

STATE, PDMA AND CSA DISTRIBUTION REQUIREMENTS

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- Compliance Trends
- State Requirements
- PDMA/FDA Requirements
 - Physician Samples
 - Wholesale Distribution
- Part 11 – Electronic Records
- CSA Requirements
 - Controlled Substances
 - List I Chemicals
- Operational Considerations / Discussions



- Increase inspections by DEA, FDA and State Agencies
 - Multi-Million dollar fines, suspension of registration and administrative penalties being levied for storage, record keeping and reporting violations
 - Suspicious Order Monitoring (SOMs)
 - Pedigree
 - State licensing
- Companies must ensure that:
 - There is a consistent implementation of the federal and state regulatory requirements
 - Their training programs provide an understanding of the federal and state regulatory requirements, such as security, reporting, records, registration verification, suspicious order monitoring, pedigree, etc
 - There is an understanding of federal and state licensing requirements



- Guidance on regulatory requirements comes from:
 - Prescription Drug Marketing Act
 - 21 CFR Part 203 and 205
 - Part 11
 - Controlled Substances Act
 - The implementing regulations
 - State requirements
 - VAWD Requirements
 - NABP

STATE REQUIREMENTS





- Site license
- Out-of-state
 - List I chemicals
 - Prescription Drugs
 - Controlled Substances
 - Medical Devices
 - Herbal/Dietary Supplements
- Product registration
 - Puerto Rico
 - Resident Agent
 - Registration of product



- Is there a current organization chart prepared?
- A list of officers and directors?
- Responsible persons
 - Description of their duties and summary of their qualifications
- Standard Operating Procedures
 - Receiving
 - Inventory
 - Distribution
 - Reporting
 - Security
 - Storage
 - FIFO
 - Etc.



- Surety Bond
- Pedigree
- Primary/Secondary Wholesaler
- Security / access
- Storage
- Records
- Inventory
- Reporting
 - Gifts
 - Losses and thefts

PRESCRIPTION DRUG MARKETING ACT of 1987 (PDMA)





■ Records

- Written Request
- Maintain for 3 years

■ Licensed Practitioner

■ Annual Inventory

■ Storage

■ Reporting

- Thefts
- Significant Losses
- Violations of PDMA or State Requirements
- Responsibility

■ Penalties



- Responsibility remains with manufacturer / authorized distributor for sample drug delivery and assisting in meeting other PDMA requirements
 - 3rd Party Logistics
 - Fulfillment houses
 - Contract distributors
 - Co-marketing
 - CSO



- Sample Distribution By Mail or Sales Representative
 - Written request executed by licensed practitioner
 - Verify licensed practitioner is authorized to prescribe (as well as receive samples under state law)
 - Hand Carry by Sales Representative- Written request and receipt can be the same form
 - Mail Requests-need Delivery Receipt and Acknowledgement of Content returned to manufacturer



- Site license
 - Out-of-state
- Practitioner state license verification, including mid-level
- Annual inventory
- Reconciliation
- Reporting
 - Loss and thefts, including in-transit losses
 - Significant loss threshold
 - Falsification of records
- Storage and handling
 - Access
 - Temperature controls
- Maintain a list of the sales rep names and addresses of their storage sites



- Policies and Procedures; Administrative Systems
 - Establish, maintain, and adhere to written policies and procedures
 - Distribution of samples by mail or common carrier
 - Methodology for reconciliation of requests and receipts and identifying patterns of non-response
 - **Distribution of drug samples by sales representative:**
 - Reconciling requests and receipts and patterns of non-response and the manufacturer's or distributor's response
 - Conducting annual inventory and preparation of reconciliation report



- Distribution of drug samples by sales representative: (continued)
 - Implementing a security and audit system, including conducting random audits, and for-cause audits of sales representatives conducted by personnel independent of the sales force
 - Storage by sales representatives
 - Identifying any significant loss and reporting to the FDA
 - Monitoring any loss and theft



- Sample Diversion Detection Program
 - Sample inventory reconciliation
 - Random inventory audits
 - For-Cause audits
 - Trend analysis – identification of patterns of non-compliance
 - Practitioner signature verifications



- Investigation and Notification Requirements
 - Loss, theft and falsification of drug sample records
 - Notification to FDA within 5 working days
 - Initiate Investigation
 - Provide FDA with a complete written report within 30 days of initial notification

WHOLESALE DISTRIBUTION PRESCRIPTION DRUGS





- State licenses
 - Site
 - Out-of-state

- Personnel
 - Education and/or experience

- Storage and handling
 - Facilities
 - Suitable size to facilitate cleaning, maintenance and proper operations
 - Provide adequate lighting, ventilation, temp, sanitation, humidity, space, equipment and security conditions
 - Quarantine area
 - Maintained in a clean and orderly condition
 - Be free from infestation by insects, rodents, birds, or vermin of any kind



- Storage and handling (continued)
 - Security
 - Secured from unauthorized entry
 - Access from outside kept to a minimum and be well controlled
 - Outside perimeter well lighted
 - Entry into areas with prescriptions must be limited to authorized personnel
 - Equipped with an alarm system to detect entry after hours
 - Provide suitable protection against theft and diversion
 - Provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records
 - Storage
 - Temperature and conditions in accordance with requirements in the labeling or with requirements of official compendium, such as the USP/NF
 - Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, and/or logs to document storage of prescription drugs



- Storage and handling (continued)
 - Examination of drugs
 - Receipt / Outside shipping containers
 - Identity
 - Prevent acceptance of contaminated prescription drugs
 - Container damage
 - Distribution / Outside shipping containers
 - Identity
 - Prevent delivery of damaged prescription drugs
 - Held under improper conditions
 - Returned, damaged and outdated prescription drugs
 - Quarantined and physically separated



■ Recordkeeping

- Maintain inventories and records for all transactions for receipts and distributions
 - Source of drugs
 - Name and principal address of the seller or transferor
 - Address of the location from which the drugs were shipped
 - Identity and quantity of the drugs received, distributed or disposed of
 - Dates of receipt and distribution or other disposition of the drugs
- Maintain for 3 years and available for inspection and copying
 - Maintained at the inspection site or immediately retrieved by computer or other electronic means
 - Central location – within 2 working days upon request



- Standard Operating Procedures
 - Receipt
 - Security
 - Storage
 - Inventory
 - Distribution
 - Identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories
 - FIFO
 - Handling recalls and withdrawals
 - Prepare for, protect against and handle any crisis that affects security or operation in the event of strike, fire, flood or other disaster
 - Quarantine and segregation
 - Establish and maintain lists of officers, directors, managers and other persons in charge of distribution, storage and handling, including a description of their duties and a summary of their qualifications

REQUEST AND RECEIPT FORMS, REPORTS AND RECORDS Part 11





- Use of electronic records, electronic signatures and handwritten signatures executed to electronic records
 - Part 11 compliant
 - May be used as an alternative to paper records
 - Secure link between the paper based and electronic components exists such that the combined records and signatures are trustworthy and reliable and to ensure that the signer can not readily repudiate the signed records or records as not genuine
 - Scanned records are electronic records
 - Resistant to tampering, fraud, adulteration
- All records maintained for 3 years from the date of creation and available within 2 business days of a request

CONTROLLED SUBSTANCE ACT





■ Drug Schedules

■ Records/Reports

■ Registration

■ Export

■ Security

■ Import

■ Quotas

■ Prescriptions



■ Schedule I

- Marijuana
- Heroin

■ Schedule II

- Morphine
- Codeine
- Secobarbital

■ Schedule III

- Hydrocodone
Combinations
- Codeine Combinations

■ Schedule IV

- Diazepam
- Lorazepam

■ Schedule V

- Cough Syrups



- Manufacturing

- Distribution

- Dispensing/Instruction

- Chemical Analysis

- Research

- Import

- Export

- NTP

- List I Chemicals

- Distribution

- Import

- Export

- Manufacturing for
Distribution



- Schedule I and II
 - DEA Form 222 Order Form
 - Name, address, DEA registration number, actual date of receipt / distribution, drug, quantity, strength, finished form

- Schedule III, IV and V
 - Invoice/Packing Slip
 - Name, address, DEA registration number, actual date of receipt / distribution, drug, quantity, strength, finished form

- List I Chemicals
 - Invoice/Packing Slip
 - Name, address, DEA registration number of each party to the regulated transaction, date of receipt, name, quantity and form of packaging of the chemical, method of transfer (company truck, pick up by customer, etc.), type of identification used by the purchaser and any unique number on that identification.
 - Proof of Identity



- Inventories for controlled substances:
 - Date conducted
 - Drug name, strength, dosage form
 - Quantity and number of commercial containers
 - Indicate whether taken as of the opening or close of business
 - Include all controlled substances in the control and possession of the registrant
 - Every two years
- Perpetual
- Need for documentation, reviews and approvals prior to an inventory adjustment



- Schedule I, II, III, IV and V
 - Schedule II
 - Separate
 - Schedule III, IV and V
 - Readily retrievable



- Disposal (DEA Form 41)

- ARCOS
 - Schedule I and II
 - Schedule III (narcotic)

- Significant Losses and Thefts (DEA Form 106)
 - What is a significant loss



- Chemicals
 - Extraordinary Quantity
 - Uncommon Method of Payment or Delivery
 - Description on Other Identifying Characteristics Previously Furnished
 - Unusual or Excessive Loss, Including In-Transit Losses

- Earliest Opportunity After Becoming aware and as Much in Advance of the Conclusion or the Transaction
 - Written Report Within 15 Days
 - Description – Do Not Complete



■ Registration Verification

- name and address
- schedules
- expiration date

■ Suspicious Order Monitoring

- orders of unusual size
- deviating from a normal pattern
- unusual frequency



- Pre-employment Screening for Handling Controlled Substances
 - Employees and Temps
 - past five years
 - past three years
 - authorization in writing
 - report drug diversion
 - illicit activities

- Pre-employment Screening for Handling List I Chemicals
 - Employees and Temps
 - Exercise Caution
 - Aware of Circumstances of Action and Rehabilitative Efforts
 - Access Risk



- Alarms
- Cameras
- Physical
 - Schedule II
 - Vault
 - Schedule III, IV and V
 - Cage
- Carriers
 - Selection
- Shipping Containers
 - Labeling



- Sealed Containers
 - Indicate Tampering
- Physical Means
- Human or Electronic Monitoring



Are there opportunities?

- Current Industry
 - Manufacturers
 - Full-line Distributors
 - 3rd Party Logistics
 - Warehousing and distribution on behalf of the client
 - Chain Pharmacy
 - Distribution centers
 - Buying Groups

Thank You

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