BAY-ARENAC BEHAVIORAL HEALTH
POLICIES AND PROCEDURES MANUAL

Chapter: 6	**Medication Management**		
Section: 1	**Operational**		
Topic: 6	**Medications: Storage, Samples, Injectable, Disposal, Expirations and Recalls**		
Page: 1 of 10	**Supersedes Date:** **Pol:** **Proc: 9-1-21,6-18-18, 5-17-17, 11-28-16, 6-19-12, 5-15-09, 4-15-08, 4-18-06, 11-16-04, 2-17-04, 5-21-02, 5-26-00, 7-28-98**	**Approval Date:** **Pol: 3-18-04** **Proc: 1-23-2024**	_____ ***Board Chairperson Signature*** _____ ***Chief Executive Officer Signature***
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Policy

It is the policy of Bay-Arenac Behavioral Health (BABH) to be fully committed to carrying out its Mission, Vision, Values and Strategic Plan to include the high standards of consumer safety regarding medications.

Purpose

This policy and procedure is established to ensure appropriate standards and practices are maintained regarding the proper use, storage, disposal, expiration and recall of medications and injectables (including sample medications and patient assistance program medications).

Education applies to

☐ All BABH Staff
☒ Selected BABH Staff, as follows: Clinical Management, Agency Nurses - Residential and Clinical, Ancillary Care, Direct Care Staff (e.g. respite, day program), and ACT Staff
☐ All Contracted Providers: ☐ Policy Only ☐ Policy and Procedure
☒ Selected Contracted Providers, as follows: Physicians, Nurses/other Licensed Health Care Providers who are Licensed Independent Practitioners, Primary Care Providers, Specialized Residential Providers, Contracted Nursing Providers and Organizations, Community Living Supports and Day Program Providers
☐ Policy Only ☒ Policy and Procedure ☐ Other:

Background

Complimentary starter packs are also known as manufacturer samples. These are prescription medications that are prescribed at no cost to physicians by manufacturer representatives for the purpose of trying a consumer on a medication to see how well it works. Community Mental Health's Services Programs (CMHSPs) have found the starter packs useful and fiscally responsible when providing medication to persons served who are indigent or have not met their Medicaid spend down. Patient Assistance Programs are sponsored by manufacturers to provide prescription medications to individuals who are low-income and would benefit from the product,

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but do not have insurance or the means to pay for the medications. Sample medications are not meant for on-going use by any individual.

Definitions

PAP: Patient Assistance Program

Procedure

I. Medication Storage (Based on the approved inventory by the Medical Director):
   A. All medications (either samples or medications from a PAP, hereafter to be referred to as "sample medications") shall be stored in the original containers in which a licensed pharmacist/pharmaceutical company dispensed them.
   B. Medications requiring refrigeration are stored in the medication refrigerator (appropriate temperatures will be recorded and maintained).
   C. Vaccines requiring storage in refrigerator and or freezer will be stored at appropriate temperatures according to the manufacturer and according to the BABH/ CDC COVID-19 Vaccination Program Provider Agreement.
   D. Medication cabinets:
      - Shall not be located over heated areas (heat can change the chemical properties).
      - Shall be used only for medication storage.
      - Shall be kept clean and orderly and inspected appropriately.
      - Shall have sufficient storage space and adequate lighting.
      - Shall be kept locked except when putting in or taking out medication.
   E. All external medication (e.g., ointments, salves, powders, etc.) should be stored separately from internal medications per manufacturer's specifications.
   F. Controlled substances/narcotics shall be stored to prevent diversion according to state and federal laws and regulations. Controlled substances in specialized residential homes should be double locked and counted at the end of each shift. The following list of medications should be included, but is not necessarily limited to: Benzodiazepines: Xanax, Ativan, Klonopin, Valium, and Restoril. Opiates: Oxycodone, Oxycontin, Vicodin, Norco, Morphine, Tramadol (Ultram),

Tylenol 3, Tylenol 4. Stimulant medications: Ritalin, Vyvance, Adderall, and Concerta. Ambien (Sleep aid)

G. An annual review of all "look-alike, sound-alike" medications and/or containers will be completed to ensure they are stored in separate areas (e.g., different shelves).
H. Key(s) to the locked medication storage cabinets must be secured by designated staff.

II. Sample Medications:

A. A prescribing professional can only dispense medications to his/her persons served.
B. All sample medications are to be in their original sample containers as provided by the pharmaceutical representative, affixed with a label, or the person served will be provided written directions that meet the Public Health Code (PHC) which include:
    - The individual's name,
    - The prescriber's name,
    - The name and strength of the medication,
    - The date the prescription medication was dispensed,
    - The directions for use,
    - The quantity dispensed, and
    - The Lot # and expiration date of the medication.
C. Sample medications located in the nurse's treatment office are to be locked in the cabinet. The cabinet in the office is to be locked at all times when not in use and to be opened when the prescribing professional wishes to dispense sample medications. The key to a locked medicine cabinet must be kept in a secure area. Only the nurse or the prescribing professional can use the key. At no time is the key to be taken out of the building.
D. The prescribing professional or nurse will complete a Sample Medication or PAP dispensing record and give the sample medication to the persons served with appropriate directions per the prescribing professional's order.
E. Only a prescribing professional may accept free samples of medications from the pharmaceutical representative. A logbook is to be kept in the medication storage cabinet (or alternative secure area) or in an electronic medication inventory

system. The prescribing professional, or nurse when accepting medication samples, must write legibly in the log book or enter into an electronic medication inventory system, the brand name (the generic name) as it is written on the box or label of the bottle of the sample, ex: Wellbutrin SR (bupropion hydrochloride), it's dosage strength, the total amount received, the lot number*, expiration date, and date received. There is no need to log the PAP sample medications into the inventory as they are specific to an individual and not part of the inventory. This can be completed through the prescriber's designee.

F. When a sample medication is dispensed, the name of the medication, the dosage, the amount given, lot numbers*, expiration dates and the date given will be documented in the logbook or entered into an electronic medication inventory system. A log of medications dispensed must be kept for at least five (5) years.

G. The professional will provide medication information (educational materials) to the person served or appropriate person regarding the medication and obtain the necessary signatures on the informed consent.

H. All expired sample medications shall be disposed of by grinding them up and mixing them with an undesirable substance, such as coffee grounds or kitty litter. Place them in impermeable, non-descript containers, such as sealable bags or empty cans, and throw them in the trash or keep segregated until sent to a pharmacy for disposal (a witness shall observe and a notation will be made in an electronic medication inventory system or appropriate log regarding the disposal and who observed).

I. Immediately before the sample medications are dispensed, the professional will inspect the medication, label, amount of product, and review for any allergies or adverse reactions.

J. A copy of this information will be given to the person served or appropriate person with a copy placed in his/her medical record.

K. The nurse will conduct a quarterly audit by comparing the logbook or electronic medication inventory system with actual inventory and providing this report to the medical director for signature and/or designated physician for review (see related form)

**The lot number will be recorded to perform necessary pharmaceutical recall activity in the individual's file, in the logbook, and in an electronic inventory system.*

III. Injectable Medications:

A. All injectable medications are to be delivered directly from the pharmacy. Injections that are delivered by a consumer should not be administered since refrigeration, stabilization, and other storage and handling requirements cannot be guaranteed unless delivered by the pharmacy. The injection must be administered by a nurse or prescribing professional. Persons served receiving injections of psychotropic medications will have their medication locked in a medication cabinet. The injectable drug must be administered to the beneficiary within 14 days of the arrival of the drug to the physician's office. For multi-dose vials, the first dose must be administered to the beneficiary within 14 days of the arrival of the drug to the physician's office. The vials, ampules, or bottles are to be labeled with the individual's full name, date seal is broken (good for 45 days unless it expires prior to 45 days), prescription number (if applicable), and prescribing professional's name. Only the nurse, prescribing professional or supervisor will have access to the medication cabinet.

B. Ordering: Prescribers add the medication in the prescribing module and indicate dose/frequency. The next step is to Process Prescriptions. All medications should default to E-Rx except injectable medications that default to None. All non-injectable medications will process to the preferred pharmacy selected in the system. Injectable medications need to be sent to the Override Pharmacy (Currently Walgreens in McLaren at 1900 Columbus Ave, Bay City, MI 48708). Allow pharmacy overrides for specific medications radio button should be checked. (See Figure 1 & 2):

Figure 1

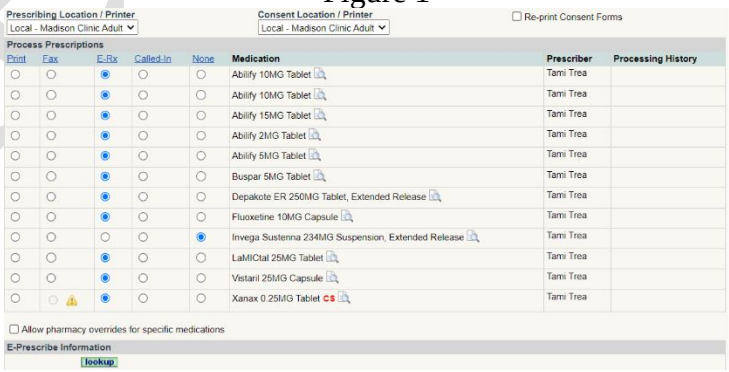
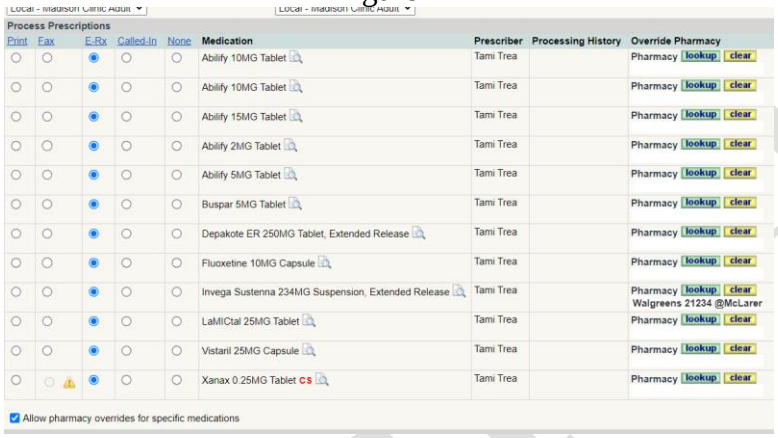


Figure 2



C. Prior to giving an injection, the nurse will check the medication order in the individual's chart and the nurse will use two (2) unique identifiers to identify the person served (e.g., 2nd facility person recognition, picture, birth date, or social security #, etc.), and check all 5 rights of medication administration and compare with the current medication order and double check to ensure the patient is not on more than one injection.
D. Consumer's that are on more than one injectable medication will have a pink alert sheet attached to each of their injectable medications. The medication will be reviewed by a second nurse as a witness to ensure the proper medication is being administered prior to administration.
E. Before giving injection, check the individual's vital signs, and applicable labs as indicated.
F. Draw up the solution in a safety syringe with a 22 gauge and 1 ½' needle (or other appropriate syringe and needle) and administer the injection.
G. Rotate the injection sites, alternating between the right and left dorsal gluteal or deltoid muscles, unless medically contraindicated, or pursuant to the individual's preference.
H. Document the injection per protocol, which must include the date, name of the drug, dosage, location of injection, nurse's signature, and include the individual's or family's response, if appropriate. Each injection is to be used with a new sterile disposable safety syringe/needle.

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I. All used, disposable, safety syringes/needles are to be disposed into a sharps container, and subsequently removed per protocol.

J. All the outdated injectable are to be disposed of by mixing them with an undesirable substance such as, coffee grounds or kitty litter. Place them in impermeable, non-descript containers, such as, sealable bags or empty cans, and throw them in the trash, or return them to the pharmacy that filled the prescription, for appropriate disposal. A second person must be present for the disposal and sign the logbook or make a notation in an electronic medication inventory system.

K. All individuals with an injection prescribed to Walgreens at McLaren need to sign the Walgreens consent to delivery form. The signed consent form will be uploaded to consumer chart before being given/faxed to Walgreens for their records.

IV. Naloxone Kit storage and Dispensing: Distributed to family/friends/community member or person served; anyone who has reason to believe someone is at risk of opiate overdose.

A. The prescriber of each kit will be the physician at Mid-State Health Network who will be supplying kits to each designated CMH site for community use.

B. ~~Naloxone Issuance and Tracking Form will be used to track kits delivered to the clinic sites and dispensed to the community.~~Clinic sites will store and document supply kept on hand and where kits were dispensed to i.e. local law enforcement, vending machines (grant funded so tracking is required), and clinic sites (number of kits placed in the lobbies or common areas for individuals to take as needed).

C. Kits are to be stored in a locked cabinet at any of the three clinic sites (Madison, Arenac, ACT).

~~D. Naloxone Kit Checklist and Order to Dispense Form will be used by clinic professionals for dispensing the kit(s). The Checklist will be given to the individual receiving the kit as well as saved to the EHR specific to a person served. If there is not an identified person served and the kit is being distributed to assist an anonymous community member, then a copy of the Checklist will be kept in a binder at the clinic site. This checklist documents required education that is given to individuals accepting kit(s).~~

~~E.~~D. Disposal of expired kits will be the responsibility of nursing staff at the clinic sites and will follow the rules specific to Naloxone.

~~F. Naloxone Issuance and Tracking Form will be reviewed at least quarterly at Healthcare Practices Committee.~~

~~G. If BABHA staff become aware of a known overdose of an active person served, and Incident Report form must be filed to track outcomes.~~

V. Fentanyl and Xylazine Test Strips: Distributed to family/friends/community member or person served; anyone who has reason to believe someone is at risk of overdose.

A. Testing Supplies are to be stored in a locked cabinet at any of the three clinic sites (Madison, Arenac, ACT).

B. Clinic sites will store and document supply kept on hand and where kits were dispensed to i.e. local law enforcement, vending machines (grant funded so tracking is required), and clinic sites (number of kits placed in the lobbies or common areas for individuals to take as needed).

C. Disposal of expired testing materials will be the responsibility of nursing staff at the clinic sites and will follow the rules specific to test strips.

~~V.~~VI. Vaccines: BABH will comply with all CDC COVID-19 Vaccination Provider Agreement terms. (See Attachment)

~~VI.~~VII. Recall Of Medications:

A. As BABH staff (e.g. ~~Clinic Practice~~ Clinical Services Program Manager~~-~~ Psychiatric Clinic and Outpatient Services, prescribing professionals, or nursing staff) become aware of medication recalls, a notice will be distributed to all appropriate BABH sites and contracted physician practices regarding the recall.

B. Recall alerts may come from the MEDWATCH (a publication from the FDA, Safety Information and Adverse Event Reporting Program), a subscription maintained by the Medical Practice Manager, the manufacturer or a pharmacy.

C. All medications that are recalled will be disposed of appropriately or sent back as directed.

D. If the prescription was ordered through a BABH site or a contracted physician practice, the individual will be notified and an alternative medication will be prescribed, if appropriate.

E. As medication adverse reactions are reviewed through the Medical Management/Peer Review Committee and recommendations are made for further

action (e.g. ordering of pertinent labs, recommended dose ranges, etc.), all appropriate BABH sites and contracted physician practices will be notified.

Attachments

~~CDC COVID-19 Vaccination Program Provider Agreement~~
BABHA list of Treatment Providers
Discontinued/Expired Medication Disposal Form
Look-Alike, Sound Alike Meds
~~MDHHS Bulletin, "Coverage of Pharmacy Claims for Certain Outpatient Physician Administered Injectable Drugs" July 1, 2015~~
Medication Inventory Form
Naloxone Kit Checklist and Order to Dispense Form
Narcan Database
Narcan Kit Dispensing Directions
Opioid Education Handout II
Overdose Response Procedure
PAP or Sample Medication Dispensing Record
ACT Medication Protocol
Walgreens: Health Care Provider (HCP) Representative Patient Choice and Record of Delivery Form

Related Forms

BABH Consumer Medication or Food Refrigeration Temperature Log (G:\BABH\Safety Materials\Inspection Forms, Schedule and Logs)

Related Materials

N/A

References/Legal Authority

CARF
State Pharmacy Regulations

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SUBMISSION FORM

AUTHOR/ REVIEWER	APPROVING BODY/COMMITTEE/ SUPERVISOR	APPROVAL /REVIEW DATE	ACTION (Deletion, New, No Changes, Replacement or Revision)	REASON FOR ACTION - If replacement list policy to be replaced
M. Bartlett	MMPRC	04/15/08		
M. Bartlett	MMPRC	04/21/09		
M. Bartlett	MMPRC	05/15/09	Revision	Updated to recognize those controlled substances that need to be double locked and counter at the end of each shift.
M. Bartlett	M. Bartlett	08/17/09	Revision	Reviewed/forms added
M. Bartlett	MMPRC	06/19/12	Revision	Revised to reflect actual practice
Amy Folsom/Karen Amon	HPC	11/28/16	Revision	Revised to add the addition of accepting, storing and dispensing Naloxone Kits.
S. VanParis	HPC	5/17/17	Revision	Reviewed/updated controlled substance to be more inclusive.
S. Van Paris	Healthcare Practices Committee	6/18/18	Revision	To include MDHHS rules regarding injectable medications for Medicare/Medicaid-Triennial Review
S. Van Paris	HPC	9/1/21	Revision	To include information on safety witness for a consumer on more than one injectable. Added reference to CDC COVID-19 Vaccination Provider Agreement
S. VanParis	S. VanParis	9/7/2023	No changes	Added ACT Med Protocol as attachment
A. Folsom/S. VanParis	HPC	1/23/24	Updated to current practice	Added specific information about the intended use of Sample meds and updated Narcan distribution protocols.