



Health Care Agency Mental Health and Recovery Services Policies and Procedures	Section Name:	Compliance
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Director of Operations Mental Health and Recovery Services		<u>Signature on File</u> <u>5/17/2023</u>

SUBJECT: Outpatient Clinic Medication Rooms - Receipt, Storage, Administration, Disposal and Accountability of Medication

PURPOSE:

To ensure the receipt, storage, administration and disposal of medications is safe, effective and accountable.

POLICY:

Health Care Agency (HCA) Mental Health and Recovery Services (MHRS) medical staff must follow specific procedures for the clinical receipt, storage, administration and disposal of medications for clients being treated through Orange County's Mental Health Plan (MHP) or Substance Use Disorder (SUD) program.

SCOPE:

This procedure outlines a specific role of the medical and nursing staff in county operated programs. Unescorted access to the medication room is limited to Mental Health and Recovery Services Behavioral Health (BH) Nurses and Psychiatrists/Physicians.

REFERENCES:

[SD/MC Provider Certification & Re-Certification Protocol, Department of Health Care Services \(DHCS\), September 2019 \(Quality Management Services version\)](#)

[Code of Federal Regulations Title 21 \(Food and Drugs\), Chapter II \(Drug Enforcement Administration, Department of Justice\), Parts 1300-1321](#)

Code of Federal Regulations Title 21 (Food and Drugs), Chapter II (Drug Enforcement Administration, Department of Justice), Parts 1300-1321 Final Rule RIN 1117-AB55

21 U.S.C. 829a(a)(5) SEC. 1264. Increase In Number of Days Before Which Certain Controlled Substances Must Be Administered

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FORMS:

[Medication Refrigerator and Room Temperature Record](#) (F346-709 Rev.12/21)

[Record of Medication \(Non-Controlled Substances\) Receipt, Storage, Administration and Disposal](#) (F346-710 Rev. 12/21)

[Record of Medication Receipt, Storage, Administration and Disposal \(Controlled Substances\)](#) (QMS SUD Controlled F346-710C Rev. 5/22)

[Daily Record of Medication Storage \(Controlled\)](#) (QMS SUD Controlled Rev. 12/21)

[Orange County Mental Health & Recovery Services Medication Room Annual Review Checklist](#) (Rev. 2/22)

DEFINITIONS:

Controlled Substance Medication - medication(s) that fall under federal regulation of the Controlled Substances Act (CSA).

Bio-Hazardous Waste - any waste item that may be contaminated by blood, body fluids or other potentially infectious materials.

PROCEDURE:

- I. All sample and patient-specific medications shall be used exclusively for the treatment of patients under a current MHP or SUD episode of care.
- II. Acquired Medications
 - A. All acquired medications shall be recorded by the clinic nursing staff in the Record of Medication (Non-Controlled Substances) Receipt, Storage, Administration and Disposal (F346-710 Rev. 12/21) or Record of Medication Receipt, Storage, Administration and Disposal (Controlled Substances) (QMS SUD Controlled Rev. 5/22). This form shall be referred to as Medication Log for the purposes of this document, and shall be stored in a locked cabinet in the medication room.
 - B. All acquired medications (Patient-Specific, Samples, Patient Returned/Unused) entering the facility shall be logged sequentially and will note as appropriate: Name of the Patient, Date Ordered (N/A may be written in log for subsequent refills if initial order date of medication prescribed remains unchanged), Date Received, Expiration Date, Medication Name, Strength and Quantity, Name of Issuing Pharmacy, Type of Medication (Patient-Specific, Sample, Patient Returned) and staff initials.

SUBJECT: Outpatient Clinic Medication Rooms – Receipt, Storage, Administration, Disposal and Accountability of Medication

1. Receipt and disposal events involving controlled substance medications require the signatures of two licensed HCA clinical staff. The primary signature must always be a medically licensed staff (MHRS Psychiatrist/Physician or MHRS BH Nurse), but the second/witness signature may be a non-medically Board of Behavioral Sciences (BBS) or Board of Psychology (BOP) licensed or registered staff.
- C. Sample medications shall be stored only in the medication room.
- III. For medications obtained by prescription, staff shall ensure that prescription labels are in compliance with federal and state laws, showing: Name of the Patient, Name of the Prescriber, Name of the Medication, Dosage/Strength, Route of Administration, Frequency, Quantity of Contents, Indications and Usage (when applicable), and Date of Expiration.
 - IV. To demonstrate accountability for each medication, each line entry on the Medication Log must track receipt of every type (Patient-Specific, Sample, Patient Return) of medication received, administered or disposed/destroyed, and all applicable sections of the log must be entirely completed.
 - V. Expired medication shall be removed immediately from storage and placed in a disposal container located in a locked cabinet. Tracking the expired medication must be entered into the Medication Log demonstrating accountability and must include Date, Prescription Number, Amount of Medication Destroyed/Returned, Type (waste, return, finished) and signatures of two licensed HCA clinical staff.
 - VI. Copies of the receipt from the pharmacy or pharmaceutical company shall be kept in a binder or with the Medication Log in the medication room for three years.
 - VII. Nursing staff coordinate with front office staff when syringes and other necessary supplies are ordered. The front office staff receives the items and tracks the receipts of supplies.
 - VIII. Potential Sources of Acquired Medications
 - A. No-cost, sample medications from pharmaceutical companies ordered by clinic physician via pharmaceutical representatives.
 - B. Prescription patient-specific medications ordered from pharmacies, such as Intramuscular injection (IM) medications.
 - C. Prescription medicines obtained through a Patient's Assistance Program.
 - D. Homeless patients may request that their 'patient-specific' medications (including non-psychiatric medications) be stored in the locked medication room by a psychiatrist/physician or the nursing staff. The medication must be

logged in, and then logged out when returned to the patient or disposed of. When logging medications for storage, details of medication name, dose and quantity should be recorded. The medications may be disposed of as described in section XII when the patient verbally indicates they no longer need the medications, or when the patient is discharged from the clinic.

IX. Storage of Medication in the Medication Room

- A. The stock of all medications and syringes shall be kept at a clinically appropriate supply to safely and effectively meet the specific needs of the individual clinic.
- B. The clinic Psychiatrist/Physician and Nursing staff shall consult with the Service Chief/Program Manager to determine the need for medications to be acquired for storage in the clinic medication room.
- C. Medications and syringes shall be kept in a locked cabinet within a locked medication room or locked refrigerator. The medication room is to remain locked at all times-both during business hours and after business hours.
- D. Controlled substance medications require storage under two sets of locking mechanisms--i.e., double locked.
- E. The secured keys for the medication room, medication cabinet(s) and refrigerator shall be available only to medical personnel. Medical personnel shall exercise the highest level of vigilance in keeping assigned keys secured.
- F. Multiple programs sharing a medication room shall keep medications separated by program and clearly labeled.
- G. Controlled substance medications must be locked separately from other non-controlled medications in an additional lockbox to be bolted/mounted within a locked storage cabinet, or in a locked refrigerator dedicated solely to storage of controlled substance medications if the medication must be stored at cold temperatures.
 - 1. The keys to the controlled substance medications lock box must be keyed differently from the lock on the cabinet in which it is stored. Keys to the locked cabinet shall not be stored in the same location as keys to the controlled substance medications lockbox or refrigerator. Keys for the storage of controlled substance medications shall never be accessible to anyone other than designated MHRS Psychiatrists/Physicians and MHRS Nurses.
 - 2. Only store controlled substance medications in lockboxes or refrigerators that are designated for controlled substances. Do not mix supply and storage of medications that are controlled and those that are not controlled.

3. Controlled substance medication lockboxes or refrigerators shall only be unlocked and opened for the time needed to access a controlled substance medication for administration to a patient or for return to pharmacy or for disposal/destruction. These lockboxes and refrigerators are to remain locked at all other times.
 4. As required with all medications, administration, return and disposal of controlled substance medications must be recorded on designated Medication Logs with all fields completed.
 5. Receipt and disposal events involving controlled substance medications require the signatures of two licensed HCA clinical staff. The primary signature must always be a medically licensed staff (MHRS Psychiatrist/Physician or MHRS BH Nurse), but the second/witness signature may be a non-medically Board of Behavioral Sciences (BBS) or Board of Psychology (BOP) licensed or registered staff.
 6. Per federal regulations, long-acting injectable buprenorphine (Sublocade) must be administered to the patient within 45 calendar days after the date of receipt of the medication. If not administered within that timeframe, the medication must be disposed of/destroyed or returned to the pharmacy through the process described in this document. To support this process, 'Administer By' dates will be recorded on the Medication Log as well as on a sticker to be affixed directly on each package of Sublocade. Additional requirements for the handling of long-acting injectable buprenorphine (Sublocade) are listed in the Reference above for Final Rule RIN 1117-AB55.
- H. All medication shall remain in its original and clearly marked packaging.
- I. Medications labeled with patient's names are for use only with that patient and shall be kept separate from samples and medications.
- J. Oral and injectable medications shall be stored separately.
- K. Expired medication shall be removed immediately and placed in the disposal/waste container (see section XII C). Expired controlled substance medications must be disposed of/destroyed or returned to the pharmacy through the process described in this document (see sections XI and XII).
- L. Opened vials of long-acting antipsychotic medication shall be labeled with the date they were initially opened and with staff initials. These vials shall be discarded within 28 days after initial puncture, unless the manufacturer specifies a different period (longer or shorter).
- M. Medications, testing supplies, or laboratory samples requiring refrigeration

SUBJECT: Outpatient Clinic Medication Rooms – Receipt, Storage, Administration, Disposal and Accountability of Medication

shall be stored in a refrigerator maintained between 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit) and temperatures shall be monitored and logged on the Medication Refrigerator and Room Temperature Record (F346-709 Rev. 12/21). This form shall be referred to as Temperature Log for the purpose of this document. Temperatures shall be checked on a business daily basis in the Substance Use Disorder programs and at least weekly in the Mental Health programs. When there is nothing stored in the refrigerator for extended periods of time, this shall be indicated on the Temperature Log.

- N. Room temperature medication shall be stored between 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit) and room temperature shall be monitored and recorded on the Temperature Log at least weekly.
 - O. Food shall not be kept in the medication refrigerator.
 - P. Externally applied medications shall be kept separate from internally administered medications.
- X. Administration/Dispensing of Medications from the Medication Room
- A. Medication shall be administered or dispensed only when a physician's order is written in the patient's chart/Electronic Health Record (EHR).
 - B. When medication is administered or dispensed, the nursing staff shall enter a progress note into the patient's chart/EHR and complete the Medication Log: Date and Time Administered/Dispensed; Amount/Dosage; Route of Administration/Pick-up and signature of authorized staff who administered the medication.
 - C. If vital signs are taken or physical observations of the injection site are made, these shall be recorded in patient's chart/EHR.
- XI. Return of Medication
- A. Medication that was acquired from pharmacies may be returned for possible credit if it is not needed.
 - B. All medications returned to a pharmacy must be logged on the Medication Log. Return of controlled substance medications to a pharmacy requires the signatures of two licensed HCA clinical staff. The primary signature must always be a medically licensed staff (MHRS Psychiatrist/Physician or MHRS BH Nurse), but the second/witness signature may be a non-medically Board of Behavioral Sciences (BBS) or Board of Psychology (BOP) licensed or registered staff.
 - C. A copy of the routing slip or receipt from the pharmacy shall be kept in a binder or with the Medication Log for three years.

XII. Disposal of Medication

- A. All disposed medication must be logged in the Disposal section of the Medication Log and must include Date, Prescription number, Amount of Medication Destroyed/Returned, Type (waste, return, finished) and signatures of two licensed HCA clinical staff.
- B. Disposal/destruction of controlled substance medications requires the use of an HCA-approved drug deactivation and disposal product; this process must be witnessed by and logged with the signatures of two licensed HCA clinical staff. The primary signature must always be a medically licensed staff (MHRS Psychiatrist/Physician or MHRS BH Nurse), but the second/witness signature may be a non-medically Board of Behavioral Sciences (BBS) or Board of Psychology (BOP) licensed or registered staff. Controlled substances should never be placed into a Pharmaceutical Waste bin without first deactivating the medication—making the substance inert and unusable.
- C. All other expired or unused medication is to be kept in a rigid container provided by the medical waste contractor and shall be labeled "**Pharmaceutical Waste - Incineration Only**" with the start date of when the first waste was placed inside the container.
- D. Nursing staff coordinate with the front office staff when disposal containers are ordered. The front office staff tracks the receipts of disposal containers.
- E. The medical waste contractor shall be contacted by the clinic nurse to pick up the pharmaceutical waste annually, or when the amount approaches ten pounds, whichever occurs first.
- F. A receipt from the medical waste contractor shall be kept either with the Medication Log, or in a designated binder. These receipts shall be retained for three years and stored in the Medication Room.

XIII. Disposal of Non-Pharmaceutical Bio-Hazardous Waste

- A. When all sharp-proof containers are full, they may be placed in the larger "red-bagged bio-hazardous waste" containers or kept separate until pick-up.
- B. Other potentially infectious waste, including gloves and swabs, shall be placed in "red-bagged bio-hazardous waste" containers.
- C. All containers receiving infectious waste shall be picked up every thirty days.
- D. A copy of the receipt shall be kept for three years in a designated binder or with the Medication Log.

XIV. Transportation of patient specific medication (oral or injectable) to patient's home or between clinic sites

- A. Medication with labels containing Protected Health Information (PHI) shall not be left in an unattended vehicle at any time.
- B. Medical personnel will complete the Administration/Dispensing section of the Medication Log noting that medication was delivered. If a patient refuses the medication, the medication shall be logged in again after returning to the medication room.
- C. Place PHI-labeled medication and PHI documentation in a locked compartment, such as: locked carrier, banker's bag, or locked trunk of a vehicle. If placed in the locked trunk of a vehicle, a separate locked container is not required.
- D. When transporting injectable medication to a site other than another County clinic, medical personnel will also transport a sharps disposable container.
- E. Controlled substance medications shall not be transported off site from County clinics.

XV. Review and Monitoring of the Medication Room

- A. The stock of all controlled substance medications must be confirmed and recorded at the start of each clinic business day. A medically licensed staff (MHRs Psychiatrist/Physician or MHRs BH Nurse) must count the stock of all controlled substance medications as listed on the Medication Log and compare that to the actual number of medications that are present in the locked storage. Any long-acting injectable buprenorphine (Sublocade) medication that has reached the 45-calendar day storage limit must be removed and disposed of/destroyed or returned to the pharmacy through the process described in this document. This information must be recorded on the Daily Record of Medication Storage (Controlled) Log. Any discrepancy of medications logged versus what is present in storage or any other irregularities of security and drug storage must be reported to the Service Chief, Program Manager and Medical Director. A Special Incident Report (SIR) must also be completed within one (1) business day of discovery any irregularities of the security of the medication room or drug storage.
 - 1. Any theft or loss of a controlled substance medication must be reported to the [Field Division Office of the Drug Enforcement Administration \(DEA\) of the United States Department of Justice](#) in writing within one (1) business day of discovery of the theft or loss. The DEA Form 106 can be completed via Theft/Loss Reporting Online (TLR) or by downloading the fillable PDF version and submit to the Local Diversion Field Office.

- B. The medication room and all records shall be reviewed at least annually by the MHRS Medical Director or designee, ensuring policies and procedures are followed. Findings and plan of corrections shall be documented on the Orange County MHRS Medication Room Annual Review Checklist and submitted to the MHRS Medical Director or designee for approval.
 - 1. The completed Orange County MHRS Medication Room Annual Review Checklist shall be submitted to Quality Management Services (QMS) within 30 days of completion date.