Subject:	Original Issue Date:	Procedure #
ORDERING, SECURING, AND DISPOSING OF SCHEDULE II-V CONTROLLED MEDICATIONS (Y-D-01, Compliance Indicator #5)	01/01/13	**005**
	Supersedes:	Effective Date: 01/01/2013

Departments Consulted:	Approved By:	Approved by:
DHS Pharmacy Affairs	(Signature on File) Pharmacy Supervisor (Signature on File) Medical Director	(Signature on File) Health Services Administrator

I. PROCEDURE OVERVIEW

The Pharmacy shall maintain a system of accountability for Drug Enforcement Agency (DEA) Schedule II, III, IV and V controlled medications documenting purchases, receipt, storage, prescription, dispense, administration, return, and destruction for security and audit purposes. The theft, loss and waste of these medications shall be reported and documented to comply with DEA and state regulations.

II. PURPOSE

To ensure that DEA Schedule II, III, IV, and V medications are controlled and accounted for in compliance with the Federal Comprehensive Medication Abuse Prevention and Control Act. Only designated staff shall have access to controlled medications. These medications are ordered, received, repackaged, stored, secured, destroyed/disposed of, returned to supplier, and inventoried as required in the procedures outlined below. All pertinent records and documentation shall be accurately completed and maintained.

III. PROCEDURE

A. DEA Registration and Approved Providers

1. The pharmacy is engaged in distributing and/or dispensing of controlled substances and must register with the DEA. This registration is renewed every three years. The registration must be maintained at the registered location and kept for official inspection.
2. JCHS Medical Director or designee shall be the certifying official and the Pharmacy Supervisor is usually the registrant on the DEA registration certificate. Registrant changes must be reported to the DEA within 30 days of the change.
3. A separate registration is required for each function in which the pharmacy is involved (e.g., an additional registration is required for facilities with a methadone treatment/detoxification program).
4. JCHS Pharmacy is exempt from the registration fees. The registrant will receive a renewal form approximately 60 days before the expiration date. Renewal of DEA registration can also be performed online.
5. Each practitioner must have his/her own DEA license to write controlled substances prescriptions for youth detained within the institution, or youth who are transferred, released, or discharged.

B. Reporting Controlled Drug Substances Discrepancy to DEA

1. When controlled substances inventory losses are noted, either as one large loss or are discovered to have taken place over time, the loss shall be managed as if it were a theft. Refer to "Theft or Loss of Inventory from Pharmacy or Medication Storage Areas" policy and procedure.
2. The Pharmacy Supervisor shall immediately notify the following institution personnel and federal and state agencies of the loss:
   a. JCHS Administrator
   b. JCHS Medical Director
   c. Director of Nursing
   d. Officer on Duty
   e. Sheriff's Department
   f. California State Board of Pharmacy
   g. Drug Enforcement Agency by completing the DEA Form 106 (available online).

C. Controlled Drug Substances Inventory

1. The Pharmacy shall maintain a current, complete, and accurate record of each controlled substance received, dispensed, and destroyed.
2. A designated pharmacist shall perform a monthly physical inventory of all controlled substances in the pharmacy. The monthly physical inventory shall be verified by the Pharmacy Supervisor and kept in a log.
3. The Pharmacy Supervisor or designee shall ensure that the controlled substances inventory is correct in all medication areas of the facility at least monthly when inspections of medication areas are performed using the monthly inspection form.
4. On July 1st of each year, the Pharmacy Supervisor shall perform a complete physical inventory of the controlled substances kept in the pharmacy.
   a. This inventory will be conducted at either the beginning or ending of the business day and noted on the inventory sheet.
   b. Any discrepancies will be investigated by the Pharmacy Supervisor and one other pharmacist. If the discrepancy cannot be resolved it will be reported as detailed in Section III above.
   c. One copy of this inventory will be maintained for audit purposes and one copy will be sent to the central pharmacy administration.

D. Ordering, Procuring and Destruction of Schedule II Controlled Drug Substances

1. All Schedule II controlled substances shall be procured using DEA Form 222. The form can be obtained by contacting the DEA or from the prime vendor. The prime vendor is a prescription drug wholesaler that buys drugs directly from the manufacturer and supplies pharmacies in the United States. The prime vendor may supply the DEA Form 222 electronically via the Controlled Substance Ordering System (CSOS) purchase.

2. Authorization to purchase controlled substances rests with the registrant (usually the Pharmacy Supervisor or granted through Power of Attorney to a registered pharmacist). In cases where the Pharmacy Supervisor is not present, a registered pharmacist may act as registrant. The registrant's signature is required on DEA Form 222 for ordering/purchasing Schedule II substances or placing orders electronically via CSOS and using the CSOS procedure appropriately.
3. A sample of a Power of Attorney form is located in Title 21, Code of Federal Regulations, Chapter II – Medication Enforcement Administration, Department of Justice, § 1305.07.
4. Once DEA Form 222 is completed, an authorized registered pharmacist or registrant will sign the DEA Form 222 (s) and an order will be placed with the prime vendor. DEA Form 222 copies one and two will be given to the prime vendor. The pharmacy shall retain DEA Form 222 copy three for recording and receipt.
5. The Pharmacy Supervisor or designee is responsible for the receipt of the Schedule II controlled substances. When receiving the order, a pharmacist will inspect it to ensure the containers are sealed. If the seal is broken, the Pharmacy Supervisor will be notified immediately. The Pharmacy Supervisor or designee will notify the prime vendor of the broken seal.
6. The actual number of packages received by the pharmacy will be entered on DEA Form 222, including the actual date received by the pharmacy. There will be no back orders.
   a. The order number and the signature of the receiving pharmacist should be entered across the top of the DEA Form 222 copy three.
   b. The quantity received should be recorded into the Schedule II controlled substances Perpetual Inventory Record (PIR).
   c. DEA Form 222 copy three shall be attached to the Schedule II controlled substances invoice from the prime vendor and filed for auditing purposes. Records are retained for three years in accordance with state and federal regulations.
7. Schedule II controlled substances that need to be disposed of due to expiration date, spoilage or contamination shall be counted for return to the contracted agency for disposal using the contractor's procedures.
8. The quantity of controlled substances to be returned to the contractor shall be deducted from the PIR.
9. The contracted agency will provide DEA Form 222 copies one and two for the pharmacy and retain copy three for its record. A pharmacist will physically count and verify the quantity requested to be returned on the DEA Form 222 copies one and two. The pharmacist will confirm the quantity by initialing and dating the DEA Form 222 copies one and two, line by line and recording the DEA Form 222 serial number located at the bottom of the page into the PIR for reference. The Pharmacy Supervisor and a pharmacist will sign the PIR.

Subject:	Effective Date:	Procedure #
ORDERING, SECURING, AND DISPOSING OF SCHEDULE II, III, IV, AND V CONTROLLED MEDICATIONS (NCCHC Standard Y-D-01)	01/01/13	**005**
	Health Services Administrator's Initials: (Initials on File)	

E. Ordering, Receiving, Storage/Security and Administration of Controlled Substances for use at Medication Areas

I. Ordering/Processing

1. Patient Specific Medications
   a. Controlled substances, Schedule II, III, IV, and V will be ordered for patients using the computer physician order entry in PEMRS.
   b. Orders for controlled substance medications will be verified by pharmacists using the verification functions of PEMRS.
   c. In addition to entering an order using PEMRS, orders for Schedule II controlled substance will be accompanied with a handwritten prescription on a secure prescription pad. A copy of this prescription will be faxed to the pharmacy.
   d. The nursing staff will also send the original written prescription to pharmacy. Upon arrival to the pharmacy, the original prescription will be reconciled with the faxed copy.
   e. Daily, the pharmacy will notify the nursing staff at each hall or camp of any un-reconciled faxed prescriptions.
   f. Pharmacy will ONLY initiate the processing of a Schedule II order when a fax copy of the original written prescription is received and the prescription is evaluated by a pharmacist as being valid. Schedule III-V orders will be processed normally as with non-schedule medications.
   g. Schedule II medications will be dispensed in patient specific bubble pack administration cards. Schedule III-V agents will be dispensed in youth-specific zip-lock bags. Attached to the back of the bubble packs and the zip-lock bags will be a patient specific "Drug Administration Control Sheet".
   h. The "Drug Administration Control Sheet" is used to document the disposition of each tablet/capsule contained in the patient specific Schedule II controlled substance bubble pack and the Schedule III-V zip-lock bags.
   i. The "Drug Administration Control Sheet" should remain attached to the medication and returned to pharmacy when the medications are completed, or the order is discontinued.
   j. For delivery, Schedule II-V medications will be packaged using secured opaque transportation bags/containers and will be delivered with the other medications to the halls and camps by the pharmacy light vehicle drivers.
   k. If a contracted courier or Probation staff is needed to deliver/transfer these medications, packaging will be used such that outside wrapper or container is free of markings that would indicate the nature of the contents.

2. Floor stock
   a. Acetaminophen with codeine 300mg/30mg (Tylenol #3) will be allowed as the only controlled substance available as floor stock at the halls (CJH, BJN).
   b. Floor stock supply will only be issued upon receipt of a physician order written on a secure tamper-resistant prescription pad.

c. The supply will be issued to the ordering physician, who will be accountable for the disposition of the supply.
d. A daily inventory of the floor stock will be maintained on the "Tylenol #3 – Proof of Use Record" (Attachment #1). Any unresolved discrepancy will be immediately reported to nurse supervisor, Nursing administration and pharmacy. Pharmacy will initiate reporting process to the pharmacy board and DEA (see section B above).
e. The "Proof of Use Record" will be faxed to pharmacy every time the supply is utilized.
f. Floor stock supply of Tylenol #3 is to be used only until patient specific supply is received from pharmacy.

II. Receipt of Controlled Substances at halls and camps nursing stations

a. Upon receipt of the medication transportation bags from the pharmacy light vehicle driver, the receiving nurse/staff member will verify the contents by reconciling the packaged medications with the enclosed list.
b. After validating the contents with the invoice list, the receiving nurse will sign and date the invoice. A copy of the signed invoice will be faxed to pharmacy. The original signed copy will also be returned to pharmacy.
c. The pharmacy will be notified immediately if items are missing from the invoice list.

III. Storage and Security of Controlled Substances at halls and camps nursing stations

a. All Controlled Substances will be stored in a lockable cabinet at the medication areas.
b. Access to controlled substances stored in the medication areas shall be limited to designated nursing staff who have a key to the controlled substances cabinet on the nursing unit and who shall be responsible and accountable for the controlled substances during that shift.
c. At the camps authorized to administer Schedule II-V controlled substances, the key to the controlled substance storage cabinet will be maintained separate from the other keys to the medication room. This key will be secured in a key lock box. The access to the key lock box is restricted to the camp nursing staff.
d. A designated nurse will be responsible for the security of the controlled substances cabinet key during each shift. Hand off the key will be documented on the **"**Controlled Drug Key Inventory Record" (Attachment #2).

IV. Administration of Controlled Substances at halls and camps nursing stations

a. All controlled substances are dispensed to the nursing staff as patient specific medications.
b. All controlled substances are to be only administered to the youth-patient specified on the label affixed to the vial, bottle, zip-lock bag, or bubble pack.

c. Schedule II medications will be dispensed in patient specific bubble pack administration cards.
d. Attached to each order of Schedule II-V medications will be a youth-patient specific "Drug Administration Control Sheet" (Attachment #3)
e. The "Drug Administration Control Sheet" is used to document the disposition of each tablet/capsule removed from the youth-patient specific supply of Schedule II-V controlled substance medications.
f. The "Drug Administration Control Sheet" should remain attached to bag/bubble pack and returned to the pharmacy when the supply completed or when the order is discontinued.
g. Documentation of doses administered, as well as those "refused" or "not given" will be done in PEMRS on the youth-patient's electronic Medication Administration Record (eMAR). The documentation will also include notation that the dose was disposed/wasted.

V. Disposal/Wastage of Controlled Substances at halls and camps nursing stations

a. Documentation is required for the disposing of or wasting of a controlled substance at the hall or camp nursing station.
b. At the halls, documentation of wastage will be done in PEMRS on the youth-patient's eMAR by the nurse disposing/wasting the controlled substance. In addition, the wastage will be noted on the corresponding "Drug Administration Control Sheet", by the wasting nurse and a witness.
c. At the camps, where there is only one staff nurse, documentation of disposal/wastage will be done in PEMRS on the youth-patient's eMAR. The documenting nurse will also document the wastage on "Drug Administration Control Sheet". The nurse will immediately notify the pharmacist on duty of this wastage and obtain a wastage control number. This number will then be noted on the "Drug Administration Control Sheet". A copy of the completed Drug Administration Control Sheet will be faxed immediately to the pharmacy every time wastage occurs.
d. All disposed/wasted mediations (including all controlled substances) will be placed in the pharmaceutical waste bins located at the halls and camps medication stations.

VI. Return of Discontinued orders of controlled substances to pharmacy

a. Upon receiving an order to discontinue a Schedule II-V controlled substance order, the medication will be segregated from the other active orders and will be scheduled for return to the pharmacy.
b. Discontinued Schedule II-V controlled substances shall be stored and secured in the controlled substance cabinet, segregated in a manner such that they can be identified as discontinued and are not to be used.

c. Discontinued controlled substances **may not** and **should not** be used for other patients.
d. Un-used/un-needed Schedule II-V controlled substances should be returned to pharmacy as soon as possible, preferably when the next scheduled visit by the pharmacy light vehicle driver.
e. When returning medications to the pharmacy via the light vehicle driver, packaging will be used such that outside wrapper or container is free of markings that would indicate the nature of the contents.
f. Returned Schedule II-V controlled substances are to be returned with the corresponding "Drug Administration Control Sheet".
g. Returned Schedule II-V controlled substances received in the pharmacy will be noted in the receipt log and will be segregated in a locked cabinet in the pharmacy
h. All returned controlled substances are not to be re-used and will be scheduled for disposal/destruction by the contracted reverse distributor.

IV. REFERENCES

- Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, Title 21, § 801 et seq.
- Code of Federal Regulations, Title 21, § 1305.07 – Power of Attorney

Subject:	Effective Date:	Procedure #
ORDERING, SECURING, AND DISPOSING OF SCHEDULE II, III, IV, AND V CONTROLLED MEDICATIONS (NCCHC Standard Y-D-01)	01/01/13	**005**
	Health Services Administrator's Initials: (Initials on File)	