

STANDARD OPERATING PROCEDURES	Center Name:
	SOP No.:
	Effective Date:
	Page No.: # of #
Approval:	
PRH reference: #	
Title: Prescribed Controlled Substances	

This SOP is just an example. Each center must create their own policy to meet their students' needs that complies with applicable federal and state laws.

A. PURPOSE

To address the storage, dispensing, and availability of prescribed controlled substances (medications) on center in a safe manner that complies with federal and state pharmacy laws.

B. POLICY

Centers shall comply with all state and federal regulations regarding controlled substances.

The Health and Wellness Manager (HWM) must determine which center health practitioners are legally authorized to prescribe, dispense, or administer controlled substances according to state and Federal laws.

If applicable, the HWM will identify and train/certify unlicensed staff to be legally authorized to observe self-administration of controlled substances according to state laws when the Health and Wellness Center (HWC) is closed.

C. PROCEDURES

1. Administration of Controlled Substances During HWC Business Hours (example):

- Prescriptions must be documented in the Student's Health Record (SHR) and include the date, name of medication, how much to take, how to take it, how often, and the prescribing practitioner's name, title, and signature. Controlled substances should be prescribed in accordance with regulation 21 CFR Part 1306.
- Prescriptions must be legible. The prescription order must be capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order on center. Prescriptions can be hand printed, typewritten, or electronically generated.
- Nurses must document in the SHR that a prescription order has been transcribed to a Medication Administration Record (MAR) exactly as the order reads.

- Prescriptions generated for students by health practitioners in the community or at the student's place of residence, and brought to the center, must be reviewed and approved by the center physician/nurse practitioner/physician assistant, and if approved, transcribed on a MAR.
- Each time a prescription is filled, the student must receive consumer medicine information in accordance with state pharmacy laws.
- The administering practitioner must use the MAR as the guide to the administration of a controlled substance (See MAR Form Template). Administration includes **(this may vary in accordance with state laws)**:
 - Administering practitioner matches the student's name on the MAR against the student's ID.
 - Administering practitioner matches the drug's label against the MAR.
 - Administering practitioner makes available for self-selection the dose as prescribed on the drug label and the MAR.
 - Administering practitioner checks that the drug is being given at the correct time and confirm when the last dose was given.
 - Administering practitioner documents the time, route, and any other specific information as necessary on the MAR.
 - If the medication requires patient monitoring, such as blood pressure or blood sugar measurements, administering practitioner documents this monitoring in the SHR.
 - Administering practitioner should offer counsel and educational materials about the controlled substances they are administering upon each refill and anytime the student requests the information.
 - Administering practitioner should file the MAR in the SHR at least monthly. If there is additional narrative, document on the Chronological Summary of Medical Care (SF-600).
- When a student leaves the center, prescription medication(s) shall be made available and sent with the student. If a student separates center when the HWC is closed, medications shall be promptly sent to the student in compliance with federal laws, as well as the sending and receiving state laws.

2. Observation of Self-Administration of Controlled Substances After Hours (example):

- When the HWC is closed, the administering practitioner will place all controlled substances and a controlled medication observation record (CMOR) in the lockbox and send this lockbox to Social Development/Residential (**insert where lockbox is kept**) to be readily available to students.
- Controlled substances in the lockbox must be properly labeled and packaged in compliance with 21 CFR Part 1300 and other applicable state laws. A two-person (one must be authorized under their state license to dispense or administer controlled substances) count is required for packaging.
- Depending on state law, students may self-package their medications for the lockbox under the observation of a staff nurse.
- Unlicensed staff observe and make controlled substance(s) readily available for students to access in a safe and controlled manner. This is similar to a home "medicine cabinet." Staff observing medication must meet state laws, be trained, and have a personal authorization on file for this task.

- Observation by unlicensed staff includes (**this may vary in accordance with state laws**):
 - Authorized staff opens lockbox.
 - Student's prescribed controlled substance medication is made available to the student.
 - Authorized staff person ensures the identity of the student matches the prescription.
 - Authorized staff person observes the student self-select and self-administer the correct dose.
 - Authorized staff person documents observation on the CMOR, signs it, and has the student sign the CMOR (See CMOR Template Form).
 - Medication and CMOR is placed back in the lockbox.
 - The lockbox and observation sheets (CMORs) are returned to the HWC each _____ (**based on center's individual policy, example: each morning or each Monday**).
 - A count is completed and documented in the Controlled Substance (or Narcotic) Log Book. A two-person (one must be licensed) count should be conducted upon return.
 - The CMOR will immediately be filed in the SHR by HWC staff.

- It is the responsibility of the HWC staff (**insert responsible personnel**) to explain and ensure the student understands the process for obtaining individually prescribed medications from the assigned staff after hours, on weekends, and holidays.
 - HWC staff should explain possible consequences of not taking medications as prescribed and that medications will be monitored closely.
 - Students should be informed that they are responsible for obtaining their medications after hours and that staff will not locate and remind the student.

3. Monitoring, Storage, Purchasing, and Disposal of Controlled Substances

- Purchase, store, and administer all controlled substances in accordance with regulation 21 CFR Part 1300. Each center must maintain a controlled medication log and have a Drug Enforcement Administration (DEA) registration or use the center physician's or dentist's DEA registration number when ordering controlled substances.
- Limit the use of controlled substances and stock only a small supply of those substances that will be prescribed by the center physician, center dentist, or psychiatrist. Documentation must be maintained showing that controlled substances in stock were prescribed by one of these individuals.
- Do not stock Schedule II substances on center except when prescribed for a specific student. In such a case, the center shall order enough medication for no more than a month's treatment for the student.
- Store all Schedule II, Schedule III, and Schedule IV substances under a double-lock system in a secured area of the HWC. Only HWC staff who are authorized under their state license to dispense or administer controlled substances shall have access to the controlled substances.
- Ensure that two staff (one must be staff authorized under their state license to dispense or administer controlled substances) receive and sign for medications received, noting the name(s) of the medications, dosage, amount, and date on a controlled medication log.
- Maintain a log of all Schedule II, Schedule III, and Schedule IV substances. When dispensing or administering these medications by order of the health care practitioner, the date, time, medication, and dosage shall be noted on the log and the nurse dispensing or administering the

medication must sign his or her full name or initials if a signature key is in place. The log shall be maintained in the locked area designated for controlled substances.

- The log is a separate record from the MAR. The log book provides the mechanism for logging in, tracking the use of the medication, and conducting weekly inventory. The log is not filed in the SHR.
- The MAR is the medical record of the student that is filed in the SHR.
- Inventory and reconcile controlled substances at least once a week. Two authorized staff members shall note the results on the controlled medications log. Any miscounts or missing medications identified during the inventory shall be immediately reported to the Regional Office by the Center Director.
- Dispose of controlled substances that need to be destroyed because of expiration dates, contamination, or wastage in accordance with state law and document such actions on the controlled substances log. The log must be signed by two staff members (one of whom must be a HWC staff member).

D. DEFINITIONS

Controlled Substance

Controlled substances are highly regulated prescription medications that are classified in five categories. [The list of medications is available from: <http://www.dea.gov/druginfo/ds.shtml>]. The Drug Enforcement Administration classifies controlled substances as:

- Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
- Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.
- Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.
- Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.
- Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.

Administration

Administration of a drug means the direct application of a prescription drug whether by injection, inhalation, ingestion, or topical application to the body of a patient.

Dispensing

Dispensing means the preparing and packaging of a prescription medication, pursuant to a prescription or order, in a container and labeling the container with information required by law. Filling or refilling drug containers with prescription drugs for subsequent use by a student is “dispensing.” Providing quantities of unit dose prescription drugs for subsequent administration is also “dispensing.”

- The HWM must determine which health staff practitioners are legally authorized to dispense prescription medications.
- If the center physician applies for and receives a pharmacy license for the center, that license must be posted in the HWC.

Observation by Unlicensed Personnel

Observation by unlicensed staff means that medication self-administration is monitored or witnessed. Unlicensed staff delegated to observe medication self-administration must meet requirements outlined by state pharmacy laws. Oftentimes, laws require that unlicensed personnel pass a test and be certified before they may conduct this activity. Centers should check the requirements for observation by unlicensed personnel in their respective state.