

Controlled Substance Compliance – PIC Checklist

Instructions: The Pharmacist-In-Charge (PIC) is to review and update section 1 checklist/information at least annually. Upon completion, file previous checklist in Appendix B.

Section 1 – Compliance Checklist

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Site Information

Date of Review (DD/MM/YYYY):

Previous Annual Review (DD/MM/YYYY):

Site Name:

Address:

DEA #:

Pharmacy License #:

Pharmacist-in-Charge (printed):

Pharmacist-in-Charge (signature):

Pharmacist-in-Charge License #:

Federal Tax ID:

General Site Requirements

- Board of Pharmacy License is up to date – **Expiration Date (DD/MM/YYYY):**
- Board of Pharmacy License is displayed within pharmacy
- DEA License is up to date – **Expiration Date (DD/MM/YYYY):**
- DEA License is displayed within pharmacy
- PIC Binder is readily accessible and up-to-date – **Last review (DD/MM/YYYY):**
- Controlled Substance Related Policies are up-to-date and stored within PIC Binder (*see Tab 4*)

Security – Pharmacy Space

- Badge access is required to enter the area where controlled substances are stored
- A log book is maintained for personnel who access an area where controlled substance medications are stored without permitted access
- All Schedule II controlled substances are maintained within automation or a safe
- All Schedule III-V controlled substance are maintained within automation or a safe (inpatient). If outpatient, the controlled substances may be dispersed among non-controlled stock in a way to prevent theft and diversion.
- All controlled substances are maintained by a perpetual inventory count regardless of its storage location (can be manual or electronically captured)
- Non-automated storage areas are secured with an electronic lock, key, or bio-ID (fingerprint) – electronic lock or bio-ID is preferred
- Camera surveillance is used in primary controlled substance storage area
- Accepted deliveries to narcotic treatment program shall be made only by qualified personnel. There is a maintained logbook of the time and authorized person who accepted the delivery with a signature.
- Review user access (quarterly) to ensure list is up to date:
 - Vault/Safe (fingerprint and digital access)
 - Employee badge entries
 - Automated dispensing cabinets
 - Key access
 - Software/IT systems (Epic, Cardinal, Point-of-sale systems, etc.)
- Employees who have access to controlled substances have no prior convictions or felonies related to controlled substances and have never had a DEA registration denied, revoked, or surrendered.

Record Keeping

Required on-site:

- All controlled substance records are kept on-site and available for 5 years:
 - DEA and State registration certificate
 - Executed order forms and transfers of medication (222 forms, CSOS and transferred item receipts records of C-II through C-V)
 - Inventory Counts (Initial, Annual, DEA Biennial, change in PIC)
 - Financial and shipping records
 - Records of controlled substances distributed (transfers, sales to other registrants, return to vendors, distribution to reverse distributors)
 - Power of Attorney authorization to sign order forms
 - Records of controlled substances dispensed (including prescriptions) or a logbook which may be lawfully dispensed without a prescription (may be maintain electronically for inpatient areas)
 - Reports of Theft or Significant Loss (DEA Form 106), if applicable
 - Record of Controlled Substances Destroyed (DEA Form 41), if applicable
 - Self-certification and logbook as required under the Combat Methamphetamine Epidemic Act (outpatient)
- Schedule I and II controlled substance inventories are maintained separately from all other pharmacy records
- Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf
- A complete inventory of controlled substances is completed annually (KSBOP)
- A complete inventory of controlled substances is completed every 2 years per the DEA – NOTE: you may use the annual inventory, but they must be labeled differently
- Pharmacist-in-charge shall notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and, upon completion, shall provide the board with a copy of the completed DEA 106 form issued by the U.S. department of justice.

Prescription Records:

- Paper prescriptions for Schedule II controlled substances are maintained in a separately (applies to outpatient pharmacies only)
- Schedule III – V are maintained separately from other prescriptions. If filed with non-controlled substances, all schedule III-V must be marked with a red “C”
- All controlled substances prescriptions are filed in sequential order (applies to outpatient pharmacies only)
- Electronic prescriptions must be readily retrievable from all other records and must be easily readable

Prescription/Dispensing Requirements

- The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions
- All prescriptions for controlled substances shall be dated and signed on the day when issued and must contain the following:
 - Full name of the patient
 - Address of the patient
 - Drug name, strength, and dosage form
 - Quantity prescribed
 - Directions for use
 - Name of the practitioner
 - Address of the practitioner
 - Registration number of the practitioner
- All hard-copy controlled substance prescriptions must be signed manually
- All faxed prescriptions must be accompanied by the original prescription **before** dispensing
- All controlled substance labels must have the following information:
 - Date of fill
 - Pharmacy name and address
 - Telephone number of pharmacy
 - Serial number of the prescription
 - Name of the patient
 - Name of the prescribing practitioner
 - Directions for use
 - Brand name or corresponding generic name of the medication
 - Manufacturer or easily identified abbreviation of the manufacturer
 - Expiration date of the medication dispensed
 - Cautionary statements that are required – *“CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed”*
- All Schedule II prescriptions shall be canceled on the face of the prescription with the name of the pharmacist **filling** the prescription
- Controlled substances must be dispensed to the patient or a member of the patient’s household.
- Partial fills of Schedule II prescriptions must be completed in less than 72 hours of the initial dispensed. If not, the remainder of the prescription must be void and the prescriber must be notified.
- Partial fills of Schedule III-V prescriptions must be completed within 6 months from the date the prescription was **issued**. (NOT six months from the date it was filled).

Active DEA and Board of Pharmacy Licenses (copies)

Power of Attorney Documentation

*Active
Revocations*

Inventory Counts (Last 5 years)

Retail Inventory Guide

Sample Cover Sheet

KS BOP Annual inventory

DEA Biennial

Transfer of PIC or DEA registrant inventory counts

Controlled Substance Related Policies

Enterprise Policies

Controlled Substance Handling

Controlled Substance Significant Loss and Reporting

Reverse Distribution of Controlled Substance

Drug Diversion Detection: Prevention, Identification, and Reporting

5.20 Drug and Alcohol Free Workplace (Previously Drug/Alcohol Abuse, Diversion, and Testing, 702)

Inpatient Policies

Controlled Substance Discrepancy Resolution

Retail Policies

DEA Forms (if applicable)

Example 106 form

Completed 106 forms

Completed form 41, disposal

Internal Incident Reports

*Example Incident Report
Incident reports for past 5 years*

Audits

Type	Frequency	Completed By				Site Type
Purchase Records	Monthly	End of Month				Enterprise
Badge Access Review	Quarterly	Mar 31	Jun 30	Sep 30	Dec 31	Enterprise
BioStar Safe Access Review	Quarterly	Mar 31	Jun 30	Sep 30	Dec 31	Enterprise
Invoice Reconciliation	Daily	N/A				Enterprise
Inventory Count	Monthly	End of Month				Enterprise
Discrepancy Review	Daily	N/A				Enterprise
Expired Narcotic Reconciliation	Quarterly	Mar 31	Jun 30	Sep 30	Dec 31	Enterprise
DEA 222 Form Log	Quarterly	Mar 31	Jun 30	Sep 30	Dec 31	Enterprise
Primary Source Verification	Quarterly	Mar 31	Jun 30	Sep 30	Dec 31	Enterprise

Audit Sign-Off

Purchase Records

Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec

Badge Access Review

CY Q1	CY Q2	CY Q3	CY Q4

BioStar Safe Access Review

CY Q1	CY Q2	CY Q3	CY Q4

Inventory Count

Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec

Expired Narcotic Reconciliation

CY Q1	CY Q2	CY Q3	CY Q4

DEA 222 Form Log

CY Q1	CY Q2	CY Q3	CY Q4

Primary Source Verification

CY Q1	CY Q2	CY Q3	CY Q4

Appendix A: Document Locations

Document Type	Physical and/or electronic Location
Audit Standard Procedures	
Completed CSOS/ 222 Forms	
Invoices (CIII-CV)	
Distribution Records (sales to other registrants & returns to vendor)	
Reverse Distributor Records	
Disposal Records	
Dispensing Records	
Self-Certification certificate & Logbook as required under Combat Methamphetamine Epidemic Act	