CHAPTER 18

CONTROLLED DRUGS
CONTROLLED DRUGS

- DEA
  - DEA assigned to facility (vs. the pharmacy)
  - Director of Pharmacy considered responsible
  - DEA power of attorney

- Important responsibility

- Large number of individuals handle controlled drug

- Ordering/Receiving CIIs
  - DEA form 222 (Order up to 6 booklets)
  - Initial each line of invoice and date/initial each line on 222 form
  - CSOS – electronic ordering

- Audit trail
  - Manual process
    - Perpetual inventory
    - Nursing controlled drug record
      - One sheet lists all drugs (example page 8.4)
      - Shingle sheets
      - End of shift counts (confirmation bias)
  - Automated process
  - Electronic documentation of refills, withdrawals and waste

- Procedures for PCA, narcotic drips, etc.

- Waste
  - With witness as defined by hospital policy
  - Destruction of CS 64B16-28.303 (see page 18.5)
  - Reverse Distributor – no prior DEA approval required
  - DEA form 41 requires DEA prior approval? Depends on selection of the witness

- Storage – locked in a secure area as defined in hospital policy
  - Locked/Double locked cabinet (manual systems)
  - CIIs verses CIII-Vs
    - Key procedures
  - Automated with policies defining authorization procedures
• Monitor for diversion and tampering
  -- Monitor all processes (for example)
    -- Pharmacy Ordering Process
    -- Pharmacy Receiving Process
    -- Nursing Ordering Process
    -- Nursing Receiving Process
    -- Perpetual inventory records
    -- End of shift count discrepancies
    -- Assure order for drug and proper documentation in the medical record
  -- Missing drug
  -- Inadequate documentation
  -- Lost keys or controlled drug record
  -- Stolen passwords
  -- Waste procedures not followed
  -- Open product out of tamper seal
  -- Obvious tampering
  -- Refractive Index

• Hospital policy
  -- Drug free workplace policy
  -- Pharmacy/Nursing/Employee Health
  -- Urinalysis testing

• Records that must be maintained (2 years)
  -- Official Order Forms (DEA Form-222)
  -- Power of Attorney authorization to sign forms
  -- Receipts and invoices for schedule III, IV and V controlled substances
  -- All inventory records including the initial and biennial inventories
  -- Records of controlled substances distributed or dispensed
    -- Joint Commission standard that “abuses and losses are reported to the Director of Pharmacy and the Chief Executive Officer.
  -- Inventory of Drugs Surrendered for disposal (DEA form-41 or Reverse Distributor)
  -- Records of transfers of controlled substances between pharmacies
  -- Biennial Inventory
  -- DEA registration certificate
  -- Other issues
✓ Record of doctor DEA numbers
✓ Identification badge
✓ Prescription pad control
✓ Refractive index testing
✓ Fentanyl patch disposal
✓ Anesthesia concurrent monitoring

SAMPLE FORM
Controlled Drug Record Proof of Use Form
ORAL CONTROLLED DRUGS

NOTE: Top of box is the transaction amount.
Bottom of box is the final count.

<table>
<thead>
<tr>
<th>Date</th>
<th>Unit</th>
<th>BALANCE from previous sheet verified by:</th>
<th>Signature #1</th>
<th>Signature #2</th>
<th>Page of</th>
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<table>
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<tr>
<th>Time</th>
<th>Patient Name</th>
<th>Medication</th>
<th>Dosage</th>
<th>Nurse Signature</th>
<th>Alprazolam 0.25 MG tab</th>
<th>Alprazolam 0.5 MG tab</th>
<th>Clonazepam 0.5 MG tab</th>
<th>Clonazepam 1MG tab</th>
<th>Diazepam 5 MG tab</th>
<th>Hydrocodone/Acet 10/500 MG tab</th>
<th>Hydrocodone/Acet 5/500MG tab</th>
<th>Hydrocodone/Acet 7.5-500 MG tab</th>
<th>Hydrocodone/Acet 2/500 MG tab</th>
<th>Lorazepam 0.5 MG tab</th>
<th>Opiodone 1 MG tab</th>
<th>Methadone 10 MG tab</th>
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RECORD ALL WASTE WITH SIGNATURE ON BACK OF FORM

18.4
Medicare COP standards:
(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)
§482.25(a)(3) - Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

Interpretive Guidelines §482.25(a)(3)
Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- Records trace the movement of scheduled drugs throughout the service.
- The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.
- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.
- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?
  - diversion.

64B16-28.301 Destruction of Controlled Substances – Institutional Pharmacies.
(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.
(2) A document must be completed showing the name and quantity of the drug, strength and dosage form, patient’s name, prescription number and name of the institution. This documentation, at the time of destruction, shall be witnessed and signed by the consultant pharmacist, director of nursing, and the administrator or his designee, which may include a licensed physician, pharmacists, mid-level practitioner, or nurse.


64B16-28.303 Destruction of Controlled Substances All Permittees (excluding Nursing Homes).
(1) Controlled substances that cannot be retained as usable shall be securely stored in the prescription department of the permittee pharmacy until destroyed.
(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form 41. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager and D.E.A. agent, or a Department inspector. This method of destruction does not require prior approval from D.E.A., but does require that a copy of the completed and witnessed D.E.A. Form 41 be mailed to D.E.A. immediately after destruction.
(3) Another method of destruction requires the prescription department manager for the permit, one other pharmacist, and a sworn law enforcement officer to serve as the witnesses. A copy of the completed D.E.A. Form 41
and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.

(4) In lieu of destruction on the premises, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.


64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,

(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist’s records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person’s identity and document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.

SAMPLE POLICY: CONTROLLED DRUG MONITORING

PURPOSE

To establish monitoring controls relating to ordering, receiving, storing, dispensing and administering controlled substances and documenting such activities. The term “controlled substance” means that the drug is included in schedules I, II, III, IV, or V of the Controlled Substance Act or Florida Statutes 893 Drug Abuse Prevention and Control.

SCOPE

Personnel in all departments where controlled substance medications are utilized, particularly Pharmacy and Nursing departments.

POLICY

In order to detect intentional or unintentional breach of procedure in controlled substance handling, an assessment of compliance with policies and procedures that relate to ordering, receiving, storing, dispensing and administering controlled substances will be regularly performed and documented.

The Director of Pharmacy is responsible for insuring that the monitoring described herein is performed, monitoring results are collected, and trending data is analyzed to detect variances in practice.

The departmental manager, or designee, shall immediately investigate any discrepancies identified in ordering, receiving, administering, or reconciling the inventory of controlled substances. Similarly, the departmental manager, or designee, shall investigate any situation that indicates a breach in product integrity (e.g., broken or cracked containers, broken seals) or a failure to follow appropriate policies related to controlled substances.

A. Ordering and Receiving Controlled Substances.

1. Authority to Purchase Controlled Substances. The Director of Pharmacy shall have a duly executed power of attorney, signed by the Chief Executive Officer of the facility, authorizing the director and other authorized pharmacy personnel to order controlled substances in schedules II for the institution. The power of attorney should be permanently kept with other controlled substance records in the pharmacy in a secured location.

2. Control of and Access to DEA Form 222. DEA 222 forms are the official forms used to order controlled substances in Schedules I & II from manufacturers, wholesalers, or other sources. Upon receipt of DEA 222 forms from the Drug Enforcement Agency, the Pharmacy Director or designee shall record each DEA 222 form number onto a control log to document all forms received into the Facility. Unused DEA 222 forms should be stored in a secured area.
3. **Pre-Signing DEA Form 222.** The authorized individual should sign DEA Form 222 only as orders are placed. Blank forms are never pre-signed in anticipation of future use.

4. **Execution of DEA Form 222.** In completing DEA Form 222, care should be taken so that no erasures or alterations are made anywhere on the form. If a mistake is made, void all copies of the form and maintain the voided copy in your records. Only one item should be ordered on a single line and the number of different items ordered should always correspond to the “number of items ordered” entry on the form. The Supplier’s Copy 1 and DEA Copy 2 are sent to the drug wholesaler/supplier and Purchaser’s Copy 3 retained in the pharmacy.

5. **Use of CSOS (DEA electronic ordering system).** Schedule I and II controlled substances may also be ordered using the DEA approved electronic ordering system, CSOS, following DEA regulations. The Digital certificate is downloaded to an ordering computer and a backup is copied to a flash drive. Orders and receipt of orders are downloaded to the hospital g:drive. After receipt of the order in CSOS the downloaded file is copied to a flash drive. The flash drive is maintained in a secure area.

6. **Separation of Ordering/Receiving Functions.** Check and balance systems are in place so that different individuals perform the ordering and receiving of controlled substances unless mitigating circumstances prevent this from occurring. In such instances an additional retrospective review is performed.

7. **Direct Delivery of Controlled Substances to Pharmacy Department.** All controlled substances are delivered directly to the Pharmacy Department and not through an intermediary, such as the Materials Management Department.

8. **Reconciliation of Invoices/Packing Slips for Controlled Substances.** The receiving process includes a reconciliation of drugs received against the packing slip or invoice accompanying the order as well as the DEA 222 ordering form. On the “blue” copy (Purchaser’s Copy 3) of the DEA Form 222, the number of packages received and date received shall be filled in. A copy of the DEA 222 form is stapled to a copy of the invoice or packing slip and stored in a notebook separate from the original DEA 222 forms.

9. **Immediate Resolution of Order Discrepancies/Shortages/Breakage.** In case of any order discrepancy, shortage or breakage, the wholesaler/supplier shall be immediately notified and the incident documented on the packing slip/invoice.

10. **Inventory System for Controlled Substances.** An inventory system that assures accuracy of all controlled substances is required. For all Schedule II, II-N, III, III-N controlled substances, a perpetual inventory system shall be maintained. The inventory system may be either manual or computerized as long as the disposition of all controlled substances (e.g., all controlled substances received, dispensed to nursing units, or returned to reverse wholesalers) is accurately tracked.
11. Monthly Record of Controlled Drug Purchases. The Pharmacy Director maintains the “Monthly Customer Record of Controlled Substances” purchasing summary available from drug wholesalers, or a written history of all controlled drug purchases made by the facility for the month, sorted by date.

12. Monitoring Procedure for Ordering and Receiving Controlled Drugs. The Pharmacy Director or designee monitors the ordering and receipt of controlled drugs by randomly selecting 3 deliveries per month and confirming the presence of proper documentation on the DEA 222 form or CSOS records, match units received as documented by invoice and receiving personnel notation on the DEA 222 form, and match units received against the master log book or computer log.

B. Controlled Substance Dispensing
1. Ordering and dispensing controlled substances shall conform to all Facility Policies and Procedures as well as all State and Federal regulatory requirements.

2. Each month an audit assessing a 48-hour supply of controlled substances dispensed from the pharmacy NarcStation is compared to the documentation from the receiving department to assure accountability of the dispensed supply. The documentation includes assessment of electronic receipts (AcuDose) and manual controlled substance record forms.

3. Security of AcuDose
   a. The granting of user access is restricted to the Director of Pharmacy or designee.
   b. Workforce members are granted access according to their specific job requirements and a copy of the request is retained for 6 years:
      i. Employees after clearance by the Human Resources Department
      ii. Contracted vendors after clearance by the Human Resources Department or NFRMC Department Director.
      iii. Agency staff after clearance by the Patient Care Coordinator or a senior hospital administrator, such as the CNO, AVP Nursing, VP Human resources.
      iv. Physicians, nurse anesthetists and other allied health professionals after clearance by Medical Staff Office.
   c. Categories of users include:
      i. Pharmacy (Registered pharmacists, buyer, administrative assistant, interns and technicians) with approval to access the NarcStation, AcuDose, Robot, and packagers.
      ii. Nursing (Registered nurses, licensed practical nurses, certified nurse anesthetists) with approval to access AcuDose
      iii. Respiratory (Respiratory Therapists) with approval to access AcuDose
      iv. Physicians and Allied Health Practitioners (Anesthesiologists, CRNAs, Emergency Room Physicians and others authorized by the Director of Pharmacy) with approval to access AcuDose
      v. Cath lab and radiology technicians only to serve as a witnesses in AcuDose (but not authorized to independently handle controlled substances).
d. Upon termination access is removed from any approved access lists including but not limited to the AcuDose cabinets. The Department Director and/or Human Resources Department and Medical Staff Office are responsible for notifying the Director of Pharmacy or designee the names of users whose privileges are to be changed or terminated. A copy of the request is retained for 6 years.
e. AcuDose and NarcStation keys are secured in the pharmacy and are only issued to a pharmacy employee for Department use or maintenance by authorized personnel.
   i. Pharmacy staff shall remain with the automated dispensing cabinet during the entire time the cabinet is unlocked, unless all drugs have been removed.
   ii. Keys are not given to maintenance/service personnel.

4. Patient’s controlled substance prescriptions brought from home that are approved for use (reference Policy 900-1.440.03 Use of Patient Personal Medications) are kept in a locked area on the nursing unit and inventoried initially and at least daily. A perpetual inventory is maintained that becomes part of the patient’s medical record.

C. Controlled Substance Administration

1. Count Verification. Count verification will be performed any time a controlled substance medication is accessed.

2. Wastage Documentation.
   a. Any wastage of a controlled substance must be recorded.
   b. Wastage documentation will be performed involving two (2) licensed healthcare professionals unless otherwise specifically authorized by the Director of Pharmacy (such as pharmacy technicians per pharmacy procedures and radiology and cath lab staff who may serve as witnesses).
   c. Signature of each individual involved with the wastage of a controlled substance medication must be performed electronically or ascribed to the manual documentation form.

3. Order Verification on Chart. All controlled substance medication administration must be validated by a physician order contained in the patient’s medical record.

4. Administration Documentation. Documentation of administration of a controlled substance shall occur immediately after administration, by the administering individual.

5. Controlled Substance Medication Audit.
   a. Some of the Facility Nursing Units shall perform a review monthly over a specified period of time but should cover at least a 48-hour period of retrospective review. At a minimum this involves a quarterly audit of two controlled substance medications, one drug shall be a high volume product and one drug can be a low volume product. Audit of two drugs per quarter shall be conducted on each Nursing Unit and any other department/area utilizing controlled substances. The review includes an assessment of the
volume of drugs used per individual drug administer to determine high volume
drug administering staff. The audit results are forwarded to the AVP Nursing.

b. Drugs identified in each area shall be reviewed for policy compliance in each
of the following items: administration, documentation, discrepancy resolution,
charted order for medication, wastage documentation, and verification of
current inventory levels of selected medications.

c. A process is established to monitor controlled drug usage in the Surgical
Services area each day. A concurrent audit and reconciliation occurs
Monday-Friday.

d. The Pharmacy Department in collaboration with the AVP Nursing is
responsible for assuring that reports and audits carried out by area
management are completed. Records are maintained by the Pharmacy
Director and are readily retrievable for internal and external audits.
Controlled Drugs in the Nursing Home

I. Regulatory Overview

1. Board of Pharmacy Regulations 64BB16-28.301 Destruction of Controlled Substances –
   Class I (Institutional Pharmacies – Nursing Homes)

2. Controlled Substances Act 10D-46

3. Nursing Home Regulations 59A-4.112 Pharmacy Services
   (1) The consultant pharmacist shall establish a system to accurately record the receipt and
       disposition of all controlled drugs in sufficient detail to enable an accurate
       reconciliation.
   (2) The pharmacist shall determine that drug records are in order and that an account of all
       controlled drugs is maintained and periodically reconciled.
   (3) All controlled substances shall be disposed of in accordance with State and federal laws.
       All non-controlled substances may be destroyed in accordance with the facility’s
       policies and procedures. Records of the disposition of all substances shall be maintained
       in sufficient detail to enable an accurate reconciliation.


   F431 MEDICATION STORAGE, LABELING, AND CONTROLLED SUBSTANCES GUIDANCE
   (Excerpts)

   INTENT (F431) 42 CFR 483.60(b)(2)(3)(d)(e)

   The intent of this requirement is that the facility has in place a functioning medication system that includes the
   services of a licensed pharmacist and provides for:
   • Safe and secure storage (including proper temperature controls and limited access) and safe handling
     (including disposition) of all medication;
   • Accurate labeling to facilitate consideration of precautions and safe administration of medications;
   • Accurate and timely medication records and periodic reconciliation and accounting of all controlled
     substances; and
   • Prompt identification of loss or diversion of controlled substances so as to minimize the time between actual loss or
     diversion and the detection and determination of the extent of loss or diversion.

   CONTROLLED SUBSTANCES
   The facility should have a system to account for the receipt and disposition of all controlled substances. This system
   includes, but is not limited to:
   • Record of receipt of all Schedule II medications specifying the name and strength of the medication, the quantity
     received, and designating the name of the resident or the emergency medication supply (consistent with state law);

   NOTE: The facility may store some controlled medications in an emergency medication supply in accordance with
   state law. The system must address the reconciliation and monitoring of this supply as well as the supply for
   individual residents.
   • Documentation of usage, which may include for example, the medication administration record, proof-of-
     use sheets, or declining inventory sheets;
   • Documentation of disposition including destruction, wastage, return to the pharmacy/manufacturer, or
     disposal in accordance with applicable state law, and
• Periodic reconciliation of the records (generally, at least monthly or more frequently as defined by facility procedures).

The pharmacist is not required by these regulations to complete the reconciliation, but rather to determine that there is an effective system to do so and that the facility has completed the reconciliation according to its procedures and/or state laws and regulations. Although this regulation does not set a time frame for reconciliation, this system should identify how often, how, when, and by whom the reconciliation will be done. The system should be capable of readily identifying loss or diversion of controlled substances so as to minimize the time frame between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should be done often enough to identify problems. (Some state or other federal laws or regulations may specify the frequency of reconciliation, which may be reflected in the facility’s procedure and practices.) If the systems have not been effective in preventing or identifying diversion or abuse, the pharmacist and the facility should review and revise the monitoring procedures, as necessary, such as increasing the frequency of reconciliation efforts.

II. DEA’s view of the facility nurse as an agent of the prescriber

In most LTC facilities the nurse will accept a verbal order from the prescriber, prepare a telephone order and fax that order to the vendor pharmacy. While a nursing home nurse is generally considered an agent of the prescriber by state Boards of Pharmacy, the DEA has not made that determination.

III. Chart Order vs Prescription Order

DEA – “… a drug order written on a patient’s chart in a long term care facility is not an “effective” controlled substances prescription, unless it contains all necessary information as described in “Manner of Issuance of Prescriptions” in the DEA code.

IV. Audit Trail - Security, Accountability, Disposal

a. Drugs received into the facility
   1) By patient
   2) By pharmacy
   3) Name, date, quantity received

b. Drugs administered to the resident
   1) Medication administration record (MAR)
   2) Proof of use sheets - required for Schedule II, desirable for the rest

c. Drugs not administered to the resident
   1) Wastage, contamination (witness)
   2) Pilferage
   3) Sent home with the resident
   4) Destroyed in the facility

V. Change of Shift Inventory Count

a. Date, hour, signature of on-coming and off-going nurses
b. Discrepancy
c. Monitoring

VI. The Process for removing Controlled Substances from the floor

a. End of shift
   b. When the D.O.N. is not available (ex. Weekends)
VII. Reconciliation of Controls in the Facility

Once this system is established, the consultant can “determine that reconciliation is done” by either:

1. Reviewing internal audits done by the facility
2. Spot checking documentation at the nursing station
3. Monitoring shift counts
4. Doing a complete audit of all controlled substances records in the facility.
   This option may be reserved for those cases when the facility identifies multiple discrepancies or suspected diversion.

VIII. Destruction of Controlled Substances (by Facility Type)

1. Class I Institutional Pharmacy (Nursing Homes & ICF-DD’s)
   1) May destroy drugs on the premises
   2) Policy and procedures required
   3) A receipt document kept of drugs destroyed
   4) Witnessed by the consultant pharmacist, the director of nursing, and the administrator or designee.

2. Class II Institutional Pharmacy including Modified IIA, B and C
   1. May destroy drugs on the premises or approved disposer (reverse distributor) depending on whether the hold a DEA license or not.
   2. Policy and procedures required
   3. Send a completed DEA Form 41 and a letter to DEA for approval providing a proposed date of destruction and the names and titles of the proposed witnesses
   4. Witnessed by the consultant pharmacist, the hospital administrator or designee, and one other person which may be a sworn law enforcement officer.
   5. A copy of the completed and witnessed DEA Form 41 sent to DEA.

3. Florida ALF’s

   WITH PHARMACY PERMIT
   Follow the same procedures spelled out for a nursing home (per Board of Pharmacy regulation)

   WITHOUT PHARMACY PERMIT
   May destroy on-site without the assistance of a consultant pharmacist. This type of destruction should always be documented on a form of some type and witnessed by a minimum of two people

IX. PHARMACY OPERATIONAL ISSUES

1. Emergency CII orders – must get “original” within 7 days

2. Faxed C-II medications as original II – in the LTCF and Hospice.
   “The term Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.” (See pages 18.27- 18.28 for actual language)
3. **Partial Fills of a CII** – may be partially filled for up to 60 days
   Requirements:
   1) Patient must be a resident of a Long Term Care Facility OR a terminally ill patient
   2) The Pharmacist must record on the original prescription either “LTCF patient” or “terminally ill”
   3) For each partial filling, the dispensing pharmacist:
      Must record on the back of the prescription or on another appropriate record, uniformly maintained, and readily retrievable
      (1) The date of the partial filling
      (2) Quantity dispensed
      (3) remaining quantity
      (4) identification of the dispensing pharmacist

X. **Theft or Diversion**
   1. Report to administrator and director of nursing
   2. If substantiated:
      or may be submitted on line on an electronic version of Form 106
      b. Report to ACHA
      c. Report to local police
   3. Types of Diversion in the nursing home
      a. Removal of controlled substances and documentation
      b. Reordering Controls when not needed
      c. Ordering new Controls without a valid order
      d. Diverting discontinued controls
      e. Documenting Administration for orders not administered
      f. Diversion from the Emergency Kit
      g. Tampering with the dosage form (ex. removing the contents of a capsule)
      h. Diversion of used dosage Forms (used Duragesic patches)

XI. **Biennial Inventories**
   1. Facilities that are DEA registrants must do a complete inventory at least every other year even if they maintain perpetual inventories
   2. Nursing Homes are not required to do Biennial inventories since they are not DEA registrants
   3. The vendor Pharmacy is required to do biennial inventories and must include any controlled substances in the Emergency Kits

XII. **Summary of Consultant Responsibilities**
   1. Oversight of the audit trail to ensure that controls can not diverted without the system identifying the loss.
   2. Ensure that “reconciliation” is occurring in the facility
   3. Review of shift count procedures at each nursing unit
   4. Review of security of Controlled Substances in the Emergency Kits

Suggestions:
1. Destroy discontinued controls frequently to prevent large supplies being stored in the facility
2. Destroy controls prior to any change in D.O.N. or consultant
SAMPLE POLICY & METHODS

DISPOSITION OF CONTROL DRUGS

POLICY:

It is the policy of this facility to dispose of control drugs in accordance with all state and federal laws.

METHOD:

All control drugs which have been discontinued or control drugs not being sent home with discharged patients will be returned to the drug enforcement agency for destruction.

When control drugs are to be removed from the nursing unit, the nurse in charge will prepare a disposal of medication form, indicating the name of the patient, prescription number, name of the drug, quantity of drug, and signature of the nurse in charge. This form along with the medication and the proof of use sheet will be returned promptly to the director of nursing office. The director of nursing and the consultant pharmacist will certify as to the accuracy of the disposal of medication form and both will sign this form if correct. This form and the proof of use sheet will be maintained in the patient medical record or as a separate file.

The consultant pharmacist will prepare DEA Form 41 in four copies. Each entry will indicate the name of the control drug, the quantity, and the name of the patient. One copy will remain with the director of nursing, one copy shall be sent under separate cover to the regional drug enforcement agency. The drugs will be packed by the consultant pharmacist with two copies of Form 41 enclosed and mailed by registered mail, return receipt requested. The return signature receipt and a certified copy of the control drugs destroyed by the DEA will be returned to the facility. This certified copy will be filed and maintained for a minimum of two years.
SAMPLE POLICY & METHODS

PROOF OF USE FORMS

POLICY:

It is the policy of this facility that the administration of all control substances shall be properly recorded on a proof of use form and retained in the patient records as required by law.

METHODS:

1. When receiving a control substance (II through V), a proof of use form shall be properly completed listing the name of the patient, the name, strength, and quantity of the drug.

2. When administering a control drug this proof of use form will be properly completed listing the drug given, the time of administration, and the signature of the licensed person administering the drug.

3. If any control drug is wasted for any reason, an explanation shall be promptly recorded on the back of this form and witnessed by another licensed person.

4. When this form is completed it shall be retained on the patients chart.
### Controlled Substances Audit

**FACILITY:**

**DATE:**

<table>
<thead>
<tr>
<th>Resident’s Name</th>
<th>Drug &amp; Strength</th>
<th>Control Log Count</th>
<th>Doses on MAR/PRN</th>
<th>Notes</th>
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# NARCOTIC SHIFT COUNT

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<th>NURSE ONCOMING 7AM</th>
<th>E.D.K. LOCK * G or Y</th>
<th>NURSE OFFGOING 3PM</th>
<th>NURSE ONCOMING 3PM</th>
<th>E.D.K. LOCK * G or Y</th>
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* G = Green Lock  L= Yellow Lock

Nursing: If Yellow lock Present, please Document lock Number And contact Pharmacy To replace kit  

18.20
SCHEDULE II EMERGENCY PRESCRIPTION
TO INITIATE THERAPY

PATIENT NAME: __________________________________________
FACILITY NAME: __________________________________________

DRUG NAME & STRENGTH: ______________________________________
QUANTITY: _____________________
DIRECTIONS: __________________________________________________
_________________________________________________________________

_________________________________________________________________

PHYSICIAN SIGNATURE: _________________________________________
DATE: __________________________________________________________
DEA NUMBER: __________________________________________________

"Authorization for Emergency Dispensing,"
L.T.C.F. PATIENT

The above patient resides in a nursing facility. DEA regulations allow you to initiate therapy of a Schedule II medication as a verbal emergency prescription for up to a 7 day supply. The pharmacy must obtain your signature within 7 days to cover this verbal order. Verbal CII prescriptions not covered within 7 days may result in a DEA fine of $25,000 per prescription.

If you wish to continue this order beyond the emergency supply you must sign a second order (continuation of therapy) per DEA regulations.

Please complete this document, sign and date the order and fax back to (xxx) xxx-xxxx. This fax will serve as the original hard copy prescription.
The above patient resides in a nursing facility. DEA regulations allow you to prescribe up to a 60 day supply of a Schedule II medication. The pharmacy is authorized to partial fill this prescription up to 60 day from the original date.

Please complete this document, sign and date the order and fax back to (xxx) xxx-xxxx. This fax will serve as the original hard copy prescription.
Dear Colleague:

On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled Issuance of Multiple Prescriptions for Schedule II Controlled Substances (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the Rule's preamble are in opposition to policy posted on the DEA Diversion website regarding changes a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. In a Question and Answer section, the website instructed that a "pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner."

DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.

Questions regarding this correspondence may be directed to the Liaison and Policy Section, Office of Diversion Control, DEA at (202) 307.7297.

Sincerely,

[Signature]
Joseph T. Rannazzisi
Deputy Assistant Administrator/Deputy Chief of Operations
Office of Diversion Control
**PHARMACEUTICAL DISPOSER REGISTRANTS**

<table>
<thead>
<tr>
<th>Name</th>
<th>Registration Number</th>
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<tbody>
<tr>
<td>S.A.I. TRANSPORT</td>
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<tr>
<td>3420 YOUNGS RIDGE ROAD</td>
<td></td>
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<tr>
<td>LAKELAND, FLORIDA 33809</td>
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</tr>
<tr>
<td>(813) 858-7110</td>
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<tr>
<td>B.F.I. PHARMACEUTICAL SERVICES</td>
<td>RB0165313</td>
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<tr>
<td>801 NORTH BLACKLAWN ROAD</td>
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<td>CONYERS, GEORGIA 30207</td>
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<tr>
<td>(800) 777-6565</td>
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<tr>
<td>1890 S.E. MORAN BLVD. SUITE 385</td>
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<tr>
<td>STATE ROAD 436</td>
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<tr>
<td>WINTER PARK, FLORIDA 32792</td>
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<tr>
<td>(800) 238-7774</td>
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<tr>
<td>EASY RETURNS MIDWEST, INC</td>
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<tr>
<td>201 SAN AUGUSTINE CENTER, TEXAS 75935</td>
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<td>REVERSE DISTRIBUTOR SERVICES</td>
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<tr>
<td>FORT WORTH TEXAS 76155</td>
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<tr>
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<tr>
<td>DEVOS, LTD</td>
<td>RD0188311</td>
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<td>D.B.A. GUARANTEED RETURNS</td>
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<tr>
<td>140 N. BELLE MEAD ROAD UNIT 3</td>
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<tr>
<td>EAST SETAUKET, NEW YORK 11733</td>
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<tr>
<td>(800) 473-2138</td>
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<tr>
<td>CAPITAL RETURNS. INC</td>
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<td>9600 W. FLAGG AVENUE</td>
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<td>MILWAUKEE, WI. 53225</td>
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<td>(800) 950-5479</td>
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<td>2516 RADLEY COURT, SUITE 9</td>
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<td>HAYWARD, CA 94545</td>
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<tr>
<td>(510) 887-5750</td>
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</table>
**DEA Forms Available on Web Site**

The US Drug Enforcement Administration (DEA) recently announced the availability of selected reports and applications required by the federal Controlled Substances Act on the DEA Web site at www.deadiversion.usdoj.gov. The following forms are currently available:

**DEA Form Description**

<table>
<thead>
<tr>
<th>Form</th>
<th>Description</th>
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<tbody>
<tr>
<td>41</td>
<td>Registrants’ Inventory of Drugs Surrendered</td>
</tr>
<tr>
<td>106</td>
<td>Report of Theft or Loss of Controlled Substance</td>
</tr>
<tr>
<td>161</td>
<td>Application for Permit to Export Controlled Substances</td>
</tr>
<tr>
<td>189</td>
<td>Application for Individual Manufacturing Quota</td>
</tr>
<tr>
<td>224A</td>
<td>Renewal Application for Registration – Retail</td>
</tr>
<tr>
<td>225</td>
<td>New Application for Registration – Wholesale</td>
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<tr>
<td>225A</td>
<td>Renewal Application for Registration – Wholesale</td>
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<tr>
<td>236</td>
<td>Controlled Substances Import/Export Declaration</td>
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<td>250</td>
<td>Application for Procurement Quota for Controlled Substances</td>
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<tr>
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<td>Application for Permit to Import Controlled Substances</td>
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<tr>
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<td>New Application for Registration – Narcotic Treatment Program</td>
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<tr>
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<td>Renewal Application for Registration – Narcotic Treatment Program</td>
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<tr>
<td>486</td>
<td>Import/Export Declaration – Chemical</td>
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<td>510</td>
<td>New Application for Registration – Chemical</td>
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<td>510A</td>
<td>Renewal Application for Registration – Chemical</td>
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</tbody>
</table>

The forms are available in PDF format, so it will be necessary to have Adobe Acrobat or Adobe Acrobat Reader installed on your computer. Two versions of each form will be available:

1) an interactive version, which will allow the user to complete the form online and print it on his or her printer for signature and mailing; and
2) a blank form, which can be printed and completed manually.

The DEA recommends completing the form online to reduce errors.
The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

**NOTE:** CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

<table>
<thead>
<tr>
<th>NAME OF DRUG OR PREPARATION</th>
<th>Number of Containers</th>
<th>CONTENTS (Number of grams, tablets, ounces or other units per container)</th>
<th>Controlled Substance Content, (Each Unit)</th>
<th>DISPOSITION</th>
<th>QUANTITY</th>
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<td>NAME OF DRUG OR PREPARATION</td>
<td>Number of Containers</td>
<td>CONTENTS (Number of grams, tablets, grains or other units per container)</td>
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The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in packages purporting to contain the drugs listed on this inventory and have been: **1** Forwarded tape-sealed without opening; **2** Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; **3** Forwarded tape-sealed after verifying contents.

DATE DESTROYED BY:  

** Strike out lines not applicable.

WITNESSED BY:

**INSTRUCTIONS**

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (125 mg.), etc.

2. All packages included on a single line should be identical in name, content and controlled substance strength.

3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.

4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.

5. Drugs should be shipped tape-sealed via prepaid express or certified mail (return receipt requested) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

**PRIVACY ACT INFORMATION**


PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.

ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFICT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

<table>
<thead>
<tr>
<th>1. Name and Address of Registrant (include ZIP Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>2. Phone No. (Include Area Code)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>3. DEA Registration Number</td>
</tr>
<tr>
<td>2 ltr. prefix</td>
</tr>
<tr>
<td>7 digit suffix</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>4. Date of Theft or Loss</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>5. Principal Business of Registrant (check one)</td>
</tr>
<tr>
<td>1   Pharmacy</td>
</tr>
<tr>
<td>2   Practitioner</td>
</tr>
<tr>
<td>3   Manufacturer</td>
</tr>
<tr>
<td>4   Hospital/Clinic</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>6. County in which Registrant is located</td>
</tr>
<tr>
<td></td>
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<tr>
<td>7. Was Theft reported to Police?</td>
</tr>
<tr>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>8. Name and Telephone Number of Police Department (Include Area Code)</td>
</tr>
<tr>
<td></td>
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<tr>
<td>9. Number of Thefts or Losses Registrant has experienced in the past 24 months</td>
</tr>
<tr>
<td>10. Type of Theft or Loss (Check one and complete items below as appropriate)</td>
</tr>
<tr>
<td>1   Night break-in</td>
</tr>
<tr>
<td>2   Armed robbery</td>
</tr>
<tr>
<td>3   Employee pilferage</td>
</tr>
<tr>
<td>4   Customer theft</td>
</tr>
<tr>
<td>5   Other (Explain)</td>
</tr>
<tr>
<td>6   Lost in transit (Complete Item 14)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>11. If Armed Robbery, was anyone:</td>
</tr>
<tr>
<td>Killed? [ ] No [ ]</td>
</tr>
<tr>
<td>Yes (How many) [ ]</td>
</tr>
<tr>
<td>Injured? [ ] No [ ]</td>
</tr>
<tr>
<td>Yes (How many) [ ]</td>
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<tr>
<td></td>
</tr>
<tr>
<td>12. Purchase value to registrant of Controlled Substances taken?</td>
</tr>
<tr>
<td>$</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>13. Were any pharmaceuticals or merchandise taken?</td>
</tr>
<tr>
<td>No [ ] Yes (Est. Value) [ ]</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:</td>
</tr>
<tr>
<td>A. Name of Common Carrier</td>
</tr>
<tr>
<td>B. Name of Consignee</td>
</tr>
<tr>
<td>C. Consignee's DEA Registration Number</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>D. Was the carton received by the customer?</td>
</tr>
<tr>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>E. If received, did it appear to be tampered with?</td>
</tr>
<tr>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>F. Have you experienced losses in transit from this same carrier in the past?</td>
</tr>
<tr>
<td>No [ ] Yes (How Many) [ ]</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>16. If Official Controlled Substances Order Forms (DEA-222) were stolen, give numbers.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>17. What security measures have been taken to prevent future thefts or losses?</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Report theft or loss of Controlled Substances.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FORM DEA - 106 (11-06) Previous editions obsolete

CONTINUE ON REVERSE
<table>
<thead>
<tr>
<th>Trade Name of Substance or Preparation</th>
<th>Name of Controlled Substance in Preparation</th>
<th>Dosage Strength and Form</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desoxyn</td>
<td>Methamphetamine Hydrochloride</td>
<td>5 mg Tablets</td>
<td>3 x 100</td>
</tr>
<tr>
<td>Demerol</td>
<td>Meperidine Hydrochloride</td>
<td>50 mg/ml Vial</td>
<td>5 x 30 ml</td>
</tr>
<tr>
<td>Robitussin A-C</td>
<td>Codeine Phosphate</td>
<td>2 mg/cc Liquid</td>
<td>12 Pints</td>
</tr>
</tbody>
</table>

I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature ___________________________ Title ___________________________ Date ___________
§ 1301.27 Separate registration by retail pharmacies for installation and operation of automated dispensing systems at long term care facilities.

(a) A retail pharmacy may install and operate automated dispensing systems, as defined in §1300.01 of this chapter, at long term care facilities, under the requirements of §1301.17. No person other than a registered retail pharmacy may install and operate an automated dispensing system at a long term care facility.

(b) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one registered retail pharmacy operates automated dispensing systems at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility.

(c) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

[70 FR 25465, May 13, 2005]

****************************************************************************************************

Section 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Sec. 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.
(d) In the case of an emergency situation, as defined by the Secretary in Sec. 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Sec. 1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Sec. 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

(f) A prescription prepared in accordance with Sec. 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with Sec. 1304.04(h).

(g) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing
pharmacy by facsimile. The practitioner or the practitioner’s agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

CONTROLLED DRUG POLICY AND PROCEDURE

OBJECTIVE:

1. To provide physical facilities and method of operation for the administration and control of Schedule II-V drugs, which will meet the requirements of state and federal narcotic enforcement agencies.

2. To ensure maximum safety for residents and nursing personnel.

THE NARCOTIC BOX:

A separate locked compartment for control drugs is provided within a locked cart. The compartment has a special lock and key and must be kept locked at all times.

THE NARCOTIC KEY:

1. The narcotic key shall be in the possession of the charge nurse, or a nurse especially designated by her during her hours of duty.

2. Upon being relieved from duty, the nurse shall transfer the key to the nurse taking her place.

3. The nurse shall have the key in his/her possession at all times while on duty. The key shall not be left lying around loose.

4. The narcotic key is not to be given to private duty nurses, or any other nurse not responsible, or to doctors, nurses aides, or practical nurses who are not permitted to give medications.

THE NARCOTIC COUNT AND INVENTORY:

1. Control drugs are counted every 8 hour tour by the nurse reporting on duty with the nurse reporting off duty.

2. The inventory of the control drugs must be recorded on the narcotic records and signed for correctness of count.

3. The controlled drug check list must be signed by the nurse coming on duty and going off duty to verify that the count of all control drugs is correct.
4. If a discrepancy is found, check the resident’s order sheets and chart to see if a narcotic has been administered and not recorded. Check previous recording on the control sheets for mistakes in arithmetic. If the cause of the discrepancy cannot be located and/or the count does not balance, report the matter to the supervisor and director of nursing.

5. In counting control drugs, the nurse must be alert for any evidence of a substitution. Inspect tablets and solutions closely, noting any defects in drug container. Any suspicion of substitution or tampering with controlled drugs must be reported to the supervisor immediately.

6. All control drug discrepancies require the initiation of an incident report. This incident report shall be reviewed by the consultant pharmacist, medical director, and administrator and reported at the next pharmacy services committee meeting.
Section 1305.21 Requirements for electronic orders.

(a) To be valid, the purchaser must sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided in part 1311 of this chapter.

(b) The following data fields must be included on an electronic order for Schedule I and II controlled substances:

(1) A unique number the purchaser assigns to track the order. The number must be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.

(2) The purchaser's DEA registration number.

(3) The name of the supplier.

(4) The complete address of the supplier (may be completed by either the purchaser or the supplier).

(5) The supplier's DEA registration number (may be completed by either the purchaser or the supplier).

(6) The date the order is signed.

(7) The name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).

(8) The quantity in a single package or container.

(9) The number of packages or containers of each item ordered.

(c) An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

Section 1305.22 Procedure for filling electronic orders.

(a) A purchaser must submit the order to a specific supplier. The supplier may initially process the order (e.g., entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The registrant must maintain control of the processing of the order at all times.
(b) A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under §1305.06.

(c) A supplier must do the following before filling the order:

(1) Verify the integrity of the signature and the order by using software that complies with Part 1311 of this chapter to validate the order.

(2) Verify that the digital certificate has not expired.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List. The supplier may cache the Certificate Revocation List until it expires.

(4) Verify the registrant's eligibility to order the controlled substances by checking the certificate extension data.

(d) The supplier must retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record must also include any data on the original order that the supplier completes. Software used to handle digitally signed orders must comply with part 1311 of this chapter.

(e) If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (h) of this section.

(f) A supplier must ship the controlled substances to the registered location associated with the digital certificate used to sign the order, except as specified in paragraph (h) of this section.

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

(h) Registered procurement officers of the Defense Supply Center of the Defense Logistics Agency may order controlled substances for delivery to armed services establishments within the United States. These orders may be shipped to locations other than the registered location, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Section 1305.23   Endorsing electronic orders.

A supplier may not endorse an electronic order to another supplier to fill.

Section 1305.24   Central processing of orders.

(a) A supplier that has one or more registered locations and maintains a central processing computer system in which orders are stored may have one or more of the supplier's registered locations fill an electronic order if the supplier does the following:

(1) Assigns each item on the order to a specific registered location for filling.
(2) Creates a record linked to the central file noting both which items a location filled and the location identity.

(3) Ensures that no item is filled by more than one location.

(4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

Section 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with §1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

Section 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is “Not Accepted” and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.
Section 1305.27  Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

Section 1305.28  Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy "Void," and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

Section 1305.29  Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.
DEPARTMENT OF JUSTICE

Drug Enforcement Administration


Issuance of Multiple Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing a Notice of Proposed Rulemaking published on September 6, 2006 (71 FR 52724). In that document, DEA proposed to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance.

DATES: Effective Date: This rule is effective December 19, 2007.

64930 Federal Register / Vol. 72, No. 222 / Monday, November 19, 2007 / Rules and Regulations

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

3. Section 1306.14 is amended by adding a new paragraph (e) to read as follows:

§ 1306.14 Labeling of substances and filling of prescriptions.

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.


Michele M. Leonhart,
Deputy Administrator.
[FR Doc. E7–22558 Filed 11–16–07; 8:45 am]
64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,
(b) Only controlled substance medications are prescribed for a patient,
(c) One person presents controlled substance prescriptions with different patient names,
(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,
(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist’s records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person’s identity and document on the back of the prescription complete information on which the confirmation is based.
(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.