



# P&T/Medication Committee Manual

Revised 2016

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# Chapter I

CHAPTER: 4	SECTION: 23	SUBJECT: INDIVIDUAL CARE TO CONSUMERS
TITLE: <b>PHARMACY AND THERAPEUTICS/MEDICATION COMMITTEE</b>		
EFFECTIVE DATE: <b>6/1/88</b>	REVISED/REVIEWED DATE: <b>12/15/95; 11/15/99; 9/25/02; 6/7/05; 03/14/08; 6/1/10; 5/21/12; 4/15/13, 4/28/14, 3/23/15, 5/17/16</b>	
ISSUED AND APPROVED BY:  EXECUTIVE DIRECTOR		

## I. PURPOSE:

To establish policy and procedure concerning the use of medication, and to provide review of medication services to assure quality services are being provided in accordance with applicable standards within Community Mental Health of Ottawa County (CMHOC) and national standards of care.

## II. APPLICATION:

To all CMHOC operated and contracted programs as specified by contract.

## III. DEFINITIONS:

**Medication Service:** refers only to medication prescribed through CMHOC prescribers.

**Prescriber:** an MD, DO, NP, or PA who directs the selection, preparation, or administration of medication(s).

**Psychotropic Medication:** means any medication for the treatment or amelioration of disorders of thought, mood, or behavior.

## IV. POLICY:

It is the policy of CMHOC that a Pharmacy and Therapeutics (P&T)/Medication Committee will be appointed and maintained to review the utilization of medications in Board operated programs and contract agencies.

## V. PROCEDURE:

1. The P&T/Medication Committee shall be appointed by the Executive Director and at a minimum be responsible for the following:
  - a) Reviewing medication errors and significant medication errors.
  - b) Providing assistance to programs for the purpose of developing procedures for handling medication, and reviewing these program procedures on a regular basis.
  - c) Assuring compliance with internal and external standards and policies.

- d) Reviewing and suggesting needed revisions to CMHOC policy and procedure regarding medication.
2. The committee will also identify issues and make recommendations to management staff regarding medication treatment and staff training needs.
3. The committee shall be chaired by the CMHOC Medical Director, or another prescriber designated by him/her. Membership shall include an RN, a representative from the Recipient Rights office, a consulting pharmacist, and other staff as deemed appropriate by the committee and appointed by the Executive Director. Experience with individuals diagnosed with a developmental disability and/or mental illness shall be represented among the health care professionals.
4. As resources allow, the committee may provide consultation to CMHOC programs and contractors as requested and provide training to providers in the area of medication use.
5. A P&T/Medication Committee Manual shall be developed which provides specifications regarding responsibilities and activities of CMHOC prescribers, and assures program procedures are developed to address medication use for applicable programs. The Manual will be consistent with applicable Michigan Department of Health and Human Services standards and applicable Medicaid standards, and will provide guidelines for monitoring activities. The Manual will be reviewed at least every two years and revisions will be made as needed. The Manual must be approved by the Executive Director.
6. The P&T/Medication Committee will approve auditing standards for medication prescription, based on the recommendations of the consulting pharmacist. These will be forwarded to the appropriate prescriber for final evaluation and/or corrective measures. All prescribers will be educated in these auditing standards.
7. The committee will determine whether to review records based on type of medication, by program, by diagnosis, or by prescriber in order to assess trends and patterns agency wide. All categories may in fact be selected throughout the year.
8. The sample size for the yearly reviews will be selected to represent a minimum of 10% of the total number of CMHOC consumers receiving medication services on an annual basis.
9. The monthly review will consist of the following distinct phases:
  - a. The CMHOC Nursing staff will audit records for the presence of required paperwork and content based on the audit form approved by the committee.
  - b. The consulting pharmacist will conduct a Drug Regimen Review of a sampling of the records to look at individual drug usage and adverse side effects based on the review format approved by the committee. The purpose of this review is to improve where possible the drug therapy for each consumer. Outcomes of these reviews will be forwarded to the P&T/Medication Committee for discussion of future treatment decisions with individual prescribers.
  - c. A monthly Prescriber Peer Review will also be conducted on a small sampling of the pulled charts to review for compliance with approved Prescriber Peer

Review audit standards. The P&T/Medication Committee Recorder will assign these cases on a rotating basis to prescribers. Outcomes of these reviews will be forwarded to the individual prescriber and Leadership Group for consideration in future treatment decisions.

10. The committee will monitor for trends and patterns and will recommend improvements to the system where indicated.
11. Semi-annual reports will be prepared and presented by the P&T/Medication Committee to Leadership Group as a part of the QI department.
12. Medications may be administered only by a physician, PA, nurse, medical assistant or by direct-care staff who have taken and passed a CMH medications training class.
  - a) Specific clinical programs will determine which non-Health Practitioner staff shall be trained and authorized to administer medications.
  - b) Training shall be provided for designated staff.
  - c) Documentation of dates and attendance will be kept by the site supervisor and CMH training unit.

**ATTACHMENT:**

None Applicable

**REFERENCE:**

Michigan Department of Health and Human Services “Psychotropic Medication in Foster Care,” May 2015  
CARF Behavioral Health Standards  
Michigan Department of Health and Human Services  
CMHOC P&T/Medication Committee Manual

## Chapter II

### II. Authority and Purpose

#### A. Authority

The Pharmacy & Therapeutics/Medication Committee is developed under the authority of the Ottawa County Community Mental Health Administrative Manual Policy 4.23; approved on December 7, 1988, and currently revised in 2016.

#### B. Purpose

To establish policy and procedure concerning the use of medication, and to provide review of medication services to assure quality services are being provided in accordance with applicable standards within Community Mental Health of Ottawa County (CMHOC) and national standards of care.

#### C. Goals and Objectives

1. Assure and monitor medication services to consumers to demonstrate compliance with Committee requirements.
2. Receive, evaluate, and respond to data from medication service staff regarding availability and efficient use of resources, including staff, budget, equipment, and space (resources).

#### D. Application

All programs operated by the Community Mental Health Services of Ottawa County or contracted providers. This policy does not supersede or replace licensing requirements, but rather supplements any state and federal regulations which apply.

#### E. Authorized Duties

Reference Policy 4(23) Pharmacy and Therapeutics/Medication Committee; Section V.

#### F. Definition of Terms

1. *Quality Assurance*: Determining whether services meet standards of appropriate and acceptable clinical care.
2. *Utilization Review*: Review of use of resources and/or services based upon established criteria.
3. *Cost Containment*: Efforts to eliminate unnecessary or inappropriate treatment, and to achieve appropriate economies in providing treatment.
4. *Psychotropic Medication*: For purposes of the Manual, psychotropic medications include:
  - a. antipsychotics,
  - e. sedatives/hypnotics,

- b. antidepressants,
  - c. mood stabilizers,
  - d. anxiolytics,
  - f. CNS stimulants,
  - g. antiParkinsonian drugs
  - h. other classes of medications, when used for treating psychiatric symptoms or side effects.
5. *CMH or CMHOC*: Community Mental Health of Ottawa County.
  6. *Recipient or Consumer*: Any person receiving mental health services at CMH.
  7. *Involuntary Recipient*: A recipient under Probate Court ordered treatment.
  8. *Record*: The recipient's clinical chart/electronic medical record (EMR).
  9. *Medication*: Prescription or over the counter medications ordered for the treatment of psychiatric disorders, or for treatment of side effects of psychotropic medications, or any medications stored or administered by CMH staff or kept on CMH premises.
  10. *Physician*: An M.D. or D.O. licensed in Michigan, and under contract with CMH.
  11. *PA-C*: Physician's Assistant licensed in Michigan and under contract with CMH.
  12. *Nurse*: Registered Nurse (RN) or Nurse Practitioner (NP) licensed in Michigan.
  13. *HP*: Health Professional - physician, PA-C, nurse, nurse practitioner or pharmacist.
  14. *Primary Worker*: Case manager/supports coordinator, primary therapist, or other clinical staff person who is assigned primary responsibility for case coordination.
  15. *CMA*: Certified Medical Assistant
  16. *Liver Enzymes*: Testing will include one or more liver enzymes (ALT, SGPT, ALP, LAP, 5'NT, LD, GGT and/or GGTP)
  17. *MDT*: Multidisciplinary Team
  18. *ID Meds*: Drug manufacturer's Prescription Assistance Program which provides free medication to consumers with limited income.
  19. *CID Meds*: Original unopened medication containers provided by drug manufacturers prescription assistance programs that remain in CMHOC possession and are not currently prescribed to the original recipient.
  20. *MAR*: Medication Administration Record – used by group homes and Community Based Services programs to document medication administered.
  21. *MDR*: Medication Distribution Record – used by Assertive Community Team (ACT) to document medication distributed to a consumer to self-administer at a later time.

## CHAPTER III

### III. Manual and Reports

- A. The Pharmacy & Therapeutics/Medication Committee Manual defines the scope, authority, and responsibilities of the P&T/Medication Committee and provides procedures for the operation of the Medication Committee.
- B. A biennial review of this manual will be completed by the Committee. Other revisions will be made during the year as needed. All revisions must be approved by the CMHOC Executive Director.
- C. Semiannual Quality Indicator Reports will be submitted by the Committee to Leadership as scheduled.
- D. Quality Indicators have been established for each calendar year and are monitored as indicated.

## CHAPTER IV

### IV. Responsibility

- A. The P&T/Medication Committee is a standing CQI Committee that is directly responsible to Leadership Group and the Executive Director of Community Mental Health of Ottawa County, to whom the Board has designated the authority for the existence, composition, and general functioning of the Committee. It is the responsibility of the Committee to make recommendations to Leadership Group to improve medication management at CMHOC.
- B. The Chairperson, or his/her designee on the Committee, is responsible for scheduling and conducting meetings, preparing agendas for those meetings, and performing other related tasks as required by the Executive Director and CMHOC Policy.

## CHAPTER V

### V. Membership

- A. The P&T/Medication Committee shall consist of the following:
  - 1. One member of the Committee shall be a prescriber who shall serve as the Committee Chairperson (the Medical Director or his/her designee)
  - 2. The Medication Committee shall have at least two representatives from various service areas of Community Mental Health and, if possible, a Registered Nurse (RN)
  - 3. One member of the Committee shall be the Recipient Rights Officer.

4. One member of the Committee shall be a Pharmacist.
- B. Members of the Committee are appointed by the Executive Director. Rotation of membership will be encouraged to involve greater numbers of the staff in the Medication Committee process.
- C. Committee members may be terminated by the Executive Director at his/her discretion. Committee members may resign from the Committee by written notice to the Executive Director subject to his/her approval.
- D. The P&T/Medication Committee Manual will be available to all staff via the CMHOC database. Revisions will be placed on the database as they become available.
- E. It may be desirable for actual Committee membership to exceed the minimum number required by CMHOC policy 4(23). Nominations to add optional members to the existing P&T/Medication Committee may be made at any time to the Executive Director.

## **CHAPTER VI**

### **VI. Prescribing**

#### **A. Rationale for Drugs Prescribed:**

A psychotropic drug that may offer the most effective treatment for the basic psychiatric disturbance exhibited by the consumer shall be selected from medications on the current year's Michigan Medicaid Formulary. Rationale for each prescribed psychotropic drug shall be documented in the consumer's record. The rationale for poly pharmacy will be clearly documented as well.

#### **B. Dosage Range:**

Dosage levels shall not ordinarily exceed those specified in the PDR and general guidelines from current psychiatric literature. If dosage levels are prescribed in excess of the maximum recommended daily dose, rationale shall be documented in the consumer's clinical record and the medication consent form must reflect the actual dose prescribed.

# 1. Psychotropic Medication List

Antianxiety Agents			Antimanic Agents			Hypnotics		
<b>Benzodiazepines</b>			Lithium (Eskalith, Lithobid)	2400mg	B*	Diphenhydramine (Benadryl)	300mg	
Alprazolam (Xanax, XR)	10mg		<b>Antipsychotics</b>			Estazolam (Prosom)	2mg	
Chlordiazepoxide (Librium)	300mg		Aripiprazole (Abilify)	30mg	A B*	Eszopiclone (Lunesta)	3mg	
Clonazepam (Klonopin)	20mg		Asenapine (Saphris)	20mg	A B*	Flurazepam (Dalmane)	30mg	
Clorazepate (Tranxene)	90mg		Brexpiprazole (Rexulti)	4mg	A B*	Ramelton (Rozerem)	8mg	
Diazepam (Valium)	40mg		Chlorpromazine (Thorazine)	800mg	A B*	Temazepam (Restoril)	30mg	
Diazepam (Valium) intencol	60mg		Clozapine (Clozaril)	900mg	A B*	Triazolam (Halcion)	0.5mg	
Lorazepam (Ativan)	10mg		Fluphenazine (Prolixin)	40mg	A B*	Zaloplon (Sonata)	20mg	
Oxazepam (Serax)	120mg		Haloperidol (Haldol)	100mg	A B*	Zolpidem (Ambien, CR)	12.5mg	
Quazepam (Doral)	30mg		lloperidone (Fanapt)	24mg	A B*	<b>Mood Stabilizers/Anticonvulsants</b>		
<b>Misc</b>			Loxapine (Loxitane)	250mg	A B*	Carbamazepine (Tegretol)	1200mg	B*
Hydroxyzine (Vistaril, Atarax)	400mg		Lurasidone (Latuda)	80mg	A B*	Carbamazepine (Tegretol/Equetro)	1600mg	B*
Buspirone (Buspar)	60mg		Mesoridazine (Serentil)	400mg	A B*	Gabapentin (Neurontin)	3600mg	
<b>Antidepressants</b>			Olanzapine (Zyprexa)	20mg	A B*	Lamotrigine (Lamictal)	700mg	
<b>Tricyclic Antidepressants</b>			Olanzapine/Fluoxetine (Symbyax)	12mg/50mg	A B*	Oxcarbazepine (Trileptal)	2400mg	
Amitriptyline (Elavil)	300mg		Paliperidone (Invega)	12mg	A B*	Pregabalin (Lyrica)	600mg	
Clomipramine (Anafranil)	250mg		Perphenazine (Trilafon)	64mg	A B*	Tiagabine (Gabitril)	56mg	
Desipramine (Norpramin)	300mg		Pimozide (Orap)	10mg	B	Topiramate (Topamax)	1600mg	B*
Doxepin (Sinequan)	300mg		Quetiapine (Seroquel, XR)	750mg	A B*	Valproic Acid (Depakote)	60mg/kg	B*
Imipramine (Tofranil)	300mg		Risperidone (Risperdal)	16mg	A B*	<b>Stimulants</b>		
Nortriptyline (Pamelor)	200mg		Thioridazine (Mellaril)	800mg	A B*	Armodafinil (Nuvigil)	250mg	B/P
<b>SSRI's</b>			Thiothixene (Navane)	60mg	A B*	D-Amphet/Amphet (Adderall)	2mg/kg	B/P
Citalopram (Celexa)	40mg		Trifluoperazine (Stelazine)	40mg	A B*	Dexmethylphenidate (Focalin, XR)	1.5mg/kg	B/P
Escitalopram (Lexapro)	20mg		Ziprasidone (Geodon)	160mg	A B*	Dextroamphetamine (Dexedrine)	2mg/kg	B/P
Fluoxetine (Prozac)	80mg		<b>IM Injections</b>			Lisdexamphetamine (Vyvanse)	70mg	B/P
Fluvoxamine (Luvox)	300mg		Aripiprazole (Abilify) maintena	400mg IM q4w k	A B*	Methylphenidate (Daytrana)	30mg	B/P
Paroxetine (Paxil, CR)	62.5mg		Aripiprazole (Aristada)	882mg IM q 4-6	A B*	Methylphenidate (Metadate CD, ER)	60mg	B/P
Sertraline (Zoloft)	200mg		Fluphenazine decanoate (Prolixin)	25mg IM q 2-3w k	A B*	Methylphenidate (Ritalin)	60mg	B/P
Vilazodone (Viibryd)	40mg		Haloperidol decanoate (Haldol)	450mg IM q 4 w k	A B*	Methylphenidate (Ritalin LA, Concerta)	3mg/kg	B/P
Vortioxetine (Brintellix)	20mg		Olanzapine (Zyprexa Relprevv)	300q2w k,405q4	A B*	Modafinil (Provigil)	400mg	B/P,B
<b>Dopamine Reuptake Inh</b>			Paliperidone palmitate (Invega sustenna)	234mg IM q 4	A B*	<b>SNRI for ADHD</b>		
Bupropion (Wellbutrin) SR/XL	400mg/450		Paliperidone palmitate (Invega Trinza)	819mgIM q 3 mos	A B*	Atomoxetine (Strattera)	1.8mg/kg	B/P, B
<b>5-HT/NE Reuptake Inh</b>			Risperidone (Risperdal Consta)	50mg IM q 2 w ks	A B*	Guanfacine (Intuniv)	4mg	B/P
Amoxapine (Asendin)	600mg	A	Naltrexone (Vivitrol)	380mg q 4 w ks	A B*	<b>Miscellaneous</b>		
Desvenlafaxine (Pristiq)	400mg	B/P	<b>Beta Blockers</b>			Acamprosate (Campral)	1998mg	
Duloxetine (Cymbalta)	120mg	B/P	Atenolol (tenormin)	1200 mg	B/P	Benzotropine (Cogentin)	6mg	
Evomilnacipran (Fetzima)	120mg		Pindolol (Visken)	60mg	B/P	Buprenorphine/Naloxone (Suboxone)	32mg	B/P
Venlafaxine (Effexor, XR)	375mg	B/P	Propranolol (Inderal)	640mg	B/P	Clonidine (Catapres)	2.4mg	B/P
Maprotiline (Ludiomil)	225mg		<b>Lab Monitoring Key:</b>			Disulfiram (Antabuse)	500mg	
<b>5-HT2 Receptor Antag</b>			<b>A= AIMS monitoring</b>			Docosate (Colace)	500mg	
Nefazodone (Serzone)	600mg		<b>B= Baseline Lab</b>			Donepezil (Aricept)	23mg	
Trazodone (Desyrel)	600mg		<b>B*=Baseline Lab and Monitoring</b>			Guanfacine (Tenex)	3mg	B/P
<b>Noradrenergic Antagonist</b>			<b>B/P=Blood Pressure</b>			Memantine (Namenda)	20mg	
Mirtazapine (Remeron)	45mg		<b>D=Special Diet</b>			Pramipexole (Mirapex)	4.5mg	
<b>MAOI Inhibitors</b>			<b>E= EKG (Routine)</b>			Prazosin (Minipress)	15mg	B/P
Isocarboxazid (Marplan)	60mg	D				Rivastigmine (Exelon)	12mg	
Phenelzine (Nardil)	90mg	D				Ropinirole (Requip)	4mg	
Selegiline (Emsam)	12mg	B/P				Trihexyphenidyl (Artane)	15mg	
Tranlycypromine (Parnate)	60mg	B/P	Revised 3/2016					

### **C. Individualized Care:**

1. All individuals receiving psychiatric services from Community Mental Health of Ottawa County (CMHOC) shall be given a Psychiatric Evaluation before the onset of any psychiatric services and/or treatment.
2. Medication regimens must be individually determined by considering the consumer's need, age, sex, weight, physical condition, medical history, other medications and previous medication history including history of adverse side-effects or reactions. If indicated, a non-formulary drug may be prescribed.
3. Whenever a consumer is prescribed medication, at least one treatment goal will be written addressing medication. Specific goals might include educating the consumer about medication, eliminating target symptoms, reducing side-effects, monitoring adherence and/or obtaining the minimum effective dosage.

### **D. Side-Effects:**

1. The prescribing professional will assess the consumer's learning needs regarding safe and effective use of medication.
2. Consumers/guardians are informed of the name and description of the medication, dosage, method of administration, intended outcomes, potential side-effects, drug and food interactions to be avoided, and proper storage and disposal.
3. The consumer will be instructed to report any occurrence of side-effects to clinical staff as soon as possible.
4. A Patient Information leaflet will be offered to the consumer/parent/guardian. This medication-specific Patient Information leaflet summarizes common adverse side-effects, purpose of medication, etc.

### **E. Request for Refills/Report of Medication Issues:**

1. Phone calls from consumers with requests for medication refills will be transferred to the Team Nurse's office.
2. Phone calls from consumers with problems and/or issues related to their CMH prescribed medication will also be forwarded to the Team Nurse's office.
3. New consumers will be informed by the team members that medication refill requests should be made one week prior to running out of medication.
4. Signs will be posted in the adult and child waiting rooms and in nursing offices, reminding consumers of the need to call one week in advance for medication refill requests.

5. Refill requests and medication-related issues will be documented utilizing the Medication Clinic Request progress note option and forwarded to the “To Do List” of the consumer’s prescriber (see Operational Guideline: Guidelines for Medication Clinic Requests).
6. Transcription of the phone message, and subsequent calls to obtain additional detailed information regarding the consumer’s medication related phone message, will be completed by Clinical staff.
7. If the recipient’s assigned prescriber is not working at CMHOC on that day, the Team Nurse will utilize his/her professional judgment regarding whether the phone request should be forwarded to another prescriber for handling, or if it is able to wait until the assigned prescriber returns to CMHOC.
8. IF a MA transcribes the medication-related phone message, and the assigned prescriber is not present, the MA will check with the Team Nurse regarding the professional judgment required in number 7 above.
9. All CMHOC prescribers are expected to share the responsibility of refilling medications, responding to medication-related issues, and evaluating consumers in crisis when a consumer’s assigned prescriber is not available.

## Operational Guideline for Medication Clinic Requests

### COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY OPERATIONAL GUIDELINE

<b>TITLE: MEDICATION CLINIC REQUESTS</b>	
<b>ISSUED BY:</b> Dr. Bruce Walters	
<b>EFFECTIVE DATE:</b> 5/1/2010	<b>REVIEW DATES:</b> 11/19/12, 11/18/13
<b>AUTHORIZED BY:</b>  <b>EXECUTIVE DIRECTOR</b>	

- V. **PURPOSE:**  
To enact a protocol identifying a consistent manner of documentation for medication related to requests, issues or observations of an active consumer receiving psychiatric services by utilizing the CMHOC electronic medical record system.
- VI. **APPLICATION:**  
CMHOC treatment teams serving consumers who receive psychotropic medication.
- VII. **DEFINITIONS:**  
N/A
- VIII. **PROCEDURE:**
- A. Any CMHOC staff person with access to the CMHOC electronic health record system may utilize the Medication Clinic Request template by performing the following steps:
- STAFF RESPONSIBILITIES:**
1. Log on to AVATAR.
  2. Select the chosen consumer by name or ID number.
  3. Select AVATAR PM > PROGRESS NOTES > PROGRESS NOTE.
  4. Select active TEAM EPISODE, then OK.
  5. Choose INDEPENDENT NOTE, then DRAFT.
  6. From dropdown listing under NOTE TYPE, choose MEDICATION CLINIC REQUEST.
  7. Type message into body of NOTES FIELD, including name of caller and phone number to return call if provided.
  8. Click arrow on top left of field to advance to second page of progress note (page 2 of 2).
  9. Select MENTAL HEALTH.
  10. Select prescriber's name from dropdown listing near "User to Send Co-Sign To Do item to" if action from a CMHOC prescriber is required.
  11. Return to page 1 of Progress Note using arrow icon on top of page.
  12. Change DRAFT to FINAL.
  13. Utilize SUBMIT icon on top of form to send message to the To Do List of chosen Prescriber.
  14. Staff utilizing the Medication Clinic Request template may choose to develop a system (log, list, reminder on Lotus Notes Calendar, etc.) to log communication sent in this manner awaiting a response from the prescriber. NOTE: When selecting a reminder system, consider that it may need to be shared with your supervisor and/or other co-worker(s) to follow up if you are off work due to illness or vacation.
  15. The current AVATAR system does not allow Prescribers to send the item back to your To Do List to alert you when they have responded. You will receive a response via your Lotus Notes email.

16. Medication Clinic Request progress note entries will also be utilized to document other medication related consumer phone or in person contact that does not require Prescriber action. This may include pharmacy contacts, insurance prior authorization requests, questions or education.

**PRESCRIBER RESPONSIBILITIES:**

1. Prescribers will regularly monitor their AVATAR To Do List for incoming communication that requires their attention.
2. Prescribers will address items when time permits between appointments, during “paperwork time” or during times when consumers fail to keep appointments.
3. All prescribers have access to check dates of future medication review appointments, past history of “no shows”, medication reviews and prescription & pharmacy information on Order Connect to review on an as needed basis.
4. All Medication Clinic Requests sent to prescriber To Do Lists require written documentation indicating that the prescriber has reviewed the communication, taken some action (or chosen not to) and/or requests that the CMHOC staff member who originated the message take additional action.
5. By double clicking on an entry in the To Do List, prescribers will be able to review the message and type their response. Prior to submitting the response by clicking on the Submit icon at the top of the page, Prescribers will copy and paste the body of the reply into a new email addressed and transmitted to the Medication Request sender. The date, time and prescriber’s name will automatically be attached to the AVATAR entry.

## **F. Medication Monitoring:**

Consumer’s response to medication will be monitored and recorded as clinically indicated.

After the desired clinical result is obtained and the consumer’s condition has stabilized, the medication shall be maintained at the minimum maintenance dose needed, or the consumer may be titrated off the medication. The prescriber may also refer the consumer back to the PCP for ongoing medication treatment.

If the consumer has stabilized but needs long-term maintenance medication, the prescribing professional shall document such, and specify the frequency of face-to-face medication review appointments.

### **1. Required Testing:**

- a. Baseline studies for psychotropic drug use are related to the pharmacology of the specified drug used.
- b. Unless the rationale for delaying/omitting tests is documented in the record, the following guidelines for monitoring psychotherapeutic medications are required:
- c. Optional Testing: Prescribers may utilize Pharmacogenetic Testing as indicated.

### **2. Required Monitoring:**

- a. **ANNUALLY – If not done by Primary Care Physician**
  - CBC with Differential

- Comprehensive Metabolic Profile
- Cardiac Lipid Panel
- TSH

**b. LITHIUM, TEGRETOL, DEPAKOTE**

- Blood levels within 7-10 days of beginning the medication
- Blood levels at 6 months
- Blood levels annually
- Blood levels as needed and when dosage is changed

**c. CLOZAPINE**

- *Labs according to the registry requirement*

**3. Monitoring of Children and Adolescents Being Treated with Antidepressants**

**COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY  
OPERATIONAL GUIDELINE**

<b>TITLE: Monitoring of Children and Adolescents Being Treated with Antidepressants</b>	
<b>ISSUED BY:</b> Community Mental Health of Ottawa County	
<b>EFFECTIVE DATE:</b> 5/19/2010	<b>REVIEW DATES:</b> 6/21/16
<b>AUTHORIZED BY: Ann M. Heerde, LMSW</b>	
<b>PROGRAM SUPERVISOR FOR FAMILY SERVICES</b>	

**I. SUBJECT:**

Monitoring Children and Adolescents being treated with Antidepressants.

**II. SCOPE:**

CMHOC Prescribers.

**III. PURPOSE:**

To ensure that all children and adolescents who are prescribed antidepressants from Agency Physicians or Physician Assistants are monitoring for suicidal thoughts and behavior.

**IV. PROTOCOL:**

The frequency and nature of the monitoring should be individualized to the needs of the family and the consumer. CMH staff should enlist the parents/guardians in the responsibility of monitoring the individual at the time of the prescription. The primary care worker will contact the family during the first month of initiation of an antidepressant to monitor progress. If family members become concerned about changes they should contact Ottawa County Community Mental Health if the child:

1. Expresses new or more frequent thoughts of wanting to die, or engages in self-destructive behavior;
2. Shows signs of increased anxiety/panic, agitation, aggressiveness, or impulsivity;

3. Experiences involuntary restlessness (akathisia), or an extreme degree of unwarranted elation or energy accompanied by fast, driven speech and unrealistic plans or goals.

Adverse reactions to antidepressants are more likely to occur early in the course of treatment or in changes of the dose. It may become appropriate to adjust the dosage, change to a different medication, or stop using the medication.

**The Physician/PA should warn the parents/guardian of abruptly discontinuing the medication due to possibly adverse withdrawal effects such as agitation or increased depression. The Psychiatrist/PA should convey the importance of consulting with their provider before changing or terminating their child's antidepressant treatment.**

#### **G. Prescription Quantity and Refills:**

1. Medication quantity for all community-based programs will be based on sound clinical judgment. Requests for medication refills for consumers who have missed two consecutive psychiatric appointments will be evaluated on an individual basis by the prescriber.
2. Unless other clinical reasons are present, prescribers shall authorize enough prescription refills to last until the date the consumer is to schedule a follow up medication review appointment.

#### **H. Changes in Medications:**

1. If a consumer's medication is changed between Medication Review appointments, a progress note stating the rationale shall be written by the prescribing professional or other staff person to correspond with that change.
2. If a medication change occurs at the time of a Medication Review appointment, the Avatar CWS documentation of this appointment will include the rationale for all medication changes.
3. When a medication is initially prescribed, or when a significant change occurs, the consumer's primary care physician and/or other service provider will be notified (only when a release of information form is complete and up to date).

#### **I. Prescriptions:**

##### **1. Order Connect**

- a) Prescriptions will be processed through Order Connect
- b) Only a Health Professional may clarify Order Connect prescriptions with a pharmacy.

## **J. PRN Medication:**

1. When PRN orders are written, the prescribing professional shall document in the progress note or Medication Review documentation the justification of such.
2. There shall be an order and a dose for the specific conditions in which the PRN order is to be administered.
3. PRN orders shall limit the number of doses to be administered within 24 hour time period.

## **K. Screening for Medical Comorbidities**

The following are steps CMHOC takes to ensure that Medical Co-Morbidities are screened for:

1. 10 Health Measures are completed at intake in the Access Department
2. All population health questions
3. CSM annual updates
4. Nursing assessment
5. Psych evaluations and each medication review
6. Psychosocial assessment
7. Confirmation of current treatment is completed annually
8. Verbal coordination with the primary care physician and specialists as needed

## L. Clozapine Prescribing and Management

### **CLOZAPINE REMS**

The Single Shared System for Clozapine  
No Blood, No Drug™

# **Clozapine and the Risk of Neutropenia:**

## **A Guide for Healthcare Providers**

### **This Guide discusses:**

- What is the Clozapine REMS Program?
- Clozapine and the risk of severe neutropenia
- Treatment recommendations and patient ANC monitoring
- Prescriber requirements for the Clozapine REMS Program
- Pharmacy requirements for the Clozapine REMS Program

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## 1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ $\mu$ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the **C**lozapine **R**isk **E**valuation and **M**itigation **S**trategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key program requirements:

### Prescribers

- Must certify in the Clozapine REMS Program to prescribe clozapine
- Must enroll all patients in the Clozapine REMS Program
- Must report patient ANC to the Clozapine REMS Program for every prescription of clozapine

### Pharmacies

- Must certify in the Clozapine REMS Program to dispense clozapine. This includes both inpatient and outpatient pharmacies
- Must verify the prescriber is certified and the patient is enrolled, prior to dispensing clozapine
- Must verify ANC is current and acceptable for each patient, or the prescriber authorized the continuation of clozapine treatment by providing the treatment rationale, prior to dispensing clozapine

### Patients

- Must be enrolled in the Clozapine REMS Program by the prescriber to receive clozapine
- Must comply with the ANC testing requirements

## 2 ANC, Neutropenia, and Patient ANC Monitoring

### What is ANC?

ANC is the laboratory parameter for monitoring patients for clozapine-induced neutropenia. Prescribers must report the ANC before starting and during clozapine treatment.

ANC is usually available as a component of the complete blood count (CBC), including differential:

- ANC is more relevant to drug-induced neutropenia than white blood cell (WBC) count
- ANC may also be calculated using the following formula:

$$\text{ANC} = \text{Total WBC count} \times \text{Total percentage of neutrophils* obtained from the differential}$$

\* neutrophil includes "segs" and "bands"

Other granulocytes (basophils and eosinophils) contribute minimally to neutropenia and their measurement is not necessary.

### What is the risk of severe neutropenia associated with clozapine?

Clozapine can cause severe neutropenia, which can lead to serious infections and death. Severe neutropenia occurs in a small percentage of patients taking clozapine.

- Severe neutropenia is defined as ANC less than 500/ $\mu\text{L}$
- Severe neutropenia replaces the previous terms "severe leukopenia", "severe granulocytopenia", and "agranulocytosis"
- The risk appears greatest during the first 18 weeks of clozapine treatment
- The mechanism is not dose-dependent
- It is unclear if concurrent use of other drugs known to cause neutropenia increases the risk or severity of clozapine-induced neutropenia
- If clozapine is used concurrently with a medication(s) known to cause neutropenia:
  - consider monitoring patients more closely than the treatment guidelines recommend, and
  - consult with the treating oncologist in patients receiving concomitant chemotherapy

For a complete discussion of other risks, including other Boxed Warnings, please see the full Prescribing Information available at [www.clozapinerems.com](http://www.clozapinerems.com).

## What is Benign Ethnic Neutropenia (BEN)?

BEN is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine.



When enrolling a patient in the Clozapine REMS Program, identify if the patient has been diagnosed with BEN, so the patient is monitored according to the correct ANC monitoring algorithm.

A few important things to know about patients diagnosed with BEN:

- It is most commonly observed in individuals of African descent (approximate prevalence of 25-50%), some Middle Eastern ethnic groups, and in other non-Caucasian ethnic groups with darker skin
- BEN is more common in men
- Patients with BEN have normal hematopoietic stem-cell number and myeloid maturation, are healthy, and do not suffer from repeated or severe infections
- Patients with BEN **are not** at increased risk for developing clozapine-induced neutropenia

Additional evaluation may be needed to determine if baseline neutropenia is due to BEN.

Consider a hematology consultation before starting or during clozapine treatment as necessary.

## What are the treatment recommendations and monitoring requirements for patients taking clozapine?

The recommended ANC monitoring schedules for patients in the General Population as well as patients who have been diagnosed with BEN are shown in **Table 1**. The table also provides recommendations for monitoring patients who experience a decrease in ANC during the course of treatment.

Patients may transition to less frequent ANC monitoring based on the number of weeks of continuous clozapine therapy and the patient's ANCs. Weekly ANC monitoring is required for all patients during the first six months of treatment. If the ANC remains in the normal range (ANC greater than or equal to 1500/ $\mu$ L for the General Population, ANC greater than or equal to 1000/ $\mu$ L for Patients with BEN) for the first six months of therapy, monitoring frequency can be reduced to every 2 weeks.

If the patient's ANC continues to remain in the normal range for the second six months of treatment, ANC monitoring may be reduced to once every 4 weeks.

The Clozapine REMS Program will alert prescribers when a patient qualifies for a change in ANC monitoring frequency.



**Before starting treatment with clozapine, the baseline ANC must be:**

- at least 1500/ $\mu$ L for the General Population
- at least 1000/ $\mu$ L for patients diagnosed with BEN

**During treatment, monitor ANC regularly as described in Table 1 below.**

**Table 1: Recommended Monitoring Frequency and Clinical Decisions by ANC Level**

ANC Level	Treatment Recommendation	ANC Monitoring
<b>Normal Range for a New Patient</b> <b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>ANC ≥ 1500/μL</li> </ul>	<ul style="list-style-type: none"> <li>Initiate treatment</li> <li>If treatment interrupted:                             <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li>≥ 30 days, monitor as if new patient</li> </ul> </li> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<ul style="list-style-type: none"> <li>Weekly from initiation to six months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> <li>See Section 2.4 of the full Prescribing Information</li> </ul>
<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>ANC ≥ 1000/μL</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> </ul>		
<b>Mild Neutropenia</b> (1000 - 1499/μL)*	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Continue treatment</li> </ul>	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>Once ANC ≥ 1500/μL return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Mild Neutropenia is normal range for BEN population, continue treatment</li> <li>Obtain at least two baseline ANC levels before initiating treatment</li> <li>If treatment interrupted                             <ul style="list-style-type: none"> <li>&lt; 30 days, continue monitoring as before</li> <li>≥ 30 days, monitor as if new patient</li> </ul> </li> <li>Discontinuation for reasons other than neutropenia</li> </ul>	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Weekly from initiation to six months</li> <li>Every 2 weeks from 6 to 12 months</li> <li>Monthly after 12 months</li> <li>See Section 2.4 of the full Prescribing Information</li> </ul>
<b>Moderate Neutropenia</b> (500 - 999/μL)*	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Resume treatment once ANC normalizes to ≥ 1000/μL</li> </ul>	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 1000/μL, then</li> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>Once ANC ≥ 1500/μL check ANC weekly for 4 weeks, then return to patient's last "Normal Range" ANC monitoring interval**</li> </ul>
	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Continue treatment</li> </ul>	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Three times weekly until ANC ≥ 1000/μL or ≥ patient's known baseline.</li> <li>Once ANC ≥ 1000/μL or patient's known baseline, check ANC weekly for 4 weeks, then return to patient's last "Normal BEN Range" ANC monitoring interval.**</li> </ul>
<b>Severe Neutropenia</b> (< 500/μL)*	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<b>GENERAL POPULATION</b> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 1000/μL</li> <li>Three times weekly until ANC ≥ 1500/μL</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC ≥ 1500/μL</li> </ul>
	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Recommend hematology consultation</li> <li>Interrupt treatment for suspected clozapine induced neutropenia</li> <li>Do not rechallenge unless prescriber determines benefits outweigh risks</li> </ul>	<b>BEN POPULATION</b> <ul style="list-style-type: none"> <li>Daily until ANC ≥ 500/μL</li> <li>Three times weekly until ANC ≥ patient's established baseline</li> <li>If patient rechallenged, resume treatment as a new patient under "Normal Range" monitoring once ANC ≥ 1000/μL or at patient's baseline</li> </ul>

\* Confirm all initial reports of ANC less than 1500/μL (ANC < 1000/μL for BEN patients) with a repeat ANC measurement within 24 hours

\*\* If clinically appropriate

## **Can a patient continue clozapine treatment with an ANC less than 1000/ $\mu$ L?**

### **For Patients in the General Population**

Yes. Prescribers may choose to continue clozapine treatment in patients with ANCs less than 1000/ $\mu$ L. However, prescribers should follow the treatment recommendations as noted in **Table 1** and carefully determine if the benefits of continuing clozapine treatment outweigh the risks.

The recommendations to interrupt treatment are provided to ensure patient safety. If monitoring ANC and symptoms of infection is not done appropriately, patients with ANCs less than 1000/ $\mu$ L are at risk of developing complications of severe neutropenia (including death).

Refer to Section 3 of this document for more details on how to authorize a patient to continue treatment.

### **For Patients with BEN**

Yes. The Prescribing Information for clozapine recommends interrupting clozapine treatment for patients with BEN only when the ANC is less than 500/ $\mu$ L. No interruption in treatment is recommended for ANC 500-999/ $\mu$ L, although a hematology consultation is recommended.

## **If a patient develops a fever, how is clozapine treatment managed?**

Generally, clozapine treatment should be interrupted as a precautionary measure in any patient who develops a fever of 38.5°C (101.3°F) or greater, and an ANC should be obtained. Fever is often the first sign of a neutropenic infection.

If fever occurs in any patient with an ANC less than 1000/ $\mu$ L, initiate appropriate neutropenia workup and treatment for infection. Refer to **Table 1** for ANC monitoring recommendations.

If any patient presents with evidence of fever and/or neutropenia, consider a hematology consultation.

## How is clozapine discontinued for neutropenia?

The method of treatment discontinuation will vary depending on the patient’s last ANC. Abrupt treatment discontinuation is necessary for moderate to severe neutropenia that you suspect is caused by clozapine.



**REMEMBER** to report the decision to discontinue clozapine for a patient to the Clozapine REMS Program. You can do this one of three ways:



By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)



By calling the Clozapine REMS Program contact center at 844-267-8678



By completing the “Patient Update – Change Treatment Status” section of the *ANC Lab Reporting Form* and faxing it to the Clozapine REMS Program at 844-404-8876

## How is a patient monitored if clozapine treatment is discontinued for neutropenia?

After discontinuing clozapine, monitor ANC according to the recommendations in Table 1 as shown below.

<p><b>Moderate Neutropenia</b> (500 to 999/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L, then</li> <li>• Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> </ul>
<p><b>Severe Neutropenia</b> (less than 500/<math>\mu</math>L)*</p>	<p><b>GENERAL POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 1000/<math>\mu</math>L, then</li> <li>• Three times weekly until ANC <math>\geq</math> 1500/<math>\mu</math>L</li> </ul> <p><b>BEN POPULATION</b></p> <ul style="list-style-type: none"> <li>• Daily until ANC <math>\geq</math> 500/<math>\mu</math>L</li> <li>• Three times weekly until ANC <math>\geq</math> patients established baseline</li> </ul>

\* Confirm all initial reports of ANC less than 1500/ $\mu$ L (ANC < 1000/ $\mu$ L for BEN patients) with a repeat ANC measurement within 24 hours

- Monitor ANC in any patient reporting a fever (temperature of 38.5°C or 101.3°F or greater) during the 2 weeks after discontinuation
- Monitor all patients carefully for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such as profuse sweating, headache, nausea, vomiting, and diarrhea
- For abrupt clozapine discontinuation for a reason unrelated to neutropenia, continuation of the existing ANC monitoring is recommended for General Population patients until their ANC is greater than or equal to 1500/ $\mu$ L and for Patients with BEN until their ANC is greater than or equal to 1000/ $\mu$ L or above their baseline

Refer to Section 2.4 of the clozapine Prescribing Information for further information

### **Can a patient be rechallenged with clozapine?**

Yes. For some patients who experience, or have experienced, moderate clozapine-related neutropenia (ANC less than 1000/ $\mu$ L) or severe clozapine-related neutropenia (ANC less than 500/ $\mu$ L), the risk of serious psychiatric illness from discontinuing clozapine may be greater than the risk of rechallenge. This may be relevant for patients with severe schizophrenic illness who have no treatment option other than clozapine.

In making the decision to rechallenge a patient, consider:

- a hematology consult
- the ANC ranges defined in the full Prescribing Information
- the patient's medical and psychiatric history
- a discussion with the patient and his or her caregiver about the benefits and risks of clozapine rechallenge
- the severity and characteristics of the neutropenic episode

Refer to Section 2.5 Re-initiation of Treatment in the clozapine Prescribing Information for more information on how to restart clozapine in patients who have discontinued clozapine.

### 3 Clozapine REMS Program Requirements for Prescribers

#### What is the role of prescribers in the Clozapine REMS Program?

**Step 1: Review the full Prescribing Information for clozapine**

**Step 2: Certify in the Clozapine REMS Program by:**

-   Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-   Passing the *Knowledge Assessment for Healthcare Providers*
-   Completing the *Clozapine REMS Prescriber Enrollment Form*

**Step 3: Enroll every new patient in the Clozapine REMS Program**

**Step 4: Counsel each patient (or their caregiver) about the risk of severe neutropenia**

**Step 5: Check the ANC for each patient according to the monitoring requirements**

**Step 6: Report each ANC for each patient to the Clozapine REMS Program**

**Step 7: Provide authorization to continue treatment, if necessary, through the Clozapine REMS Program when the patient's ANC results meet criteria for interruption of therapy and you decide to continue clozapine treatment.**

Refer to the section titled "What is a treatment rationale?" on page 13 for more details on how to authorize a patient to continue treatment.



Prescribers may designate other healthcare providers or office staff to enroll patients and enter ANC results on the prescriber's behalf.



Find more information about designees at [www.clozapinerems.com](http://www.clozapinerems.com).

#### What do I tell my patients about clozapine?

Use the patient counseling tool titled *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers*. Review this information with patients or their caregivers as often as needed to ensure they understand the risk of neutropenia associated with clozapine and the importance of ANC monitoring. Refer to Section 17 of the clozapine Prescribing Information for additional important counseling messages for your clozapine patients.

You may choose not to provide *What You Need to Know about Clozapine and Neutropenia: A Guide for Patients and Caregivers* to the patient or caregiver, if you determine that the patient's adherence to clozapine treatment will be negatively impacted by providing it.

## How do I enroll a patient?

You can enroll a patient one of two ways:

-  By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com) and enrolling the patient online
-  By downloading a *Clozapine REMS Patient Enrollment Form* from the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com), and faxing the completed form to 844-404-8876.

**Complete a *Clozapine REMS Patient Enrollment Form* if:**

- The patient has never been treated with clozapine before, or
- If you have never treated this patient with clozapine, regardless of the patient's history of clozapine treatment

## What if my patient has been treated with clozapine before?

If you have treated the patient with clozapine after **October 1, 2012** and that patient was registered in any of the individual clozapine patient registries, the patient's information is listed in the Clozapine REMS Program where you can access the patient's profile.

Patient information before **October 1, 2012** was not transferred into the Clozapine REMS Program, unless the patient was listed in the National Non-Rechallenge Master File (NNRMF) (see the following Section for a definition of the NNRMF).

If another prescriber has previously treated the patient with clozapine, you must enroll the patient by completing and submitting the *Clozapine REMS Patient Enrollment Form* to the Clozapine REMS Program (online or by fax) to access the patient's ANC history.

If you cannot find the patient, contact the REMS program at 844-267-8678 for assistance or re-enroll the patient.

If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program at 844-267-8678 for assistance.

## How do I find out if my patient was listed in the National Non-Rechallenge Master File (NNRMF)?

Patients were listed in the NNRMF if a patient had a WBC less than 2,000/ $\mu$ L or an ANC less than 1,000/ $\mu$ L.



All patients who were listed in the NNRMF and all their lab data were transferred into the Clozapine REMS Program. These patients are identified with a red flag in the Clozapine REMS Program at [www.clozapinerems.com](http://www.clozapinerems.com).

To access patient information through the Clozapine REMS Program, you must enroll the patient. If you would like to inquire about a patient's previous clozapine history before enrolling the patient, please call the Clozapine REMS Program at 844-267-8678 for assistance.

## How do I report ANC results for my patients?

### For Outpatients:

Prescribers or their designees are responsible for reporting ANC for each prescription to the Clozapine REMS Program before clozapine can be dispensed.

### For Inpatients: If your patient is hospitalized...

Before dispensing clozapine to patients, pharmacists must be able to verify the ANC is current and acceptable for each patient, or the prescriber has authorized the continuation of clozapine treatment by providing a "treatment rationale."

While you are not required to submit ANCs to the Clozapine REMS Program before clozapine can be dispensed to an inpatient, you (or the certified pharmacy responsible for the patient in the hospital) must submit ANCs to the Clozapine REMS Program within 7 days of the blood draw.



While the patient is hospitalized, remember to monitor ANC according to the patient's ANC monitoring frequency.

### For both Inpatients and Outpatients:

Prescribers or their designees must report the ANC one of three ways:

- By signing in to the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
- By calling the Clozapine REMS Program contact center at 844-267-8678
- By faxing the ANC results to the Clozapine REMS Program at 844-404-8876

## How do I authorize continuation of clozapine when my patient's ANC is less than 1000/ $\mu$ L (General Population) or less than 500/ $\mu$ L (Patients with BEN)?

### What is a treatment rationale?

When a patient's ANC is less than 1000/ $\mu$ L (General Population) or less than 500/ $\mu$ L (Patients with BEN), a prescriber may authorize clozapine treatment to continue. This authorization, called a treatment rationale, requires the prescriber to confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia.

### How do I report a treatment rationale?

- The Clozapine REMS Program will alert the prescriber if an ANC is provided that is below the recommended thresholds for a patient. Clozapine will not be dispensed to the patient unless the prescriber provides a treatment rationale to authorize continued treatment
- The Clozapine REMS Program will change the treatment status of a patient with a low ANC to "interrupted" or "discontinued", according to the recommendations in the Prescribing Information, found in **Table 1** above
- If the prescriber wishes to continue clozapine treatment, the prescriber must change the patient's treatment status to "active", and confirm that the benefits of continuing clozapine treatment outweigh the risks of developing severe neutropenia (i.e., the 'treatment rationale')

Prescribers must confirm treatment continuation one of two ways:

-  By signing into the Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
  -  By faxing a signed *ANC Lab Reporting Form* to 844-404-8876 with a completed "Treatment Rationale" section
- After the prescriber provides the treatment rationale, the Clozapine REMS Program will issue a Predispose Authorization (PDA) which allows the outpatient pharmacy to dispense clozapine
  - Information provided in the Clozapine REMS Program is not a substitute for appropriate documentation in the patient's medical record regarding the prescriber's decision to continue, interrupt, or discontinue clozapine treatment

### What if my clozapine patient is under hospice care?

For hospice patients (i.e., terminally ill patients with an estimated life expectancy of six months or less), the prescriber may reduce the ANC monitoring frequency to once every six months, after a discussion with the patient and his/her caregiver. Individual treatment decisions should weigh the importance of monitoring ANC in the context of the need to control psychiatric symptoms and the patient's terminal illness.

## 4 Clozapine REMS Program Requirements for Pharmacies

### What types of pharmacies must be certified?

All inpatient and outpatient pharmacies must certify in the Clozapine REMS Program to purchase and dispense clozapine. The requirements for outpatient pharmacies are different from the requirements for inpatient pharmacies. The different requirements are explained in Section "What are the requirements for different pharmacy types?"

The designated authorized representative for the pharmacy will complete the *Pharmacy Enrollment Form*. This form is to certify a single inpatient *or* a single outpatient pharmacy location.

- **For outpatient pharmacies**, the authorized representative must confirm if your pharmacy management system can or cannot support electronic communication with the Clozapine REMS Program to verify the Clozapine REMS Program safe use requirements.
- **For inpatient pharmacies**, a pharmacy management system that supports electronic communication with the Clozapine REMS Program is not needed.

The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax. Certifying multiple pharmacy locations must be done online.

## What is an authorized representative?

In general, an authorized representative for a pharmacy:

- coordinates the activities required in the Clozapine REMS Program
- establishes and implements processes and procedures to ensure compliance with the safe use conditions required in the Clozapine REMS Program

Specific duties of an authorized representative are noted in the section, "What is the role of pharmacies in the Clozapine REMS Program?"

For a pharmacy with a single location, the authorized representative may be a:

- Pharmacy Manager
- Staff Pharmacist

If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the authorized representative may be a:

- Director of Pharmacy Services
- Corporate Executive overseeing Pharmacy Service

## What is a Predispose Authorization (PDA)?

Before dispensing clozapine to an **outpatient**, the pharmacy must obtain a Predispose Authorization, or PDA, from the Clozapine REMS Program. A PDA is an electronic code that indicates the Clozapine REMS Program has verified:

- Patient is enrolled in the Clozapine REMS Program
- Prescriber is certified in the Clozapine REMS Program
- Pharmacy is certified in the Clozapine REMS Program
- ANC is current (reported within 7 days of the blood draw)
- ANC is within an acceptable range, or the prescriber provided a treatment rationale



Once a PDA is obtained, the outpatient pharmacy can dispense clozapine to the patient.

### Obtain a PDA in one of three ways:

-  By enabling your pharmacy management system to support electronic communication with the Clozapine REMS Program
-  By signing into Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
-  By calling the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies are not required to obtain a PDA before dispensing clozapine.

### What is the role of pharmacies in the Clozapine REMS Program?

Designate an authorized representative for your pharmacy. The authorized representative for every pharmacy must:

**Step 1: Review the full Prescribing Information for clozapine**

**Step 2: Certify in the Clozapine REMS Program by:**

-   Reviewing *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
-   Passing the *Knowledge Assessment for Healthcare Providers*
-   Completing the *Clozapine REMS Pharmacy Enrollment Form*

**Step 3: Ensure training for all relevant staff involved in the dispensing of clozapine on the Clozapine REMS Program requirements**

**Step 4: Put processes and procedures in place to verify:**

- The prescriber is certified in the Clozapine REMS Program prior to dispensing clozapine
- The patient is enrolled in the Clozapine REMS Program prior to dispensing clozapine
- The ANC is current (reported within 7 days of the blood draw) and acceptable according to the patient's monitoring schedule, or the prescriber has provided a treatment rationale to authorize the continuation of clozapine treatment

**Step 5: Renew certification in the Clozapine REMS Program every 2 years from initial enrollment**

### How do I verify the patient is authorized to receive clozapine?

How you verify the patient is authorized to receive clozapine depends on your pharmacy type and your pharmacy's telecommunication capabilities.

## Outpatient Pharmacies WITH Electronic Telecommunication Verification

### Certification

As part of certification in the Clozapine REMS Program, an authorized representative for the pharmacy must:

- Ensure the pharmacy enables its pharmacy management system to support electronic communication with the Clozapine REMS Program
- Run the standardized verification test transactions to verify the system connectivity

### Dispensing

Before you dispense clozapine to each patient, you must:

- Process all clozapine prescriptions through the pharmacy management system to obtain a PDA
- Obtain a PDA. The PDA indicates that:
  - the prescriber is certified,
  - the patient is enrolled, and
  - the ANC for the patient is current and acceptable according to the patient's monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment

Once a PDA is obtained, you can dispense clozapine to the patient

- You do not need to document the PDA on the prescription or in your pharmacy management system



#### Dispensing Information for **All Pharmacies**

- The amount of clozapine that can be dispensed depends on when the patient's next blood draw is, according to the monitoring requirements
- Pharmacies should dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber
- If you do not receive a PDA, you will receive a message explaining why you are not authorized to dispense clozapine to the patient

## Outpatient Pharmacies WITHOUT Electronic Telecommunication Verification

### Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements, which include how your pharmacy will ensure a PDA is obtained for each clozapine prescription dispensed.

### Dispensing

Obtain a PDA in one of two ways:

-  By signing into Clozapine REMS Program website at [www.clozapinerems.com](http://www.clozapinerems.com)
-  By calling the Clozapine REMS Program contact center at 844-267-8678

To obtain a PDA, you must provide the following information to the Clozapine REMS Program:

- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days' Supply
- Quantity

The Clozapine REMS Program will verify the following for you and issue a PDA:

- The prescriber is certified in the Clozapine REMS Program
- The patient is enrolled in the Clozapine REMS Program
- The ANC is current and acceptable according to the patient's monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment

Once a PDA is obtained, you can dispense clozapine to the patient. You do not need to document the PDA on the prescription or in your pharmacy management system. If you do not receive a PDA, the Clozapine REMS Program will explain why you are not authorized to dispense clozapine to the patient.

## Inpatient Pharmacies

### Certification

As part of certification in the Clozapine REMS Program, the authorized representative for your pharmacy must implement processes to comply with program requirements.

### Dispensing

Obtaining a PDA is not required in an inpatient setting.

**Before you dispense clozapine for the first time to each inpatient, the inpatient pharmacist must:**

**Step 1: Access the Clozapine REMS Program by:**

-  Signing into the website at [www.clozapinerems.com](http://www.clozapinerems.com), or
-  Calling the Clozapine REMS Program contact center at 844-267-8678

**Step 2: Provide the following information:**

- Pharmacy Location Information
- Patient Name
- Patient Date of Birth
- Prescriber
- Dispense Date
- NDC
- Days' Supply
- Quantity

**Step 3: Verify patient eligibility to receive clozapine by:**

- Verifying the prescriber is certified in the Clozapine REMS Program
- Verifying the patient is enrolled in the Clozapine REMS Program

**Step 4: Verify that the ANC is current and acceptable according to the patient's ANC monitoring schedule, or the prescriber has authorized the continuation of clozapine treatment by:**

-  Signing into the website at [www.clozapinerems.com](http://www.clozapinerems.com),
-  Calling the Clozapine REMS Program contact center at 844-267-8678, or
-  Reviewing the patient's medical record in their hospital's medical record system

**Throughout the patient's hospitalization:** In accordance with the patient's ANC monitoring schedule, continue to verify that the ANC is current and acceptable (or the prescriber has authorized the continuation of clozapine treatment) using one of the ways listed above.

## 5 Reporting Adverse Events Associated with Clozapine

Report suspected adverse events directly to the Clozapine REMS Program at 844-267-8678. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088 or by mail using Form 3500A, available at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## 6 Clozapine REMS Program Information and Resources

Additional Clozapine REMS Program information and resources are available online at [www.clozapinerems.com](http://www.clozapinerems.com) or by contacting the Clozapine REMS Program contact center at 844-267-8678.

**CLOZAPINE REMS**  
The Single Shared System for Clozapine  
No Blood, No Drug™

## Knowledge Assessment for Healthcare Providers

Phone: 844-267-8678  
Fax: 844-404-8876  
www.clozapinerems.com

Please select the best answer for each of the following questions. All questions must be answered correctly to become certified:

### Question 1

All clozapine products are only available under the shared Clozapine REMS Program.

- A. True
- B. False

### Question 2

Clozapine is associated with severe neutropenia.

- A. True
- B. False

### Question 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ $\mu$ L
- B. An absolute neutrophil count (ANC) less than 1000/ $\mu$ L
- C. An absolute neutrophil count (ANC) less than 500/ $\mu$ L
- D. None of the above

### Question 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ $\mu$ L for a patient with documented Benign Ethnic Neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ $\mu$ L for a patient who is part of the General Population (i.e., the patient does not have BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

### Question 5

Before clozapine is dispensed to a patient, a prescriber must:

- A. Determine if the patient has Benign Ethnic Neutropenia (BEN)
- B. Enroll the patient in the Clozapine REMS Program
- C. Counsel the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain an ANC
- E. Review the ANC and provide it to the Clozapine REMS Program
- F. All of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

**Question 6**

For outpatients, prescribers must report the ANC to the shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

**Question 7**

Before clozapine can be dispensed, a pharmacist must:

- A. Verify the prescriber is certified in the shared Clozapine REMS Program
- B. Verify the patient is enrolled in the shared Clozapine REMS Program
- C. For outpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by obtaining a pre-dispense authorization from the Clozapine REMS Program
- D. For inpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by accessing the Clozapine REMS Program or by accessing the ANC through the hospital's medical record system
- E. All of the above

**Question 8**

How much clozapine can be dispensed?

- A. A 30 day supply
- B. A 90 day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

**Question 9**

Regarding patients with benign ethnic neutropenia (BEN), which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patient with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

**Question 10**

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

**Question 11**

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until  $ANC \geq 1500/\mu L$ . If the patient is part of the General Population (i.e., if the patient does not have Benign Ethnic Neutropenia (BEN))
- B. Mild neutropenia is within the normal range for a patient with BEN
- C. If the patient has BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

**Question 12**

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the General Population or has Benign Ethnic Neutropenia (BEN)
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt therapy and conduct ANC monitoring: daily until  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$ ; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the General Population or has BEN
- D. None of the above

**Question 13**

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the General Population or has Benign Ethnic Neutropenia (BEN) and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt treatment and conduct ANC monitoring: daily until  $ANC \geq 1000/\mu L$ ; three times weekly until  $ANC \geq 1500/\mu L$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

## **M. Medications for Behavior Management**

1. Medication may be prescribed without approval of BTRC when use of medication is part of generally accepted medical practice for the diagnosed condition. In this instance, if the treatment team has concerns about behavior management implications of the medication treatment, referral to the BTRC for approval or advice would be acceptable.

All other uses of psychotropic medications will be reviewed and approved by the Behavior Treatment Review Committee.

2. The Behavior Treatment Review Committee has its own Operation and Procedure Manual. In summary, the BTRC will review use of medications in order to determine the clinical appropriateness of medication versus a behavioral program for controlling behavior. The BTRC will not recommend specific medications or dosages once approval for medication use has been granted.

## N. Controlled Medications

### 1. Information Sheet to Consumers on Controlled Medications

- a. The Information sheet below is given to consumers eligible for psychiatric services at CMHOC by the Access Clinician completing an assessment interview. The information sheet contains a brief orientation to MDT Services and Controlled Substance Use Policy.
- b. The information provided in the sheet will also be discussed by the assigned MDT Therapist during pre-treatment planning sessions and other team members when appropriate.

#### *Controlled Substance Use Policy*

*We have recently implemented a new set of guidelines for our medication practices. These guidelines were developed to be more consistent with Psychiatric Best Practices and to better address our philosophy of treatment. The medications affected by these guidelines are controlled substances and include: stimulants, benzodiazepines, hypnotics (for sleep) and other medications that might foster dependence. They include, but are not limited to:*

*Adderall  
Ambien and Ambien CR  
Ativan  
Concerta  
Dalmane  
Focalin and Focalin XR  
Halcion  
Klonopin  
Librium  
Lunesta  
Restoril  
Ritalin and Ritalin LA/SR  
Seconal  
Tranxene  
Valium  
Vyvanse  
Xanax and Xanax XR*

*Short term use of these medications may be helpful. Long term use is not recommended because the risk of becoming dependent on them increases over time. Our doctors follow recommended guidelines for dosages of these medications and will limit the length of time for these prescriptions. Other medications known to be effective, but not addictive, will be made available to you.*

*Your prescriber will discuss your individual situation at your medication review appointment. If you are also taking pain pills or muscle relaxers, this may also impact the medications you will receive from us.*

## CMHOC Mental Health Services for Adults

### A Brief Orientation to MDT Services

You are eligible for CMH services and are being referred to the multidisciplinary team listed below. I will send the information that we gathered today to the supervisor for that team, who will assign you to a clinician as your primary team contact person. The clinician will get in touch with you within the next couple of days to set up an appointment.

At the first meeting the clinician will complete a psychosocial assessment with you to further evaluate your needs. At the second meeting with your clinician you will develop your Plan of Service. Your Plan of Service will list the specific services that CMH will provide to help you meet your goals. Between now and your person-centered planning meeting, please think about your recovery goals and what you would like to accomplish with our services.

Our CMH adult treatment teams offer a variety of services that are recovery-oriented. These include targeted case management, individual or group therapy, peer support specialist services, nursing, psychiatric services, and others.

You will notice our Controlled Substance Use Policy to the left. Our philosophy is that medications are not intended to remove normal painful feelings. They are meant to reduce debilitating symptoms in order to facilitate the process of developing healthy coping skills. Welcome to CMH of Ottawa County. If you do not receive a phone call from your assigned clinician within the next two business days, please call the supervisor indicated below.

*Assertive Community Treatment Team (ACT/IDDT)  
\_\_\_\_ Keith Morley, 616/786-2643*

*Holland Multidisciplinary Treatment Team 1  
\_\_\_\_ Michele VanderSchel, 616/494-5451*

*Grand Haven Multidisciplinary Treatment Team  
\_\_\_\_ Lisa Casler, 616/846-8234*

*Contractual Outpatient Team  
\_\_\_\_ Vanessa Werle, 616/393-4480*

## 2. Consumer Reactions & CMHOC Recommended Responses

- a. Refusing to see a particular prescriber and/or demands to change prescribers
  1. Staff explains there is (usually) only one prescriber option per team.
  2. Reinforce to consumer that all prescribers operate from the same guidelines.
  3. Consumer's holder of record brings issue to the next Team Meeting to get input from the team regarding rationale and recommendation to change prescribers.
    - a. Coordinate the transfer to an "alternate but equal" CMHOC MDT, if available, and the consumer is agreeable to receive all CMH services from the alternate site.
    - b. The consumer has the option of finding a new community prescriber (at his/her expense) to prescribe his psychotropic medications.
  
- b. Consumer demands controlled medications from prescriber
  1. Prescriber calmly explains CMHOC Practice Guidelines, rationale, and plan for slow tapering to consumer.
  2. Prescriber stands firm in response to consumer demands.
  3. Prescriber may choose to do a MAPS search to check for the possibility of multiple controlled prescribers.
  4. Consumer has the option of making a complaint to Recipient Rights Officer, if desired.
  5. Consumer has the option of finding a new community prescriber (at his/her expense) for psychotropic medications.
  
- c. Consumer is adamant about wanting to continue controlled meds, but has no interest in stopping admitted substance abuse.
  1. Prescriber calmly explains rationale, but remains firm in ONLY prescribing medications that are safe with the use of illegal substances.
  2. Prescriber may link prescribing practices to results of regular or irregular urine drug screens.
  3. Consumer has the option of making a formal complaint to the CMHOC Recipient Rights Officer.
  4. Consumer has the option of finding a new community prescriber (at his/her expense) for psychotropic medications.

- d. Consumer makes threats either prospectively or retrospectively, that planned or actual decreases in controlled medications will (or have) resulted in increased substance abuse, suicide attempt, etc.
  1. Prescriber stands firm in only prescribing medications that are safe with the use of illegal substances.
  2. Prescriber may link prescribing practices to the results of regular or irregular urine drug screens.
  3. Therapist, Case Manager, and Prescriber reinforce that each consumer has a right to make his/her own choices. Coach consumer in proper steps to take if that choice causes him/her serious problems, i.e. call 911, go to the hospital, ER, etc.

#### **O. Medications Not Related to Mental Health**

1. Only psychotropic medications are to be prescribed: Prescribing professionals employed by or under contract with CMHOC shall not routinely prescribe medications except those specifically involved in the treatment of psychiatric disorders and side effects.
2. Anti-Epileptic Drugs: Anti-epileptic medications will not routinely be prescribed, except when used for psychiatric diagnosis and/or for behavioral management. Anti-epileptic medications, when used for non-psychiatric convulsive disorders, will be referred to a neurologist or other physician.
3. Non-psychiatric medication may only be prescribed temporarily, at the discretion of the prescriber, in situations where:
  - a. The consumer is already using the medication
  - b. Interruption of the medication might be potentially harmful
  - c. No other source for obtaining the medication is readily available
  - d. Medications are prescribed to treat side effect(s) documented rationale

## P. Substance Abuse

### 1. Alcohol and Other Drugs of Abuse Treatment, CMHOC Policy 4.21

#### COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY

#### INDIVIDUAL CARE TO CONSUMERS

Page 1 of 3

CHAPTER: 4	SECTION: 21	SUBJECT: INDIVIDUAL CARE TO CONSUMERS
TITLE: SUBSTANCE USE DISORDER TREATMENT		
EFFECTIVE DATE: 12/15/95	REVISED/REVIEWED DATE: 11/28/01, 10/19/04, 12/7/04, 8/16/05, 8/7/07, 8/2/10, 2/13/13, 5/9/14, 7/10/15, 2/25/16	
ISSUED AND APPROVED BY:  EXECUTIVE DIRECTOR		

#### I. PURPOSE:

In providing quality mental health care to consumers with developmental disabilities and/or mental or emotional disorders, a substance-related disorder is recognized as a limiting factor in achieving self-sufficiency and self-reliance. Therefore, Community Mental Health of Ottawa County (CMHOC) seeks to assess consumers for the presence of a substance-related disorder and to address the problem as needed.

#### II. APPLICATION:

To all CMHOC providers.

#### III. DEFINITIONS:

**Substance use disorder** – A problematic use of a substance leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12 month period:

- a) The substance is often taken in larger amounts or over a longer period of time than was intended.
- b) There is a persistent desire of unsuccessful efforts to cut down or control substance use.
- c) A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
- d) Craving, or a strong desire or urge to use a substance.
- e) Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home.
- f) Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of a substance.
- g) Important social, occupational, or recreational activities are given up or reduced because of substance use.
- h) Recurrent substance use in situations in which it is physically hazardous.
- i) Substance use is continued despite knowledge or having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by substance use.

- j) Tolerance, as defined by either of the following:
  - a. A need for markedly increased amount of a substance to achieve intoxication or the desired effect.
  - b. A markedly diminished effect with continued use of the same amount of a substance.
- k) Withdrawal, as manifested by either of the following:
  - a. The characteristic withdrawal syndrome for the substance used.
  - b. The substance, or a closely related substance, is used to relieve or avoid withdrawal symptoms.

**IV. POLICY:**

It is the policy of CMHOC to maintain a cohort of staff who are properly credentialed as providers of treatment for persons with mental illness and co-occurring substance use disorders, and to be a provider of treatment for persons with mental illness and co-occurring substance use disorders.

CMHOC will support integrated treatment for substance abuse and MI as a preferred mode of service delivery, that both disorders should be considered primary, that both disorders should be treated within a philosophical disease and recovery framework, that there is no single correct intervention for individuals with co-occurring disorders, and that clinical outcomes for individuals with co-occurring disorders must be individualized and based on stages of change and phase of recovery.

**V. PROCEDURE:**

1. CMHOC will strive to assure that all employees are welcoming of individuals with co-occurring disorders, and that staff who are providing services for individuals with co-occurring disorders will display an empathic and hopeful orientation with the individual.
2. At the time of request for CMHOC services, persons who are eligible for services based on their mental illness will be welcomed regardless of their alcohol or drug abuse or dependence. If a substance-related disorder is reported to be the primary reason for service in the absence of a co-occurring mental illness/emotional disturbance/developmental disability, a referral will be made to a community provider of treatment for substance use disorders.
3. At the time of the initial psychosocial assessment, individuals will be screened and assessed for substance use disorders. Service recommendations will be in accordance with the individual's stage of change and phase of recovery.
4. Individual and group services for persons with co-occurring disorders will employ motivational interviewing strategies, substance abuse counseling, and dual

recovery support groups as appropriate to the individual's stage of change and phase of recovery.

5. Every crisis assessment will include an evaluation of the individual's current and past substance use and treatment history. A determination will be made as to whether there is evidence of substance abuse at the time of the assessment, and whether substance abuse impacts the individual's psychiatric condition. When substance abuse impacts the individual's psychiatric condition, the emergency worker will make recommendations for treatment that are in keeping with the individual's stage of change and phase of recovery. Inpatient detoxification will be recommended when the individual's substance use puts them at serious medical risk.
6. Psychiatric services: Medications for the treatment of substance-related disorders (e.g., Disulfiram, Methadone, Buprenorphine, Naltrexone) may be prescribed by Agency prescribers when privileged to do so. Consumers with an identified substance abuse history or current use may be referred for a substance use lab screen as indicated by the prescriber.

Provision of necessary non-addictive medication for treatment of psychotic illness and other known serious mental illness will be initiated or maintained regardless of continuing substance use. Individuals whose substance use appears to be significantly risky will warrant closer monitoring or supervision, not treatment discontinuation.

7. Referrals to CMHOC by community substance abuse treatment providers will be accepted for mental health and/or integrated mental health and substance abuse treatment when it is determined that the individual meets eligibility criteria for CMHOC services.

**VI. ATTACHMENT:**

Revised Controlled Substance Education document

**VII. REFERENCE:**

The Michigan Department of Health and Human Services Standards for Mental Health Services, and MDHHS Administrative Rules.

## 2. Handling of Drugs, Weapons, and Medications, CMHOC Policy 4.39

### COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY INDIVIDUAL CARE TO CONSUMERS

Page 1 of 2

CHAPTER: 4	SECTION: 39	SUBJECT: <b>INDIVIDUAL CARE TO CONSUMERS</b>
TITLE: <b>HANDLING OF DRUGS, WEAPONS, AND MEDICATIONS</b>		
EFFECTIVE DATE: 6-7-05	REVISED/REVIEWED DATE: 9/4/07, 1/27/10, 12/16/11, 3/25/13, 3/17/14, 3/17/15, 4/21/16	
ISSUED AND APPROVED BY:  EXECUTIVE DIRECTOR		

#### I. **PURPOSE:**

To establish policy and procedure that addresses the handling of items brought into CMHOC's program by the persons served and personnel.

#### II. **APPLICATION:**

To all Community Mental Health of Ottawa County (CMHOC) programs.

#### III. **DEFINITIONS:**

**Legal Drug** – A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication that has been recognized or defined by the U.S. Food, Drug, and Cosmetic Act. Typically these are most commonly available to the general public and referred to as:

1. "over the counter" (OTC) medications
2. prescription medications (those prescribed by an authorized professional)
3. Alcohol: The use of Alcohol in this country is legal. There are aspects of alcohol use (such as drinking alcohol before driving and public order offences involving alcohol) which are controlled by law, but generally the legal controls focus on the sale of alcohol to others. It is not against the law to produce alcohol in the form of beer or wine, but distillation is illegal.

**Illegal Drugs** – are those drugs whose use is considered illegal by any individual in the United States (e.g. cocaine, crystal meth,) or prescription medications that have not been prescribed to the individual (e.g. narcotics prescribed to someone else).

**Weapons** – are described as guns, knives, and any other implement brought to and/or used on the premises with intent to threaten or inflict harm on someone or something, or which can be viewed as threatening or harmful to someone or something.

#### IV. **POLICY:**

It is the policy of CMHOC to maintain a safe environment, in conformance with the law.

#### V. **PROCEDURE:**

1. Consumers and staff who have a need to bring legal medications (with the exception of alcohol) onto the premises of any CMHOC program must have those medications in the original container. These medications must be held by the consumer or staff to whom they are prescribed, and in keeping with guidelines contained in the Medication Committee Manual stored in a locked cabinet, drawer, or room. These medications may not be distributed to anyone else (consumers or staff).
2. Illegal drugs are not permitted on the premises of any CMHOC program.
3. Alcohol is not permitted on the premises of any CMHOC program.
4. Weapons are not permitted on the premises of any CMHOC program. The only allowable exception is for on duty police officers who may carry firearms and/or other weapons in order to protect and serve the public.
5. Should any of the procedures 1-4 be violated, the appropriate incident report must be completed by any individual that has knowledge.
6. Failure to comply with any of the procedures 1-4 may result in:
  - a. Suspension or termination of service to the consumer, and/or
  - b. Disciplinary action for staff, and/or
  - c. Report to law enforcement if harm or threat of harm is present.

**VI. ATTACHMENT:**

None applicable.

**VII. REFERENCE:**

CARF Standards; Ottawa County Policy HR-Employee Behavior, Discipline, and Rules of Conduct, CMHOC Medication Manual

### 3. CMHOC Suboxone Procedure

- a. Prescribing Staff:
  - 1. Prescribers require special training and certification.
- b. Patient Eligibility:
  - 1. Suboxone treatment is a planned component to a comprehensive treatment plan that includes substance use counseling. Suboxone treatment is not available to a Meds-Only patient. The individual receiving Suboxone treatment should be receiving services in the CMHOC IDDT program. Psychosocial recovery is essential in addition of Suboxone medication.
- c. The prescriber will follow current manufacturer recommendations and procedures for the induction and maintenance of Suboxone.
- d. CMHOC Suboxone Treatment Contract:

Community Mental Health of Ottawa County  
12265 James Street  
Holland, MI 49424

## SUBOXONE TREATMENT CONTRACT

Consumer Name: \_\_\_\_\_

Date: \_\_\_\_\_

As a participant in Suboxone treatment for opioid misuse and dependence, I freely and voluntarily agree to accept this treatment contract as follows:

- 1. I agree to keep and be on time to all my scheduled appointments.
- 2. I agree not to sell, share, or give any of my medication to another person. I understand that such mishandling of my medication is a serious violation of this agreement and could result in my treatment being terminated without any recourse for appeal.
- 3. I agree not to deal, steal, or conduct any illegal or disruptive activities in the doctor's office.
- 4. I understand that if dealing or stealing, or if any illegal or disruptive activities are observed or suspected by employees of the pharmacy where my Suboxone is filled, that the behavior will be reported to my doctor's office and could result in my treatment being terminated without any recourse for appeal.
- 5. I agree that my medication/prescription can only be given to me at my regular office visits. A missed visit may result in my not being able to get my medication/prescription until the next scheduled visit.
- 6. I agree that the medication I receive is my responsibility and I agree to keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of why it was lost.
- 7. I agree not to obtain medications from any doctors, pharmacies, or other sources without telling my treating physician.
- 8. I understand that mixing Suboxone with other medications, especially benzodiazepines (for example, Valium\*, Klonopin\*\*, or Xanax\*\*\*), can be dangerous. I also recognize that several deaths have occurred among persons mixing Suboxone and benzodiazepines (especially if taken outside the care of a physician, using routes of administration other than sublingual or in higher than recommended therapeutic doses).
- 9. I understand that medication alone is not sufficient treatment for my condition, and I agree to participate in counseling as discussed and agreed upon with my doctor and specified in my treatment plan.

10. I agree to abstain from alcohol, opioids, marijuana, cocaine, and other addictive substances (excepting nicotine).
11. I agree to provide random urine samples and have my blood alcohol level tested.
12. I understand that violations of the above may be grounds for termination of treatment.

---

Consumer Signature

---

Date

\*Valium is a registered trademark of Roche Products, Inc.

\*\*Klonopin is a registered trademark of Roche Laboratories, Inc.

\*\*\*Xanax is a registered trademark of Pharmacia & Upjohn Company

#### **Q. Over-the-Counter (OTC) Medications:**

1. Over-the-Counter (OTC) Medications include vitamins, herbal products, and many other drugs or medications that can be purchased without a prescription.
2. In residential settings and Community Based Education settings, OTC medications require a written prescription from a licensed prescriber for staff to administer to residents or consumers.
3. OTC medications must be listed on OrderConnect and included in the Psychiatric Evaluation report. It is required to include the drug name, strength, route, dosing instructions, and the name of the prescriber. This is the responsibility of the prescriber and/or team nurse.

## CHAPTER VII

### VII. Documentation

#### A. **Prescriber Documentation:**

##### 1. Psychiatric Evaluation

All consumers will be requested to bring the original containers of all over-the-counter and prescription medications they receive from any prescriber, or take without prescriber approval, to their Psychiatric Evaluation appointment.

Prescriber documentation will be completed utilizing the Avatar CWS Psychiatric Evaluation format for the initial appointment with a new consumer.

Prescriber will also complete a Psychiatric Evaluation if a consumer's case is reopened, and the previous Psychiatric Evaluation was completed more than one year prior.

##### a. Psychiatric Evaluation Format:

The Psychiatric Evaluation is a stand-alone document reflecting a thorough assessment and description of the consumer's current and historical circumstances as they relate to his/her mental illness, medical conditions and significant psychosocial factors. It should reflect a high degree of professionalism. It will include the presenting problem with current signs and symptoms, medical history, family history, treatment history, results of mental status exam and document any medication side effects that are currently present. A diagnosis of Axis I –V will be documented, as well as the rationale for all treatment recommendations and psychotropic medications prescribed.

- Psychiatric Evaluations must be finalized within 14 days of the face-to-face contact.
- All sections of the Psychiatric Evaluation template must be completed. If the section does not apply to the consumer, indicate "Assessed, none noted" or a similar statement.
- All narrative sections must include a complete statement that summarizes the consumer's current condition.
- A statement that the evaluation is a face-to-face meeting shall be included.
- Use full sentences.
- Use spell check.
- Use correct grammar (e.g. if pronouns are used, ensure that the reader knows to whom you are referring).
- Include a list of all OTC medications/herbals and prescription medications ordered by other medical health professionals.
- Ensure that adequate medication refills are authorized to last until the consumer's next psychiatric appointment (OrderConnect).
- Communicate to the consumer and document when the next psychiatric appointment should be scheduled.
- Obtain consumer's signature on Medication Consent form and provide adequate education for all prescribed medications. Sign and complete all appropriate blank spaces on the form.
- Order lab work as needed to assess the consumer's response and assure the safety of prescribed medications.
- Answer all "Yes – No" questions.

b. Psychiatric Evaluation Form  
**PSYCHIATRIC EVALUATION**

<b>CLIENT NAME</b>		<b>CASE COORDINATOR</b>
<b>Date:</b>	<b>Start Time:</b>	<b>Stop Time:</b>

**IDENTIFYING INFORMATION/DIAGNOSTIC RATIONALE/SIGNS AND SYMPTOMS**

**PRESENTING PROBLEM**

**MEDICAL HISTORY**

**TREATMENT HISTORY**

**FAMILY HISTORY**

**MENTAL STATUS EXAM**

**SIDE EFFECTS**

**DIAGNOSIS**

Axis I		
Axis II		
Axis III		
Axis IV		
Axis V		

**TREATMENT RECOMMENDATIONS**

<b>CURRENT PSYCHOTROPICS</b>				
<b>CONTINUATIONS</b>		<b>DOSAGE</b>	<b>#</b>	<b>REFILLS</b>
<b>EFFECTIVE DATE</b>	<b>CHANGES</b>	<b>DOSAGE</b>	<b>#</b>	<b>REFILLS</b>
<b>OTHER MEDICATIONS</b>				
(Including non-psychiatric medications, herbs, over the counter, etc.)				

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Is notification to the primary care physician and/or other service provider required as part of this status report or goal? Yes No  
 Consumer/family advised of potential suicide risks with antidepressant and/or anticonvulsant medication therapy?  
 Yes No N/A

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**RETURN VISIT**

Signature/Credentials: \_\_\_\_\_

Date: \_\_\_\_\_

## 2. Medication Review

After a Psychiatric Evaluation is completed, following appointments with a prescriber will be documented utilizing the Avatar CWS Medication Review template.

### a. Medication Review Format:

The Medication Review document should provide a thorough picture of the consumer's current mental status and response to treatment. It should reflect a high degree of professionalism. Documentation of the following should be included.

- All sections of the Medication Review template must be completed. If the section does not apply to the consumer, indicate "Assessed, none noted" or a similar statement.
- All narrative sections must include a complete statement that summarizes the consumer's current condition.
- Document whether the consumer is taking all medications as prescribed. If not, summarize current medication adherence and consumer's reported rationale.
- Document that the medication review was a face-to-face meeting.
- Document whether the consumer is having any current medication side effects. If so, describe symptoms and indicate which medication(s) may be associated.
- If the consumer is taking antipsychotic medications (other than Clozaril only), document that AIMS testing was completed at least every three months.
- Review any lab work results with consumer/guardian that were received since the last psychiatric appointment. Document this action and any recommendations.
- Review all Axis diagnoses, making changes when needed and including the rationale.
- Document all psychotropic medication changes and rationale.
- Ensure that adequate medication refills are authorized to last until the consumer's next psychiatric appointment (OrderConnect).
- Update and complete the Medication Consent form as needed.
- Order lab work when necessary.
- Provide and document any medication-related or other education given to the consumer/guardian when applicable.
- Answer all "Yes – No" questions.

b. Medication Review Form

**MEDICATION REVIEW**

<b>CLIENT NAME</b>		<b>CASE COORDINATOR</b>
<b>Date:</b>	<b>Start Time:</b>	<b>Stop Time:</b>
<b>Site of Service:</b>		

**REVIEW OF PROGRESS/DIAGNOSTIC RATIONALE/SIGNS AND SYMPTOMS**

**MENTAL STATUS EXAM**

**SIDE EFFECTS**

**LABORATORY TEST REVIEW**

**SIGNS AND SYMPTOMS OF TARDIVE DYSKINESIA (AIMS)**

**DIAGNOSIS**

Axis I		
Axis II		
Axis III/Allergies		
Axis IV		
Axis V		

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Is notification to the primary care physician and/or other service provider required as part of this status report or goal? Yes No  
 Consumer/family advised of potential suicide risks with antidepressant and/or anticonvulsant medication therapy?  
 Yes No N/A

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**PLAN**

**RETURN VISIT**

Prescriber's Signature: \_\_\_\_\_  
 \_\_\_\_\_

Date:

3. OrderConnect: Computer based system that electronically transmits prescriptions and stores medication information.
  - a. The prescriber is responsible for documenting the name, strength, route and dose of all medications prescribed by CMHOC.
  - b. The prescriber and/or team nurse are also responsible for documenting the name of the prescriber, medication name, strength, route, and dose for any over-the-counter medications, as well as prescription medications prescribed to the consumer by other individuals.
  - c. Team nurses will also update the OrderConnect allergy, pharmacy, and listing of over-the-counter and non-CMH prescribed medications when identified through Nursing Assessments and/or communication with primary care providers.
  - d. Prior to the Psychiatric Evaluation appointment, the team RN will document in OrderConnect, the consumer's Axis I & II diagnosis, allergies, CMHOC medication prescribed, and the individual's chosen pharmacy.
  - e. During follow up Medication Review appointments, the prescriber will document all CMHOC medication changes, changes in diagnosis, changes in preferred pharmacy, and new allergies. The team RN will document any changes in over-the-counter or prescription medications prescribed by others.

## B. Prohibited Abbreviations (“Do Not Use List”):

### Prohibited Abbreviations “Do Not Use List”

Abbreviation	Potential Problem(s)	Preferred Term(s)
A.S., A.D., A.U., O.S., O.D., and O.U.	Mistake for each other	Write “left ear”, “right ear”, “both ears”; “left eye”, “right eye”, “both eyes”
c.c.	Mistaken for U (units) when poorly written	Write “ml” for milliliters
U (for unit)	Mistaken as zero, four, or cc	Write “unit”
IU	Mistaken as IV (intravenous or 10)	Write “international unit”
Q.D. (Latin abbreviation for once daily)	Mistaken for Q.O.D. and the period after the Q can be mistaken for an “I”	Write “daily”
Q.O.D. (Latin abbreviation for once every other day)	Mistaken for Q.D. and the period after the Q can be mistaken for an “I” and the “O” can be mistaken for an “I”	Write “every other day”
Trailing Zero (X.O mg)	Decimal point is missed	Never a zero by itself after a decimal point (X mg)
Lack of Leading Zero (.X mg)	Decimal point is missed	Always use a zero before a decimal point (0.X mg)
MS	Confused for MSO <sub>4</sub> and MgSO <sub>4</sub>	Write “morphine sulfate”
MSO <sub>4</sub>	Confused for MS and MgSO <sub>4</sub>	Write “magnesium sulfate”
SOB	Confused with an epithet	Write “shortness of breath”
T.I.W.	Mistaken for three times a day or twice weekly, resulting in overdose	Write “3 times weekly” or “three times weekly”

## CHAPTER VIII

### VIII. Informed Consent for Medications

1. **Criteria:** Informed consent assumes all of the following:
  - a. **Capacity:** That a consumer has the capacity to make a decision and to understand the nature of the medication, its risks, or other consequences, and other relevant information.
  - b. **Information:** That a consumer has been made aware of the medication risks and benefits reasonably to be expected, and of appropriate alternatives that are advantageous to the consumer. There shall be an offer to answer any questions the consumer may have.
  - c. **Consent:** That a decision is or will be an exercise of free power of choice without intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion. The consumer shall be instructed that he/she is free to withdraw consent or to discontinue a medication at any time without prejudice.
2. **Medication teaching sheets (leaflets)** are available for all medications on the Michigan Medicaid Formulary through the OrderConnect medication consent. They will be offered to all consumers when new medications are ordered. The prescriber will indicate a check mark on the “Teaching sheet given” column of the medication consent form when a leaflet is given, or write “declined” if the leaflet is refused by the consumer. The leaflet will provide updated information with existing medical knowledge of each drug’s purpose, benefits, risks, side effects, and approved dosage range.
3. **The consumer and/or guardian will be informed** verbally and in writing of the medication name, therapeutic dosage range, maximum recommended dosage, purpose, benefits, risks, and side effects of each medication as well as other viable options to treatment with psychotropic medication.
4. **Women of childbearing age** will be informed by a health practitioner about medication risks that are associated with pregnancy.
5. **The prescriber or team RN will** complete the medication consent form completely; including the consumer’s name, allergy status, guardian status, the code for the purpose and/or benefits of new medication, date, name of medication, maximum therapeutic dosage/day, prescriber’s signature, and question regarding pregnancy, if female. It is also the prescriber’s responsibility to obtain the consumer’s, or their guardian’s signature on this form before a prescription will be authorized at a pharmacy.
6. **The consumer, or guardian, will** sign a Release of Information form, allowing CMHOC to exchange information with the recipient’s primary care provider.
7. **Competent Consumer:** Staff members shall accept as valid, and act upon, the consent or refusal of any consumer who is 18 years or older, has not been declared legally incompetent, and who is presumed to be clinically competent to give informed consent.
8. **Minor or Incompetent Consumer:** Any consumer who is under 18 years of age, or has been declared legally incompetent, may not give informed consent. Either the parent or guardian of a minor, or the guardian of an adult, must provide informed consent to take psychotropic medication.

If a recipient is legally competent on his/her eighteenth birthday, previous consent obtained from the parent or guardian expires on that date, and a new consent must be obtained from the recipient.

9. **Court Ordered Consumer:** When a consumer is Court Ordered into treatment, written consent will still be requested for any medication service. If the consumer refuses to sign consent for specific medications, it will be so documented on the consent for medication form and placed in the consumer record. A copy of the Court Order will also be placed in the consumer record. The prescriber will be permitted to write prescriptions and injections will be permitted to be given as long as the consumer shows up for appointments and is not physically objecting to an injection. At no time will force be used in order to require a consumer to take their medication.
10. **Recipient's Decline to Sign Consent or Release of Information:** If the recipient/guardian declines to sign the Consent for Use of Psychiatric Medications or Authorization for Exchange of Information with the Primary Care Physician, the Health Professional will document such refusal. Medications will not be prescribed or administered whenever the recipient or guardian refuses to give consent or give permission to exchange information with the primary care physician or withdraws consent or Release of Information.
11. **Written Consent Not Immediate Available:** If immediate written consent from a recipient/guardian is not possible, verbal consent may be obtained and documented by the health professional. A signed consent must then be obtained as soon as possible.
12. **Change in Dosage:** A change in dosage within the approved range does not require obtaining a new consent.
13. **Informed Consent:** Informed consent for use of medication must be obtained at the time a medication is initially prescribed. This is the responsibility of the prescribing physician, NP or PA-C.

# COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY

## INSTRUCTIONS

### INFORMED CONSENT FOR MEDICATION

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#### INSTRUCTIONS FOR COMPLETING FORM:

#### INFORMED CONSENT FOR MENTAL HEALTH TREATMENT USING MEDICATION:

- Complete the form in its entirety including the indicated fields which are self-explanatory.
- Be sure to indicate:
  - Whether the consumer has or does not have a legal guardian,
  - Include every medication requiring informed consent,
  - Document allergies,
- Discuss with the consumer:
  - The most common side effects, risks, and consequences of treatment,
  - The prognosis if treatment is not given and any feasible treatment alternatives,
  - The need to notify you and/or other CMH staff of any unexpected changes in health,
- Answer any and all questions the consumer may have in terms they can understand.
- Give the consumer or guardian the Patient Education Leaflet specific to the medication(s) prescribed to take with them.
- A new consent form must be obtained when:
  - Interim circumstances substantially affect the risks, benefits, or outcome of treatment,
  - A legally competent minor reaches his/her eighteenth birthday,
  - A consumer is legally declared incompetent (should complete consent with the guardian).
- Informed consent must be obtained by the prescriber if he or she is in-house. If the prescriber is not in-house, informed consent must be obtained by a CMH registered nurse.

**SPECIAL CASES:** The consent may need to be mailed to the guardian, parent, or (on very rare occasions) the consumer themselves. If this consent is mailed, the witness signing this form is asserting that the responsible party has received all the information about the medication treatment and has had the opportunity to ask any questions by contacting appropriate staff. Medication fact sheets, along with any other information about the medication treatment should be mailed to the parent, guardian, or responsible party.

**If the consumer chooses to retract the Informed Consent for Medication, draw a line across the current form and have the consumer sign and date it.**

**INFORMED CONSENT FOR MENTAL HEALTH TREATMENT USING MEDICATION**

Consumer Name: \_\_\_\_\_

Allergies: \_\_\_\_\_

This individual  has  does not have a legal guardian.

I understand that I am to advise my prescriber of my use of all prescription and non - prescription medications, including alcohol, tobacco, caffeine, illicit drugs and alternative medications.

The purpose and possible benefits of this medication include:

1	To reduce or stop hearing or seeing things not normally seen or heard (hallucinations)	9	To reduce/stop troublesome and recurring thoughts
2	To reduce irritability, tension or agitation	10	To improve orderly thinking and concentration
3	To relieve depression	11	To reduce anxiety or fear
4	To control mood swings	12	To help reduce aggression
5	To control mania, or hyperactive mood	13	To improve sleep
6	To reduce inattention, impulsivity, and/or hyperactivity	14	To control seizures
7	To control behaviors as part of a Management Plan	15	To control side effects
8	Other: _____	16	Other: _____

**CONSENT**

- Verbal consent may be obtained with written consent to follow. If verbal consent is obtained, a written consent will be mailed to the person with the legal authority to give consent.
- I agree that prescriptions may be transmitted electronically to my pharmacy.
- CMH Clinical staff may communicate with my pharmacy regarding my medication treatment.
- I am free to withdraw my consent at any time.

Date	Medication	Maximum dosage/day	Health Professional Signature	Consumer/ Guardian Signature	Purpose given	Teaching sheet given	If female, are you pregnant
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
						<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

## CHAPTER IX

### **IX. Coordination of Care with Primary Care Physician**

By checking a box on the Psychiatric Evaluation or Medication Review, prescribers will indicate to team support staff that they request a copy of their documentation be sent to the consumer's primary care physician.

A current Release of Information form is required to be in the consumer's medical record if medications are prescribed by CMHOC.

Team members shall keep the prescriber and other team members abreast if a valid Release of Information form is not obtained.

A copy of the Psychiatric Evaluation shall always be sent to the Primary Care Physician (PCP).

If no unusual incidents arise, a Medication Review copy should also be sent at minimum of once per year.

Other situations, i.e. the start new medication, medication changes, hospitalization, crisis events, crisis home admissions, etc. shall also require additional communication with the primary care physician by requesting a copy of the Medication Review be forwarded to the PCP.

At a minimum of an annual basis, either the Team Nurse, or other team member, will send a Confirmation of Current Treatment Request to the consumer's PCP. If no response is received to this request within three weeks, the team member will contact the primary care office by phone to obtain current medical treatment and medication status.

The Team Nurse will update OrderConnect with current medications and dosage instructions received from the PCP office.

A. Confirmation of Treatment Cover Letter

January 31, 2016

Type in Physician's name and address

Dear Type in Physician's name,

Our records indicate that you are currently providing medical treatment to a consumer who is also receiving services from our agency.

We are requesting confirmation of this consumer's diagnosis and treatment. Please complete the Confirmation of Current Treatment Request form attached and return to the office address that is checked on the form.

Thank you for your cooperation.

Sincerely,

Type in your name and credentials

Enclosure(s):

B. Confirmation of Treatment Request Form

**CONFIRMATION OF TREATMENT REQUEST FORM**

Our records indicate that TYPE IN CONSUMER'S NAME is an individual currently receiving medical care through your office. We are requesting confirmation of his/her diagnosis and treatment. Please find attached authorization for communication between our offices.

At this time our records indicate TYPE IN CONSUMER'S NAME is receiving ongoing treatment and/or monitoring of the following conditions:

\_\_\_\_\_

Our records also indicate the following prescribed medications and/or treatment for the above noted conditions:

\_\_\_\_\_

If this information is correct, please check the appropriate box below accompanied by the signature of a licensed independent practitioner. If the above is not accurate or is incomplete, please make any corrections/additions below:

\_\_\_\_\_

The information above is consistent with our records of prescribed treatment.

The information is not accurate and the corrections are noted above.

\_\_\_\_\_  
Signature of Provider

\_\_\_\_\_  
Date

Please send your response to the office identified below, attention TYPE IN YOUR NAME:

If you have questions or need to speak with me, I can be reached at \_\_\_\_\_.

**Holland office – MI Services**

**12265 James St.  
Holland, MI 49424**

**Fax: (616) 393-5657**

**Holland office – DD Services**

**12263 James St.  
Holland, MI 49424**

**Fax: (616) 393-5692**

**Grand Haven office**

**1111 Fulton St.  
Grand Haven, MI 49417**

**Fax: (616) 842-0886**

**Other**

\_\_\_\_\_

Dear Dr. \_\_\_\_\_

Fax#: \_\_\_\_\_

Community Mental Health of Ottawa County is very committed to coordinating the care we both provide to the individual named below. To this end, we would like to share with you relevant information and encourage you to do likewise (as clinically indicated and with the consent of the individual). Please see my notes below regarding:

Individual: \_\_\_\_\_

DOB: \_\_\_\_\_

<input type="checkbox"/>	<b>Our agency assessed this individual and has recommended:</b> <input type="checkbox"/> Inpatient psychiatric hospitalization <input type="checkbox"/> Services at _____ agency <input type="checkbox"/> CMH Services to include:
<input type="checkbox"/>	<b>Medication Changes:</b> <input type="checkbox"/> CMH ordered changes to include <input type="checkbox"/> Please inform CMH of your most recent prescription drug orders:
<input type="checkbox"/>	<b>Diagnosis(es) Change</b>
<input type="checkbox"/>	<b>Lab Results:</b> <input type="checkbox"/> Please send us your most recent results <input type="checkbox"/> Our most recent results are summarized below
<input type="checkbox"/>	<b>Most recent assessment of this individual:</b> <input type="checkbox"/> Please send your last assessment/note <input type="checkbox"/> Our most recent assessment is attached
<input type="checkbox"/>	<b>For your information</b>
<input type="checkbox"/>	<b>Please respond to question/comments below</b>
<input type="checkbox"/>	<b>The individual is no longer receiving CMH services</b>

Question/Comment: \_\_\_\_\_

You may forward correspondence to my attention at the location checked (✓) below:

12265 James Street  
Holland, MI 49424  
Phone (616) 392-1873  
Fax (616) 393-5679

1111 Fulton Street  
Grand Haven, MI 49417  
Phone (616) 842-5350  
Fax (616) 842-1150

12263 James Street  
Holland, MI 49424  
Phone (616) 392-8236  
Fax (616) 393-5692

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Confidential notice:

The information contained in this message is privileged and may contain Protected Health Information as such term is defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This information is intended for the use of the addressee listed above; if you are neither the intended recipient nor the employee or agent responsible for delivering this information to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or taking of any action in reliance on the content of this information is strictly prohibited. If you receive this copy in error, please immediately notify us by telephone. This information has been disclosed to you from records whose confidentiality is protected by Federal Law. Federal regulations (42CFR part 2) prohibits you from making any further disclosure of it without the specific written consent of the person to whom it pertains or as otherwise permitted by such regulations. A general authorization for the release of medical or other information is NOT sufficient for this purpose.

<Date>

<Name>

<Address>

<City, State, Zip>

Dear <Prescriber>,

We would like to inform you that our consumer, <name>, no longer requires or has completed his/her treatment with Community Mental Health of Ottawa County. One aspect of treatment we have provided for this consumer is psychiatric medications and we are recommending this service be continued in the community. This consumer has identified your clinic as their current provider or their provider of choice for this service.

It is our goal to make this treatment transition in a manner that benefits the patient and assists you in becoming the new prescriber for these medications. We are attaching the most recent psychiatric medication review to facilitate this process. The medication review contains information about the patient's prescription status, diagnoses and lists the current medications, dosages, and administration information.

We will be able to consult with you should you have any questions about the patient's medications or their treatment at Community Mental Health of Ottawa County. We can be reached by contacting our office at 616-392-1873. The receptionist will notify the appropriate prescriber, who will then contact your office within the hour.

Sincerely,

## CHAPTER X

### X. Sample & Patient Assistance Program Medication

#### A. Control of Sample & Patient Assistance Program Medications

1. Sample medication delivered to physicians during the course of their work duties at CMHOC become the property of CMHOC and remain under the control of designated CMHOC nursing staff.

#### B. Logging of Medications Provided

1. Sample & Patient Assistance Program medication must be logged in OrderConnect when provided; including lot number and expiration dates for sample medication.
2. This function is completed by nursing or medical assistant staff when they are present.

#### C. Guidelines for Sample Medication Distribution

1. In an effort to share limited samples in a just and fair manner, the following guidelines should be considered in determining eligibility for sample medication.
2. The following consumers would be eligible to receive a **one month supply** of available sample medications:
  - a. Consumers with no insurance and currently applying for Medicaid.
  - b. Consumers with no insurance and **actively participating** in applying for patient assistance programs.
  - c. Consumers who have reached the Medicare Part D doughnut-hole and are applying for any available patient assistant programs.
  - d. Consumers who are unable to meet their Medicaid spend-down in that particular month, despite actively participating in available opportunities to meet spend-down and submitting all eligible charges.
  - e. Consumers with high spend-down amounts must continue to submit charges month to month in order to eventually meet their spend-down. In the months that this occurs, no samples will be given. Note: some patient assistance programs are open to consumers who rarely meet Medicaid spend-downs.
  - f. At the discretion of the prescriber in other rare circumstances.
3. Consumers are not eligible for samples.
  - a. To avoid paying prescription copays.
  - b. To replace lost or stolen medications
  - c. To replace medication purposely destroyed.

#### D. Protocol for Sample and Stock Medication Requests

1. Prescriber will enter new medication order into OrderConnect as below:

- a. Custom Order Screen
    - i. Enter strength, dose, & schedule
    - ii. In Special Instructions screen, enter “Dispense Samples”
    - iii. Click on small + next to Note to Pharmacist save this phrase for future use
    - iv. Submit order
  - b. Order Confirmation System
    - i. Change days from 30 to 0
    - ii. Enter number of months until return appointment under refills
    - iii. Select “note” under Output choices
    - iv. Accept order
2. Prescriber will refer consumer to Team Nurse or Medical Assistant (MA), who will print out appropriate Drug Assistance Program Application form, with listing of required information to accompany application, from [www.Rxassist.org](http://www.Rxassist.org) website.
  3. Medical Assistant/Nurse will advise consumer to call him/her to schedule an appointment once they have the application completed and have a copy of all required proofs of income available.
  4. An appointment will then be scheduled for the MA/Nurse to review the application and proofs. Consumer will bring required information and completed application to the appointment.
  5. MA/Nurse/Prescriber will complete CMHOC portion of form for initial application or program renewal of available patient assistance drug program and fax or mail form.
  6. Note that all patient assistance program medication must be mailed directly to CMHOC. They will be stored in the locked Medication Room. This is necessary because the psychiatric stability of the consumer may vary over time, and they may not always be safe with the 90 day supply of medication provided by the drug manufacturer.
  7. When patient assistance application is completed, and all required information is received, Nurse/MA will provide sample or stock medication (if available).
  8. Nurse/MA will print one copy of the prescriber’s OrderConnect medication order for all sample medications; copy will be stapled to the bag of medications provided to the consumer.
  9. If neither sample, stock, or the consumer’s patient assistance program medication is available, the Team Nurse/CMA will inform the prescriber, utilizing Medication Clinic Request Progress Note, of the situation so that the prescriber can choose either waiting for patient assistance program medication to arrive vs. ordering an alternative medication for the consumer.

## **E. Management of Patient Assistance, Sample, and Stock Medications**

1. All sample, stock, and patient assistance medication will be stored in a locked Medication Room.

2. Sealed stock medication bottles may be used as sample medications, if they are no longer prescribed to the original consumer.

#### **F. Sample Medication Distribution Procedure**

1. When sample medications are distributed, the Nurse/MA shall record the following in the recipient's OrderConnect record:
  - a. Date medication is ready for pick-up
  - b. Medication name and strength
  - c. Number of dosage units dispensed
  - d. Directions for taking medication
  - e. Lot number and expiration date
2. Protocol for sample and stock medication requests will be followed.
3. Support staff will require that the consumer signs his/her name on the individual Pick-Up Log and provide proof of identification when necessary.
4. Sample medications may only be picked up by the consumer (or guardian), unless the consumer has called the Team Nurse, and the Nurse authorizes that another person may pick it up. In that instance, at staff discretion, a copy of the person's photo ID will be made and stapled to the pick-up log. Staff will also be required to sign for the sample medication received.
5. Sample medication may be picked up between the hours of 8:00am – 11:45am and 1:00pm – 4:00pm, unless other arrangements have been made.
6. Support staff will refer consumers to the Team Nurse if questions arise regarding the medication or prescription received.

#### **G. Sample Medication Receipt and Distribution to Other CMHOC Locations**

1. When sample medications are added to inventory, the person delivering the medications will place documentation of the quantity of each medication received in a specified medication log. This will include:
  - a. Name of the medications received as manufacturer's samples and the lot number
  - b. Medications prescribed and prepared for a recipient that have not been picked up after one month, are then turned to stock. A progress note stating this action will be documented in the consumer's medical record.
2. When medications are distributed to another location in the CMHOC system, documentation stating the quantity of each medication distributed and the receiving location will be recorded in the Sample Book. The receiving office will also document receipt of the medication on their Medication Log.

## **H. Sample Medication Inventory**

1. A Medication Log sign-in sheet will be maintained for sample medications received. This may be completed by the Team Nurse or Medical Assistant.
2. For each sample medication dispensed, the following will be recorded in OrderConnect:
  - a. A copy of the prescriber's order
  - b. Documentation of date, quantity, and lot number distributed
3. Every six months an inventory of all sample medications on hand will be counted. This report will be completed by the Team Nurse/MA. It will be forwarded to the Program Evaluator for review at the next Medication Committee meeting.

## **I. Sample Medication Room Inspection**

1. Monthly, the Team Nurse or MA will perform a quality assurance inspection utilizing the "Medication Distribution System Quality Assurance Report". That person will remove all medications that will expire prior to the next month's audit.
2. Any outdated medications found during this inspection will be destroyed following the approved procedure (see Disposal of Medications).
3. A copy of the inspection report will be forwarded to the Program Evaluator for inclusion in the Medication Committee meeting agenda.

Medication Distribution System Quality Assurance Report

Community Mental Health of Ottawa County  
Medication Distribution System Quality Assurance Report

.....

Location: \_\_\_\_\_

Date: \_\_\_\_\_

Performed By: \_\_\_\_\_

Reviewed With: \_\_\_\_\_

.....

	<u>Yes</u>	<u>No</u>
1. All medications are stored in a locked location and are inaccessible to unauthorized personnel.	_____	_____
2. Medications are stored in a clean and organized manner.	_____	_____
3. Countertops and work areas are clean and uncluttered.	_____	_____
4. Work areas are well lighted.	_____	_____
5. Medication room temperature appropriate.	_____	_____
6. All medications are labeled and contain an expiration date.	_____	_____
7. All medications present are within their expiration dates.	_____	_____
8. A log of all incoming medications is kept.	_____	_____

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **J. Medication Recall Procedure**

The medication recall procedure is as follows:

1. Upon receipt of a recall notice, the Team Nurse/MA at each location will review the medication inventory log and OrderConnect Rx Lots report for that medication/lot number.
2. If any of that medication's lot number has been distributed by CMHOC, the Team Nurse/CMA will note on the prescription copy of affected consumers the actions detailed below.
3. All consumers who have received the recalled medication's lot number will be contacted.
4. If the consumer has any of the recalled medication/lot number, they will be asked to return the recalled samples. The sample medication will be replaced with a different lot number if possible.
5. The person calling the consumer will document in Avatar:
  - a. The date the consumer was contacted
  - b. The caller's name
  - c. Notation regarding whether any medication remains in the consumer's possession
  - d. Instructions given for disposition of remaining medication
6. Copies of the involved prescriptions will be forwarded to the Team Nurse, or P&T/Medication Committee if necessary, for review following contact with the recipients.
7. If a consumer brings recalled medication back to the CMHOC distributing facility, the medication will be placed in a bag clearly marked "recalled medication" and destroyed following the approved procedures, or returned to the manufacturer if requested.

## **CHAPTER XI**

### **XI. Storage, Access and Preparation of Medications**

- A. All medications will be stored in a locked cabinet, drawer, or room. The key/keycard will either be carried by on duty staff or kept in a secure location in an area not accessible to consumers.
- B. Any medications requiring refrigeration will be stored in a separate medication refrigerator, or in a locked box inside another refrigerator that is regularly monitored and maintains a temperature between 33-40 degrees Fahrenheit.
- C. Each program will determine procedures for access and security to the locked area. These procedures will be developed in consultation with the P&T/Medication Committee.

- D. Each consumer requiring oral medications will have a plastic bin or container labeled with his full name and any allergies. If other types of medications are prescribed, they will be stored in a different labeled bin or container.
- E. Preparation of medication will only occur in a designated area, consistent with standards taught in Medication Administration Class.
- F. Prescription and OTC medications administered must be accompanied by a written order from a licensed prescriber, be in the original pharmacy container or packaging, and include the full name of the consumer.
- G. Any change in prescription medication that requires an alteration in a dose of the medication will be treated as a new prescription. The Medication Administration Record will reflect the change.
- H. Consumers who are permitted to self-administer medications while at the CMHOC facility will have written authorization to do so by a licensed prescriber. The order will be available at CMHOC, and renewed annually by the prescriber.
- I. Administration of medication includes accurate documentation of medications administered on the Medication Administration Record.
- J. Medications will not be administered if they are one year past the fill date on the prescription label or past the expiration date labeled on the container.
- K. Medications belonging to staff will not be stored with consumer medications. A separate locked area for purses and/or other personal belongings will be made available to staff for this purpose.
- L. Any expired medications from CBS programs will be returned to the group home or the recipient's guardian.
- M. All medication administered in CMHOC programs and residential facilities will be stored in locked cabinets or boxes accessible only to Health Professionals, contracted pharmacists, and staff members trained by nurses.

## **CHAPTER XII**

### **XII. Medication Administration**

- A. Medications may be administered only by a physician, PA-C, Nurse, or by direct-care staff who have taken and passed a CMHOC Medication Administration training class.
  - 1. Specific clinical programs will determine which non-Health Practitioner staff will be trained and authorized to administer medications.
  - 2. Training shall be provided for designated staff by the Training Center. This class will be taught by a qualified healthcare professional (Registered Nurse, Pharmacist, or his/her designee).
  - 3. Documentation of dates and attendance will be kept by the site supervisor and the CMHOC training unit.

- B. The minimum qualifications for unlicensed staff who administer medication are:
1. 18 years of age or older
  2. High school graduate or G.E.D.
  3. English language proficiency (which includes reading, writing, and speaking)
  4. Satisfactory references including criminal background checks
  5. Successful completion of Medication Administration class that meets the curriculum requirements of CMHOC, demonstration of safe medication administration practice, and completion of a facility orientation program.

C. Injectable Medication

1. Injectable medications may be given by a physician, RN, or LPN
2. Nurse will verify last physician, PA-C, or NP's prescription on OrderConnect
3. Current order must be within 90 days
4. Nurse will record all new orders on Avatar Medication Injection Record
5. Injection medication, dose, route, and site will be documented by the Nurse on the Avatar Medication Injection Record
6. Team nurses will schedule appointments for all injections when a prescriber is scheduled to be present in that building
7. Team nurses may give injections one day earlier than ordered if the consumer presents at the CMHOC office without requiring a change in prescriber's order
8. If a consumer does not keep his/her appointment for an injectable medication, the RN will call the consumer to reschedule the appointment as soon as possible

Injectable Medication Inventory

Injectable medications are prescribed by the Prescribers and administered by the Nurses of Community Mental Health (CMH). The medications that are part of the inventory are purchased with CMH Funding and do not include any medication that is purchased by an individual and stored at any CMH site.

At the end of each month, the nurses or their designee at three different sites takes an inventory of all CMH Injectable medication:

- MDT1 Team – Holland
- MDT Team – Grand Haven
- ACT

The inventory is e-mailed to the CMH Accountant I. The e-mail is then forwarded to the CMH Account Clerk.

The Account Clerk researches the amount paid for the medications from the most recent invoices and writes that amount on the inventory list that was provided from each site. The Account Clerk then returns the inventory to the CMH Accountant I for the processing of a month end Journal Entry.

Twice a year (March and September) a physical count and verification of inventory is required to comply with policy. The CMH Accountant I goes to each individual site and physically confirms with the nurse or their designee, the inventory that is at each site. The CMH Accountant I sets a time with each of the nurses from the individual sites to count the medications that are in inventory. A medication inventory sheet is completed and then signed and dated by the nurse or their designee and the CMH Accountant I. {See sample below}. The sheet is then given to the CMH Accounts Payable Account Clerk for regular month end processing.

Balance as of (DATE)

Site Name	Medication	Quantity
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

\_\_\_\_\_  
Nurse Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Fiscal Services Signature

\_\_\_\_\_  
Date

D. Duplicate Pharmacy Protocol

1. Some pharmacies are unable to obtain all injectable medications. Therefore, some consumers may require more than one designated pharmacy. When this occurs, the treatment team nurse will make a list of injection consumers on their team and identify the proper pharmacy or stock supply for the prescriber.
2. Prescribers or the Team Nurse will be responsible for e-Rx or faxing of all prescriptions to appropriate pharmacies

### CHAPTER XIII

#### **XIII. Storage and Administration of Medication for At Risk Outpatient Consumers:**

On rare occasions outpatient consumers receiving medication services may be determined to be at risk of self-harm through the inappropriate use of their medications. In such circumstances the Pharmacist may be asked to dispense less than a one month supply (such as a 7 day supply) for safety reasons.

### CHAPTER XIV

#### **XIV. Distribution of Medication & Prescriptions**

A. Protocol for Distribution of Medication and/or Prescriptions by CMHOC Staff

1. Samples, patient assistance program medication, and prescriptions will be prepared by prescribers, nurses, and medical assistants in response to requests of CMHOC consumers.
2. All consumers are requested to call one week in advance of needing additional medication. Signs reminding consumers of this requirement will be posted in waiting rooms and nurse offices.
3. When the medication and/or prescriptions are ready for pick-up, the prescriber, RN or MA will make one phone call to the phone number left by the consumer to inform them that they may pick-up the requested medications. If there is no answer, and staff are unable to leave a voice message, no additional calls will be made.
4. After receiving email notification from the prescriber that a prescription has been entered into OrderConnect, sample and patient assistance program medications will be bagged, labeled, and dated by RN/MA and placed in a designated locked cabinet or drawer in the medical records room. Prescriptions will be placed in an envelope labeled with the consumer's name, name of the medication, and date.
5. Consumer will pick up medications and prescriptions at the medication clinic reception<sup>81</sup> desk. A consumer signs their individual Medications/Rx Pick-Up Log, kept filed

alphabetically in the accordion file, if they are picking up a stimulant, or if the medication is handled by a support staff. Support staff will complete the date and description of what is given and initial the form. The form will then be re-filed for future use. The log is not needed when an RN handles the non-stimulant medication. The RN will document the pick up by the consumer or family member in a progress note, or in OrderConnect for sample medication.

6. Medications and prescriptions may only be picked up by the consumer, unless the consumer has called the Team Nurse and he/she has authorized that another person may pick it up. The consumer must also have a signed, valid Release of Information form for that person in their medical record. If so, a copy of that person's photo ID will be made and stapled to the pick-up log. That person will also be required to sign for the medication and/or prescription received.

## CHAPTER XV

### **XIV. ACT Medication Protocol**

#### A. Medication Distribution to ACT Consumers

1. Medications will be distributed to ACT consumers for a specified period of time, as determined by each individual's severity of symptoms, ability to adhere to prescribed orders and other factors.
2. When transporting medication to ACT consumers in the community, medications will be carried in a container where they are out of direct sight of the public.
3. Medication must be under the direct supervision of the ACT team member (i.e. carried by them or in their direct sight or locked in the glove compartment or trunk of the car).
4. Medications are to be left only with the consumer or a responsible adult in the household, when approved by the ACT supervisor.
5. As medications are set up by the team RN or CMA, a penciled "x" will be placed in the box indicating the last dose of each medication included in the set-up.
6. When medications are delivered to the consumer, the ACT team member delivering the medications will place an "x" in ink in the boxes corresponding to the doses of each medication left with the consumer. That person will also place their initials under the column corresponding to the last dose of each medication left with the consumer. This ACT team member will also date and sign their name on the back of the Medication Distribution Record.
7. Occasionally, the Medication Distribution Record is not available for a team member to take with them when dropping off medications. That person should "x" off the doses left, sign and date the MDR at the first available opportunity after the medication drop is completed.

8. Sometimes medications are left over from a previous medication drop due to the consumer missing doses, discontinued doses or other reasons. Indicate the disposition of the left-over medication in one of the following ways:
  - a. If left-over medications are used to make up part of the current medication drop, place a box around each “x” to indicate the number of doses “made up” from left-over medications.
  - b. If no medications are left, the empty boxes corresponding to the dates and doses involved should be outlined in ink. A brief explanation should also be provided in the empty boxes or lengthier explanation can be provided on the back of the MDR.
9. Some common reasons for not leaving medications with a consumer are “unable to locate”, “hospitalized”, “refused”, or “not safe to self-medicate”.
10. If medications are returned to the ACT office, list the number and type of medications returned and an explanation of the reason they were returned, i.e. Artane=5, Cogentin=6, returned due to missed doses.

#### B. PRN Medications

1. PRN medications are set up according to the maximum amount of medication ordered for the time period covered by the medication drop. For example, if the order reads Trazadone 100mg, ½ - 1 tablet at bedtime, and medication is left for four days, four 100mg tablets would be left with the consumer. As a pattern of PRN use is established, the number of PRN tablets for each medication drop will be adjusted to reflect the consumer’s average use.
2. If the consumer is refusing to take medications, or not using PRN doses, the medication order will be brought to the attention of the ACT prescriber and discontinued.
3. OrderConnect records will reflect on the current “active” medications taken by the consumer.

#### C. New Medication Orders

1. When the ACT physician orders a new medication, the ACT Team RN will transcribe the order onto the Medication distribution Record. This order will include the start date for each order and the stop date, if the order is time-limited.
2. Each step of the titration should be entered on a separate line. Place a line through the boxes up to the starting dose, and if there is a stop date, place a line from the box immediately after the last dose through the last date on the Medication Distribution Record.

#### D. Discontinued Orders

1. When a medication is discontinued, write “D/C’d” in bold letters where the next dose would have been recorded.
2. Then draw a wavy line through the remaining boxes to the end date of the Medication Distribution Record.

3. Highlight the entire discontinued medication order in pink.

#### E. Changes in Dose or Frequency

1. When the physician gives an order to change the dose or frequency of a medication, the current order is "D/C'd" and the new order is transcribed onto the MDR.

#### F. Transcribing Orders

1. The ACT team RN will make all changes on the Medication Distribution Record.
2. The ACT team RN will check OrderConnect following consumer appointments with the ACT Team Psychiatrist, noting any changes in medication orders on the MDR.
3. The ACT team RN or CMA will coordinate order changes with the consumer's designated pharmacy.
4. Medication changes, and any concerns regarding medications, will be communicated during daily team meetings to assure that all team members remain informed.
5. New Medication Distribution Records are sent out by the pharmacy on a monthly basis.
6. The ACT team RN will proofread each new MDR, comparing it to the current month's MDR, and making necessary changes.
7. The ACT team RN will initial the upper right hand corner of the new month's MDR to indicate that it is accurate.
8. The completed month's MDR will be filed in each consumer's medical record after the month is completed.
9. A second "paper copy" of the MDR is kept in the ACT office for reference purposes. This second copy is also proofread and initialed monthly by the ACT team RN for accuracy.
10. The past month's "paper copy" will be shredded once it is replaced by the current month's copy.

#### G. Transition Consumer to Self-Management of Medications

1. The entire ACT team will have input as to the appropriateness and timing of the transition.
2. The ACT team RN and CMA will coordinate the transition.
3. Coordination includes the following:
  - a. Establishing a timeline for switching to a local pharmacy.

- b. Providing demographic data, insurance information, allergies and signed Release of Information form to the local pharmacy.
- c. Communicating any special needs to the local pharmacy. This includes whether the consumer will pick-up their medications or have them delivered to their residence, the frequency which medications will be dispensed (weekly, biweekly or monthly) and past history of abuse or overdose, unusual reactions or side effects, etc.
- d. Discontinuing delivery of automed strips.
- e. Providing remaining medications from ACT office to the consumer.

#### H. Transfer of Consumer to Multidisciplinary Team (MDT)

1. The ACT team RN will provide a verbal report to the MDT receiving nurse. This report will include the current medication list, pertinent nursing history regarding medications and medical problems, the name of the local pharmacy the consumer has chosen and the date his/her next injection is due, if applicable. The ACT RN will also write a CWS Progress Note including such information. This will confirm documentation, in the medical record, that coordination of care has taken place.

## CHAPTER XVI

### **XVI. Discharge Medication**

1. Staff will assure an adequate supply of medication is available for a reasonable period of time (suggested period is 60-90 days) to allow the recipient to become established with another provider whenever possible.
2. Only medications authorized by a prescribing professional are to be given at discharge.
3. Discharge from Robert Brown Center

COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY  
OPERATIONAL GUIDELINE

Page 1 of 2

<b>TITLE:</b> Discharge from Robert Brown Center Against Clinical Advice	
<b>EFFECTIVE DATE:</b> May 2, 2011	<b>REVIEW DATES:</b> 7/1/16
<b>AUTHORED BY:</b> Barb <u>Sychowski</u> , RN BSN	

**I. PURPOSE**

To provide a safe and consistent procedure to be utilized when CMHOC consumers choose to leave Robert Brown Center prior to CMHOC & Hope Network staff's agreement that they have achieved adequate stability for safe discharge.

**II. APPLICATION**

All CMHOC directly operated and contractual treatment providers, Robert Brown Center Staff

**III. DEFINITIONS**

N/A

**IV. PROCEDURE**

1. Robert Brown staff will prepare the individual's medications for discharge. Each medication will be clearly marked with the name of the medication and dosing instructions.
2. Robert Brown staff will give the person only enough medication to last through the following CMHOC business day. If the person is assigned to a CMH Multidisciplinary Team (MDT), CMH DD Services, or a CMH contractual outpatient provider, Robert Brown staff will inform the consumer that they may pick up the balance of their medication at the 12265 James St. location, following a crisis team assessment to establish low risk of harm.
3. If the consumer appears to be a risk to self or the community, or is staying at Robert Brown Center under court order, Robert Brown staff will call 911 & Helpline to inform them of the consumer's discharge against clinical advice status and any ongoing concerns or symptoms relative to safety in the community. Helpline will be requested to relay this information to the on call crisis worker immediately.
4. A copy of the RBC discharge summary, including any clinical concerns and documenting that the discharge was against clinical advice, will be faxed to the CMHOC Crisis Team Supervisor before the end of the discharging RBC worker's shift.

5. Remaining medications for that person will be bagged and stapled shut, with a copy of the Medication Administration Record attached to the outside.
6. If the consumer is assigned to a CMHOC treatment team including a contractual provider, Robert Brown staff will deliver the bagged medication to a Nurse or Medical Assistant at 12265 James St., Holland by the beginning of the next CMHOC business day.
7. CMHOC Nurse/Medical Assistant will mark the date of receipt on the medication bag.
8. When a consumer arrives at the CMHOC James Street office, a crisis worker will be requested to evaluate the consumer to determine whether there would be a significant risk at this time for the consumer to have possession of his remaining medications. The crisis worker will make an attempt to contact the assigned case manager and/or therapist for input during this process. The ACT/IDDT team will assess consumers assigned to that team for risk level, and make a determination of further disposition and amount of medication to be released to the consumer.
9. If the crisis worker determines that the consumer is at low risk, the crisis worker will release the medications to the consumer. Proof of identification, with a picture ID, will be required for all individuals unknown.
11. If the crisis worker or determines that potential risk of harm remains, the crisis worker will consult with an available CMHOC prescriber to determine how many days of medications would be safe to release. Nursing staff will set up the approved days of the medications, utilizing separate envelopes labeled with the name, dose and directions for each medication.
12. Medications should not be released until a crisis consultation has occurred.
13. If release of the total amount of medications is not possible, consumer will be requested to return at the interval specified by the consulted prescriber, to obtain additional medication from the Team Nurse/MA until a Medication Review appointment with the consumer's regular prescriber has been completed.
14. If the consumer's bagged medications are not picked up within two weeks after receipt from Robert Brown Center, CMHOC Medical Assistant will dispose of medication(s) in accordance with Medication Committee Manual protocol.

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## CHAPTER XVII

### **XVII. Disposal of Medication**

#### **A. Disposal of Non-controlled Medications**

1. Returned or expired medication will be disposed of by a Nurse, MA, or the consumer. Medication should remain in the original bottle with the label removed or obscured. The collection bin allows for pills to remain in original packaging. On a monthly basis, each team will provide for the medication bag to be taken to an Ottawa County Health Department location. The Health Department will provide safe disposal of all medications they receive. Consumers and contracted providers will be requested to dispose of non-controlled medications by utilizing the same procedure.

#### **B. Disposal of Schedule II – V Controlled Medications**

1. CMH clinical staff will accept controlled medication from consumers only in the event that the medication has been discontinued, the staff member has concerns regarding the person's safety with any remaining pills, and the consumer agrees to relinquish control of the medication. In these instances, the clinical staff person or the consumer if

appropriate will take the medication to the Health Department to dispose of it by the end of the work day.

## CHAPTER XVIII

### XVIII. Transportation and Tracking of Potentially Infectious Waste

#### A. Definitions:

1. Infectious Waste is defined as the following in the CMHOC context:
  - a. Blood or fecal material with blood that is visible to the naked eye and sufficient in quantity so as to release blood in a liquid or semi-liquid state if compressed, but NOT including urine or materials stained with blood or body fluids (i.e. sanitary napkins or diapers)
2. Sharps (needles, scalpels, syringes).
3. Containers are defined as:
  - a. Sharps container: A puncture proof, access restricted container which safely protects the sharp objects from puncturing the outside, does not permit easy access to the discarded materials contained therein, and are clearly identified (typically by a bright red color) as containing “Biohazards” and “Sharps”.
  - b. “Red Bag” is the term frequently used to describe the bag or leak proof container used to hold contaminated materials (such as blood soaked gauze or bandages). These bags need to ensure that the blood or fecal material cannot leak out of the bag and are clearly labeled as containing “Biohazards” with a red label. Some of these bags are commercially prepared and are red in color. If those are not available, any leak proof plastic bag can be used and a warning sticker applied.

#### B. Procedures:

1. Potentially contaminated items and sharps will be disposed of in accordance with Ottawa County policies (“The County of Ottawa: Bloodborne Pathogen Exposure Control Plan”).
2. Disposal of containers (Sharps and Red Bags):
  - a. All containers are to be stored in location(s) inaccessible to the public (e.g. locked storage closet, locked cabinet, personal office space, etc.)
  - b. All potentially infectious waste is to be picked up by the licensed hauler at 12265 James Street, Holland at a minimum of every 90 days. There are NO contracts with the hauler to pick up this waste at any other CMHOC site.
  - c. In order to promote compliance with pick up of waste every 90 days, staff are encouraged to date the outside of the container/bag when the first item is placed

therein. (NOTE: potentially infectious waste MAY NOT remain at any site for more than 90 days).

- d. Potentially infectious waste may be hauled by any CMHOC staff who have current and up-to-date training in Universal Precautions through the “Bloodborne Pathogen” training offered by the agency in cooperation with Ottawa County’s Human Resources Department.
- e. Upon receipt of this notice, each site should begin to prepare for transport. (NOTE: potentially infectious waste MAY NOT remain at any site for more than 90 days).
- f. When ready to transport red bag(s) and/or sharps containers(s):
  1. Close the container to prevent spillage and protrusion of contents during handling, storage, transport, and shipping.
  2. Placed in a secondary container if leakage is possible. The second container shall be:
    - i. Closeable
    - ii. Constructed to contain all contents and prevent leakage during handling, storage, transport, and shipping.
    - iii. Labeled or color-coded according to this standard.
    - iv. Maintain the container upright.
    - v. Do not overfill.
    - vi. Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

C. Upon arrival at 12265 James Street, Holland, MI (otherwise known as A Building):

1. Place the red bag or sharps in the designated container located in the mechanical room off of the lobby. The code to the door is 3-1-3.
2. If you need assistance in accessing the storage area, please ask the receptionist to locate the health and safety coordinator, building designee, or building manager.
3. It is the responsibility of the person transporting the waste INTO the building to ensure that it is properly stored and made inaccessible to the public. DO NOT LEAVE WASTE UNATTENDED IN THE BUILDING!
4. Complete and initial the log posted above the container before leaving

## CHAPTER XIX

### XIX. Medication Errors

A. **Definition:** Office of Recipient Rights Policy and Procedure Manual states:

1. All medication errors shall be reported, reviewed, and when appropriate, investigated so that appropriate follow-up and/or remedial action is taken to assure the safe and humane treatment of all consumers.

B. **“Medication Error”** shall herein be defined as any medication administration involving one or more of the following:

1. The wrong dosage (lower or higher)
2. The wrong time (failure to give the medication within ½ hour before or after the scheduled time)
3. The wrong medication
4. The wrong consumer
5. The wrong route of administration
6. A missed dosage of medication (this does not include instances when a consumer refused medication)

C. **“Significant Medication Error”** is one that has the potential for causing a **significant adverse effect** and may include one or more of the following:

1. The wrong medication
2. The wrong dosage (higher)
3. The wrong consumer
4. The wrong route of administration
5. Discontinuing a medication or modifying the dose without written orders from the prescriber

D. **Individual Responsibility:** It is required that all medication errors, be documented on an Incident Report (IR) by any person observing the event or identifying the problem.

E. **P&T/Medication Committee Responsibility:** The procedures outlined for the filing of an Incident Report shall be used for all medication errors.

1. CMHOC Incident Report form (see form: [miottawa.org/CMH/RR](http://miottawa.org/CMH/RR))
2. The P&T/Medication Committee will, at the Recipient Rights Officer’s request, review an Incident Report and aid in remedying and/or preventing reoccurrence of the incident.

3. Per request of the Office of Recipient Rights (ORR), the P&T/Medication Committee will provide ORR with technical medical judgment.
4. Monthly medication error reports will be provided to the P&T/Medication Committee by the Recipient Rights Officer. All **significant medication errors** will be reviewed by the P&T/Medication Committee to assure appropriate corrective action has taken place.

**F. National Poison Control Hotline/Prescriber/Pharmacy:**

1. All CMHOC employees responsible for the administration of medication, either through direct or contracted employment, shall post the phone number of the National Poison Control Hotline (1-800-222-1222) above a telephone near where medication is prepared.
2. In the event that a medication error results in the accidental administration of a higher dose, wrong person, wrong medication, or wrong route of medication administration, the employee should immediately check the consumer for injury, notify their supervisor, call Poison Control, and then write an Incident Report.

## CHAPTER XX

### **XX. Significant Adverse Effects**

- A. All significant adverse effects shall be reported to the prescriber, reviewed, and when appropriate, investigated by the Office of Recipient Rights (ORR) so that appropriate follow-up and/or remedial action is taken to assure the safe and humane treatment of all consumers. CMH staff and/or contracted providers will take action as necessary to assure appropriate medical care for the recipient.

It is believed that all significant adverse drug reactions are unusual incidents and, as such, do need to be reported via an Incident Report. The Incident Report will be reviewed by the ORR and treatment team.

B. Definitions:

1. **Adverse Effect:** The development of undesired side effects or toxicity due to the administration of drugs
2. **Significant Adverse Effect:** Unintended, undesirable, or unexpected effects of prescribed medications or of medication errors that result in initial or prolonged hospitalization, result in disability, result in prolonged and/or permanent cognitive deterioration or impairment, are life threatening, result in death, or result in congenital anomalies.

C. Reporting Procedures:

1. At every contact with the prescribing professional, the prescriber shall document, in the Psych Evaluation or Medication Review, any side effect reported by the consumer or observed by staff or family, as well as the action taken and any preventative measures to avoid reoccurrence.

2. For any significant adverse effects the prescribing professional shall ensure that this is also documented in the Psych Evaluation or the Medication Review.
3. The prescriber will notify the ORR if a rights violation is suspected.
4. The P&T/Medication Committee shall provide recommendations for improving the safe administration of medication.

## CHAPTER XXI

### XXI. Pharmacy Services Policy 4.13

COMMUNITY MENTAL HEALTH OF OTTAWA COUNTY  
INDIVIDUAL CARE TO CONSUMERS

Page 1 of 2

CHAPTER: 4	SECTION: 13	SUBJECT: INDIVIDUAL CARE TO CONSUMERS
TITLE: <b>PHARMACY SERVICES</b>		
EFFECTIVE DATE: 12/15/95	REVISED/REVIEWED DATE: 12/15/96, 12/20/00, 8/6/04, 2/1/05, 2/7/06, 1/21/08, 2/05/08, 12/14/09, 12/06/10, 2/28/12, 5/10/13, 4/21/14, 5/26/15, 3/30/16, 6/21/16	
ISSUED AND APPROVED BY:  EXECUTIVE DIRECTOR		

- I. **PURPOSE:**  
To establish policy and procedures concerning pharmacy services to Agency consumers.
- II. **APPLICATION:**  
To all Community Mental Health of Ottawa County (CMHOC) operated programs.
- III. **DEFINITIONS:**  
Not Applicable.
- IV. **POLICY:**  
It is the policy of CMHOC to refer outpatient consumers to the pharmacy of the consumer's choice for pharmacy services, whenever possible.
- V. **PROCEDURE:**
  1. When a Licensed Prescriber provides a consumer with a prescription, the prescriber directs the consumer to use the pharmacy of the consumer's choice to fill the order.
  2. If the consumer is determined to be without prescription insurance coverage and/or the financial means to purchase the medication, the prescription may be filled through the use of manufacturer's samples, coupons, or the manufacturer's patient assistance program, if available.
  3. When sample medications are provided, the procedures outlined in the Pharmacy & Therapeutics Manual will be followed.
  5. In rare situations when none of the above means of procuring medication is available to the consumer, CMHOC's internal medication program may be utilized. Under this program, the consumer will be directed to a specific participating pharmacy to fill the order for medication. The cost of medication will be paid by CMHOC. Authorization of the medication program will be through the Program Coordinator for Crisis Services.

6. When a long-acting injectible medication is ordered by the prescriber, the medication will be administered by a CMHOC registered nurse. Consumers with only Medicaid will receive their medication from a stock supply purchased specifically for this purpose, if available. Consumers with no insurance will purchase their medication from the pharmacy or receive the medication from the drug manufacturer's patient assistance program. All other consumers will obtain their injectible medication from their chosen pharmacy, or it may be delivered directly to CMH by the pharmacy.

**VI. ATTACHMENT:**  
Not Applicable.

**VII. REFERENCE:**  
CMHOC Medication Committee Manual

## CHAPTER XXII

### **XXII. CMHOC Medication Assistance Program**

**A. Definition:**

1. CMHOC allows for the provision of medications to indigent consumers following psychiatric inpatient hospitalizations, crisis home stays, or during rare instances when a consumer is unable to meet Medicaid spend-down despite actively participating in all available opportunities.
2. Psychiatric medications are provided through local pharmacies at no cost to the consumer. This program allows for the continuation of newly prescribed medications for periods of time ranging from a few days to several weeks, when the consumer has exhausted other options (i.e. temporary financial assistance from family, friends, etc.).
3. To be eligible, the consumer must apply for a benefit program that will cover medications on a long term basis. Examples are a Medicaid and/or a Patient Assistance Drug program, if one is available.

**B. Procedure:**

1. The CMHOC staff managing the discharge of the consumer from the inpatient or crisis home setting completes a CMHOC MEDICATION AUTHORIZATION REQUEST form when the consumer is identified as an individual who will be unable to pay for medications. The assigned Team Nurse will coordinate the process for individuals unable to meet their Medicaid spend-down.
2. Hospital or CMHOC staff will assist the consumer to complete an application for Medicaid and/or a drug manufacturer's Patient Assistance Drug program, if available. This is a requirement for any consumer using the CMHOC Medication Assistance program.
3. The CMHOC MEDICATION AUTHORIZATION REQUEST form is then faxed to a local identified pharmacy.

4. Upon discharge from the psychiatric facility, the consumer receives the prescription(s) for psychiatric medication(s) which are then taken to the identified pharmacy.
5. The prescription medication(s) are filled at the pharmacy and provided at no cost to the consumer.
6. CMHOC discharge and treatment team staff will work with the consumer to ensure that adequate steps have been taken to allow for the provision of psychiatric medications following this process.
7. An invoice is received monthly from the pharmacies and is compared with the authorizations for accuracy, and is then processed by CMHOC Fiscal Services.

## **CHAPTER XXIII**

### **XXIII. Quality Assurance**

1. The following shall be monitored by CMHOC Quality Improvement Department:
  - a. Drug use evaluations: Indications for prescribing the medication.
  - b. Critical path reviews: Standards of practice for prescribing and monitoring the medication.
  - c. Records pertinence.
  - d. Satisfaction of internal and external consumers.

## **CHAPTER XXIV**

### **XXIV. Educational Opportunities**

- A. Educational activities of the P&T/Medication Committee shall include the following:
  1. Assure that staff are aware of the P&T/Medication Committee procedures by having the P&T/Medication Manual available for all staff via the CMHOC database. The committee shall respond to requests for further information from staff and programs.
  2. Provide consultation and training to staff regarding medication issues when the need arises.

## CHAPTER XXV

### XXVI. Approval of CMHOC Executive Director

The Medication Committee Manual, dated September 26, 2016 has been reviewed by me and is approved for use.



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Lynne Doyle  
Executive Director  
Community Mental Health of Ottawa County