

HEALTHWEST

Policy and Procedure

No. 06-010

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Approved by:

Subject: Medication Management

DocuSigned by:



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I. POLICY

Medications listed on the HealthWest 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 HealthWest 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. INDIVIDUAL RECEIVING SERVICES: Any person receiving mental health services at HealthWest.
- C. INVOLUNTARY INDIVIDUAL: An Individual receiving services under Probate Court-ordered treatment.
- D. RECORD: The individual's Electronic Clinical Record (ECR).

- E. 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 HealthWest staff or kept on HealthWest premises.
- F. PHYSICIAN: An M.D. or D.O. licensed in Michigan, and under contract with HealthWest.
- G. PA: Physician's Assistant licensed in Michigan and under contract with HealthWest.
- H. NP: Nurse Practitioner licensed in Michigan, and employed or under contract with HealthWest.
- I. NURSE: Registered Nurse (RN) licensed in Michigan.
- J. HP: Health Professional – Physician, PA, NP, or Nurse.
- K. PRIMARY WORKER: Supports Coordinator (SC), primary therapist, or other clinical staff person who is assigned primary responsibility for case coordination.
- L. PSYCHOTROPIC DRUG: Any medication administered for the treatment or amelioration of disorders of thought, mood, or behavior.
- M. STAT: Immediately.

V. PROCEDURES

Overview of Sections:

- A. General
- B. Documentation
- C. Prescriptions
- D. Administration and Storage
- E. Medication Teaching Sheets
- F. Informed Consent
- G. Involuntary Movements
- H. Specific Medications
- I. Medical Use of Cannabis
- J. Laboratory Monitoring Guidelines for Psychotropic Medications
- K. Antidepressant Medication for Children and Adolescents
- L. Medications for Behavior Management
- M. Serious Adverse Drug Reactions
- N. Medical Abbreviations and Symbols
- O. Quality Assurance

A. GENERAL

1. Medication shall be prescribed only by a Physician, PA, or NP under the supervision of a physician.
 - a. All such HealthWest/IHC 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 HealthWest/IHC 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 HealthWest/IHC Physician/PA/NP shall be scheduled at least every three months for the purpose of documenting the continued need for medication as well as the presence/absence of side effects. If the individual is treated in a HealthWest residential setting, the individual's medication shall be reviewed at least once every thirty (30) days by a HP 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 HealthWest/IHC Physician/PA/NP may prescribe an FDA-approved medication for an unlabeled indication when such use is based on sound scientific evidence, sound medical opinion, or anecdotal clinical evidence. When a HealthWest/IHC 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 psychotropic medication from the same medication class is encouraged. (*Practice Guideline No. 12-010, Simultaneous Use of Multiple Psychotropic Medications - Appendix A*).

2. Formulary of Approved Medications (*Appendix B*)
 - a. Dosage levels for medications shall not ordinarily exceed those specified in the current Physician Drug Reference (PDR) and listed in the HealthWest Formulary on the HealthWest Intranet.
 - b. When dosage levels are prescribed above the range listed in the HealthWest Formulary of Approved Medications (*Appendix B*), the HealthWest/IHC 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.
 - c. The HealthWest Formulary of Approved Medications will be maintained according to Procedure 06-009 – Maintenance of Formulary of Approved Medications (*Appendix C*).
 - d. Request for Changes in the Formulary of Approved Medications (M010) shall be used to request changes to the HealthWest 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 HP.
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 HealthWest/IHC 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 HealthWest:
 - 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 nonpsychiatric medication history.

- 3) Mental status examination.
- 4) Diagnosis by HealthWest/IHC Physician/PA/NP.
- b. HealthWest/IHC Physician/PA/NP 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 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 HealthWest/IHC Physician/PA/NP. The history of medications prescribed will be maintained using current electronic format.
- e. Individual Plan of Service (IPOS) authorized by HealthWest/IHC Physician/PA/NP: Whenever an individual is prescribed medications by HealthWest, at least one 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 HealthWest/IHC 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 HealthWest/IHC 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-HealthWest sources and over-the-counter drugs and nutritional supplements using current electronic format. This shall be a nursing responsibility, updated at each HealthWest/IHC Physician/PA/NP contact.
- i. List of HealthWest Approved Medical Abbreviations and Symbols (M007) shall be used when documenting.

C. PRESCRIPTIONS

Prescription medication quantity for all individuals receiving services may be up to three 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 noncontrolled drug.

- 1. Electronic Orders
 - a. Prescriptions shall be completed using the current electronic format.
 - b. The prescription shall be signed only by a HealthWest/IHC Physician/PA/NP. A Schedule II prescription shall be printed on tamperproof paper and countersigned by a physician.
- 2. Written Orders: Whenever the current electronic format is not available, prescriptions shall be written only on HealthWest duplicate tamperproof printed forms. HealthWest/IHC Physician/PA/NP will use HealthWest prescription forms only for HealthWest 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 the Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005). The form will be forwarded promptly to the HealthWest/IHC

Physician/PA/NP for signature. The form will be scanned into the client record.

- e. Consent for new medications initiated by the Consent for Use of Psychiatric Medications & General Medication Teaching (C148) shall be obtained as outlined in Section F - INFORMED CONSENT - of this Policy and Procedure.

D. ADMINISTRATION AND STORAGE

1. All medication administered in HealthWest programs and HealthWest residential facilities shall be kept in locked cabinets or boxes accessible only to HP/contracted pharmacist, and staff members trained by HealthWest 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. Daily temperature will be monitored and recorded.
 - 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. See Medication Storage Area Inspection (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 a 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 a HealthWest Incident Report (C260).
3. All nonprescription 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 nonprescription medication will only be administered per the HealthWest/IHC Physician/PA/NP orders.
4. Medications may only be administered when the following are in the record:
 - a. Current prescription, or Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005).
 - b. Signed informed consent for medications prescribed by a HealthWest/IHC Physician/Physician's Assistant/Nurse Practitioner Verbal Orders (C005) with documentation that medication teaching sheets were given as outlined in Section F – INFORMED CONSENT - (C148 – Consent for Use of Psychiatric Medications & General Medication Teaching) of this Policy and Procedure.
 - c. Identity Verification & Photo Consent for Medication Administration (C154).
 - d. Medication brought into a HealthWest 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 a HP.
5. Medications may be administered only by HealthWest/IHC Physician/PA/NP/ Nurse or by direct-care staff who have taken and passed a HealthWest medications training class and according to the Medication Administration Guidelines (*Appendix D*).
 - 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 HealthWest nurse and/or qualified staff on an ongoing basis.
 - c. Documentation of dates and attendance will be kept by the site supervisor and/or the HealthWest Quality Improvement Project Coordinator.
6. Self-Administration of Oral or Topical Medication: While receiving services from a HealthWest-operated or contracted residential program, an individual may self-administer his/her medication only when approved in a written order (Order for Self-Administration of Oral or Topical Medications, C279) by the HealthWest/IHC Physician/PA/NP specified in the Individual Plan of Service (IPOS) and monitored by trained staff. The HealthWest/IHC 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.
7. Medication Compliance Packaging Program:

- a. If it is determined that medication assistance is needed, it must be documented in a psychiatric progress note and incorporated in the IPOS. The nature and duration of HealthWest assistance must be specified. Once sufficient competency is acquired on the part of the individual, assistance in self-administration of medication will be discontinued. Only a HealthWest/IHC Physician/PA/NP can discontinue the order.
 - 1) HealthWest staff will use Medication Compliance Packaging Evaluation (C349) to inform the appropriate licensed health care provider of the client's needs. The form will be forwarded to the RN for review. RN will complete the form and forward to HealthWest/IHC Physician/PA/NP.
 - 2) HealthWest/IHC Physician/NP/PA will write an order on the Order for Medication Compliance Program (C352). This form will also be used to discontinue the order.
 - 3) Information will be put in the IPOS regarding goals and objectives to be met, utilizing Medication Compliance Packaging Evaluation Registered Nurse Assessment (C358).
 - 4) Team members will implement the order in coordination with the team RN.
 - 5) Quarterly reevaluation will consist of a repeat of issuing the Medication Compliance Packaging Evaluation (C349), the Medication Compliance Packaging Evaluation Registered Nurse Assessment (C358), and a medication review with the health care provider.
- b. All medications determined to require assistance with self-administration will be dispensed by Mercy HealthWest Pharmacy.
- c. Medications will be provided in recommended format by the dispensing pharmacy according to the Order for Medication Compliance Program (C352).
- d. Use of the Medication Sheet (C145) will be used for all assistance by HealthWest staff. Completion of form at each medication assistance encounter is required.
- e. All medications from the medication storage bin must be signed in and out using the Medication Container Log (M169). This form must be kept in the individual medication storage bin.
- f. Scheduled Drugs Count Log (M170) must be completed at each medication assistance encounter when prescribed scheduled medications are used. This form must be kept with the medication storage bin. The completed count log must be scanned into eClinical under "Prescriptions." On medications obtained by Mercy HealthWest Pharmacy that are controlled

substances, the prescription number will begin with the number 2 or the number 4.

- g. The start and end count is always an actual count of the medication in the container.
 - h. Transporting of medications into the community by HealthWest staff must be in designated provided containers.
- 8. 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.
- 9. Procedure for Administration of Injectable Psychotropics
 - a. Nurse will verify last HealthWest/IHC 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 the Injection Record (C264) and in the HealthWest Injection Database. Nurse will highlight each prescription entry made on the Injection Record.
 - 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.
- 10. Procedure for STAT Medications
 - a. STAT Medications shall be secured from the Mercy HealthWest Pharmacy for use at HealthWest Main Campus.
 - b. An emergency STAT medication box shall be secured at Brinks' Sample Medication Cabinet.
 - c. 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, and Adult EpiPen. Additions or deletions will be subject to the approval of the Doctors Work Group.

- d. The STAT medications will only be used to fill a STAT order given by a HealthWest/IHC 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.
- e. A log will be kept with the STAT medication box, which will include a list of the contents, medication usage logs, and quarterly inspection records.
- f. RN will document STAT orders on a Physician/Physician's Assistant/Nurse Practitioner Verbal Orders form (C005), including all pertinent information if no written order from the HealthWest/IHC 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.
- g. 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
- h. The designated HealthWest 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).
- i. Replacement medications will be prescribed by a HealthWest/IHC Physician/NP/PA ordered from the Mercy HealthWest Pharmacy and delivered to 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.

11. Management of Medication Samples

- a. Samples will be received (signed for) from a pharmaceutical representative by a HealthWest/IHC 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 quarterly by a nurse for expired medications. Outdated 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 HealthWest/IHC Physician/PA/NP order (prescription or Physician/Physician's Assistant/Nurse Practitioner Verbal Orders form (C005) 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 (C113) 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 HealthWest/IHC Physician/PA/NP.
 - 3) An entry must be made in the current electronic format to account for each sample medication issued.
12. Management of Patient Assistance Medications
- a. Patient Assistance forms are obtained from each drug company. Form is completed by the designated HealthWest representative or nurse and signed by the HealthWest/IHC 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 (C113) 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.
13. Refused/Dropped Medications: If medication is refused/dropped or contaminated, staff must complete an IR and forward it to a nurse/their supervisor. Two staff must

be present to dispose of or destroy the medication. Two nurses must be present to dispose a Schedule II – V Medication (Q052-Q052A).

14. 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. 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.
15. 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.
16. Discontinuation, Holding, and Disposal of Medication

- a. On admission to a HealthWest residential facility, the HealthWest/IHC 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 HealthWest/IHC 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 HealthWest 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 the Destroyed Schedule II-V Medications Common Schedule II-V Medications that Require Monitoring (Q052-Q052a) 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 HealthWest by a 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 HealthWest 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 this Policy and Procedures document.

F. INFORMED CONSENT (*HealthWest Policy 04-003: Consent - Appendix E*)

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 that the personal implications of providing consent will be based on the information provided under Paragraph F.1.b above.
 - 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 prescribed by a HealthWest Physician/PA/NP (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.

Exchange of information is required and authorized by the individual's signature on the Medicaid application to ensure coordination of care with Medicaid provider.
 - b. Be informed of the dosage range, purpose, benefits, risks, and side effects of each medication by a HP, as well as alternative medications and viable options to treatment with psychotropic medication. Women of childbearing age shall be informed by a 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 (C148 - Consent for Use of Psychiatric Medications and General Medication Teaching).
 - e. Be informed that consent for use of medication may be withdrawn at any time.
- 3. To ensure coordination of care, if a physician outside of HealthWest prescribes medication, HealthWest staff will ensure medication education occurs for client/guardian and direct care staff. Education provided will be documented. Medication education will be included in the treatment plan.
- 4. An individual under Court Order for continued treatment may be prescribed/ administered outpatient medications without providing informed consent.
- 5. The HealthWest/IHC Physician/PA/NP Progress Note shall indicate if the individual demonstrated the capacity to understand the information provided. 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.
- 6. If the individual/guardian declines to sign the Consent for Use of Psychiatric Medications (C148) 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.
- 7. If immediate written consent from an individual/guardian is not possible, verbal consent may be obtained and documented by the HP and one witness. A signed consent must then be obtained as soon as possible.
- 8. 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.
- 9. Informed consent for use of medication must be obtained at the time a medication is initially prescribed. This is the responsibility of the prescribing HealthWest/IHC Physician/PA/NP. This consent remains in effect until revoked by the individual or the medication is discontinued by the HealthWest/IHC Physician/PA/NP.
 - a. HealthWest shall accept as valid, and act upon the consent or refusal of any individual/guardian who is age 18 or over, has not been declared legally incompetent, and who is presumed by the HealthWest/IHC Physician/PA/NP to be clinically capable of providing informed consent.
 - b. Any individual who is under age 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 18th 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. 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 HealthWest/IHC Physician/PA/NP determines that a discontinuation of medication will have an unfavorable effect. The HealthWest/IHC 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 HealthWest/IHC 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 HealthWest/IHC 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 a HP, at least quarterly, or more frequently if determined by a HealthWest/IHC Physician/PA/NP, and completed in the current electronic record or Abnormal Involuntary Movement Scale (AIMS) (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: 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 nonadherence, 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 HealthWest/IHC Physician/PA/NP shall provide ongoing documentation of the justification for use of an anticholinergic agent in progress notes.
2. Clozapine (Clozaril): Refer to Procedure 06-016 - Clozaril/Clozapine Treatment System (CTS) Procedures (*Appendix F*).
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 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 Hemoglobin A1C and Cardiac Lipid Profile.

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

- 1) Monitor individual's weight, Body Mass Index (BMI), waist circumference, and blood pressure regularly.
- 2) Follow up with Hemoglobin A1C and Cardiac Lipid Profile at three 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 Laboratory Monitoring Guidelines for Use of Psychotropic Medications (*Appendix G*) for complete laboratory monitoring requirements.

3. Controlled Substances

- a. When a prescription for a controlled substance is written by a HealthWest/IHC 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 & General Medication Teaching (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (M145) 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 HealthWest/IHC Physician/PA/NP will be required to sign the Consent for Use of Psychiatric Medications & General Medication Teaching (C148) and adhere to the conditions outlined in the Consumer Controlled Substance Standard (M145) if one has not previously been signed.

- c. HP will provide the individual (if an adult) or parent/guardian (if individual is a minor child) with a Consumer Controlled Substance Education sheet (M145) and review the contents as necessary.
- d. A Written Prescription Tracking form (C274) will be attached to the Schedule II prescription. The HealthWest 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.

4. Stimulants

- a. Psychiatric Assessment should include a detailed history as well as documentation of medical conditions. If possible, collateral information from parents or significant others should be obtained. Prior to the initiation of stimulant therapy, a baseline blood pressure, pulse, height, and weight should be obtained. Collaboration with the primary care provider or specialist may be necessary if there are comorbid cardiac or neurological issues of concern.
 - 1) Conditions that may benefit from stimulant use include the following:
 - a) ADHD. The prescriber should document whether the patient has a diagnosis of ADHD based on DSM IV TR criteria.
 - b) Narcolepsy. If an individual has a confirmed diagnosis of Narcolepsy, stimulants may be part of the treatment plan. If possible, the prescribing for this condition should be through the primary care provider or sleep specialist.
 - c) Apathy due to general medical condition. Individuals with Traumatic Brain Injury (TBI), stroke, or degenerative neurological illness may at times have a degree of apathy in which stimulant medications may prove to be of assistance in treatment.
 - d) Treatment refractory depression. In rare cases, low-dose stimulants may be used in cases of treatment refractory depression as an augmentation strategy.
 - 2) Contraindications: Aside from comorbid medical conditions that would preclude the use of stimulant medication, the following conditions should be considered relative contraindications to stimulant use:
 - a) Substance abuse. If an individual has an Axis I diagnosis of substance abuse or dependence, caution should be exercised in prescribing stimulant medication. If the benefit

is thought to outweigh the risk, extreme caution and careful monitoring for misuse should be undertaken. If possible, Strattera or other nonstimulant options should be considered as first-line agents.

- b) A member of the individual's household has a history of stimulant abuse. This should be discussed during the Psychiatric Evaluation.
 - c) Stimulants are not indicated in individuals with an active psychotic disorder.
- 3) Stimulants in Mood and Anxiety Disorders: Both anxiety and mood disorders may be comorbid with ADHD. Caution and careful clinical judgment should be exercised when prescribing stimulants in this population as they can lead to an increase in either mood fluctuations or an increase in anxiety in certain individuals. In the majority of these cases, the underlying anxiety or mood disorder should be the initial focus of treatment.

5. Medication-Assisted Treatment

a. Vivitrol:

<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf>

- 1) Naltrexone/Vivitrol: Positive drug screens will be repeated in seventy-two (72) hours. The drug screen is to be negative prior to the injection being given.
- 2) Onsite drug screening for opioid use with a negative result to be performed prior to the initial injection and every injection given not within the dosage regimen (every thirty-five (35) days).
- 3) Vivitrol will be held if the drug test is positive for opioids, and the Individual receiving services will be asked to repeat the test on the following day.

b. Suboxone:

<http://www.suboxone.com/content/pdfs/medication-guide.pdf>

- 1) Teaching and consent by HealthWest/IHC Physician/PA/NP at time of prescribing: A medication guide will be given to the individual receiving services at this time (see link above and HealthWest Formulary of Approved Medications, *Appendix B*).
- 2) Monthly Michigan Automated Prescription System (MAPS) will be printed by RN and presented to prescribing physician.
- 3) In-house drug testing for Opioid Panel monthly.

- 4) Drug results will be documented in a progress note and forwarded to the physician for signature.

I. MEDICAL USE OF CANNABIS

Consideration will be given to possible drug-drug interactions, where one of the drugs is marijuana, as applicable. This consideration may result in limiting psychiatric medication treatment, including medication assisted treatment (MAT), per the clinical judgment of the psychiatrist.

HealthWest will follow the position of the American Psychiatric Association (APA) on the use of cannabis for psychiatric indications.

1.) The APA's position:

- a. There is no current scientific evidence that cannabis is in any way beneficial for the treatment of any psychiatric disorder. In contrast, current evidence supports, at minimum, a strong association of cannabis use with the onset of psychiatric disorders. Adolescents are particularly vulnerable to harm, given the effects of cannabis on neurological development.
- b. Further research on the use of cannabis-derived substances as medicine should be encouraged and facilitated by the federal government. The FDA has approved synthetic cannabis-derived medications for specific indications (examples of medications are Marinol, Syndros, Cesamet and Epidiolex.) The adverse effects of cannabis, including, but not limited to, the likelihood of addiction, must be simultaneously studied.
- c. There is great variability of in the form, dose and potency of cannabis. Furthermore, there are numerous other compounds in products marketed as cannabidiol or cannabis with unknown health effects.
- d. Policy and practice surrounding cannabis-derived substances should not be altered until sufficient clinical evidence supports such changes.
- e. If scientific evidence supports the use of cannabis derived substances to treat specific conditions, the medication should be subject to the approval process of the FDA.

2.) Regarding state initiatives to authorize the use of cannabis for medical purposes:

- a. Medical treatment should be evidence-based and determined by professional standards of care; it should not be authorized by ballot initiatives.
- b. No medication approved by the FDA is smoked. Cannabis that is dispensed under a state authorized program is not a specific product with controlled dosages. The buyer has no complete way of knowing the strength or purity of the product, as cannabis lacks the quality control of FDA-approved medicines, although in some states the percentage of delta-9- tetrahydrocannabinol (THC) and cannabidiol (CBD) are listed on the products sold in state legalized stores or dispensaries.
- c. Prescribers and patients should be aware that the dosage administered by smoking is related to the depth and duration of the inhalation and therefore difficult to standardize. The content and potency of various

cannabinoids contained in cannabis can also vary, making dose standardization a challenging task.

- d. Even non-smoked means of consumption, such as edible forms of cannabis, tinctures, and ointments have variable absorption, bio-availability, and a range of phyto-cannabinoids and other biologically active compounds which are not measured or controlled for in production.
- e. Physicians who recommend use of cannabis for “medical” purposes should be fully aware of the risks and liabilities inherent in doing so.
- f. The APA does not endorse cannabis as medicine.

J. LABORATORY MONITORING GUIDELINES FOR USE OF PSYCHOTROPIC MEDICATIONS

Baseline and periodic laboratory studies shall be performed in accordance with the pharmacology of the specific drug prescribed. (See Laboratory Monitoring Guidelines for Use of Psychotropic Medications (*Appendix G*) 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.

K. ANTIDEPRESSANT MEDICATION FOR CHILDREN AND ADOLESCENTS

Upon initiation of prescribing an antidepressant medication to a child or adolescent, the HealthWest/IHC Physician/PA/NP shall follow HealthWest Practice Guideline 12-008 – Monitoring of Children and Adolescents Being Treated with Antidepressants (*Appendix H*).

L. 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 HealthWest/IHC Physician/PA/NP may be administered following an individualized protocol in order to prevent physical injury to self or others. It is the intent of HealthWest 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 Psychological and Physical Intervention (NAPPI)).

M. SERIOUS ADVERSE DRUG REACTIONS (*See Page 1, Definition/Section IV, A.*)

1. In case of a serious adverse drug reaction (ADR), HealthWest staff and/or contracted providers will take action as necessary to assure appropriate medical care for the individual.
2. Any HealthWest staff person or contracted provider may initiate an inquiry regarding a possible serious adverse drug reaction stemming from HealthWest

prescribed medications by filling out Part One of the Report of Serious Adverse Drug Reaction form (C033).

3. If not previously completed, the HealthWest staff person/contracted provider will fill out an IR as soon as possible and forward it to a HealthWest 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 (C033) 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 HealthWest primary worker/supervisor shall promptly notify the treating HealthWest/IHC 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 HealthWest/IHC Physician/PA/NP as soon as possible.
5. The HealthWest/IHC 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. This may or may not involve a face-to-face examination of the individual, at the discretion of the HealthWest/IHC Physician/PA/NP.
6. The Pharmacy Work Group, in consultation with the HealthWest Medical Director, shall further review the suspected serious ADR to confirm its occurrence.
 - a. The ADR form, with Part Three completed, shall be a permanent part of the Alerts section of the individual's electronic clinical record.
 - b. The HealthWest 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 HealthWest Recipient Rights Officer and the HealthWest/IHC 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 (*See Appendix I*) of a confirmed serious ADR.
 - e. The Pharmacy Work Group shall monitor all confirmed serious ADRs and note trends and patterns.

N. MEDICAL ABBREVIATIONS AND SYMBOLS

All HealthWest staff shall use only approved abbreviations and symbols (M007).

O. 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 HealthWest Individuals receiving services.

VI. REFERENCES

J. AM. ACAD. Child Adolescent Psychiatry 41:2 Supplement February 2002

MDHHS Group Home Curriculum

MDHHS Public Mental Health Manual III.7158-R.GL.07
(further references are cited therein)

The American Psychiatric Association (APA) Position Statement in Opposition to Cannabis as Medicine

FORMS

C005	Physician/Physician's Assistant/Nurse Practitioner Verbal Orders
C033	Report of Serious Adverse Drug Reaction
C113	Medication Instruction Sheet
C145	Medication Sheet
C148	Consent for Use of Psychiatric Medications & General Medication Teaching
C153	Consent Form: Individual with Tardive Dyskinesia
C154	Identity Verification & Photo Consent for Medication Administration
C179	Medication Request Form
C204	Physician's Appointment/Communication
C210	Abnormal Involuntary Movement Scale (AIMS)

C260	HealthWest Incident Report
C264	Injection Record
C274	Written Prescription Tracking Form
C279	Order for Self-Administration of Oral or Topical Medications
C349	Medication Compliance Packaging Evaluation
C352	Order for Medication Compliance Program
C358	Medication Compliance Packaging Evaluation Registered Nurse Assessment
M007	List of Approved Medical Abbreviations and Symbols
M010	Request for Changes in the Formulary of Approved Medications
M012	Laboratory Telephone Report
M083	STAT Medications Inventory and Use
M084	STAT Medications Quarterly Inspection Form
M145	Consumer Controlled Substance Standard
M169	Medication Container Log
M170	Scheduled Drugs Count Log
Q001	Medication Storage Area Inspection
Q052-Q052a	Destroyed Schedule II-V Medications Common Schedule II-V Medications that Require Monitoring

VII. APPENDICES

<u>Appendix A</u>	Practice Guideline 12-010: Simultaneous Use of Multiple Psychotropic Medications
<u>Appendix B</u>	HealthWest Formulary of Approved Medications
<u>Appendix C</u>	Procedure 06-009: Maintenance of Formulary of Approved Medications
<u>Appendix D</u>	Medication Administration Guidelines
<u>Appendix E</u>	Policy 04-003: Consent
<u>Appendix F</u>	Procedure 06-016: Clozaril/Clozapine Treatment System (CTS) Procedure

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[Appendix G](#) Laboratory Monitoring Guidelines for Use of Psychotropic Medications

[Appendix H](#) Practice Guideline 12-008: Monitoring of Children and Adolescents
Being Treated with Antidepressants

[Appendix I](#) Form FDA 3500: For Voluntary Reporting of Adverse Events, Product
Problems, and Product Use Errors

CB/jec