COMMUNITY MENTAL HEALTH SERVICES OF MUSKEGON COUNTY

PROCEDURE

NO. 06-009

Prepared by:

Pharmacy Work Group

Effective: 2/26/97
Revised: 5/02/07
Revised: 6/1/11

SUBJECT: Maintenance of Formulary of Approved Medications

Approved by:

_____

John North, Executive Director

I. PURPOSE:

To assure the maintenance of an approved formulary for all medications prescribed or administered at Community Mental Health Services of Muskegon County, for the treatment of psychiatric disorders or the side effects of psychotropic medications.

II. APPLICATION:

Medications prescribed by CMHS contracted Physicians/PA/NP to individuals receiving services, for the treatment of psychiatric disorders or the side effects of these medications.

III. DEFINITIONS:

Formulary: A catalogue of the medications approved for agency use in the treatment of psychiatric disorders and the side effects of those medications. The formulary shall include the generic name of the drug, common proprietary name, normal dosage range, and number of the corresponding medication teaching sheet.

IV. PROCEDURE:

A. The Formulary of Approved Medications (M016 – Attachment A) in its entirety shall be reviewed and updated by the Pharmacy Work Group, and approved by the Doctors Work Group, annually during the first quarter of each calendar year.

B. The formulary may also be revised and approved by the Doctors Work Group as needed throughout the year, without amendment to this procedure.

C. The chairperson of the Pharmacy Work Group shall ensure that a copy of the current formulary is forwarded for attachment to this procedure and kept by contracted Physicians/PA/NP in all areas where medications are prescribed.

D. Physicians/PA/NP shall routinely prescribe for individuals receiving services only medications from the formulary.

1. Medications included on the formulary shall be specifically prescribed in order to treat psychiatric disorders or medication side effects, but not non-psychiatric medical disorders.

2. In cases where non-psychiatric medications are indicated and no primary care physician is available, only existing prescriptions may be extended; however, the primary worker shall make every effort to promptly link the individual with a primary care physician.

E. Addition of non-formulary medications.

1. In cases where non-formulary medications are prescribed, a request for inclusion of the medication in the formulary must be submitted to the chairperson of the Pharmacy Work Group by the physician using the Request for Changes in the Psychotropic Medication Formulary form (M010 – Attachment B).

2. The Pharmacy Work Group shall review the request for inclusion and ensure that it is placed on the agenda with recommendations for consideration at the next monthly meeting of the Doctors Work Group. Minutes of the Doctors Work Group meeting will include documentation of Formulary decisions.

3. Without specific exceptions approved by the Pharmacy Work Group and the Doctors Work Group, non-formulary medications may not be prescribed for an individual receiving services for more than three months, without inclusion in the formulary. These exceptions would allow further evaluation of the use of a specific medication.

F. Implementing Additions of Medications to the Formulary

1. Following approval by the Doctors Work Group, the Pharmacy Work Group Chairperson shall facilitate updating of the formulary by:

   a. Providing the recommended dosage range for inclusion in the formulary.
   b. Developing a Medication Teaching Sheet.
   c. Ensuring prompt distribution of the revised Formulary and Teaching Sheet to affected staff.

G. Deletion of medications from the formulary.

1. A Physician/PA/NP may request that a medication be deleted from the formulary by completing and forwarding a Request for Changes in the Psychotropic Medication Formulary form (M010) to the chairperson of the Pharmacy Work Group.

2. The Pharmacy Work Group shall review the request for deletion and ensure that it is placed on the agenda with the recommendations for consideration at the next

monthly meeting of the Doctors Work Group. Minutes of the Doctors Work Group meeting will include documentation of Formulary decisions.

3. The Pharmacy Work Group chairperson shall facilitate updating of the Formulary and ensure prompt distribution of the revised Formulary to affected staff.

V. REFERENCES:

ATTACHMENT A: M016 – Formulary of Approved Medications
ATTACHMENT B: M010 – Request for Changes in the Psychotropic Medications Formulary

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APPENDIX A

MEDICATION ADMINISTRATION GUIDELINES

A. ADMINISTERING

1. Observe the Five Rights:

    a) Right person
        1) Prior to administering medication, staff will confirm the identify of the recipient using at least two approved sources specified on CMH Form C154R
    b) Right time
    c) Right route
    d) Right dosage
    e) Right medication

        1) If there is anything unusual about the appearance or smell from the previous supply, do not give the medication until you check with the pharmacist/nurse. If the medication must be held, the nurse must be notified.

        2) If the wrong medication or dosage is supplied by the pharmacy, the staff member will immediately notify the RN who will then inform the pharmacy of the error, and facilitate securing the right medication. The staff person will promptly complete an incident report.

    f) Right reason – for prn medication

2. Work with adequate light.

3. Always wash hands before preparing medications and between each client.

4. Provide a clean environment for preparing medications and assemble all supplies needed to administer medications, (water, spoons, applesauce, etc.).

5. Use the monthly medication sheet to prepare medication. Check with the monthly medication sheet:

    a) To label on medication card/bottle.
    b) When removing medication from card/bottle.
    c) Before giving medication to the client.

6. While preparing or administering medications, concentrate on this alone.

7. Medications shall be prepared at the time of administration for each individual client.

8. Medications are never to be left out unattended for any reason.

9. Be knowledgeable about the medications you give:

    a) Why and how it is being given.
    b) Possible side effects and adverse reactions, and what to do if they occur.

10. Administer only medications that you have prepared personally and administer only in designated medication-passing areas.

11. Give medications as prescribed and on time. Medications can be administered 30 minutes before or after the prescribed time. To administer outside of this time frame, the RN must be notified.

12. Persons with known drug allergies must have charts and medication bins labeled with red "allergic" labels. Medication record must have allergies noted and highlighted in red.

13. Have prescriptions refilled several days before medications run out. (Seven days for group homes).

14. The nurse will check any changes to the medication orders, on the medication sheet, made by someone other than the nurse, at the earliest feasible time. The staff member making the change will be responsible for alerting the nurse of the change.

15. If you find any discrepancy between the medication record or pharmacy label, consult with the nurse consultant for clarification.

16. If a documentation error is made on the medication sheet, circle it, notify the home supervisor, document explanation and fill out an incident report.

17. Only approved abbreviations can be used. Abbreviation form (M007) should be posted.

18. All pertinent information must be documented! If it is not documented, it didn't happen!

19. Document medications immediately after you pass them and before starting preparation for the next client.

20. Avoid interruptions or distractions while preparing or administering medications. Be attentive.

B. SPECIFIC TYPES OF MEDICATIONS

1. Suspensions are to be shaken well and measured into a measuring cup, with care being taken to keep the outside of the container and cap free of medication.

2. Oral medications may be offered with liquids or applesauce followed with a glass of liquid.

C. GIVING THE MEDICATIONS TO THE RECIPIENT

1. Positively identify the recipient using at least two sources of identification.

    a) **NEVER** give anyone any medication that has not been prescribed by a person who is licensed to prescribe.
    b) **NEVER** use a medication ordered for one person to treat another.
    c) **NEVER** give a medication to one person from another person's medication bottle.
    d) **NEVER** force a medication.
    e) **NEVER** return an unused dose of medication to the bottle.

2. Provide privacy if appropriate.

3. Give the recipient the medication(s) being careful not to handle the medication with fingers.

4. Assure that medications have been swallowed by visually checking the mouth cavity if necessary.

D. STAT MEDICATION ADMINISTRATION FOR BRINKS RESIDENCE, ACT AND COUNTY MENTAL HEALTH CENTER (SOUTHERN)

1. Refer to STAT Medication protocol at each site.

/lec (3/19/03)

COMMUNITY MENTAL HEALTH SERVICES OF MUSKEGON COUNTY

POLICIES AND PROCEDURES

NO. 06-010

Prepared by:
Cyndi Blair, Chairperson
Pharmacy Work Group

Effective: June 1, 1989
Revised: February 6, 2008
Revised: August 9, 2011

Subject: Medication Management

David Parnin, Chief Operating Officer
Community Mental Health Services of Muskegon County

I. POLICY

Medications listed on the Community Mental Health Services of Muskegon County formulary and deemed medically appropriate for individuals receiving services at this agency will be prescribed and managed in a safe and effective manner.

II. PURPOSE

To establish policies and procedures for prescribing, monitoring, administering, storing, and documenting the use of medications.

III. APPLICATION

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

IV. DEFINITIONS

A. **SERIOUS ADVERSE DRUG REACTION:** Any adverse event occurring at any medication dose that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization, or prolongation of an existing hospital stay, a persistent or significant disability/incapacity, or a congenital anomaly or birth defect, or requires medical or surgical intervention to prevent permanent impairment or damage to the individual receiving services.

B. **CMH:** Community Mental Health Services of Muskegon County.

C. **INDIVIDUAL RECEIVING SERVICES:** Any person receiving mental health services at CMH.

D. **INVOLUNTARY INDIVIDUAL:** An individual receiving services under Probate Court-ordered treatment.

E. **RECORD:** The individual's electronic clinical file.

F. **MEDICATION:** Prescription medications given 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.

G. **PHYSICIAN:** An M.D. or D.O. licensed in Michigan, and under contract with CMH.

H. **PA:** Physician's Assistant licensed in Michigan and under contract with CMH.

I. **NP:** Nurse Practitioner licensed in Michigan, and employed or under contract with CMH.

J. **NURSE:** Registered Nurse (RN) licensed in Michigan.

K. **HP:** Health Professional – Physician, PA, NP, or Nurse.

L. **PRIMARY WORKER:** Supports Coordinator (SC), primary therapist, or other clinical staff person who is assigned primary responsibility for case coordination.

M. **PSYCHOTROPHIC DRUG:** Any medication administered for the treatment or amelioration of disorders of thought, mood, or behavior.

N. **STAT:** Immediately.

V. PROCEDURES

Overview of Section:

A. GENERAL

1. Medication shall be prescribed only by a Physician, PA, and Nurse Practitioner (NP) under the supervision of a physician.

   a. All such Physician/PA/NP shall demonstrate competency with medications through medication utilization studies, peer review, pharmacy and therapeutic reviews, and record pertinence.

   b. Medication regimens must be determined by considering the individual's diagnosis, age, sex, weight, physical condition, other illnesses, other medications, and previous medication history including history of adverse side effects or reactions.

   c. The Physician/PA/NP or nurse must directly assess the individual as frequently as necessary to establish a maintenance dosage, decrease or eliminate target symptoms, and monitor for side effects of medications.

d. Medications shall be maintained at the minimum dose necessary to decrease or eliminate target symptoms. Once a maintenance dosage is reached, direct contact with a Physician/PA/NP shall be scheduled at least every three (3) months for the purpose of documenting the continued need for medication as well as the presence/absence of side effects.

1) If the individual is treated in a CMH residential setting, the individual's medication shall be reviewed at least once every thirty (30) days by a Health Professional to determine the appropriateness of continued use.

e. All medication reviews shall be documented in the record as a progress note or psychiatric evaluation.

f. Medications prescribed for an individual shall be given to and used only by that individual.

g. No psychotropic medication should be prescribed during pregnancy unless it is clearly needed and potential benefits for the individual outweigh potential hazards to the fetus.

h. A Physician/PA/NP may prescribe an FDA approved medication for an unlabeled indication when such use is based upon sound scientific evidence, sound medical opinion, or anecdotal clinical evidence. When a Physician/PA/NP departs from the FDA's labeling, with regard to indication, a Physician's Progress Note (or Psychiatric Evaluation) must be written and included in the individual's record documenting clinical justification.

i. The prescribing of only one (1) psychotropic medication from the same medication class is encouraged. (See Appendix G: Practice Guideline 12-010: Simultaneous Use of Multiple Psychotropic Medications.)

2. Formulary of Approved Medications

a. Dosage levels for medications shall not ordinarily exceed those specified in the current Physician Drug Reference (PDR) and listed in the formulary.

b. When dosage levels are prescribed above the range listed in the formulary, the Physician/PA/NP shall document the medical rationale via each Physician's Progress Note/Psychiatric Evaluation. Specific informed consent shall be obtained per established protocols, but indicating the dosage range is above the normal range listed in the formulary.

3. Unfilled Schedule II prescriptions expire in sixty (60) days.

4. PRN (as needed) medications:

a. Orders for PRN medications shall contain precise instructions about dosage and clear descriptions of the intermittent target symptoms for which the medication is to be administered.

b. The use and benefit of PRN doses must be documented by a Health Professional.

5. When individuals are discharged from residential settings, medication instructions shall be written and explained to the individual and/or guardian.

   a. Only those medications authorized by a Physician/PA/NP are to be given to the individual/guardian at discharge or leave of absence.

   b. Enough medication will be made available to ensure the individual has an adequate supply until he or she can become established with another provider.

B. DOCUMENTATION

1. The following documentation shall appear in the record of any individual receiving medication at CMH:

   a. Psychiatric evaluation shall include the individual's:

      1) Psychiatric history, including psychiatric medications within the previous year, if available.
      2) Medical history, including significant non-psychiatric medication history.
      3) Mental status examination.
      4) Diagnosis by Physician/PA/NP.

   b. Physician's/PA's/NP's Progress Note shall include the individual's:

      1) Description of target symptoms, their improvement or lack of improvement.
      2) Medication side effects.
      3) Medication changes.
      4) The use and benefits of PRN medication, if prescribed.
      5) Lab tests ordered and/or review of results.

   c. If more than one (1) psychotropic agent is simultaneously prescribed from the same medication class (i.e., antipsychotic, antidepressant), the rationale for continuation or a plan for discontinuation must be documented in the record via each Physician's Progress Note/Psychiatric Evaluation.

   d. Medication dosage, schedule, amount, and refills, with signature of Physician/PA/NP.

      1) The history of medications prescribed will be maintained using current electronic format.

   e. Individual Plan of Service authorized by Physician/PA/NP.

      1) Whenever an individual is prescribed medications by CMH, at least one (1) health and safety goal will be written addressing medications

by the primary worker responsible for documenting the plan. These goals/objectives may include educating the individual about the medications, eliminating target symptoms, reducing side effects, ensuring adherence, obtaining the minimum effective dosage and/or wellness management and recovery.

f. Laboratory monitoring as appropriate to medication ordered.

1) Only a Physician/PA/NP may order lab work.

2) The Laboratory Telephone Report (M012) allows an HP to obtain lab values over the phone; this should be discarded when the final written lab report is placed in the record.

3) The Physician/PA/NP will review and initial the laboratory report, and write or dictate a progress note or make a notation on the lab sheet addressing any significant abnormalities in the results.

4) Nurse will complete Physician's Appointment/ Communication (C204) and forward with the lab results to the primary care physician.

g. Informed consent (C148) for each medication prescribed, with documentation that educational materials were given to the individual.

h. Other prescribed medications from non-CMH sources and over-the-counter drugs and nutritional supplements using current electronic format.

1) This shall be a nursing responsibility, updated at each Physician/PA/NP contact.

i. Approved CMH medical abbreviations shall be used when documenting. (See Appendix B).

C. PRESCRIPTIONS

Prescription medication quantity for all individuals receiving services may be up to three (3) months' supply. A Physician's/PA's/NP's Progress Note must describe in detail each prescription written including name of drug, strength, dosage, and target symptoms. Medication requests between appointments will be documented using the Medication Request form (C179). A controlled substance shall not be ordered on the same prescription form as a non-controlled drug.

1. Electronic Orders

a. Prescriptions shall be completed using the current electronic format.

b. The prescription shall be signed only by a Physician/PA/NP. A Schedule II prescription shall be printed on tamperproof paper and countersigned by a Physician.

2. Written Orders

   a. Whenever the current electronic format is not available, prescriptions shall be written only on CMH duplicate tamperproof printed forms.

      1) Physicians/PAs/NPs will use CMH prescription forms only for CMH individuals receiving services.

3. Verbal Orders

   a. Only a HP may receive and document a verbal order.

   b. When receiving a verbal order, the HP will write down the order and then repeat it back verbatim to the prescriber. The prescriber will then verbally confirm that the order is correct. This should include name of drug, strength, dosage, quantity, and rationale for the medication change.

   c. Only a HP may call the prescription in to a pharmacy. The prescription shall be entered into the current electronic format. The HP will notify the individual/care giver/guardian.

   d. When current electronic format is not available, the HP will document on a Verbal Order form (C005). The form will be forwarded promptly to the Physician/PA/NP for signature. The form will be scanned into the client record.

   e. Consent for new medications initiated by Verbal Order shall be obtained as outlined in Section F.

D. ADMINISTRATION and STORAGE

1. All medication administered in CMH programs and CMH residential facilities shall be kept in locked cabinets or boxes accessible only to HP's/contracted pharmacists, and staff members trained by CMH nurses and/or qualified staff.

   a. If medications require refrigeration, they will be stored in a locked box in the refrigerator on site, with the temperature maintained between 36-44 degrees Fahrenheit.

   b. Medication cabinets or carts shall not be located in areas with excessive heat or moisture.

   c. Medication cabinets or carts shall be used only for medication storage. They shall be kept clean and orderly.

   d. If medication bins are used, each bin shall be labeled with the individual's name and allergies.

   e. Medication storage sites shall be inspected quarterly by a nurse or pharmacist. Monthly repeat inspections will be completed if a deficiency is identified. (Inspection Checklist for Medication Storage Sites [Q001].)

2. All prescription medications must be kept in an original pharmacy container with the original label.

    a. Prescription medication containers shall have the following information: the individual for whom they are ordered, pharmacy name and address, medication name, dose and frequency of administration, quantity dispensed, name of prescriber, date filled, and initials of pharmacist filling the prescription.

    b. If a prescription dosage is changed, then a new label must be written and initialed by an HP or obtained from the pharmacy indicating the new regimen, and the new label shall be affixed to the container.

    c. If any discrepancy is found between the medication record and pharmacy label, the staff member must consult with the nurse or pharmacist for clarification and complete an Incident Report (IR).

3. All non-prescription medications must be kept in the original stock bottles with the original label.

    a. The bottle will be labeled with the individual's name.

    b. The non-prescription medication will only be administered per the Physician's/PA's/NP's orders.

4. Medications may only be administered when the following are in the record:

    a. Current prescription or Verbal Order form.

    b. Signed informed consent for medications prescribed by a CMH Physician/PA/NP with documentation that medication teaching sheets were given as outlined in Section F.

    c. Medication brought into a CMH or contracted facility by an individual or a significant other will not be administered from containers or prescriptions dated more than thirty (30) days from the date of receipt by staff. Medication with a container/prescription older than thirty (30) days can only be administered after reauthorization by an HP.

5 Medications may be administered only by a Physician/PA/NP/Nurse or by direct-care staff who have taken and passed a CMH medications training class and according to guidelines contained in Appendix A.

    a. Specific clinical programs will determine which non-HP staff shall be trained and authorized to administer medications.

    b. Training shall be provided for designated staff by a CMH nurse and/or qualified staff on an ongoing basis.

    c. Documentation of dates and attendance will be kept by the site supervisor and CMH training unit.

6. Self-Administration of Oral or Topical Medication

   a. While receiving services from a CMH operated or contracted residential or day program, an individual may self-administer his/her medication only when approved in a written order by the Physician/PA/NP, specified in the Person-Centered Plan, and monitored by trained staff. The Physician/PA/NP must assess the individual's capacity to self-administer medication and document that an appropriate level of competency exists at the time the order to self-administer medication is written.

   b. Significant care givers, such as parents, spouses, etc., who administer CMH prescribed medications to individuals must receive instruction from an HP or authorized supervisory or direct care staff and be provided with the following information:

      1) The nature of the medications to be administered.
      2) How to administer medications such as the appropriate frequency, route of administration and dose.
      3) The expected actions and side effects of the medications to be administered.
      4) How to monitor the effects of the medications on the Individual.

      The staff who provide the specific instruction must determine and document if the significant care giver is competent to safely administer the prescribed medications.

   c. When it is determined by a CMH Physician/PA/NP that an individual receiving outpatient services (i.e., therapy, case management, ACT) requires CMH assistance in learning to safely self-administer their medication, it must be documented in a psychiatric progress note and incorporated in the individual's Plan of Service. The nature and duration of CMH assistance must be specified. Once sufficient competency is acquired on the part of the individual, assistance in self-administration of medication will be discontinued.

7. Procedure for Insulin Administration and Blood Glucose Monitoring

   a. Nurse will assess the clarity of the physician's orders and the individual's ability to self-administer insulin, to monitor blood glucose, to understand the physician's orders, to prepare accurate amount of insulin and administer the insulin.

   b. If a Nurse determines the individual is not capable of all or some aspects of self-administration of insulin, a Nurse or staff appropriately trained by a Nurse will monitor/assist with prescribed orders for insulin administration.

8. Procedure for Administration of Injectable Psychotropics

   a. Nurse will verify last Physician/PA/NP progress note and prescription. Current order must be within ninety (90) days.

b. Nurse will note all new orders or changes in orders on Injection Record (C264) and in the CMH Injection Database. Nurse will highlight each prescription entry made on the Injection Record sheet.

c. Medication will be administered with an appropriate 21-guage needle. Medication will be administered IM, with the exception of Haldol Decanoate, which will be administered Z-track.

d. A nursing progress note will be completed after each injection.

e. Injection Database will be updated after each injection.

9. Procedure for STAT Medications

a. An emergency STAT medication box shall be secured at the Mental Health Center Main Medication Room and Brinks sample medication cabinet.

b. The contents of the STAT medications box as determined by the Doctors Work Group and the medical director will include: Zyprexa Zydis (Olanzapine) 10 mg #5 tabs, Ativan (Lorazepam) 1 mg #5 tabs, Cogentin (Benztropine) 1 mg #5 tabs. Additions or deletions will be subject to the approval of the Doctors Work Group.

c. The STAT medications will only be used to fill a STAT order given by a Physician/PA/NP. The only time staff other than an RN will administer the oral medication is when they are given a handwritten prescription or a verbal order from an RN.

d. A notebook will be kept with the STAT medication box, which will include a list of the contents, medication usage logs, and quarterly inspection records.

e. RN will document STAT orders on a Verbal Order Form (C005), including all pertinent information if no written order from the Physician/PA/NP is available. All staff involved in administering STAT medication will document on a progress note all instructions received from the nurse and will include a note regarding the effect of the STAT medication administered.

f. An entry must be made on the STAT Medication Inventory and Use log (M083) any time a medication is taken from the box, including:

1) Date
2) Name of medication
3) Dose
4) Name of individual receiving services
5) Case number
6) Name of the person who prescribed the medication
7) Name of the person administering the medication

g. The designated CMH RN responsible for the quarterly medication storage inspection will be responsible for inventory of medication in the STAT medication box to ensure that outdated medications are removed, destroyed, and replaced. This will be documented on the STAT Medications Quarterly Inspection form (M084).

h. Replacement medications will be prescribed by a CMH Physician/NP/PA ordered from the pharmacy and delivered to the Mental Health Center/Brinks under the supervision of the designated program RN. These medications will be paid for as a program expense since they will not be ordered for a specific individual receiving treatment.

10. Management of Medication Samples

a. Samples will be received (signed for) from a pharmaceutical representative by a Physician/PA/NP.

b. The Medication Sample Inventory Database must be maintained of sample medications received, administered, and/or destroyed by a nurse at each location that stores and utilizes sample medications.

1) The inventory shall document date received, name of drug, strength, quantity, lot number, expiration date, date issued, recipient ID, and staff ID Number.
2) The samples inventory must be checked monthly by a nurse for expired medications. Out-dated samples shall be removed from stock, destroyed appropriately, and removal recorded in the Medication Sample Inventory Database.

c. Samples must be kept in a locked cabinet accessible only by a nurse.

d. Medication samples shall be issued on a Physician's/PA's/NP's order (prescription or verbal order form) in the manufacturer's original packaging.

1) Instructions for taking each medication will be provided to the individual by a nurse using the Medication Instruction Sheet (C113P) produced in duplicate by the Medication Sample Inventory Database and attached to the bag. One copy will be signed by the individual and nurse indicating the individual has received verbal and written instruction. The signed copy will be scanned into the individual's electronic clinical record.
2) A thirty-four (34) day supply or less of medication will be issued unless otherwise authorized by a Physician/PA/NP.
3) An entry must be made in the current electronic format to account for each sample medication issued.

11. Management of Patient Assistance Medications

a. Patient Assistance forms are obtained from each drug company. Form is completed by the designated CMH representative or nurse and signed by the Physician/PA/NP when needed, and submitted as instructed.

b. The medication received must be given to a nurse. The medication is logged into the Medication Sample Inventory Database and the current electronic format by a nurse, the medication is locked in the storage area with the individual's name on the package.

c. Instructions for taking each medication will be provided to the individual by a nurse using the Medication Instruction Sheet (C113P) produced in duplicate by the Medication Sample Inventory Database and attached to the bag. One copy will be signed by the individual and nurse indicating the individual has received verbal and written instruction. The signed copy will be scanned into the individual's electronic clinical record.

d. Discontinued medications in the original packages will be logged into the Medication Sample Inventory Database by a nurse.

12. Refused/Dropped Medications

a. If medication is refused/dropped or contaminated, staff must complete an Incident Report (IR) and forward it to a nurse/their supervisor. Two (2) staff must be present to dispose of or destroy the medication. Two (2) nurses must be present to dispose a Schedule II – V medication.

13. Individuals Receiving Medications Away From the Usual Facility (e.g., outings or Leaves of Absence [LOA] from residential settings or day programs.)

a. Envelopes may be used for providing medication for such individuals.

1) Printed on the envelope shall be the individual's name, medication and strength, time to be administered, and the number of pills included in the envelope. The envelope must then be sealed. Multiples of pills to be taken at the same time may be placed in the same envelope.

b. Such medication shall be recorded in the medication administration record/LOA form.

c. Medication not taken for any reason while away shall be secured in the medication storage area.

1) An Incident Report (IR) shall be completed and sent to the site supervisor.
2) The medication sheet entry for the LOA medications shall be circled in black ink.
3) If authorized by the nurse, the missed medication should be given to the individual, with the time given noted on the medication administration record.
4) If the medication envelope is returned unsealed, the Nurse and staff will verify contents of the envelope prior to administration.

14. Transporting Medications to Individuals in the Community

    a. Each program administering and/or delivering medications in the community (e.g., ACT) shall utilize a medication inventory sheet, indicating signature of person receiving medication, the number of doses transported, administered, or returned.

    b. If number of doses remaining in original package is inaccurate when monitored, then an Incident Report (IR) shall be completed and sent to the Program Supervisor according to procedures.

    c. Medication may be transported using duplicate pharmacy containers.

    d. Medication not taken when designated from the mediset (daily medication reminder container) may be left in the mediset to be used for the next period of time, or destroyed. Do not return medication to the original pharmacy container.

15. Discontinuation, Holding, and Disposal of Medication

    a. On admission to a CMH residential facility, the Physician/PA/NP will review the individual's medication regimen, and will discontinue any medication contraindicated by the individual's treatment plan.

    b. An individual's medication(s) can only be held for up to fourteen (14) days if ordered to do so by a Physician/PA/NP for a specific purpose.

    c. An HP will document the discontinuation or holding of a medication in the Medication Administration Record/current electronic format.

    d. The current supply of an individual's medication must be administered or destroyed before a new supply of the same medication is initiated. Storage of a duplicate supply of the same medication will not be allowed.

    e. If an individual is discharged or leaves against medical advice from a residence or program, the individual's currently prescribed medications will be given to the individual or a responsible party, or destroyed.

    f. Discontinued or expired medication stored at a CMH site will be destroyed or transported by an HP for temporary storage pending disposal with the agency's medical waste within thirty (30) days.

        1) Destroyed Schedule II – V medications will be documented on Form Q052 by the HP disposing of the medication. The signature of a witness is also required.

        2) Non-controlled medications shall be secured in an appropriate container, transported to Mental Health Center by an HP and secured in the locked metal cabinet in the medication storage room in the Med Pod pending disposal with the agency's biohazard waste at the county's licensed waste disposal site.

E. Medication Teaching Sheets

1. Medication teaching sheets shall be available for all medications on the CMH Formulary and written and updated with existing medical knowledge of each drug's purpose, benefits, risks, side effects, and approved dosage range.

2. Teaching sheets may be revised or deleted, or new ones added, as needed, without amendment to the Policy and Procedures document.

F. Informed Consent *(Also see CMH Policy and Procedures No. 04-003.)*

1. All of the following are elements of informed consent:

   a. LEGAL COMPETENCY: An individual shall be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian or exercise by a court of guardianship powers and only to the extent of the scope and duration of the guardianship. An individual shall be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.

   b. KNOWLEDGE: To consent, a recipient or legal representative must have basic information about the procedure, risks, other related consequences, and other relevant information. The standard governing required disclosure by a doctor is what a reasonable patient needs to know in order to make an informed decision. Other relevant information includes all of the following:

      1) The purpose of the procedures.
      2) A description of the attendant discomforts, risks, and benefits than can reasonably be expected.
      3) A disclosure of appropriate alternatives advantageous to the recipient.
      4) An offer to answer further inquiries.

   c. COMPREHENSION: An individual must be able to understand what the personal implications of providing consent will be based upon the information provided under subdivision (b) of this sub-rule.

   d. VOLUNTARINESS: There shall be free power of choice without the intervention of an element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, including promises or assurances of privileges or freedom. There shall be an instruction that an individual is free to withdraw consent and to discontinue participation or activity at any time without prejudice to the recipient.

2. All individuals receiving medication (or their parent or guardian) shall:

   a. Sign a Release to Exchange Information with the individual's primary care physician to minimally include: all medications prescribed lab orders and results, and diagnoses in order to safely and effectively coordinate medical and psychiatric services.

b. Be informed of the dosage range, purpose, benefits, risks, and side effects of each medication by an HP, as well as alternative medications and viable options to treatment with psychotropic medication. Women of childbearing age shall be informed by an HP about the risks associated with pregnancy.

c. Receive a Medication Teaching Sheet for each medication. This shall be indicated on the consent form.

d. Sign a written voluntary consent form to receive psychotropic drugs, which shall be posted in the record (Consent for Use of Psychiatric Medications [C148]).

e. Be informed that consent for use of medication may be withdrawn at any time.

3. An individual under court order for continued treatment may be prescribed/ administered outpatient medications without providing informed consent.

4. The Physician/PA/NP Progress Note shall indicate if the individual demonstrated the capacity to understand the information provided.

   a. If the individual is deemed competent but intellectually limited, the progress note shall document how the information was given at a level of understanding consistent with individual's functioning.

5. If the individual/guardian declines to sign the Consent for Use of Psychiatric medications or Authorization for Exchange of Information with the primary care physician, the HP will document such refusal. Medications will not be prescribed or administered whenever the individual or guardian refuses to give consent or give permission to exchange information with the primary care physician or withdraws consent or Release of Information.

6. If immediate written consent from an individual/guardian is not possible, verbal consent may be obtained and documented by the HP and one (1) witness. A signed consent must then be obtained as soon as possible.

7. A change of dosage within the approved range does not require obtaining a new consent. A change of dosage outside the approved range, or a change of medication within the same class, does require a new consent.

8. 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/PA/NP. This consent remains in effect until revoked by the individual or the medication is discontinued by the Physician/PA/NP.

   a. CMH shall accept as valid, and act upon the consent or refusal of any individual/guardian who is age eighteen (18) or over, has not been declared legally incompetent, and who is presumed by the Physician/PA/NP to be clinically capable of providing informed consent.

b. Any individual who is under age eighteen (18), or has been declared legally incompetent to make medical treatment decisions, may not give informed consent. Either a parent or guardian with authority to make medical treatment decisions must provide informed consent to take medication.

c. If an individual is legally competent on his/her eighteenth (18^{th}) birthday, previous consent obtained from the parent or guardian expires on that date, and a new consent must be obtained from the individual.

d. If long-term clinical incapacity is determined, the physician will so document and request that a guardian be appointed.

1) Medication should not be initiated until incapacity is established judicially and a guardian is appointed.

a) If individual meets the legal criteria for involuntary treatment, then involuntary proceedings should take place.

2) If the individual is already taking the medication and agrees to continue doing so, the medications can be continued if the Physician/PA/NP determines that a discontinuation of medication will have an unfavorable effect.

a) The Physician/PA/NP shall document the circumstances in a progress note.

e. Medication can be prescribed and administered to an individual without informed consent only when the person poses a risk of harm to himself, herself, or others. The circumstances must be clearly documented in the individual's clinical record by the prescribing Physician/PA/NP.

1) The initial administration of psychotropic medication may not extend beyond forty-eight (48) hours unless informed consent is obtained.
2) The duration of psychotropic chemotherapy under these circumstances shall be as short as possible and at the lowest dosage that is therapeutically effective.
3) Psychotropic chemotherapy shall be terminated as soon as there is little likelihood that the individual will pose a risk of harm to self or others.
4) Additional courses of psychotropic chemotherapy may be prescribed and administered if an individual decompensates and poses a risk of harm to self or others.

G. INVOLUNTARY MOVEMENTS

1. The following applies to all individuals receiving antipsychotic medications or Amoxapine (Asendin):

a. Individual shall be evaluated by a Physician/PA/NP for the presence and extent of involuntary movement disorders prior to treatment with said medications.

b. While taking such medications, an individual shall be given an Abnormal Involuntary Movement Scale (AIMS) evaluation by an HP at least quarterly or more frequently if determined by a Physician/PA/NP and completed in the current electronic record or AIMS form (C210).

2. Any staff person who suspects that an individual may have involuntary movements will promptly refer the individual to the appropriate HP for an AIMS test and medication review.

3. If the AIMS score determines Tardive Dyskinesia is present, the individual or guardian must complete a special consent form annually (Consent Form for Individual with Tardive Dyskinesia [C153]).

H. SPECIFIC MEDICATIONS

1. Anticholinergics/Antiparkinsonian

a. Routine prophylactic use of anticholinergic agents with antipsychotic agents is discouraged. Anticholinergic agents will generally not be prescribed at the initiation of antipsychotic therapy, except for groups at high risk of extrapyramidal side effects (EPSE) or non-adherence, or a history of such side effects from similar medications.

b. When an individual does experience extrapyramidal side effects anticholinergics may be used, but periodic attempts should be made to discontinue these medications.

c. The Physician/PA/NP shall provide ongoing documentation of the justification for use of an anticholinergic agent in progress notes.

2. Clozapine (Clozaril) – Refer to the Clozapine/Clozaril Procedure.

3. Atypical Antipsychotics

a. Individuals with risk factors for diabetes mellitus who are starting treatment with atypical antipsychotics should undergo baseline screening and routine monitoring throughout treatment.

b. The following risk factors may increase an individual's potential of developing Type 2 Diabetes:

1) Family history of diabetes
2) Age over forty-five (45)
3) Race or ethnic background
4) Being overweight
5) Hypertension
6) Abnormal cholesterol levels
7) History of gestational diabetes
8) History of polycystic ovarian disease
9) Sedentary lifestyle
10) History of vascular disease

c. Before starting an atypical antipsychotic medication:
   1) Assess and document the above risk factors.
   2) Obtain a baseline fasting blood sugar level and cardiac lipid profile.

d. Following initiation of an atypical antipsychotic medication, the Physician/PA/NP shall minimally:

   1) Monitor individual's weight, Body Mass Index (BMI), waist circumference, and blood pressure regularly.
   2) Follow up with fasting blood sugar level and cardiac lipid profile at three (3) months and at least annually thereafter.
   3) If any abnormalities in lab results are noted, inform the individual's primary care physician for follow up.
   4) See Appendix E for complete laboratory monitoring requirements.

4. Controlled Substances

a. When a prescription for a controlled substance is written by a CMH Physician/PA/NP for an individual responsible for self-administration of medication, or who will soon be responsible for self-administration of medication, he/she will be required to sign the Consent For Use Of Psychiatric Medications (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (Appendix C) if one has not previously been signed.

b. The parent(s)/guardian(s) of a minor child who is prescribed a controlled substance by a CMH Physician/PA/NP will be required to sign the Consent for Use of Psychiatric Medications (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (Appendix C) if one has not previously been signed.

c. An HP will provide the individual (if an adult) or parent/guardian (if individual is a minor child) with a Consumer Controlled Substance Education Sheet and review the contents as necessary.

d. A Written Prescription Tracking form (C274) will be attached to the Schedule II prescription. The CMH staff person and the person picking up the written prescription will sign and date the form to acknowledge receipt of the prescription. The form will then be placed for priority scanning into the Prescription section of the electronic clinical record.

5. Stimulants

a. When prescribing stimulants for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), the Physician/PA/NP will follow CMH Practice Guideline 12-005.

I. LABORATORY MONITORING GUIDELINES FOR PSYCHOTROPIC MEDICATIONS

Baseline and periodic laboratory studies shall be performed in accordance with the pharmacology of the specific drug prescribed. (See Appendix E for complete monitoring guidelines.) The exact laboratory tests required depend on clinical judgment, the individual's medical and drug history, the pharmacology of the medication to be used, and the anticipated duration of time it will be prescribed.

J. ANTIDEPRESSANT MEDICATION FOR CHILDREN AND ADOLESCENTS

Upon initiation of prescribing an antidepressant medication to a child or adolescent, the CMH Physician/PA/NP shall follow the agency Guidelines for the Monitoring of Children and Adolescents Being Treated With Antidepressants (Appendix F).

K. MEDICATIONS FOR BEHAVIOR MANAGEMENT

1. Medication shall not be used as punishment, for the convenience of staff, or as a substitute for other appropriate treatment.

2. Medications ordered by a Physician/PA/NP may be administered following an individualized protocol in order to prevent physical injury to self or others.

    a. It is the intent of CMH to have individuals who are determined by assessment to be a danger to self or others due to mental illness or developmental disability admitted (by involuntary commitment if necessary) to an inpatient psychiatric unit or center. Staff will be encouraged to protect themselves and others from injury (e.g., Non-Abusive Psychiatric and Physical Intervention NAPPI).

3. The use of chemical restraint for an individual who poses an immediate danger to self or others or is causing substantial property damage may only be authorized by a CMH Physician/PA/NP as outlined in Section V of CMH Policy/ Procedure 04-009, Restraint, Seclusion, and Physical Intervention.

L. SERIOUS ADVERSE DRUG REACTIONS *(See Definition/Section IV, A.)*

1. In case of a serious adverse drug reaction (ADR), CMH staff and/or contracted providers will take action as necessary to assure appropriate medical care for the individual.

2. Any CMH staff person or contracted provider may initiate an inquiry regarding a possible serious adverse drug reaction stemming from CMH prescribed medications by filling out Part One of the Adverse Drug Reaction form (C033).

3. If not previously completed, the CMH staff person/contracted provider will fill out an Incident Report form (DCH-0044) as soon as possible and forward it to a CMH nurse for review. The nurse will note the possible occurrence of an ADR in the Alert section of the individual's electronic clinical record and the Allergy section of the medication database.

4. The ADR form shall be given to the individual's Primary Worker as soon as possible. If the primary worker is not available, the ADR form should be given to their supervisor.

    a. The CMH Primary Worker/Supervisor shall promptly notify the treating CMH Physician/PA/NP of the possible serious adverse drug reaction.

    b. The Primary Worker/Supervisor will give the ADR form with Part One completed to the CMH Physician/PA/NP as soon as possible.

5. The CMH Physician/PA/NP shall complete Part Two of the ADR form and forward it to the chairperson of the Pharmacy Work Group within seven (7) calendar days of receipt of the form.

    a. This may or may not involve a face-to-face examination of the individual, at the discretion of the Physician/PA/NP.

6. The Pharmacy Work Group, in consultation with the CMH Medical Director, shall further review the suspected serious ADR to confirm its occurrence.

    a. The ADR form, with Section Three completed shall be a permanent part of the Alerts Section of the individual's electronic clinical record.

    b. The CMH Senior Nurse will note the final outcome of the ADR review in the Allergy Section of the individual's medication database.

    c. The findings of the Pharmacy Work Group review shall be promptly reported to the CMH Recipient Rights Officer and the CMH Physician/PA/NP for follow up with the individual/guardian as appropriate.

    d. The Pharmacy Work Group shall notify the Federal Drug Administration (FDA) via FDA Voluntary Form 3500 of a confirmed serious ADR.

    e. The Pharmacy Work Group shall monitor all confirmed serious ADR's and note trends and patterns.

M. MEDICAL ABBREVIATIONS AND SYMBOLS

All CMH staff shall use only approved abbreviations and symbols (M007) found in Appendix B.

N. QUALITY ASSURANCE

1. The Pharmacy Work Group will assure that elements of this Policy shall be studied and monitored yearly by means of:

    a. Drug use evaluations: indications for prescribing the medication.

    b. Critical path reviews: standards of practice for prescribing and monitoring the medication.

c. Pharmacy therapeutics reviews: signed orders, etc.

d. Records pertinence.

e. Satisfaction of internal and external customers.

2. Emphasis shall be placed on areas of high risk, high volume/frequency, high cost, ease of data collection, and clinical benefit to CMH Individuals receiving services.

VI. REFERENCES:

MDCH Group Home Curriculum
MDCH Public Mental Health Manual III.7158-R.GL.07 (further references are cited therein)
Laboratory Telephone Report (M012)
Physician's Appointment/Communication (C204)
Consent for Use of Psychiatric Medications (C148)
Medication Request (C179)
Physician's Verbal Order (C005)
Inspection Checklist for Medication Storage Sites (Q001)
Injection Record (C264)
STAT Medications Inventory and Use (M083)
STAT Medications Quarterly Inspection (M084)
Medication Instruction Sheet (C113P)
Destroyed Schedule II – V Medications (Q052)
Abnormal Involuntary Movement Scale (C210)
Consent Form: Individual with Tardive Dyskinesia (C153)
Written Receipt Tracking Form (C274)
Adverse Drug Reaction (C033)
Incident Report (DCH-0044)
FDA Voluntary Form 3500

VII: APPENDICES:

APPENDIX A: Medication Administration Guidelines and Identity Verification & Photo Consent for Medication Administration (C154)
APPENDIX B: List of Approved Medical Abbreviations and Symbols (M007)
APPENDIX C: Consumer Controlled Substance Standard
APPENDIX D: Procedure 06-009: Monitoring of Formulary of Approved Medications
APPENDIX E: Laboratory Monitoring Guidelines for Use of Psychotropic Medications
APPENDIX F: Practice Guideline 12-005: Prescribing Psychotropic Medications for Children and Adolescents
APPENDIX G: Practice Guideline 12-010: Simultaneous Use of Multiple Psychotropic Medications

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