Title: Psychotropic Medications Procedure

Prepared By: Medical Director

Purpose:

To define the process of administering and monitoring psychotropic medications, including the proper dispensing of medication, expiration of medication orders, and documentation for medication errors.

Scope:

This procedure applies to all employees (including full-time and part-time employees), contract providers, volunteers, students, and/or interns, of Huron Behavioral Health (HBH).

Information:

1. Psychotropic medications are prescribed only when therapeutically appropriate for the treatment of targeted signs, symptoms, or behaviors indicative of illness and must be administered by or under supervision of personnel who are qualified and trained. Psychotropic medications may be used when it is not possible to manage behavior or treat a psychiatric disorder utilizing a less restrictive technique after consent has been obtained. Psychotropic medications are never to be used as punishment, for the convenience of staff, or as a substitute for other appropriate treatment.
2. In accordance with the Michigan Mental Health Code (Administrative Rule 330.7158 and the Michigan Medicaid Provider Manual, psychotropic medications shall be prescribed only by a person licensed in the State of Michigan with prescriptive authority granted from the Michigan Department of Commerce, Licensing and regulation, and possessing a Controlled Substance Registration Drug Enforcement Administration (DEA) number and a National Provider Identification (NPI) number.
3. Staff is never to administer prescribed medications without a physician's order.
4. Medication prescribed for a consumer shall be given to and used only by that consumer.
5. Medications shall be kept in a secured/locked location according to the directions with each medication. Medications taken internally (orally or injectable) are to be kept separate from medications that are applied externally/topically (such as ointments and creams).
6. Verbal orders should be avoided, but in the event that a verbal order is given by a physician or other licensed prescriber, a record is noted in the Electronic Medical Record (EMR) system. Any verbal or telephone orders for medication or changes in dosage are to be signed by the authorized prescriber within twenty-four (24) hours or the next working day.
7. A record of the prescription is placed in the consumer's case record as well as all medication history sheets.
8. All HBH staff is responsible to be alert and aware of possible side effects of medications and call 911 or provide assistance for the consumer to get to the nearest hospital emergency room if there are any adverse medication side effects occur. Staff who observes a medication error or adverse drug reaction shall immediately report it to the supervisor and nurse in charge (who may consult with the physician) and the staff is to complete an Incident Report (See also "Unusual Incident Report Procedure" RR.2.37). Documentation of medication errors and adverse reactions will be retained in the consumer's case record in the EMR system.
9. If a consumer has no insurance, HBH staff may attempt to assist with obtaining pharmaceutical services for indigent-qualified medications, including various patient pharmaceutical assistance programs. (See also "Management of Sample Drug Program Procedure" RR.2.43).
10. A single psychotropic drug which offers the most effective treatment shall be selected whenever possible. And, whenever possible, only one (1) psychotropic drug should be prescribed at one time. When two (2) or more psychotropic drugs are used, the physician shall document the justification/rationale for the concomitant use of two (2) or more psychotropic drugs. Choice of a psychotropic medication will follow the standards of medical practice, medical rationale, and shall be documented in the consumer's case record by the treating psychiatrist or other licensed prescriber.

11. Prescription psychotropic medications are approved by the Food and Drug Administration (FDA) and referenced in publications such as the Physician's Desk Reference (PDR) manual or other generally accepted reference and are based upon relevant clinical evidence and sound professional judgment. Medication dose shall not ordinarily exceed those generally accepted standards unless there is sufficient medical rationale which shall be documented in the consumer's record by the treating psychiatrist or other licensed prescriber.
12. The medication regimen must be individually determined by considering the consumer's diagnosis, age, gender, weight, physical condition, current illnesses, other medications, and any previous adverse reaction to medications. Any recommended essential laboratory tests/services will be ordered and conducted, including an annual physical examination for those who receive psychotropic medications from HBH.
13. Whenever a psychotropic prescription is provided, the consumer (or parent of a minor child or the empowered guardian) shall be advised of specific risks, benefits, and possible adverse effects. The consumer is also instructed to report the occurrence of any adverse effects to the physician, other licensed prescriber, or nurse promptly who will document same in the medical record. The consumer will be given a written summary of the most common adverse effects associated with the drug by giving the consumer a patient medication information (PMI) sheet for each drug prescribed. Documentation of this will be included in the consumer's case record.
14. Informed written consent shall be obtained from the consumer, parent/guardian (depending upon guardianship status) for each psychotropic medication prescribed. Also, a "Release of Information Form" (in EMR) for the pharmacy must be signed by the consumer before medication information may be sent to any pharmacies. Consents are to be obtained initially and annually thereafter by the physician/psychiatrist, other licensed prescriber, or a Registered Nurse (RN). The consent shall include:
    a. name of the medication;
    b. dosage and frequency prescribed;
    c. an explanation of the risks and benefits of the use of the medication;
    d. an explanation of the expected results of the medication and any possible side effects; and
    e. an explanation that the consent may be withdrawn at any time;
15. Once the desired clinical result is achieved and the consumer's condition has stabilized, the medication shall be maintained at the minimum maintenance dose needed. If a consumer's medication is changed, a physician's note shall be entered to correspond to that change and include the rationale for that change.
16. When the consumer's condition has stabilized and there is no longer a need for psychotropic treatment, medications will be titrated/discontinued and documented in the consumer's case record.
17. Unused medication shall be disposed of in accordance with GL.2.05 Handling Discontinued, Contaminated or Expired Medications Procedure).
18. Psychotropic medications shall not be administered to a consumer unless the consumer/guardian/parent consents, unless administration of psychotropic medication is necessary to prevent physical harm or injury to the consumer or others, or with a court order per the following:
    - A provider may administer psychotropic medications to prevent physical harm or injury a) ONLY when the actions of a consumer, or other objective criteria, clearly demonstrates to a physician that the consumer poses a risk of harm to himself, herself, or others; and b) ONLY after signed documentation by the licensed prescriber is placed in the consumer's case record.
    - Initial administration of psychotropic medication must be limited to a maximum of forty-eight (48) hours, unless there is consent. The duration of use of psychotropic medication shall be as short as possible and at the lowest possible dosage that is therapeutically effective. The psychotropic medication shall be terminated as soon as there is no longer a risk of harm.
19. All psychotropic medications are to be reviewed by a physician or other licensed prescriber at least every six (6) months and are based upon the consumer's clinical status.
20. Sample medications are dispensed under the direction of the HBH physicians or other licensed prescriber. (See also "Management of Sample Drug Program Procedure" – RR.2.43.)

21. All medications given are to be current. Any expired/outdated medications are disposed of with documentation. (See also the various handling and disposal of medications procedures in RR.2.43 – Management of Drug Program Procedure; or GL.2.05 - Handling Discontinued, Contaminated, or Expired Medications Procedure.
22. Huron Behavioral Health's physician or nurse practitioner shall review and approve or disapprove all Individual Plan Of Services (IPOS) involving the use of psychotropic agents when they are applied for behavior control purposes (see also "Behavior Treatment Plan Policy" BM.1.01).
23. The Behavior Treatment Plan Review Committee (BTPRC) shall review behavior plans which include chemical restraint or are identified as Level II and Level III and make recommendations when appropriate to these plans. The primary worker is responsible for presenting all behavior plans to the Behavior Modification Committee. See also "Behavior Treatment Plan Policy" - BM.1.01 and "Responsibilities for Creating, Reviewing, and Implementing Behavior Treatment Plans Procedure" BM.2.02.

Procedure:

1. A psychiatric evaluation must be performed prior to prescribing any psychotropic medications.
2. Psychotropic agents are to be prescribed by the agency psychiatrist or another licensed prescriber. These medications are to be prescribed only for those consumers who have demonstrated need for psychotropic medication based on a comprehensive clinical assessment.
3. Each consumer has a primary worker who is responsible for the case record and makes certain that the documentation is both ongoing and adequate to show evidence of the collaboration and coordination/integration of care between the primary worker and the physicians. (See also "Coordination/Integration of Care Policy" SD.1.26 and "Coordination/Integration of Care Procedure" SD.2.12)
4. Physical Examination and Laboratory Studies:
   a. All consumers who are on psychotropic agents should have an annual physical examination including appropriate laboratory studies. Any medical or osteopathic physician who is licensed by the State of Michigan, and has a physician/client relationship with agency consumers may conduct the physical health examination. A health assessment or screening will be completed by the consumer upon intake and reviewed by the registered nurse. Consumers in need of specific medical care are to be referred to appropriate resources.
   b. Consumers on Lithium:
      i. Determine baseline laboratory values, prior to initiating Lithium therapy, to include at least Complete Blood Count (CBC), Blood Urea Nitrogen (BUN), Creatinine, Thyroid function and Electrolytes.
      ii. Determine serum Lithium levels during therapy as follows:
         - The last dose shall be given between ten (10) and fourteen (14) hours before blood is drawn for the Lithium determination
         - Such determination shall be done within two weeks and then as determined by the licensed prescriber until the patient is stabilized, thereafter, at least every six (6) months to screen for toxicity.

      iii. Clinical monitoring shall have the goal of maintaining serum Lithium levels within acceptable therapeutic range unless the licensed prescriber determines otherwise.
   c. Consumers on Clozaril:
      i. Current protocol calls CBC with differential (DIFF) blood tests weekly and gradually increase to every four weeks while on the medication. More frequent blood tests may be ordered if medically necessary. Blood tests every four (4) weeks is the current guidelines set by the Clozaril Registry. Consumers/guardians must sign the "Clozaril Consent Form" (90-190) before being prescribed Clozaril.
   d. Consumers on Anticonvulsants Used for Psychiatric Conditions:
      i. Valproic Acid-Depakote:

1) Determine baseline laboratory values prior to initiating Valproic Acid therapy, to include at least CBC with DIFF, Liver Function Tests (LFT).

2) Determine serum Valproic Acid levels during therapy as follows:
   - The last Valproic Acid dose shall be given twelve (12) hours before blood is drawn
   - Therapeutic levels should be maintained within the therapeutic range of 50-100 mcg/ml unless the physician determines otherwise
   - Patients on maintenance therapy with Valproic Acid shall have Valproic Acid levels, LFT's, and CBC with DIFF monitored at least every six (6) to twelve (12) months

ii. (Tegretol) Carbamazepine:

1) Determine baseline laboratory values prior to initiating Carbamazepine therapy, to include at least CBC with DIFF, LFT's

2) Determine serum Carbamazepine levels during therapy as follows:
   - The last Carbamazepine dose shall be given twelve (12) hours before blood is drawn
   - Therapeutic levels should be maintained within the therapeutic range of 8-12 mcg/ml unless the physician determines otherwise.
   - Patients on maintenance therapy with Carbamazepine shall have Carbamazepine levels, LFT's, CBC with Diff monitored at least every six (6) to twelve (12) months.

e. Consumers on Tricyclic Antidepressants:

i. Obtain Tricyclic Antidepressants levels during therapy as follows:

1) The last Tricyclic Antidepressant dose shall be given twelve (12) hours before blood is drawn

2) It is recommended that a level be obtained early in treatment to check for rapid or slow metabolizers or if medications that interfere with metabolism are prescribed.

3) Maintenance levels are done at the discretion of the licensed prescriber. Patients on maintenance therapy with Tricyclic Antidepressants shall have levels monitored at least every six (6) to twelve (12) months

5. Prescription and Dispensing of Drugs:

i. Consumer's medications are prescribed using an electronic prescribing program or are written on an agency prescription form and signed or e-signed by the licensed prescriber.

ii. A copy of the prescription order is retained in the consumer's case record.

a) If an order for a prescription is written by the physician but is to be picked up at a later time:
   - The assigned nurse will place the prescription in the locked medication cabinet
   - The nurse will remove the prescription from the locked cabinet and hand it to the consumer/parent/guardian or designated person, with written permission.
   - When necessary the prescription will be given to the primary worker to deliver to the parent/guardian or to be taken to the pharmacy for filling.
   - Only medications authorized by a physician or licensed prescriber are to be given at discharge or leave. Enough medication is made available to the consumer to ensure the consumer has an adequate supply until he or she can become established with another provider (typically up to three months).

6. Drug Reactions, Medication Errors, and Side Effects:

i. Consumers are seen at least every six (6) months by the psychiatrist, registered nurse, or designated licensed prescriber, for monitoring of possible side effects.

ii. Primary workers who have consumers on medication are to be familiar with possible side effects and toxic reactions so that they can assist in monitoring effects of the medication.

iii. Consumers on psychotropic medication and the parents/guardians (if applicable) are to be advised of and

given a written summary of the side effects and toxic reactions of medications by the licensed prescriber, registered nurse, or primary worker. Instructions will be given to the consumer to report the occurrence of any side effects. This will be documented in the consumer's case record. Any adverse reactions to medications are to be reported to the psychiatrist/licensed prescriber and documented in the consumer's case record.

iv. Medication errors must be reported to the responsible physician, nurse, or primary worker immediately, who is responsible for the further assessment and care of the consumer. Documentation (in the form of a written incident report using Incident Report Form DHHS-0044), is required, including any adverse reactions and what action(s) were taken (see also "Unusual Incident Reporting Procedure" RR.2.37). Medication errors are also reported to the physician and documented in the consumer's case record.

v. All patients receiving anti-psychotic medications (typical and atypical) shall have an assessment for Tardive Dyskinesia performed at least every six (6) months documenting the presence or absence of Tardive Dyskinesia. The "Abnormal Involuntary Movement Screening (AIMS) Form" (in EMR) or similar standardized assessment tool is to be used.

vi. When a consumer is to receive maintenance-level dosages, the physician shall weigh the benefits of continued treatment against the risks of long-term use of psychotropic agents and document (in the consumer's case record) the basis for the decision to either continue or discontinue the medication.

vii. Concomitant use of anticholinergic agents with psychotropic agents is discouraged. However, in those instances where a consumer experiences an extra-pyramidal reaction, anticholinergic agents may be used. The rationale for concomitant use shall be documented in the consumer's case record.

COMPLAINT PROCESS:

Consumers or another individual on behalf of a consumer may file a complaint for a decision regarding Medication Administration and/or Stop Order. Complaints may be made with HBH Recipient Rights Office.

Definitions/Acronyms:

Definitions:

Extra-pyramidal Syndrome - a movement disorders that can include dystonic reactions which includes:

a. Dystonia - exaggerated posturing of the head, face or neck, or fixed upward gaze
b. Dyskinesia - involuntary, repetitive movements and muscle contractions
c. Akathisia - motor restlessness
d. Parkinsonian Syndrome - resembles Parkinson's Disease

Medication Errors - Any violation of the six (6) medication rights:

a. Right consumer
b. Right medication
c. Right dosage
d. Right time (½ hour before to ½ hour after time ordered)
e. Right route
f. Right documentation

Primary Worker - All consumers will be assigned a therapist, case manager, supports coordinator, nurse, or psychiatrist who will be responsible for the consumer and electronic medical record (EMR).

Psychotropic Medications- is the administration of psychotropic medications for the treatment of diagnosed psychiatric disorders and behavioral problems.

Psychotropic Drugs/Medications – "Psychotropic drug" means any medication administered for the treatment or amelioration of disorders of thought, mood, or behavior. For the purposes of this policy, the following medications are considered psychotropic agents:

a. anti-psychotic agents
b. antidepressant agents
c. Lithium
d. anti-anxiety agents
e. sedative and/or hypnotic agents
f. anticholinergic agents or other agents used to treat movement disorders

g. anticonvulsant medications used for psychotherapeutic means (such as: Depakote, Tegretol, etc.)
h. Psycho stimulants

Tardive Dyskinesia - slow, rhythmical, automatic stereotyped movements, either generalized or in single muscle groups. These occur as an undesired effect of therapy with certain psychotropic drugs, especially the typical anti-psychotics.

Acronyms:

AIMS – Abnormal Involuntary Movement Screening
BUN – Blood Urea Nitrogen (test)
BPRC – Behavior Plan Review Committee
CBC – Complete Blood Count
DEA – Drug Enforcement Administration
DIFF - Differential
FDA – Food and Drug Administration
HBH - Huron Behavioral Health
IPOS – Individual Plan of Services
LFT – Liver Function Test
mEq - milliequivalent
MDHHS - Michigan Department of Health and Human Services
NP – Nurse Practitioner
NPI – National Provider Identification
PA – Physician's Assistant
PCP – Person Centered Plan
PDR - Physician's Desk Reference
PMI – Patient Medication Information (sheet)
RN – Registered Nurse

Forms:

Incident Report Form (DHHS-0044)
Medication History Sheet Form (in EMR)
Abnormal Involuntary Movement Screening (AIMS) Form (in EMR)
90-190 Clozaril Consent Form

Records:

Incident Reports are retained for two (2) years by the Recipient Rights Officer in accordance with the "Recipient Right - Record Retention and Disposal Procedure" (RR.2.25). All psychotropic medications ordered, changed, titrated, or discontinued shall be documented in the consumer's case record and retained in accordance with the HBH Record Retention and Storage Policy (QI.1.23).

Reference(s) and/or Legal Authority

COA standards
Mental Health Code, 330.1718, 330.1719, 330.1752 http://www.michigan.gov/documents/mentalhealthcode_113313_7.pdf
Administrative Rule 330.7158 http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33007001&Dpt=CH&RngHigh=
BM.1.01 Behavior Treatment Plan Policy
BM.2.02 Modification Creation, Review, and Implementation of Behavior Treatment Plan Procedure
GL.2.05 Handling Discontinued, Contaminated, or Expired Medications Procedure
RR.2.25 Recipient Rights – Record Retention and Disposal Procedure
RR.2.37 Unusual Incident Reporting Procedure
RR.2.43 Management of Sample Drug Program Procedure
SD.1.26 Coordination/Integration of Care Policy
SD.2.12 Coordination/Integration of Care Procedure
QI.1.23 HBH Record Retention and Storage Policy

Change History:

Change Letter	Date of Change(s)	Changes
A	09/16/02	Procedure was brought into new format and transferred to new controlled documentation system with minimal content changes.
B	01/14/03	Page 2, #15 – changed "5" days to "sixty (60)" to comply to new regulations
C	03/01/05	Page 2, #14 – corrected to include timeframe and documentation instructions; Page 6 – clarified item #4 and added reference procedures bullet #4, removed "Council on Accreditation Standards, F.2.05; H.5.05; I.4.01; J.1.04" and added "G9" in "Reference" section., added "DMH-2550" form #, re-ordered acronyms and definitions, added references (RR.2.25, RR.2.37, RR.2.38, RR.2.41, RR.2.43,RR.2.44, RR.2.45, GL.2.05, BM.1.02, BM.2.02), added acronyms, added forms (90-035, 90-119, 90-189)
D	03/01/06	Under "Standards #13" changed "monthly" to "quarterly", in F#3 changed "monthly basis" to "quarterly basis", added reference to QI.1.23, added hyperlinks, added last sentence in "Records" section, under "Procedure C." added "and coordination of care", under "G.1", changed "monthly" to "at least quarterly",
E	06/30/06	Reworded #10, 11, & 12 under "Standards" section to more clearly capture the MHC (330.1718 & 330.1719) as a result of the Recipient Rights Audit findings, added hyperlinks.
F	08/22/06	Revised definition of "Psychotropic Drugs/Medications" to match the Michigan Administrative Rule 7001 (m) in response to the 2006 ORR Audit Report.
G	10/25/06	Revised "Standards", # 12, clarified when a medication consent must be obtained (added 12.g).
H	08/25/08	Added third bullet in "Information" section to clarify existing practice, changed all wording from "Behavior Modification" to "Behavior Plan Review Committee" to comply with regional wording changes,
I	02/07/13	Changed all references of "chemotherapy" to "psychotropic medication or medication" as appropriate, added "other licensed prescriber" when referencing prescribing medications or monitoring medications or side affects throughout document. Information- third bullet added "or other person." Standards- #5 added "or other generally.." after manual, #11 removed information after "drug" and added second sentence, #12 removed second sentence, removed second bullet, #14 removed "registered nurse or physician" and added licensed prescriber, #15 second sentence after documented, added "by the RN on the appropriate", #19 removed "destroying it beyond recovery.." and added by returning it to the pharmacy and GL.2.05, #20 added guardian in first sentence, changed "resident" to "consumer". Procedure- removed B, C 1st sentence removed "of a collaborative physicians work" and removed the last sentence. E- #1 removed "agency psychiatrist" and added "upon intake" after "registered nurse", #2 second bulletin, added wording after "done", third bullet added "accepted" and removed "0.5 mEq/liter…", 3a changed all wording after "calls", #5a removed san replaced the second and third bulletin, F #1 added "electronic prescribing program", #2 removed a, b added "parent/guardian…" to second bullet, removed third bullet, fourth bullet added "parent" and removed everything after "filling", second to last statement removed "registered nurse" and added "on at least semiannually basis", removed last statement #5 removed, G #1 changed quarterly to a minimum semi-annually, #3 added last sentence, #5 changed "quarterly" to "at least every six months" and added "ing" to "document". Forms- removed 90-035 and 90-119. Added 90-186 and 90-190.
J	06/06/13	Added last bullet in "Information" section, removed COA chapter-specific reference (G9), added 2nd sentence in #12, added reference to RR.2.41 in #15, added 4th bullet in "Information" section.
K	12/10/14	Combined several details from "Verbal Orders Procedure" (RR.2.41) into this procedure and obsoleted RR.2.41 (added last sentence in 3rd bullet in "Information" section, added 4th bullet, added last sentence in F.2.a.) in "Information" section, removed form numbers (90-186 & 90-189), as the forms are now in EMR, in "Standards" section #21 changed "BPRC" to "BTPRC" and reworded #15, in F.2 removed "a." which referenced verbal orders since this is addressed several other places in the policy, removed the form numbers (90-189 & 90-186) (2 places) since the AIMS and Med History forms are now part of the EMR system.
L	04/28/15	Reviewed by the HBH Recipient Rights Advisory Committee w/ no content changes recommended.
M	04/11/17	Reviewed by the Recipient Rights Advisory Committee – Changed "Michigan Department of Community Health/MDCH" to "Michigan Department of Health and Human Services/MDHHS" (2 places), changed form # DMH-2550" to "DHHS-0044" (2 places), added contents of RR.2.12 "Medication Administration and Stop Orders Procedure" into this procedure and obsoleted RR.2.12 which forced a nearly total rewrite of this procedure; see Controlled Documentation Manager for changes or previous versions of this procedure.
N	08/07/18	Reviewed by Recipient Rights Advisory Committee - In "Information" section #1 added "and must be administered by or under the supervision of personnel who are qualified and trained", removed "or in the presence of a court order" and in 1st bullet added "a)", in 2nd bullet changed "may not extend beyond" to "must be limited to a maximum of", in #23 added "or nurse practitioner", in "Procedure" section #5.ii 4th bullet changed "Prescriptions from a doctor" to "Only medications authorized by a physician", and changed "refills will be given by the physician" to "is made available" & changed "is scheduled for an appointment" to "can become established", made several additional wording/grammatical changes/corrections throughout document without changing sentence content.
O	11/30/18	In "Procedure" section 6.iii added last sentence, in 6.iv added last sentence to comply with Plan of Correction from October 2018 RR System Assessment.
P	07/13/20	Added reference to SD.1.26 & SD.2.12 (3 places), added/corrected hyperlinks, added "licensed prescriber in 5.ii (4th bullet) and 5.iii, in "Information" section #5 added "(such as ointments and creams)", made several minor wording/grammatical changes/corrections throughout procedure without changing sentence content.
Q	08/03/21	In "Information" section #19 added "and are based upon the consumer's clinical status", removed old #17 as it was a duplicate statement ..
R	06/22/23	In "Information" section added "/topically", in "Definitions" section "Medications" changed "five (5)" to "six (6)", made several minor wording/grammatical changes/corrections throughout procedure without changing sentence content.