Drug Diversion in the Hospital

Angelo J. Cifaldi, R.Ph., Esq.
Wilentz, Goldman & Spitzer P.A.
90 Woodbridge Center Drive
Woodbridge, NJ 07095
acifaldi@wilentz.com
732-855-6096
Objectives

- Explain the Statutes and Rules regarding dispensing prescription drugs containing controlled substances.
- Explain the common and not so common ways drugs are diverted in Hospital and Community Pharmacy.
- Develop a multi-mode monitoring plan to help prevent drug diversion.
Security Requirements for CDS

- All CDS must be stored in "a securely locked, substantially constructed cabinet." (21 CFR 1301.75(b))

- May DISPERSE the CDS among the non-CDS in such a manner as to obstruct theft (21 CFR 1301.75(b))

- May not employ a person whose registration has been denied, revoked or suspended if that person would have access to CDS stock. (21 CFR 1301.90)
Security Requirements for CDS (continued)

- Notify the Field Division Office of the Administration in his/her area of any theft or any significant loss of CDS immediately upon discovery (21 CFR § 1301.74(c))
  - DEA Form 106 is not immediately needed if registrant needs time to investigate loss/theft
  - Should provide initial notification in writing of the event to DEA
    - Fax could be sufficient, but not the only way
  - If investigation of loss/theft last more than 2 months, registrant should provide updates to the DEA
  - DEA Form 106 must eventually be filed
Security Requirements for CDS (continued)

- How Do You Determine a Significant Loss?
  - Factors to consider:
    - Actual quantity lost
    - Specific controlled substance lost
    - Loss associated with access by individuals or unique activities
    - Pattern of loss and results taken to resolve loss
    - Candidates for diversion (popular drugs for abuse)
    - Local trends and indicators of diversion potential
  - “In-transit” losses
    - ALL “in-transit” losses must be reported, not just significant losses
Obtaining Controlled Substances

- CII – Hard Copy Order Form: DEA #222
  - Triplicate form
  - Numbered serially (must account for them)
  - Issued with registrant’s name, address, registration number, and schedules authorized to handle
  - Batches of 7 or 14 forms
Obtaining Controlled Substances (continued)

- CII – Electronic Order Forms
  - Approved federally and in NJ; see previous slide
  - Requires purchaser’s digital signature
  - Unique number assigned by the purchaser to track the order
  - May include controlled substances not in CI or CII and non-controlled substances
  - No electronic order may be filled if:
    - Required fields not completed
    - Not digitally signed
    - Digital certificate used had expired or been resolved prior to signature
    - Purchaser’s public key will not validate the digital signature
CII – Electronic Order Forms (continued)

- Lost electronic orders:
  - Purchaser must provide to supplier a signed statement with a tracking number and date of the order stating that goods were not received

- Preservation of electronic orders:
  - Retain all original and linked records for 2 years
  - Retain all copies of unaccepted or defective orders and linked statements
Obtaining Controlled Substances (continued)

- CII – Hard Copy Execution
  - All 3 copies of DEA Form 222 completed at once
  - 10 lines per form, 1 item per line, each strength is a separate item
  - Signed by person who signed the most recent annual application (or person to whom ability delegated by power of attorney)
  - No erasures; errors must be voided
    - Keep voided forms
    - Change item: draw single line through item and write “canceled” in space for number of packages
  - Number of lines completed must be noted on form
  - Copy 1 and 2 sent to supplier; copy 3 retained by purchaser
    - Copy 1 retained by supplier, copy 2 sent to DEA
  - Supplier must complete shipment within 60 days
Obtaining Controlled Substances (continued)

- CII – Hard Copy Receipt
  - Purchaser must record on copy 3 the number of bulk containers received and the date it was received on

- Additional Uses of Form 222
  - Return of CII
  - Purchase by DEA registered physicians from pharmacies

- CII - Records
  - Executed order forms kept at registered location for 2 years
  - Lost or theft of order forms must be reported including serial numbers of lost/stolen order forms
  - If unfilled order form lost:
    - Fill new form 222
    - Attach a statement with the serial number of the lost form and state that goods were not received
    - Copy 3 of new form retained with copy 3 of the lost form
Obtaining Controlled Substances (continued)

- CIII, CIV, CV
  - Exempt from federal order form procedure
  - Controlled through general record-keeping regulations
  - Records include invoices and packing slips (must file and keep)
  - If sell to physician (must be registered) must use invoice. Can not exceed 5% of total dosage units of CDS sold in one year
Records

Records Maintained by Pharmacy
- On-site and kept for 2 years (NJ 5 years)
- Central record keeping (must have permission from DEA)

Inventory
- Beginning inventory
  - All CDS on-hand (including ordered not yet received, and all invoiced) on the date the pharmacy first dispenses a CDS
- Biennial Inventory
  - Must inventory every 2 years on anniversary of beginning/initial inventory date
    - Plus or minus 4 day grace period with notice to DEA
    - Or, if want to inventory on another date, can do so if within 6 months of anniversary date and DEA notified
- Newly Scheduled Drugs
  - Date of inventory specified in Federal Register; thereafter on the biennial date
  - Must do new inventory when change pharmacists in charge
Records (continued)

- **Inventory (cont.)**
  - Required Information Contained in Inventory Record
    - Date and time of inventory
    - Signature of person(s) responsible for taking inventory
    - Name of CDS
    - Dosage form/unit strengths/concentration
    - Number of units or volume in each commercial container
      - CI or CII: exact count
      - CIII, CIV, CV: estimate, unless container originally held 1000 or more
    - Number of commercial containers
    - Total quantity of substance in all forms to nearest unit weight
    - Inventory, written or typed and if done in oral recording must be promptly transcribed
    - Instructions provided
    - Separate inventories required for each separate location and each separate activity registered for
Records (continued)

- Records of Acquisition
  - Must be kept in “readily retrievable form”
  - CIIIs separate from CIII - CV
  - Controlled orders on invoices
    highlighted/underlined in red if not on separate invoices
Records (continued)

- Records of Disposition
  - CII Prescriptions
    - Separate, or with CIII-V
    - Cross out, date, sign, and write "canceled"
  - CIII – CV Prescriptions
    - Red letter "C" in lower right corner no less than 1" height if kept with other Rx's or with CIIIs
    - Either maintained separately or with other Rx's in readily retrievable form
Records (continued)

- Records of Disposition
  - Inventory
  - DEA Form 222 used to return CDS to supplier and dispensing to registered physician
  - DEA Form 106 used for theft, loss, casualty
  - Approved filing methods
    - 3-drawer method
      a) CII
      b) CIII-CV
      c) All other Rx
    - 2-drawer method
      a) CII-CV (CII-cancelled. CIII-CV have red “C” in lower right corner no less than 1” height).
      b) All other Rx
    - 2-drawer method
      a) CII
      b) CIII-CV (have red “C”) with all other Rx’s
Prescriptions for Controlled Substances

- Purpose of Issue
  - For **legitimate** medical purpose
  - Practices which should alert pharmacist to unauthorized or inappropriate prescribing
    - Larger quantities prescribed by prescriber as compared to other prescribers of same specialty
    - Dose, quantity, combination drugs outside of accepted medical practice
    - Irrational combinations frequently prescribed
    - Patients travel to pharmacy to have prescription filled
    - Erasures, misspellings, hospital Rx’s (esp. **VAMC** = Veterans Administration Medical Center), alterations
    - Nonexistent person
Prescriptions for Controlled Substances (continued)

- **Schedule II Dispensing Requirements**
  - Except in emergency only pursuant to valid, **written** prescription
  - No refills
  - If written no quantity limitation, can dispense "required amount." N.J. rules allow 30 days or 120 dosage units, whichever is less.
    - **Exceptions:** 120 dosage unit can be exceeded if physicians follow treatment plan for pain management in (30 days supply limit still applies)
      - Cancer patients
      - Patients with intractable pain
      - Patients with terminal illness
    - **Exceptions:** 30 day supply limit can only be exceeded in
      - Implantable infusion pump (90 days OK)
Prescriptions for Controlled Substances (continued)

- Schedule II Dispensing Requirements (continued)
  
  - Emergency oral CII prescriptions
    
    - All 3 determinations must be made to determine if an emergency exists (21 CFR 290.10.)
      
      a) Emergency administration of CII is needed for patient’s care;
      
      b) No proper alternative available;
      
      c) Not readily possible for prescriber to present a written Rx prior to dispensing

  - When receiving emergency oral CII (must get from prescriber)
    
    RPh must:
      
      a) Reduce Rx to writing with all required information;
      
      b) Make reasonable effort to determine prescriber’s authority (if not known) (i.e. – call back)

  - Only a 72 hour supply maximum if taken in accordance with directions can be dispensed
Prescriptions for Controlled Substances (continued)

- Schedule II Dispensing Requirements (continued)
- Emergency oral CII prescriptions (continued)
  - Prescriber must supply RPh with written Rx covering order within 7 days of oral order; In NJ, it requires 3 days N.J.A.C. 8:65-7.8
    a) Prescription must have “Authorization for Emergency Dispensing” written on face and dated as of date of oral order
      i. Original delivered by hand or mail (postmarked within 7 day period)
      ii. Upon receipt attach to oral Rx reduced to writing
    b) If not provided, RPh must notify DEA.
Prescriptions for Controlled Substances (continued)

- Schedule II Dispensing Requirements (continued)
  - Facsimile transmission of CII prescriptions
    - A pharmacist may fill a prescription for a CII transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to dispensing N.J.A.C. 13:39-7.10
      - Exception: A prescription for a CII prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner to the dispensing pharmacy by facsimile. The facsimile will serve as the original written prescription.
Prescriptions for Controlled Substances (continued)

- Schedule II Dispensing Requirements (continued)
  - Partial Filling of CII
    - Must note partial filling on prescription; date and quantity
    - Must complete order within **72 hours** but if not, must notify prescriber and receive new prescription
    - Exceptions for long-term care facilities
    - Only if full quantity is not available
Prescriptions for Controlled Substances (continued)

- Dispensing Schedule III or IV
  - Prescription may be oral (reduce to writing), written, or faxed
  - Refills – record on back of prescription or on computer
  - Partial filling allowed (same as CII)

- Dispensing Schedule V
  - OTC
  - Prescription
Prescriptions for Controlled Substances (continued)

Disposing of Controlled Substances

1. By transfer to person registered under the Act and authorized to possess the substance;
2. By delivery to an agent of the Administration or to the nearest office of the Administration;
3. By destruction in the presence of an agent of the Administration or other authorized person; or
4. By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized person.
What is Diversion?

- Diversion is best defined as “the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit marketplace.”
- Diversion of controlled-substances is a serious matter involving state and federal law, as set forth above.
Examples of Diversion

- **Point of Purchase**
  - Watch out when more CDS than are needed to refill the vault are ordered and then pocketed.

- **Patient-Specific Items**
  - Watch out for patients requiring large quantities of CDS who become targets because of high CDS usage.

- **Multi-dose Vials or Bulk Items**
  - Watch out when orders call for less than the whole content of a multi-dose vial.
Examples of Diversion (continued)

- High-Cost Medication
  - Watch out for CDS with a high value, which can be resold on the street.

- Discrepancy
  - Watch out for system users who claim an automatic dispensing cabinet (ADC) was filled incorrectly by the pharmacy.

- Substitution with Non-controlled Pain Medications
  - Watch out for substitution of CDS with non-controlled medications before given to a patient.
Examples of Diversion (continued)

- Large-volume Removals Over Short Periods of Time
  - Watch out for system users who remove large quantities of CDS from an automatic dispensing cabinet (ADC) over a short period of time.

- Tampering and Other Unauthorized Removals
  - Watch out when an empty syringe is used to remove an injectable controlled-substance from a hanging bag at the patient’s bedside.
Examples of Diversion (continued)

- Intrahospital Transfer
  - Watch out for CDS removed from the controlled-substance vault for delivery to an automatic dispensing cabinet (ADC) on the nursing unit that never make it.

- Destruction
  - Watch out for return companies who steal CDS when the pharmacy pays little attention to forms.
Signs of Diversion

- Fictitious user names are created and deleted to gain access to automatic dispensing devices.
- Employees make drug transactions during off-shifts or unscheduled times.
- Patients complain of poor pain management and their record shows erratic pain relief.
- Narcotics are pulled for excessive amounts of patients or larger doses than ordered.
Signs of Diversion (continued)

- Excessive amounts of IV leaking bags returned to the pharmacy.
- Excessive patterns of broken vials and ampoules.
- Narcotic waste is thrown into the general trash where it is later picked up by the diverter.
- Changes in patterns of narcotic-use quantities.
Signs of Diversion (continued)

- Returned capsules are missing powder or broken tablets are returned without all of their pieces.
- Diluent is substituted for active injectables for narcotics in IV bags.
- Look-alike drugs are substituted as narcotics in pharmacy storage.
Identifying Impaired Co-Workers

- Physical signs and symptoms
  - Unexpected changes in appearance
  - Sweating, lighting issues (look at pupils)

- Behavioral signs and symptoms
  - Unexpected changes in behavior, demeanor, work habits, preferences
  - Mood swings
Identifying Impaired Co-Workers (continued)

- **Productivity**
  - Absenteeism or coming into work unscheduled
  - Volunteering to complete the controlled-substance inventory
  - Sloppy, many alterations to patient’s records receiving controlled-substances

- 70% of users work full-time
- ~33% of nurses with opportunity to report an impaired co-worker do
Case – The Facts

- Dr. A, a 42-year old anesthesiologist, suffered from depression and began using IV narcotics for the past 6 months, which he obtained illicitly from his job at the hospital.
- He sought the help of a psychiatrist after a drug overdose left him unconscious and sent him to the ER, where he was revived.
After attending only 4 sessions, Dr. A was found dead in the anesthesia on-call room due to an overdose of Demerol, which he had stolen from the hospital, and Prozac, which was prescribed by the psychiatrist.

The plaintiff’s lawyer filed a $12 million malpractice lawsuit on behalf of Dr. A’s family, his wife and 2 children, against the psychiatrist for failing to prevent his death and against the hospital for failing to prevent him from stealing narcotics.
Case – Discovery

- It was revealed that Dr. A would sign out a quantity of medications at the beginning of each work day from the hospital pharmacy for use in anesthesia.

- However, the hospital failed to account for unused medication at the end of the day and this lapse in security allowed him to divert Demerol for his own use.
The plaintiff’s lawyer argued that Dr. A’s psychiatrist failed to adequately manage his drug abuse problem, which should have been more actively investigated, documented, and treated.

According to the defense, Dr. A had denied abusing drugs, claiming he had recently stopped after 6 months of sporadic IV narcotic abuse.
Case – The Verdict

- Jury delivered a $5.6 million verdict in favor of Dr. A’s family based upon an economist’s estimate of lost earnings.
- Percentages for comparative negligence – 48% of the fault was attributed to the hospital, 32% to the treating psychiatrist, and 20% to Dr. A.
Ways to Prevent Diversion

- Documentation of each step in the chain of custody
- Establish electronic ordering methods for CII
- Occasional rotation of personnel
  - Assign job responsibilities so that a single individual doesn’t order and receive controlled substances
- Lock up all controlled-substances in a central location with 1 person in charge of the key
Ways to Prevent Diversion (continued)

- Computerized record-keeping controls in nursing units
  - Dosage-unit counts at shift changes, record-of-use sheets, duplicate entry of doses administered
- Require all unused drugs to be sent back to the pharmacy for wasting so the pharmacy can monitor the destruction
- Automated dispensing cabinets that feature reports that automatically reconcile transactions to rapidly identify discrepancies
Ways to Prevent Diversion (continued)

- Patient-controlled analgesia systems
- Individualize each unit floor’s stock by sending only needed drug strengths in unit-dose containers
- Video cameras
- Identify any multi-dose or bulk controlled substances and create reports/log-sheets to track use
Ways to Prevent Diversion (continued)

- Inventory-management systems
- Periodically audit and reconcile records of controlled substances received against purchase records
- Limit physician access
- Use computerized physician order-entry
- Lock up prescription pads in a safe location
Ways to Prevent Diversion (continued)

- Pre-employment checks
- Assign 1 or 2 pharmacy employees to assist with all phases of transfer of controlled substances to an expired returns company
- Design a distribution system in the operating room that will limit the risk of diversion and detect the problem.
Ways to Prevent Diversion (continued)

- Have a reliable process for identifying discrepancies and handling discrepancies after they’ve been detected
- Track doses reported to the pharmacy as administered but not charted
- Maintain a log of photographs and signatures of staff
Ways to Prevent Diversion (continued)

- Use a controlled-substance kit prepared by the pharmacy for the OR that contains a selection of controlled-substances agreed upon by the pharmacy and anesthesia staff.
- Randomly test controlled-substances returned to the pharmacy to validate identity and assess purity.
  - Refractometer or ultraviolet light waves.
Multidisciplinary Approach to Proactive Prevention

- The primary goal is to establish a coordinated and systemic approach for prevention and detection of drug diversion, such as “CODE N”.
- CODE N (for narcotics) is sent via e-mail or alpha numeric pager to members of the CODE N team.
- CODE N is most commonly called when the proactive diversion report, generated by diversion detection software, reveals a system user who is over-utilizing 3 times more than his/her peer group.
Once detected, an investigation of the flagged user will include a charting and nurse manager review, as well as discussion and patient selection review.

When the discrepancies cannot be explained or resolved, the director of pharmacy should review the data.
Multidisciplinary Approach to Multidisciplinary Approach to Proactive Prevention (continued)

- Minimal intervention on a CODE N should require a urine drug screen
- Trends that directly point to diversion should be handled immediately through the Code N process.
- The controlled substance manager is to track, verify, and validate the usage of controlled substances throughout the institution for drug diversion issues.
Call to Risk Management to coordinate a meeting

Meeting to determine facts and roles during investigation

Investigation of Facts
Chart Reviews
Narcotic Comparisons

Employee tested for cause and placed on leave

Report to employee of cause

24–48 hours

7–14 days

24 hours
Multidisciplinary Approach to Proactive Prevention (continued)

- Provide information to help health care workers recognize the potential for diversion
- Motivate reluctant staff to do the right thing by educating them on performance improvement and consistency with improving the culture of safety.
Multidisciplinary Approach to Proactive Prevention (continued)

- Scheduled medications should be administered between 1 hour before and 1 hour after the scheduled time.
- Controlled substances should only be removed from an ADC at the time of administration.
- Medications not administered within the established time frame must be documented as to why they were not given.
- Administration of all medications must be documented in the chart.
Things to Remember

- Every individual is responsible and accountable for proper handling of medications.
- Failure to control a controlled-substance and falsification of records is a felony.
- Failure to handle controlled-substances properly will cause action to be taken by the Board of Pharmacy and DEA.
References

References

- Paloucek F. One for you and one for me: drug seeking patients and professionals. (Powerpoint) Jan 2003.