

Charleston Dorchester Mental Health Center

Drug Policy

(In conjunction with DMH Directive "Medication Control and Accountability – May 2003)

Subject:

Drug outlet room; procurement, storage, delivery, and record-keeping of medications.

Purpose:

To establish procedures for storage, handling, administration and delivery of medications in compliance with state and federal regulations and in consultation with a registered pharmacist (Pharmacist Consultant) licensed by the South Carolina Board of Pharmacy.

Responsible Persons:

Mental Health Center Executive Director, Medical Director, Physicians, Nurses, and Pharmacy Consultants.

Policy:

The Charleston Dorchester Mental Health Center (CDMHC) will comply with the following guidelines for procurement, storage, and delivery of medications. This policy provides guidelines for all medications received by the Center. This Policy is written in accordance with DHEC regulations and State Licensing Boards, and is to be updated as necessary. This organization engages in pharmacotherapy practices that include evaluating, prescribing and administering medication, as well as medication monitoring.

Procedures:

1. The following licensure shall be maintained and posted in the clinical area of the address the document:

- South Carolina Pharmacy Drug Outlet Permit
- Federal DEA Registration (if applicable)
- South Carolina Controls Substance Registration (if applicable)

A. The drug outlet permit shall be posted in a conspicuous place in the permitted facility for which it is issued. The Board of Pharmacy shall be promptly notified upon the change of the permit holder or the change of location of the permitted site.

B. A Federal DEA Registration and South Carolina Controlled Substance Registration must be maintained for each permitted site which stores controlled substances.

2. Access to medication storage areas shall be limited as follows:

A. Keys to the medication storage areas may be accessed by the chief of medical services, physicians, nurse practitioners, licensed nurses, pharmacist consultants, and/or clinic site Director as designated by the Medical Director. Keys should be kept in the possession of the designated individual responsible for the Drug Outlet Room.

3. Procedures for ordering or obtaining medication:

A. **Stock medication** will be ordered through contracted drug wholesaler selected by the Department of Mental Health.

B. **Pharmaceutical Assistance Program Medications** shall be obtained from participating companies for qualified consumers.

C. **Sample Medications** shall be obtained from participating pharmaceutical representatives.

D. Medications can also be provided by the **DMH/Prescription Drug Card Program**; however, these medications are dispensed directly by the participating pharmacies to the eligible consumer, and hence are not stored at the program sites. However, the medication may be safely stored in the Drug Outlet Room in the event a consumer cannot safely manage his or her medication. The consumer will be given a weekly pill-minder. Under the supervision of the case-manager, the consumer will fill his or her medication into the pill-minder and the remaining medication will be stored in the Drug Outlet Room.

4. Storage and Disposal of medications:

A. Stock Medication and Pharmaceutical Assistance Program medications shall be stored and locked in the Drug Outlet Room. Individual consumer's medications may be stored in the medication storage area for up to 90 days from the date dispensed.

B. Sample Medications shall be stored and locked in an appropriate area, separate from Stock Medication and Pharmaceutical Assistance Program medication.

C. Storage of medications shall meet the following requirements:

(1) All medications shall be stored under proper conditions of sanitation, temperature, moisture, ventilation, sterilization, and security.

(2) Controlled substances shall be stored using a double lock method.

(3) Medication refrigerators shall be clean, frost-free, and maintained at an internal temperature range of 36 degrees to 46 degrees Fahrenheit. Internal temperature shall be monitored at least weekly and recorded on a temperature log which shall be kept readily retrievable.

(4) Doors to medication cabinets should be kept locked at all times. Doors to medication rooms should be kept locked when not in use.

(5) Medications which are labeled "for external use only", i.e. alcohol, hydrogen peroxide, etc., must be stored separately from oral medications and injectable medications.

(6) All required records shall be held readily retrievable for a period of two years.

D. All expired medications will be given to the Pharmacy Consultant for proper disposal.

E. Transportation: Medications are securely transported daily by courier from a central location to our outlying clinic sites.

F. Utilization of pill packs or pill minders – refer to procedure outlined in **Appendix D**.

5. Utilization of Medications:

A. Stock medication:

Injectable Medications:

(1) All injectable medication dosages must be checked for proper amount and frequency of administration by having the most recent physician's order in the chart identified just prior to administering the injection. All doses administered should be recorded on a perpetual inventory log sheet. (Drug Accountability Sheet-DAS) See **Appendix A**.

(2) Opened multi-dose files are initialed and dated when opened and discarded within 12 months of date puncture, or the manufacturer's expiration date, with the exception of PPD, which must be discarded after 30 days.

(3) Procedures for injection:

-Hands should be washed or properly cleaned prior to and after injection is given. Always wash any skin surface immediately if exposed to blood or body fluids (see Exposure Control Plan Policy).

-Injectable medications, including single dose and multi-dose, will be drawn up using aseptic technique and will be used within one hour of draw. Injectable medications that require reconstitution will be reconstituted using aseptic technique and will be used within one hour.

- Needles or other sharp instruments should be handled with extreme care.
- Needles should never be cut or recapped.
- Syringes with needles attached should always be placed in the Sharp Disposal Container.
- All Sharp containers will be disposed of according to the Exposure Control Plan Policy.
- Upon removing the needle from the skin, a dry sterile dressing will be applied to the injection site.

B. Oral Stock Medication:

One dose of a Stock Medication may be administered by a registered nurse upon the order from a physician. For example, a nurse may follow doctor's orders and administer medication to a consumer presenting to the clinic with extra-pyramidal symptoms. Stock Medications cannot be dispensed, i.e., medications cannot be given to the consumer for at home use. Each Stock Medication should have a Drug Accountability Sheet (DAS) and each dose administered should be recorded.

C. Pharmaceutical Assistance Program Medications: a number of pharmaceutical companies offer pharmaceutical assistance programs for consumers unable to pay for their medications. The Center encourages physicians, nurses and clinicians to utilize the programs for the indigent consumers who are unable to pay for their medication. Application forms are available and are specific to each pharmaceutical company.

(1)Pharmaceutical Assistance Program medications are sent from the company to the Center program. The drug outlet nurse/doctor will record receipt of medication on a log sheet (see Appendix B). The consumer's physician will appropriately label the medication bottle with the consumer's name, drug and dosage, quantity, directions, date, physician's signature, and applicable cautionary statements (e.g., 'may cause drowsiness'). Upon the physician's orders, the medication may be distributed to the consumer by the clinician, nurse, or physician. The log sheet must then be completed regarding date consumer picked up medication, quantity of medication, quantity remaining, and initials of staff member.

(2)The physician and clinician are responsible for submitting renewal applications to the pharmaceutical company as needed.

D. Sample Medications may be obtained from Pharmaceutical Representatives.

The consumer's physician will appropriately label the medication bottle with the consumer's name, drug and dosage, quantity, directions, date, physician's signature, and applicable cautionary statements (e.g. 'may cause drowsiness'). Registered nurses and clinicians are not permitted to count, package or label medications. Upon the physician's orders, the medication may be distributed to the consumer by the clinician, nurse or physician.

E. The DMH/Prescription Drug Card Program is a program developed by the Department of Mental Health that allows the Center to pay for medications.

(1) Procedure:

-Application forms are available in each program area.

-The Drug Outlet Room nurse/physician of each program will oversee the plan.

-A physician and nurse designated by the Medical Director will oversee the entire pharmacy assistance plan to insure proper utilization.

-After the form is filled out by the physician or his/her designee, a copy will be faxed to the nurse who oversees the plan. An additional copy will be placed in the consumer's chart.

-A label will be placed on the consumer's chart, indicating the consumer is a participant of the plan.

(2) An eligible consumer may receive medication under this plan for a period of 6 months. The treatment team may re-apply for the medication plan if appropriate.

F. CDMHC utilizes sample medication, Patient Assistance Programs and other community resources to assist our clients in continuing on the most appropriate medication for their psychiatric illness, regardless of whether or not a generic substitution is available.

6. Record Keeping

A. Drug Accountability Sheet (DAS): A DAS shall be used by all service areas to record receipt of all (except Sample Medication) stock drugs and their distribution. All drugs must be checked monthly for expiration date and indicated as monthly audit on the back of the DAS. Controlled substances shall be counted and documented on a DAS by a registered nurse on a daily basis, and per the requirements of the Federal DEA Registration and the South Carolina Controlled Substance Registration.

B. Sample Medication: Medications identified as physicians' samples shall not be stored in the Drug Outlet Cabinet. Physicians who choose to utilize samples shall be solely responsible for secure storage and accountability. Physicians' samples of controlled substances may only be secured at a program that has obtained a Federal DEA Registration and a South Carolina Controlled Substance Registration. When dispensing physicians' samples of controlled substances, physicians must adhere to all labeling requirements as determined by the South Carolina Department of Health and Environmental Control Controlled Substances Regulation (R-91-4 of the 1976 Code of Laws of South Carolina as amended). No physician shall dispense to a single patient more than a 30 days supply of neither a controlled substance, according to labeled dosage nor more than 120 dosage units upon any single occasion.

7. Responsibilities of Pharmacist Consultants: As stated in the South Carolina Pharmacy Practice Laws and Regulations-Chapter 43.40-43-86, C.

A. Sign any new or renewal applications for a Drug Outlet Permit.

B. It shall be the Pharmacist Consultant's duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations to:

(1) Establish as applicable to the permit; policies and procedures for the procurement, storage, compounding, dispensing, and distributions of drugs;

(2) Establish and supervise the record keeping system for the purchase, sale, possession, storage, safe keeping, and return of drugs;

(3) Facilitate drug recalls and removal of outdated drugs;

(4) Supervise all of the employees of the permit holder insofar as their duties relative to the procurement, compounding, sale, distribution, and/or storage of drugs.

(5) Act as a drug information resource for the staff by bringing new and current drug information to their attention and being available by phone for questions.

C. It shall be the duty and responsibility of the outgoing Pharmacist Consultant and the permit holder to notify the Board of Pharmacy in writing within five days of the change of Pharmacist Consultant.

D. No designation of an individual as Pharmacist Consultant or delegation of duties to a Pharmacist Consultant by a holder of the Drug Outlet Permit shall relieve the permit holder of any of the permit holder's duties under the state or federal laws or regulations.

D. The pharmacist consultant shall conduct an inspection of each permitted medication storage area monthly. Documentation of inspection shall be recorded on the Medication Storage Area Audit Form (see Appendix C). A copy of the completed form shall be readily available in the medication storage area. The pharmacist consultant shall provide a summary report to the Center's Medical Director.

8. Written procedure regarding Pharmacotherapy.

A. Pharmacotherapy is an integral part of the treatment of a variety of psychiatric syndromes.

-Medication therapy is initiated with patient's consent after an adequate discussion of the risks and benefits of the selected medication(s) has occurred and patient has had the opportunity to ask questions.

-The pharmacotherapy is provided by the treating psychiatrist/MD and any other psychiatrist/or nurse practitioner in the center who may be providing crisis coverage or emergency assessment where indicated.

-The medication therapy is a part of a range of services provided to the patient, by the treatment team.

-Medication tolerability, side effects, adverse reactions, and efficacy are monitored by the doctor/nurse practitioner at every pharmacotherapy visit, furthermore, case managers communicate medication questions and concerns to the physician/nurse practitioner between visits should they arise, and documented appropriately.

-At the time of pharmacotherapy initiation, and whenever medication regimens are altered in any way, drug reactions are reviewed and instructions on handling medication related emergencies are reviewed by a member of the treatment team.

-Medications administered on an as needed basis will be documented on the PMA sheet clearly in clinical settings; and documented and ordered on a separate PRN sheet in residential care settings.

-The Physician Medication Sheet (PMA) has a record which is updated at each visit of all the patient's psychotropic medication and dosages, the frequency of administration and instructions for use, as well as over the counter medications, dietary supplement and herbal medicines and medication prescribed by other physicians in distinct columns. The health evaluation form records the names of all other physicians who treat and prescribe for the patient. The risk of drug-drug interactions and drug-food interactions are discussed during the PMA, as the need arises as determined by the physician/nurse practitioner and documented in the chart*.

-In residential settings, over the counter medication requires a physician order to be administered. Patients are discouraged from taking any OTCs without checking with a physician first.

- Other prescribing professionals are informed of adverse drug and drug-drug interactions, problems with medication tolerance and errors, when necessary. Physicians/nurse practitioners maintain contact with the primary care physician whenever the clinical situation requires it.
- In cases of off site administration of prescribed medication; pill minders are frequently used and medication instructions are clearly written out and reviewed with patient and caregiver before they leave for off site visits.

B. There is a physician on call for emergencies after hours and on weekends and can be contacted if necessary by the emergency staff (at Mobile Crisis and Crisis Stabilization Unit), regarding consultation about patient's medication concerns. Depending on the urgency or severity of the concern the patient may be referred to the emergency room or their primary care physician. The case manager and physician are then notified of the concern and the intervention and outcome of the intervention and are expected to follow up with the patient as needed.

C. The review of past medication use with attention to efficacy, side effects and tolerability, adverse drug reactions and allergy history is a part of the initial assessment of patients when charts are opened at the center.

- These factors are explored at intervals by the treating physician/nurse practitioner especially at times of medication change exploration or change in treating physician/nurse practitioner, and during the six month health evaluation update. Evaluation of coexisting medical conditions and concomitant drug or alcohol abuse are done in an ongoing way during PMAs (physician medication assessments).

- Medication errors are documented in the patients chart after they are detected and the case is discussed with the patient's physician.

- Medication errors are documented as adverse incident reports which are then reviewed by the Risk Management Committee and the committee makes recommendations to the Executive Director if necessary.

D. To address the use of medications in pregnancy and in women of childbearing age, a list of medications with their safety rating and FDA assigned categories are placed in each clinical area where PMAs are done; also this is a regular part of the risk/benefit discussion when using these medications for these groups of patients.

- All center telephones at clinical sites bear the sticker with the poison control center number which is readily accessible for program personnel to provide to persons served wherever the need arises.

- The poison control number must be posted in all medication storage areas as well as in all areas frequented by staff and consumers.

- Lab work for effective monitoring of prescribed medications are ordered as the laboratory guidelines (updated Feb 2003) dictate. Lab work requested is documented in the PMA note; and/or copy of the lab request is maintained in the chart until lab results are obtained, reviewed, dated and is signed off by physician and filed in the medical records.

E. The neuroleptic consent form is required to be signed at the time of initiation of neuroleptic therapy when possible. This form documents the unique risk/benefit characteristics of this class of medication, highlighting the risk of tardive dyskinesia which may be an irreversible side effect. If a patient refuses to sign the neuroleptic consent form, the refusal is to be documented on the form and evidence of verbal consent is noted on the PMA sheet.

F. Prescription pads must be secured and locked at all times unless in the immediate physical possession of an appropriately licensed professional or other authorized individual.

9. The mental health center takes various measures to ensure that state of the art pharmacotherapy in a safe and efficacious way is provided to our patients.

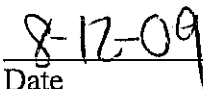
-The measures include but are not limited to:

- A. Circulation of current journals with a pharmacotherapy emphasis.
- B. Case presentations at the monthly physician meetings.
- C. Medication alerts are circulated promptly from the office of the Medical Director to all prescribers.
- D. Review of the PMA note by the QI team during chart audits are forwarded to the Medical Director where appropriateness of therapy, and other essential aspects of documentation are reviewed.
- E. Independent quarterly chart audits are conducted by the Medical Director to ensure quality of care is being maintained.
- F. Clinical case discussions occur regularly during supervision of nurse practitioners; and as needed with physicians.
- G. Our center has adapted the use of medication algorithms into clinical practice.

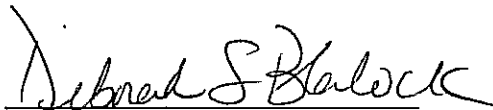
This policy and procedure policy does not prohibit each service area from further clarification of procedures specific to that area, as long as it is in compliance with this policy and procedure statement.



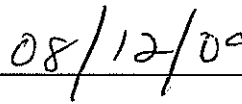
Katherine Smith, MD
Interim Medical Director



Date



Deborah S. Blalock, M.Ed., LPCS
Executive Director



Date

Revised: 10/7/03; Revised: 10/31/06; Revised: 09/05/08 Revised 08/12/09

COMMUNITY MENTAL
HEALTH CENTERS



PHARMACY SERVICES
MEDICATION STORAGE AREA AUDIT

CENTER _____ PROGRAM _____ DATE _____

PHARMACIST _____ NURSE _____

STANDARD	YES	NO	N/A
1. MEDICATION STORAGE AREA IS NEAT, CLEAN AND SECURE.	()	()	()
2. MEDICATION STORAGE REQUIREMENTS ARE MET.	()	()	()
3. ALL MEDICATIONS REQUIRING REFRIGERATION ARE STORED AT THE APPROPRIATE TEMPERATURE (36° to 46°F.) AS DOCUMENTED ON THE TEMPERATURE LOG.	()	()	()
4. AN ADEQUATE SYSTEM OF MEDICATION CONTROL AND ACCOUNTABILITY IS IN PLACE.	()	()	()
5. ALL MEDICATIONS AT OR NEAR EXPIRATION DATE AND/OR RECALLED HAVE BEEN REMOVED.	()	()	()
6. OPENED MULTIDOSE VIALS ARE INITIALED AND DATED. (12 MO. EXP. DATE or MANUF. EXP. DATE) (PPD-30 DAY EXP. DATE)	()	()	()
7. CONTROLLED SUBSTANCES ARE STORED UNDER DOUBLE LOCKS.	()	()	()
8. CONTROLLED SUBSTANCES ARE INVENTORIED AS REQUIRED.	()	()	()
9. ANTIDOTE CHART, SUBSTITUTION LIST, DRUG OUTLET PERMIT, AND OTHER REQUIRED LICENSES ARE APPROPRIATELY POSTED.	()	()	()
10. CURRENT ISSUE OF PHYSICIANS DESK REFERENCE OR OTHER APPROPRIATE CLINICAL REFERENCE IS READILY AVAILABLE.	()	()	()
11. CURRENT COPY OF PHARMACY PRACTICE ACT, CONSULTANT PHARMACIST INSPECTION REPORTS, & MEDICATION POLICIES & PROCEDURES ARE AVAILABLE.	()	()	()
12. ARE PHYSICIANS' SAMPLES PRESENT?	()	()	()
13. IF PRESENT, PHYSICIANS' SAMPLES APPROPRIATELY LABELED.	()	()	()
14. ARE PATIENTS' PERSONAL MEDS PRESENT?	()	()	()
15. DATE ON PATIENTS' PERSONAL MEDS IS WITHIN 90 DAYS OF DATE ISSUED.	()	()	()

COMMENTS:

APPENDIX D

PROCEDURE FOR ASSISTING CLIENTS TO REFILL WEEKLY PILL PACKS

1. Pill packs are defined as weekly or monthly medication minders.
2. Do only one task at a time. When dealing with the consumer please remember that you are engaged in an educational process to assist him/her in becoming capable of self management of medications. You may have to redirect the client's attention to the specific task, and you may have to do that repeatedly. Redirecting will minimize confusion, enhance the consumer's concentration and lessen the opportunity for errors.
3. The consumer is the person who handles the medication: staff's role is to educate and to observe the consumer's progress.
4. If, at any time, when you are dealing with the client about medication and you have questions, phone the office for assistance. If there is no physician or nurse available, explain to the consumer that you will clarify the issue and contact him/her later in the day.

STEPS FOR PILL PACK REFILLS

CASE MANAGERS:

1. The nurses will remove the consumer's individual prescription bottles from the locked cabinet and turn them over to the case manager along with the pill pack. If controlled substances are involved, the quantity in the prescription bottle is verified with the on hand written inventory. The case manager will sign the inventory sheet along with the nurse, taking responsibility for the medication. When it is returned, the amount used in the pill pack is subtracted from the on hand inventory and the remaining quantity is verified by both the nurse and the case manager. After receiving the consumer's individual prescriptions bottles from the nurse, the case manager will take the prescription bottles and the pill pack to the consumer's home and proceed with the following:
 - A. Observe the pill pack currently in the consumer's possession. Are there medications left? If so, make a note to bring this to the nurse's attention.
 - B. Hand the pill pack and the prescription bottles to the consumer and ask him/her to fill the pack correctly.
 - C. Observe as the consumer proceeds with each bottle. Encourage the consumer to read the label for the correct directions for use, or if appropriate, read the directions for the consumer. Discuss the number of pills to place in the container for a daily dose and the time of day it is to be taken; morning, at bedtime, etc.
 - D. When the consumer has completed filling the pill pack, check to see that it has been done correctly. If not, re-instruct the client.