE CLOZAPINE FOR
UNLABELLED TREATMENT**

Department of Veterans Affairs (VA) Form 10-0363, Application for VA Clozapine Treatment, can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.

VA FORM 10-0363B, TERMINATION OF CLOZAPINE TREATMENT

Department of Veterans Affairs (VA) Form 10-0363B, Termination of Clozapine Treatment, can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.

VA FORM 10-0363C, BRIEF PSYCHIATRIC RATING SCALE-ANCHORED (BPRS-A)

Department of Veterans Affairs (VA) Form 10-0363C, Brief Psychiatric Rating Scale-Anchored (BPRS-A), can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.

VA FORM 10-0363D, ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

Department of Veterans Affairs (VA) Form 10-0363D, Abnormal Involuntary Movement Scale (AIMS), can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.

**VA FORM 10-0363E, WEEKLY TRACKING INFORMATION, NATIONAL
CLOZAPINE COORDINATING CENTER**

Department of Veterans Affairs (VA) Form 10-0363E, National Clozapine Coordinating Center, Weekly Tracking Information, can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

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APPENDIX G

VA FORM 10-0363F, CLOZAPINE TREATMENT TEAM (CTT) DOCUMENTATION

Department of Veterans Affairs (VA) Form 10-0363F, Clozapine Treatment Team (CTT) Documentation, can be found on the VA Forms Intranet web site at <http://vaww.va.gov/vaforms>. This is to be used for local reproduction. This form will not be stocked by the Hines Service and Distribution Center.

You should use the latest version of Adobe Acrobat Reader to view this form.