Title:	3.5.1, Medication		
Subject:	MEDICAL AND NURSING SERVICES		
Section:	Clinical		
Policy: □ **Procedure: X**	**Issued by:** Medical Director	**Effective Date:** 09/15/83	**Applies to:** **X All CMHA-CEI staff** **X Contract Providers**
Page: 1 of 17	**Approved by:** **N/A**	**Review Date:** 7/14/2017	**□ Other:**

I. Purpose:

To Provide guidelines for medication administration, storage, and prescription, as well as other issues related to medication in Community Mental Health Authority of Clinton, Eaton and Ingham Counties (CMHA-CEI) directly operated and contract service sites where staff are responsible for administering medications.

All staff are responsible for safeguarding and administering prescribed and over-the-counter medications to recipients in accordance with instructions given by the recipient's physician (or other prescribing professional). Controlled substances will be secured, monitored, and kept only in the quantity and for the time absolutely necessary to meet the need of the recipient for whom the controlled substance was prescribed.

II. Procedure:

A. Medication Storage, Administration, and Preparation

1. Medications shall be provided in a safe and sanitary manner.
2. All prescribed and over-the-counter medications, including refrigerated medications, shall be stored in a clean, dry, and locked area designated specifically for medications. All prescription medications are kept in pharmacy labeled packaging. Poisons, external drugs, oral prescription drugs, and over the-counter drugs are stored in separate containers. Medications should not be exposed to extreme temperatures. Controlled substances will be double locked (e.g. held in a locked area within the locked medication storage area). Please see Section C of this procedure for further information on controlled substances.
3. Medications shall be prepared and administered by a person licensed to prepare and administer medication or by a person who is currently trained by CMHA-CEI to prepare and administer medications.
4. For recipients in residential or formal day program settings, staff are responsible for administering medications unless an individual recipient has an approved program plan for self-medication. In this situation staff remains responsible for the daily supervision and documentation as indicated.
5. All medication will be administered and documented for one recipient at a time. All medications administered are documented on the Medication Administration Record (MAR). For each medication the MAR will list the name of the medication, dosage, frequency, and instructions for use. The staff administering the medication will insure

that the right recipient is receiving the right medication, the right dose, at the right time, in the right route.

6. Each staff member administering medication will complete the CMHA-CEI medication or approved equivalent training. Staff members who are medical professionals, such as physicians and nurses, may be exempt from this requirement by virtue of their training, at the discretion of the Medical Director. In the event an untrained staff member is responsible for administering medications, the staff member is to consult by telephone with the on-call supervisor for direction.
7. Upon discharge from a program in which CMHA-CEI staff store and administer medications, the recipient shall ordinarily be provided with only those medications currently prescribed. If, however, the recipient brought additional medication with them to the program upon admission, the recipient should be encouraged to allow staff to destroy all such medications not currently prescribed to the recipient. Pursuant to current guidance (as of April 2017) from the state recipient rights office, if the recipient does not want such medication destroyed, it must be given to the recipient. In such a case, staff must consider whether allowing such disbursal of medication would pose sufficient risk to the recipient or others that the discharge must be reconsidered.
8. All medication will be administered within one hour of the prescribed time. In the event this does not occur the responsible staff will consult one of the following resources and complete the direction indicated.
    a. Physician
    b. Registered nurse (R.N.)
    c. CMHA-CEI pharmacist
9. Staff is responsible for observing the recipient to insure the medications are properly ingested or otherwise utilized.
10. Staff are responsible for monitoring and documenting the effects, side effects and adverse effects of prescribed medications and reporting the observations to the appropriate team member (prescriber, R.N., or Case Manager).
11. Only prescribed medications shall be administered except in an emergency. In an emergency, orders from the Emergency Medical Services dispatch shall be considered to be prescribed.

B. <u>Disposal of Non-Controlled Substance Medications</u>

1. For storage, administration, and disposal of controlled substances, follow the instructions under section C of this procedure (Storage, Administration, and Disposal of Controlled Substances).
2. Non-controlled substance medications, if dispensed by St. John Pharmacy, may be identified by prescription numbers beginning with 6 or 16.
3. If a non-controlled substance medication is discontinued, has expired, or is otherwise no longer needed but is still in its original container, staff shall return the medication to St. John Pharmacy as below.
    1. Fill out the “Medication Return Form” available from St. John Pharmacy.

2. Place medications in box or tote, leaving medications in their original labeled prescription bottles or cards. Give the unwanted medications to the pharmacy driver the next time they are at your facility or bring the unwanted medications to St. John Pharmacy.

4. If a non-controlled substance medication has been dropped and/or contaminated, staff shall dispose of the medication by doing the following:
   a. Place the medication in the container that has been designated for such a purpose and labeled as such by the facility or pharmacy.
   b. At least once a month, the facility's non-controlled substance medication disposal container shall be brought to St. John Pharmacy and the medications contained therein placed in the secure medication disposal container provided by the pharmacy.
   c. At the time that the medication is placed in the facility's disposal container (not the container at St. John Pharmacy), the employee will sign the MAR indicating the name of the medication, the strength, the number disposed, the method, and the reason for disposal.

C. <u>Storage, Administration, and Disposal of Controlled Substances</u>

1. All controlled substances must be stored in a locked container inside the locked medication cabinet.

2. Controlled substances must be counted at the end of every shift and the count recorded on the MAR. If there is a discrepancy between the count and the amount that should be present according to the MAR, the on-duty staff member shall contact their supervisor. In addition, the discrepancy must be reported to the pharmacy on the first business day following discovery and an incident report completed.

3. Controlled substances, when discontinued or otherwise requiring disposal, such as if expired, dropped, and/or contaminated, must be disposed of by one of the two following methods:

   a. Disposal in a secure medication disposal container:
      1) This is the preferred disposal method but may be impossible for some homes due to staffing issues.
      2) To dispose of medication in this manner, leave the medication in its original container, bring the medication to St. John Pharmacy at the CMHA-CEI Jolly Road facility, and two CMHA-CEI or contract facility staff place the discontinued medication in the secure medication disposal container provided by the pharmacy.

   b. Destruction in the home:
      1) Two staff pour the discontinued controlled substance into a sealable plastic bag. If the medication is solid (pill, capsule, etc.), crush it and/or add water to dissolve it.

2) Add kitty litter, sawdust, coffee grounds (or any other material that makes it less appealing for pets, children, or other recipients to eat) to the plastic bag.
3) Seal the plastic bag and put it in the trash.

c. No matter which disposal method is chosen, two staff must count the medication (or note the volume, if a liquid) immediately prior to destruction.

d. Once the medication has been destroyed or placed in the disposal container, remove and destroy ALL identifying personal information (prescription label) from all medication containers before recycling them or throwing them away.

e. Staff who perform the destruction or secure disposal will document on the Medication Administration Record (MAR):
1) Name of the medication
2) Number/amount of medication destroyed (43 pills, 4 oz, etc)
3) Method of destruction
4) Date, time and signature(s) of staff involved.

f. Note that controlled substances, if dispensed by St. John Pharmacy, may be identified by prescription numbers beginning with 2, 4, 12, or 14.

D. <u>Administration of Sub-Cutaneous Injections</u>

All staff administering sub-cutaneous injections will be trained by R.N. staff. The R.N. will be present and supervise each staff member until they are able to administer an injection safely and appropriately. In addition, all staff will be trained on the following:

1. Cleaning, preparation, rotation, and monitoring of the skin site.
2. Types of insulin (as applicable).
3. Appropriate disposal of needles and syringes.
4. How to accurately measure medication dosage.

E. <u>Transferring of Medications to be administered at an alternate site.</u>

When possible, prescribers will be encouraged to prescribe medications so that administration will occur at a single location (e.g. the residence of the recipient)
If a medication must be administered at more than one site, the primary site where medication is received and stored shall transfer medications to the secondary site in the following manner:

- Sent in original containers (as provided by pharmacy or as purchased for over the counter medications)
- Handed directly to receiving staff by staff from the transferring location
- A medication transfer receipt shall be signed by both staff and a copy maintained by each.
- Transferred medication will be immediately placed in locked storage as required.

- Medication transferred for a recipient from a home to school, work activity, or day activity program will be sent with a copy of the written order.

When medications are transferred from one CMHA-CEI program/site to another, the staff transferring the medication will present the medication to the staff receiving the medication and will complete a medication transfer log which includes a count of the medications transferred and a signature of both staff.

F. Documentation of Medication Administration

1. A written order completed by a licensed medical professional is required for all prescribed and over the counter medications. Verbal orders for new medications or changes in medications are given by the prescriber to a nurse or pharmacist. The nurse or pharmacist then provides instruction to staff. Verbal orders will be signed by the prescriber at or prior to the next appointment with the recipient. Records of all current prescribers' orders are maintained in the Medication Administration Record (MAR) or the designated section of the Consumer Record.

2. Administration of medication by CMHA-CEI staff shall be noted on the recipient's MAR immediately after the medication is administered. For facilities utilizing paper MARs, the staff member who administers the medications initials the chart for the appropriate date and time to indicate the medication has been administered. Initials are cross referenced with the signature of the assigned staff member (usually on the back of the MAR). If a facility is utilizing an electronic MAR, the instructions for that system shall be followed.

3. At the start of each shift the assigned staff member is responsible for checking the MAR for the previous shift. If the MAR is not completed as scheduled, staff should refer to Section G, #2 of this procedure, "Failure to Document Medication".

4. All changes to medications need to be transcribed on the MAR and reviewed by another employee and initialed. For discontinued medications a line should be drawn across the chart and noted as Discontinued (DC'd). For facilities utilizing an electronic MAR the processes for that system shall be utilized.

5. A directions change sticker will be placed on the existing medication container, but placing the sticker so the name and dosage of the medication is still visible. Stickers are available from the pharmacy.

G. Medication Administration Errors and Problems

1. Late Medications

In the event a medication is not administered according to the prescriber's instructions the responsible staff member will consult one of the following resources and complete their direction as indicated.

a. Physician

b. Registered Nurse
c. CMHA-CEI pharmacist

If the direction is to skip the next dose, the staff member documents the skipped medication on the MAR and completes the incident report, including noting all follow up actions taken.

2. **Failure to Document Medication**

In the event that a staff member observes a blank on the MAR during a period when the medication should have been administered, the staff member attempts first to contact staff members on duty during the previous shift to find out if the medication was administered or missed.

a. If the medication was missed, the staff member follows the instruction listed above in the Late Medication Section of this procedure.
b. If the medication was administered but not documented, the staff member initials the chart with his/her initials and documents the previously scheduled individual who administered the medication (e.g. BB for JS).
c. If staff members from the previous shift cannot be contacted the responsible staff member does a pill count to determine whether the medication was administered. If the pill count indicates that the medication was administered, the staff member initials using only his / her initials and writes the comment "according to pill count" If the count indicates the medication was missed staff follows the instructions listed below in the Medication Errors Medication in Section of this procedure.

3. **Medication Errors (Missed Medication/Wrong Dosage/ Wrong Time / Receipt of Wrong Medication/Wrong Route)**

In the event that a resident does not receive a medication as prescribed or is incorrectly medicated, the responsible staff person contacts one of the following resources and records their direction and action taken.
a. Physician
b. Registered nurse
c. CMHA-CEI pharmacist

The error is documented in the CMHA-CEI incident reporting system, including the follow up action taken.

4. **Refusal of a Medication**

If a resident is offered their scheduled medication and they refuse the dosage, the staff member will continue to offer the medication to the resident every 10 minutes for the next hour. If after an hour the resident continues to refuse the medication, the staff member will contact one of the following resources to determine how critical it is for the resident to receive the medication.
a. Physician
b. Registered nurse

c. CMHA-CEI pharmacist

Instructions by the health care provider must be documented in the clinical record and followed as stated.

When contacting the CMHA-CEI pharmacist after-hours for refused medication leave the following information on the pager:

a. Contact telephone number
b. Name of the home/residence
c. Name of the recipient who refused
d. Name and dose of each medication refused
e. Time that the medication was due

If the medical professional indicates that it is imperative the recipient receive the medication, the staff member contacts a supervisory staff for instructions. If it is not possible to administer the medication, the staff member transports the resident to the nearest hospital emergency room for assistance. The incident is documented in the CMHA-CEI incident reporting system, including the follow up action taken.

5. <u>Repeated refusals of medication</u>

When a recipient refuses to take the same medication(s) 2 or more times in a 24-hour period or 4 or more times in a week, the following will be done:

a. The prescriber shall be notified on the first business day of the refusals. Staff should seek written guidance from the prescriber on what action, if any, should be taken when the recipient has frequent refusals.
b. The case manager/supports coordinator shall be notified on the first business day of the refusals. An amendment to the person-centered plan should be considered to address the medication refusals.
c. When addressing repeated refusals from the same recipient the pharmacist on-call will direct staff whether it is necessary to contact the pharmacist upon subsequent refusals. The pharmacist will provide information on how staff should document any future refusals and instruct staff to continue to submit incident reports, if needed. Should the recipient refuse any medication more than five times in a month, the extended refusals must be addressed with the prescriber/case manager. The responsible staff will then contact the prescriber and case manager on the first business day following the pharmacist directive to seek clarification and direction.

6. <u>Adverse Drug Reactions</u>

In the event the recipient experiences a severe adverse reaction, staff will call 911 and provide emergency care as needed. An incident report will be completed by the involved staff. On the first business day following a severe adverse reaction, staff shall notify:

a. Pharmacy
b. Prescribing physician
c. CMHA-CEI medical director

7. **Other medication issues**
   For issues involving medications that do not require an incident report, as noted above, information regarding the situation can be sent to the CMHA-CEI Medication and Pharmacy committee via secure email at MAP@ceicmh.org

H. Preparation and Cleaning of Medication Administration and Storage Area

1. Medication storage and administration areas are cleaned at least once per month with a freshly prepared bleach solution.
2. Medication administration areas are cleaned daily with soap and water, sprayed with a bleach solution, air dried, and then rinsed. The cleaning is documented.
3. A clean cloth is used for each area cleaned. Cleaning cloths are washed with ½ cup of bleach added to the wash cycle.

I. Responsibilities of the On Site Leader

Each program site must designate a staff person responsible for the oversight of medication administration. Typically this is the home manager, team leader, site coordinator, or senior staff member. The onsite leader is responsible for the following duties:

1. Ensure that written orders are on site and filed in the MAR book or Health section of the Consumer Record.
2. Ensure medications are ordered and available as prescribed.
3. Review MAR each shift worked.
4. Ensure errors are followed up in the appropriate manner.
5. Ensure errors are reported in the CMHA-CEI incident reporting system.
6. Ensure the staff administering medications have been trained.
7. Ensure discontinued/dropped medications are appropriately disposed of.
8. Ensure emergency numbers (poison control, physician, and after hours pharmacy) are posted in the medication administration area.
9. Ensure proper storage of medications.
10. Ensure proper cleaning of the medication storage and administration areas.
11. Upon receipt of pre-printed MAR, review the MAR for accuracy and completeness.
12. Ensure accuracy of transcription of medication changes to the MAR.
13. Ensure the effectiveness and side effects of the medication are reported to the appropriate team members and prescriber.

J. Prescription of Psychotropic Medication

1. This procedure shall apply to all psychotropic medication prescribed by CMHA-CEI employed or contracted prescribers.
2. Medication shall not be used as a substitute for other appropriate treatment, as punishment, or for staff convenience. A comprehensive treatment plan should be employed whenever appropriate. Other modalities of intervention include various forms of psychotherapy, psychosocial rehabilitation, etc. The role of medication treatment as well as its goals and limitations must always be borne in mind within the context of a comprehensive treatment plan.

3. When appropriate the prescriber will review alternatives to medications and alternative medications with the patient.
4. Program plans using psychotropic medications for behavior control purposes, and when the target behavior is not due to an active psychiatric disorder, not including the neurodevelopmental disorders, as described in the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM), must be reviewed and approved by the CMHA-CEI Behavior Treatment Committee.
5. Psychotropic medication may be administered to prevent physical harm or injury in the absence of other target symptoms only after signed documentation of the prescriber is place in the resident's clinical record and when the actions of the resident or other objective criteria clearly demonstrate to the prescriber that the resident poses a risk of harm to self or others.
6. Upon intake the prescriber shall review past medication use (including effectiveness, side effects, and allergies or adverse reactions), co-existing medical conditions, use of alcohol or other drugs, use of over the counter medications, and special dietary needs and restrictions associated with medication use.
7. Prescription of anxiolytics/sedative-hypnotics shall generally be the responsibility of the patient's primary care physician except when used in conjunction with other medications prescribed by CMHA-CEI prescribers or as an adjunct to other treatment approaches (outpatient therapy, day programs, etc.). CMHA-CEI prescribers shall not prescribe anxiolytics/sedative-hypnotics for persons not receiving other services.
8. Written or electronic orders shall be completed for all medications prescribed by CMHA-CEI physicians. Prescriptions shall be written on CMHA-CEI prescription forms, prescribed electronically through CMHA-CEI's current electronic prescribing system, or printed on appropriate paper via CMHA-CEI's current electronic prescribing system. All medications prescribed shall be recorded in the patient's clinical record (including the dosage, dispensing instructions, and quantity of medication prescribed). Each medication order will have a specific expiration date, minimal duration as determined by the prescriber's prescription, and number of refills. Safe termination of a medication will be determined at the discretion of the prescriber in accordance with accepted clinical practice and guidelines.
9. Prescriber orders will be provided to a pharmacy by one of the following methods:
    - **i.** On a tamper resistant prescription given to the patient/designee to take the pharmacy of their choice.
    - **ii.** On a tamper resistant prescription mailed to the pharmacy of the patient's choice by clinic staff.
    - **iii.** Faxed to the pharmacy of the patient's choice by clinic staff.
    - **iv.** Called to the pharmacy of patient's choice by a nurse or prescriber.
    - **v.** Via electronic prescribing.

    Nursing staff shall call, fax, or electronically submit prescriptions to the pharmacy only with a specific order from a CMHA-CEI prescriber or under the purview of current standing orders signed by a prescriber.
10. Before initiating a course of psychotropic medication treatment, the prescriber or a licensed health care provider acting under the delegated authority of the prescriber shall explain the specific risks and most common adverse effects associated with that drug.

11. Prescriptions for controlled substances will be written in accordance with all Federal and state laws.
12. Patients/guardians shall provide consent for medication prior to the administering of any medication. Physicians may, however, without the consent of the patient, prescribe or administer medication in order to prevent a recipient from physically harming themselves or under a court order.
13. A written summary of common adverse effects of the prescribed medication shall be given to the patient and/or guardian. This will generally be provided by the pharmacy filling the prescription for a medication.
14. Prescribers shall take into account the patient's insurance benefits and ability to afford or otherwise obtain a mediation when making decisions about prescribing. When appropriate, prescribers will review the availability of indigent drug programs or use of samples.
15. Initial administration of psychotropic medication may not exceed 48 hours without consent of the patient/guardian. The duration of the use of psychotropic medication administered without consent shall be as short as possible and at the lowest possible dosage that is therapeutically effective. Psychotropic medication administered without consent shall be discontinued as soon as there is little likelihood that the recipient will pose a risk of harm to themselves or others. Additional psychotropic medication may be prescribed and administered if the recipient decompensates and again poses a risk to themselves or others.
16. MDHHS standards shall guide the prescription, administration, and monitoring of psychotropic medication. Reasons and/or justification for deviation from these guidelines shall be documented in the clinical record.
17. Baseline and periodic studies shall be performed in accordance with the pharmacology of the specific drug used. The exact laboratory test(s) required shall be determined by clinical judgment after considering the patient's medical and drug histories, pharmacology of the medication to be used, and the anticipated duration of medication use.
18. While monotherapy is preferred, it is also widely recognized that multiple medications, including medication prescribed off-label, may be needed to treat many psychiatric symptoms and conditions. When two or more psychotropic medications are used, the prescriber shall document in the clinic record the justification, as well as the rationale, for the concomitant use of two or more psychotropic medications. Additional psychotropic medications for associated symptoms, e.g., insomnia, anxiety, and so forth, shall be used only when the primary psychotropic medication is not controlling such symptoms.
19. Patients shall be expected to comply with treatment by taking medications as prescribed. Non-compliance shall be addressed as a treatment issue.
20. It is the responsibility of the staff person responsible for coordination of the patient's plan of service and/or the team nurse to monitor significant changes in target symptoms and behaviors, side effects, and adverse reactions. Effects observed or reported by the patient/guardian/direct care staff/caretaker shall be recorded and brought to the attention of the prescriber.
21. Clinical staff, including the prescriber, shall review the efficacy of the psychotropic medication as appropriate, as determined in the recipient's person-centered plan or by

the recipient's clinical status. The review shall include discussion of the recipient's needs and preferences; presence of adverse, side, or unusual effects; possible use of multiple medications; drug interactions; and any contraindications.

22. The contract pharmacist will contact prescribers when there is therapeutic duplication and/or other clinical issues

23. The prescriber will contact the primary care physician or other prescribers when indicated.

24. Dosing

- **i.** Dosage levels shall not ordinarily exceed those specified in the medication's FDA-approved prescribing information
- **ii.** If dosage levels are in excess of the maximum, the medical rationale shall be documented in the patient's clinical record.
- **iii.** The medication regimen shall be individually determined by considering the patient's need, age, sex, weight, physical condition, health status, other medications, and any previous adverse reactions to medication.
- **iv.** Patients, parents of minor children, empowered guardians, or other caretakers as requested by the patient shall be advised of side effects and requested to report the occurrence of side effects to a licensed health care professional.
- **v.** Patients shall be checked and routinely monitoring for the presence of any condition affecting therapy.
- **vi.** Medication quantities shall not ordinarily exceed a one (1) month supply with two (2) refills or enough refills to provide a supply to the next scheduled psychiatry appointment if the appointment is more than three months away. If staffing allows, review of medication, rewriting of medication orders, and reexamination of the patient should occur at least every three (3) months by a prescriber. A three month supply of medication may be considered by the prescriber, at the request of the patient, in cases where there is a significant hardship imposed by the cost difference of three one-month supplies and one three-month supply. Such requests will only be considered when a patient has been stable on the medication for a significant period and having such a quantity available does not pose significant clinical risk.
- **vii.** After the desired clinical result is obtained and the patient's condition has stabilized, the medication shall be maintained at the minimum maintenance dose needed, or the patient may be titrated off the medication, if clinically indicated.

25. If a patient's medication is changed, a progress note shall be entered to correspond to that change and include the rationale for that change.

26. The use of psychotropic medications on a PRN basis is seldom indicated. When PRN orders are written, the prescriber shall document in the progress notes the justification as well as the rationale for the PRN order. There shall be an order and a dose for each route of administration. Orders shall also describe the specific conditions and behaviors in which the PRN order is to be administered, and PRN orders shall limit the number of doses to be administered within a 24-hour time period.

- **i.** The dosage of PRN and scheduled orders for psychotropic drugs shall not exceed the total daily cumulative dosage as designated in #24 (Dosing) above.

ii. PRN orders of psychotropic drugs (other than oral sedative-hypnotics and anxiolytics used for the treatment of insomnia and anxiety) shall be limited to 24 hours and only renewed with significant medical justification.

27. Abnormal Involuntary Movement Scale (AIMS) screening shall be performed at least quarterly on recipients receiving antipsychotic medications, and prescribers or delegated staff shall document both positive and negative ratings. Follow-up shall be instituted as clinically appropriate. In those groups considered to be at elevated risk of tardive dyskinesia there shall be quarterly evaluation of the need for continuous use of antipsychotic agents.
28. The decision to use psychotropic medications during pregnancy and lactation must depend upon considerations of effects on fetal and neonatal development and a primary concern for the health and safety of the mother upon whom the fetus and neonate are dependent. Consideration of the risks must be documented in the clinical record.
29. Investigational drugs will only be used when approved according to CMHA-CEI Policy 1.1.6: Research, Publication, and Related Projects and Procedure 1.1.6: Research, Publication, and Related Projects.

K. <u>Informed Consent</u>

1. Consents shall be obtained by the prescriber or by a registered nurse when:
   i. A new medication is prescribed
   ii. A medication is prescribed for the first time outside of Federal Drug Administration labeling
   iii. When new and significant information about a prescribed medication (adverse reactions, serious side effects, contraindications, black box warning by the FDA) is identified.
2. Prior to obtaining informed consent for a medication, the prescriber shall provide information to the patient /guardian including but not limited to:
   i. Purpose of the medication
   ii. Benefits of the medication
   iii. Risks
   iv. Common and serious adverse effects
   v. Right to refuse medication
3. Annual medication consents will be obtained by a registered nurse or prescriber:
   i. Consent shall list all medications currently prescribed by a CMHA-CEI prescriber
   ii. Each medication clinic shall develop an operating guideline to identify the process for:
      1. Flagging the need for the annual medication consent
      2. Entering a complete list of prescribed medications on the medication consent
      3. Obtaining the consent and signature of the patient/guardian
   iii. The nurse or prescriber will meet with the patient to obtain their signature on the annual re-consent and to respond to questions/concerns as needed.

L. <u>Injectable Psychotropic Medications</u>

1. In order for injectable medications not paid at the point of sale (the pharmacy) and the administration of injectable medications to be reimbursed, the following elements are necessary prior to the finance department submitting billing:
    i. For Medicare and commercial insurance, a physician must be present in the suite where the injection is given.
    ii. For Medicaid only, the administration of the medication may be delegated to a RN. In this case, the physician does not need to be present.
    iii. Regardless of payor source, the injection must be billed under the supervising physician's staff ID code.
2. "Supervising physician" ordinarily refers to the physician who is present in the suite/office at the time the injection is administered. "Ordering physician" refers to the physician who issued the prescription itself. See below for further detail.
3. Process for injections:
    i. Program staff, generally nurses or clerical staff, enter data for both the medication and the administration
    ii. Program staff will assure that the supervising physician's staff ID code will be entered as appropriate for each J-code and administration service.
        1. If there is no physician present in the suite, the ordering physician should be listed as the supervising physician.
        2. If there is no physician present in the suite and the ordering physician is no longer affiliated with CMHA-CEI, the Medical Director should be listed as the supervising physician.
    iii. Program staff maintain a list of patients who received an injection without a physician present, and submit this list to Reimbursement on a weekly basis.
4. Expectations regarding injectable medications:
    i. It is expected for patients with Medicare or commercial insurance that every effort will be made to administer injections with a physician on-site.
    ii. Injections given without a physician present shall be completed only when the risk to the patient resulting from not receiving the injection outweighs the risk to the program by loss of reimbursement due to unavailability of a physician.
    iii. When patients insured by Medicare or commercial carriers present for an injection and a physician is not present, the following options shall be considered:
        1. If the patient's injectable medication was paid for at the point of sale (the pharmacy) or is a sample, proceed with the injection.
        2. If the injectable medication was not paid for at the point of sale and is not a sample:
            a. The patient's injection may be rescheduled to a time when a physician will be present.
            b. The patient may go to or be transported to a site/suite where a physician is present, and the injection may subsequently by administered.
            c. If there is a clear clinical need for the patient to receive an injection, and neither of the above options is practical, the injection may still be given. However, such injection will not be

reimbursable, and the program must maintain a list of all such injections for submission to Reimbursement. Note that, as above, this list should include all injections given without a physician present, regardless of payor.

M. <u>Sample Medications</u>

1. CMHA-CEI will receive all samples from pharmaceutical company sales representatives or directly from the pharmaceutical company and then transfer the supply to CMHA-CEI's contracted pharmacy.

i. CMHA-CEI and the contracted pharmacy will maintain all records necessary to comply with Federal and state law and with all applicable requirements.

ii. The contracted pharmacy will provide staffing for the transfer of samples to and from community clinics.

iii. CMHA-CEI will provide the contracted pharmacy with a list of facilities and programs that will be taking part in the program.

2. Pharmaceutical company representatives will communicate with the contracted pharmacy in order to maintain adequate inventory levels.

3. CMHA-CEI and its contracted pharmacy will maintain necessary records of the transfer of sample medications made between them.

i. The contracted pharmacy and CMHA-CEI will have a designated contact person to answer any concerns.

ii. All contact people should be available during regular business hours or should appoint alternates if they will be unavailable.

4. CMHA-CEI's contracted pharmacy will provide sample storage and a separate sample inventory from the retail stock.

i. Inventory will be perpetual and available to CMHA-CEI at mutually agreed upon intervals.

ii. The contracted pharmacy will monitor all samples and remove all expired medications from inventory.

iii. The contracted pharmacy will communicate to CMHA-CEI when samples are needed from pharmaceutical companies.

iv. The contracted pharmacy will provide a monthly sample medication inventory to CMHA-CEI clinical staff that can be used for possible future prescribing when possible.

v. If appropriate for a specific medication, the contracted pharmacy will provide an inventory of samples that will be kept at sites for emergency use.

5. The contracted pharmacy will dispense samples only to those patients designated by CMHA-CEI.

i. CMHA-CEI staff must identify those patients who are to receive samples from the contracted pharmacy.

ii. CMHA-CEI staff will provide the contracted pharmacy with a written or electronic prescription and a communication that samples can be used when dispensing occurs.

iii. The contracted pharmacy will review all designated patients for possible insurance coverage, drug interactions, and allergies prior to dispensing samples.

iv. If prescription drug benefits cannot be verified the contracted pharmacy will then dispense prescribed samples at no cost to the patient.
v. CMHA-CEI will be notified of any problems related to the provision of samples to patient.

III. Responsibilities:

A. The Medical Director shall provide consultation in regard to the prescription of medication.
B. All staff of the CMHA-CEI network and providers involved in prescribing, dispensing, storing, administering, and disposing medication shall understand and comply with the established procedures and relevant professional standards of practice.
C. The Medical Director shall ensure that all staff involved in prescribing, dispensing, storing, documenting, administering, and disposing medications and related functions have the appropriate credentials and training.
D. The Medical Director, through the quality improvement process, shall review medication errors and develop a mechanism to reduce the occurrence of such errors.

IV. Definitions:

A. ***Administering (or administration of) medications:*** Functions necessary for staff to deliver a medication to a recipient.
B. ***Competency:*** The abilities to communicate a choice, to understand the relevant information, to appreciate the medical consequences of the situation, and to reason about treatment choices. (New England Journal of Medicine, November 1, 2007)
C. ***Controlled substances:*** Those substances regulated as per the Michigan Public Health Code (Act 368 of 1978), Article 7, Part 72.
D. ***Documenting:*** Recording information regarding medications prescribed, dispensed, administered, and discontinued.
E. ***Dispensing:*** Preparing, compounding, packaging, or labeling a drug pursuant to a prescription or other authorization issued by a prescriber.
F. ***Drug:*** A medication or other substance which has a physiological effect when ingested or otherwise introduced into the body.
G. ***Informed consent:*** Written consent voluntarily signed by a recipient who is competent and who understands the terms of the consent, or by the recipient's legal guardian.
H. ***Investigational drug:*** Those drugs that have not been released by the FDA for general use or FDA-approved drugs that are being used in an investigational study.
I. ***Medication:*** A substance intended for use in the diagnosis, cure, treatment, mitigation, or prevention of disease or any substance prescribed to address a medical condition.
J. ***Mono-therapy:*** Prescription of a single drug from a specific drug class.
K. ***Off-label medication:*** FDA approved drugs used to treat conditions outside of the approved indications but consistent with standards of practice.
L. ***Polypharmacy:*** The use of multiple medications from one drug class in the same patient at the same time.

M. ***Prescriber:*** A healthcare professional licensed and authorized under state law to order medication. These include physicians, dentists, nurse practitioners, and physician's assistants.
N. ***Prescribing:*** Ordering medication in a specific type, dosage, and amount for an individual.
O. ***Prescription:*** A documented order from a prescriber for a medication to be dispensed to a specific individual. This order must contain the name of the substance, the route, dosage, frequency, number to be dispensed, and number of refills.
P. ***Psychotropic medications:*** Medications prescribed to treat disorders of mood, thought, or behavior. This may include medications in the following categories:
    a. Antidepressants
    b. Antipsychotics
    c. Lithium and other mood-stabilizing agents
    d. Anxiolytics
    e. Sedatives/hypnotics
    f. Psychostimulants
Q. ***Schedule II drugs:*** The classification of controlled drugs as defined by Article 7 of the Michigan Public Health Code (Act 368 of 1978). [MCL 333.7213 and 333.7214]

V. Monitoring and Review:

This policy is reviewed annually by the Medical Director. It is monitored by accrediting bodies and regulatory agencies as applicable.

VI. References:

A. PA 258 of 1974, "Michigan's Mental Health Code", as amended
B. PA 368 of 1978, "Public Health Code", as amended
C. MDHHS Administrative Rules R330.7158

VII. Related Policies and Procedures:

CMHA-CEI Policy 3.5.1	Medication
CMHA-CEI Policy 1.1.6	Research, Publication, and Related Projects
CMHA-CEI Procedure 3.5.1A	Zyprexa Relprevv

VIII. Review Log:

Review Date	Reviewed By	Changes (if any)
11/06/01	-	-
06/10/05	-	-
12/04/07	-	-
05/26/10	-	-
05/11/11	-	-
02/11/12	-	-
03/10/13	-	-
09/15/13	Jennifer L. Stanley, MD	None significant

10/31/16	Jennifer L. Stanley, MD	Medication disposal changes
02/21/17	Jennifer L. Stanley, MD	Minor changes
4/17/2017	Jennifer L. Stanley, MD	Major revision – combined multiple previous medication procedures and previous policy into this procedure; formatting revision
7/14/17	Medical Director	References to Yellow Jug Old Drugs removed