ASHP Controlled Substances Diversion Prevention Program Assessment Tool

ORGANIZATIONAL-LEVEL QUESTIONS

Organization Oversight and Accountability

O.01 The organization has an established Controlled Substances Diversion Prevention Program (CSDPP) committee that provides leadership and direction for developing policies and procedures for overseeing the CSDPP.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.01.1 The CSDPP committee includes representation from (select all that apply):

- ☐ Administration
- ☐ Anesthesia
- ☐ Communications/Media Relations
- ☐ Compliance
- ☐ Employee Health
- ☐ Human Resources
- ☐ Infection Control
- ☐ Information Technology
- ☐ Legal
- ☐ Medical Staff
- ☐ Nursing
- ☐ Pharmacy
- ☐ Risk Management/Safety
- ☐ Security
- ☐ None of these apply

O.01.2 The CSDPP committee implements proactive prevention efforts and actively addresses the following (select all that apply):

- ☐ Diversion prevention control
- ☐ Diversion detection
- ☐ Incident investigation procedures
- ☐ Reporting procedures (e.g., minutes that document monitoring trend reports)
- ☐ Quality improvement efforts and outcomes of those efforts,
- ☐ Compliance with existing procedures
- ☐ Reviews of internal and external audits and action plans
- ☐ None of these apply

O.01.3 The CSDPP committee meets at least quarterly and reports directly to senior leadership of the organization.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.01.4 Surveillance data is presented quarterly to the CSDPP committee or other designated oversight committee.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.01.5 Trended surveillance information is acted upon by the CSDPP committee; implementation of corrective actions and resolution of the identified issue are verified.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.02 The organization has a designated diversion officer.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.03 The organization has a diversion response team that can rapidly and effectively respond to suspected incidents.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.04 The following were assessed within the past year or when there was a relevant change in personnel (select all that apply):

- ☐ DEA registration (is up-to-date)
- ☐ Power of Attorney designees
- ☐ Authorized CSOS users
- ☐ None of these apply

O.05 Healthcare Workers (HCWs) authorized to access or handle CS are trained and competent in established policies, procedures, and regulatory requirements.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Human Resources Management

O.06 The organization has a process to remove a healthcare worker (HCW) suspected of being impaired from delivering patient care and to prevent further access to CS either pending investigation or after a confirmed diversion or policy breach.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.07 The organization has a process to report known diverters who are licensed or registered to the appropriate licensing board as required by state law.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.08 The organization's human resources and occupational health approach to diversion prevention includes (select all that apply):

- ☐ A written employee and provider substance abuse policy
- ☐ A HCW education and awareness program
- ☐ A supervisor training program
- ☐ An employee and provider assistance program
- ☐ Peer support and systems (e.g., pharmacist recovery network)
- ☐ Requirements for drug testing, including a for-cause policy for drug testing
- ☐ Return-to-work policies for HCWs
- ☐ Sanctions for performance and diversion violations
- ☐ None of these apply

O.09 Procedures support the importance of reporting a potentially impaired HCW or suspected diversion including (select all that apply):

- ☐ Outlines ramifications for failure to report
- ☐ Communicates the expectation that staff speak up when they become aware of or suspect an issue related to CS diversion
- ☐ Ensures and communicates that staff will be protected from retaliation if they report a suspected CS diversion or impaired HCW
- ☐ None of these apply

O.10 The organization's managers receive annual training in diversion prevention awareness, including signs, symptoms, and behavior alerts, what to do when they suspect a HCW may be impaired, and managing HCWs in recovery.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.11 The organization establishes a process to support recovery and peer assistance programs for those who have diverted for an active substance abuse problem.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.12 The organization permits drug testing for cause, and, as required by licensing boards or other employment contracts, implements reliable testing and validation for drug screening.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.13 The organization develops and enforces sanctions for CSDPP policy and procedure violations.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.14 Are any HCWs with access to CS contracted or temporary employees?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.14.1 Contracted and temporary HCW agreements require contractors or temporary employees with access to CS receive relevant training and education.

☐ Yes
☐ No
☐ Not Applicable

O.14.2 Contracted and temporary HCW agreements require that the company notifies the organization immediately if there is disciplinary action against a contracted HCW or if a HCW is removed because of an impairment or suspected diversion issue.

☐ Yes
☐ No
☐ Not Applicable

O.15 The organization has a policy that addresses how to handle situations when there may be an additional impact on patient care, such as an infection control risk, and address requirements for further testing (e.g., human immunodeficiency virus, hepatitis C).

☐ Yes
☐ No
☐ Not Applicable

Automation and Technology

O.16 The organization has identified high-risk areas based on a risk for diversion (e.g., known diversion points), ease of detection (e.g., high-volume locations, level of oversight and controls, state of awareness of patients), and probability of harm (e.g., potential to impact the quality of care). Areas commonly considered to be high risk include the main pharmacy CS vault, anesthesia and procedural areas, emergency departments, surgery centers, and remote locations.

☐ Yes
☐ No
☐ Not Applicable

O.17 The organization has implemented automated dispensing cabinets (ADCs) in the following high-risk areas (select all that apply):

☐ Main pharmacy-pharmacy vault
☐ Sterile compounding areas
☐ Anesthesia and surgery/procedural areas
☐ Emergency departments
☐ Surgery center
☐ Hospice unit
☐ None of these apply

O.18 The following surveillance reports are generated from automated technology solutions and are produced on a scheduled basis, as determined by the CSDPP (select all that apply):

☐ Inventory discrepancies
☐ Deviations in administration patterns
☐ CS overrides
☐ Deviations in prescribing patterns
☐ Inventory reconciliation reports
☐ Waste patterns
☐ None of these apply

O.19 Policies and procedures specify that ADC overrides are limited to clearly defined situations.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.20 CS available for dispensing by override via the ADC process are reviewed for clinical appropriateness, that a valid order exists, and there is appropriate documentation in the medical record.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.21 ADC or electronic vault downtime procedures are defined to maintain control, documentation, and accountability of CS and include (select all that apply):

- ☐ Backup surveillance (e.g., cameras)
- ☐ Access and security controls
- ☐ Information management (e.g., decision support alerts)
- ☐ System recovery/restore
- ☐ None of these apply

O.22 ADC admission, transfer, and discharge patient profile information is managed as close to real-time as possible.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.23 Technology solutions support control, surveillance, and auditing functions that have the ability to (select all that apply):

- ☐ Track chain of custody
- ☐ Track waste
- ☐ Track returns
- ☐ Flag inventory discrepancies
- ☐ None of these apply

O.24 Storage and access to CS within ADCs is limited to unit-of-use, when possible, and access is restricted to one drug and strength at a time (i.e., the use of matrix drawers for CS is avoided).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.25 Records generated from technology solutions are readily retrievable and contain information required to conduct investigations and fulfill investigator requests.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.26 Policies and procedures that address access, security, documentation, recovery, and post-event reconciliation are established in the event of automation downtime or system failure.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Monitoring and Surveillance

O.27 The organization establishes (select all that apply):

- ☐ Surveillance requirements, including defining monitoring and surveillance measures (KPIs)
- ☐ Thresholds of variance that require action
- ☐ Reporting frequency
- ☐ Monitoring and Surveillance
- ☐ None of these apply

O.28 There is a process defining the escalation of discrepancies that cannot be resolved and notification includes (select all that apply):

- ☐ The diversion officer
- ☐ Director of pharmacy or designated pharmacy manager
- ☐ Hospital leadership (including the chief executive officer, if appropriate)
- ☐ None of these apply

O.29 There is a process defining the escalation process when there are CS policy and procedure violations.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.30 The organization periodically audits the following human resources requirements for individuals authorized to handle CS, including (select all that apply):

- ☐ Completion of required background checks
- ☐ Documentation of training and competency requirements for authorized staff
- ☐ Compliance with random drug testing requirements or is not applicable
- ☐ Compliance with licensure board reporting and rehabilitation program requirements
- ☐ None of these apply

O.31 A perpetual inventory of all CS is maintained and verified on a scheduled basis including monitoring and surveillance checks.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.32 The organization has a process to generate CS trend data and reports that monitor the following (select all that apply):

- ☐ Tracking and trending of patient care usage
- ☐ Reports that compare ADC activity with the prescriber order and MAR
- ☐ Amount and quantity of CS documented administered compared to what other caregivers administer on subsequent shifts
- ☐ CS activity compared to peers with similar staffing responsibilities and appointments
- ☐ Transaction activity (e.g., inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns, and waste) compared with peers
- ☐ Review of medication administration record transactions that occur abnormally (e.g., after a patient is discharged or transferred to another unit)
- ☐ None of these apply

O.33 The supervising or other designated pharmacist is notified of unresolvable discrepancies and has responsibility for investigating the discrepancy, even when a pharmacy technician assists with these duties.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.34 Movement of CS throughout the organization is traced, and all transactions are reconciled (e.g., reports match CS vault transactions with receipt into the ADC and/or paper inventory record with nurse signature of receipt).

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Investigation and Reporting of Suspected Diversion

O.35 A process is in place to report and respond to suspected diversions and prompt an immediate investigation and includes (select all that apply):

- ☐ A way to report (anonymously, if desired) a suspected CS diversion 24 hours-per-day/7 days-per-week (e.g., pager, phone, or other emergency alert notification system)
- ☐ An interdisciplinary drug diversion response team to provide consultation, direction, and oversight for suspected diversion incidents
- ☐ Involvement of designated team members external to the area under investigation to ensure the impartiality of the incident investigation
- ☐ A standardized process for interviewing suspected CS diverters.
- ☐ Guidelines for the handling of suspected impaired HCWs and drug testing, including when for-cause testing may be initiated
- ☐ None of these apply

O.36 The pharmacy director or their designee and diversion officer (if different) are (select all that apply):

- ☐ Notified immediately of any suspected diversion within the organization
- ☐ Participate in all active investigations regarding CS diversion
- ☐ Are informed of the outcomes of all investigations
- ☐ None of these apply

O.37 There are guidelines for determining whether a CS loss is considered significant, which include the following factors (select all that apply):

- ☐ Definition of significant loss if defined by state law
- ☐ Quantity of CS lost in relation to the type of business
- ☐ The specific type(s) of CS lost
- ☐ Whether the loss can be associated with access by specific individuals or can be attributed to unique activities
- ☐ A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses
- ☐ Whether the specific CS are likely candidates for diversion
- ☐ Local trends and other indicators of the diversion potential
- ☐ None of these apply

O.38 The organization fulfills all reporting requirements (e.g., DEA 106) for diversion or other unaccountable loss of CS in accordance with laws and regulations.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.39 There are clear responsibilities for completion of a DEA Form 106 for a theft or significant loss, who within the organization is to be notified, and when.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.40 For significant diversions, a quality-improvement review is initiated, including a root cause analysis and recommendations to prevent future occurrences.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.41 Policies and procedures define the incident review process, including (select all that apply):

- ☐ Who will coordinate the investigation
- ☐ Appropriate team members, leadership, and organization legal counsel notification
- ☐ Documentation of the investigation
- ☐ Coordination of internal and any required external reporting
- ☐ None of these apply

Security Controls

O.42 Procedures are established that ensure controls are in place to secure CS and prevent diversion in the rare case CS are brought into the organization by a patient.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.42.1 Patient's own CS are only administered to the patient pursuant to an authorized prescriber's order.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

O.42.2 Documentation of patient's own CS, quantity inventoried, and signatures of two verifying HCWs are recorded in the medical record.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.42.3 Procedures ensure appropriate disposition of patient's own medications (e.g., all patients own medications to be mailed home, returned home by a designated agent of the patient, or disposed of by the patient in a collection receptacle).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.42.4 When there is a physician order to use the patient's own CS, the patient's CS are secured and tracked via a perpetual inventory record, and any remaining doses are the responsibility of the patient to take home or dispose of in a collection receptacle upon discharge.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.42.5 CS that cannot be returned to home, are unable to be secured by the patient, or are abandoned by the patient are inventoried and stored securely per organization policies until disposition can be arranged.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.42.6 The chain of custody of patient's own CS is always maintained (e.g., the patient or patient's representative signs that he or she has received the CS, noting the quantity and signature of receipt).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.42.7 If patients bring illicit substances into the organization, procedures address notification of the local DEA office and law enforcement, as required by law, and as advised by those authorities.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Procurement Controls

O.43 All CS are procured by the pharmacy. If other departments or individuals are authorized to procure CS, there are checks and balances established to ensure the same policies and procedures are consistently followed throughout the organization.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

O.44 The number of people authorized to order CS is limited to individuals authorized and defined by policy.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Waste Controls

O.45 There is a procedure for wasting fentanyl transdermal patches according to Food and Drug Administration or state-specific guidelines in a manner that renders the fentanyl non-retrievable or otherwise deactivated before disposal.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

WORK SITES

Security Controls

W.01 Which of the following most closely describes your practice location?

- ☐ Anesthesia and surgery/procedural areas
- ☐ Compounding pharmacy (503A/B)
- ☐ Emergency department
- ☐ Hospice unit
- ☐ Long term care
- ☐ Nursing Unit
- ☐ Pharmacy/main vault/central storage location
- ☐ Pharmacy/miscellaneous storage/preparation areas
- ☐ Pharmacy/sterile compounding area/central hub
- ☐ Outpatient surgery/Procedure center
- ☐ Other

W.02 In patient care areas, CS not managed through ADCs are manually inventoried by blind count by two authorized HCWs every shift.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.03 This work location/unit has implemented (Select all that apply)

- ☐ Automated dispensing cabinets
- ☐ Manual CS management system

W.04 In patient care areas, when CS are not managed through ADCs, the perpetual inventory log includes the drug product, quantity, date, and signatures of those conducting the inventory.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.05 Staff can state how to report a suspected diversion.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Monitoring and Surveillance

W.06 Staff can describe the process for escalation of discrepancies that cannot be resolved ("unresolvable discrepancies") or when there are CS policy and procedure violations.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.07 CS counts from ADCs are verified (blind count) each time a CS drawer is accessed, and a complete inventory for CS in ADCs is conducted weekly by two authorized HCWs (with the possible exception of those accessed and verified electronically during the week). The inventory count is not required for drugs accessed and verified during that week.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.08 Outside of pharmacy areas, CS storage areas in which CS are managed manually are inventoried at each shift change by two authorized HCWs.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.09 ADC override reports are reviewed daily to ensure an order exists during the time the medication was accessed from the ADC, and corresponding documentation is in the medication administration record (MAR).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.10 Prescribing practices are reviewed for unusual trends or patterns, such as variance in prescribing compared to peers.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.11 CS discrepancies are reported to the supervisor in charge of the unit/location, who reviews and attempts to resolve the discrepancy no later than the end of the work shift.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.12 A trend of poor documentation practices by a HCW is reviewed by their immediate supervisor (e.g., nursing or pharmacy manager, department chair) for possible diversion.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Monitoring and Surveillance

W.13 Pharmacy, in collaboration with nursing supervision, reconciles all CS orders against administration records, at minimum, in high-risk areas, by comparing the amount dispensed with the amount documented as administered and the amount documented as wasted. This reconciliation may occur through surveillance analytics technology. Random, monthly audits may be conducted in areas that are not high-risk or supported by surveillance analytics.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.14 Representative(s) from the area where there is a suspected diversion are engaged in the investigation and refinement of prevention strategies.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.15 Investigations involving contracted HCWs are conducted in collaboration with the contracted entity and with full transparency.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Chain of Custody

W.16 Persons transporting CS (e.g., couriers) are trained and have competency documented in relevant organizational policies and procedures related to CS.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.17 CS delivery to areas without ADCs requires co-signature for delivery and return.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.18 Hand-offs during a patient procedure are generally avoided, but in the event a hand-off is unavoidable, such as during an active surgical case (e.g., prepared case trays, break coverage, or change of shift), there are procedures to document the chain of custody and document provider transfer of CS.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Security Controls

W.19 CS are securely stored in a locked location (e.g., ADC, safe, locked cabinet/drawer, refrigerator) accessible only to authorized individuals at all times unless in the direct physical control of an authorized individual.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.20 When used, lockboxes are stored in a secure location when left unattended.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.21 Lock-out times for electronic locks on carts (e.g., medication carts, anesthesia carts) containing CS are limited to the narrowest window of time appropriate for the particular setting.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.22 There is a procedure to track keys, secure keys after hours, replace lost keys, and change locks, and there is evidence of compliance with those procedures.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.23 CS stored in compartments or boxes in refrigerators are secured and key access limited. For example, keys may be kept in a dedicated single-access pocket in the ADC that opens when the CS is selected from the patient profile and returned to the pocket after removing the CS.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.24 Backpacks, purses, and bags are prohibited in CS storage areas.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.25 Policies and procedures regarding CS access include (select all that apply):

- ☐ Access permissions
- ☐ Key controls
- ☐ Use of passwords
- ☐ Schedule for changing lock codes (where there is not biometric or card reader access)
- ☐ None of these apply

W.26 At least every 6 months there is a complete assessment of all staff with access privileges to ensure that only those permitted access have access (e.g., authorized HCWs, temporary employees, independent practitioners with privileges). Inactive users (e.g., those who have not accessed the system within a specified period of time) have their access suspended or removed.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.27 Removal of access occurs immediately when HCWs are terminated. For auditing purposes, staff termination reports (date and time) are reconciled against date and time of documented removal of access.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.28 CS counts done via ADCs and manual systems are verified by a blind count each time a CS location (e.g., drawer, pocket, and refrigerator) is accessed.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.29 In this location (select all that apply):

- ☐ Controls are in place to monitor CS inventories for discrepancies
- ☐ At least one of those conducting the inventory is licensed
- ☐ For high-volume or high-risk areas, more frequent verification audits are considered to prevent or minimize inventory count discrepancies and minimize the time window for discovery of the discrepancy
- ☐ None of these apply

W.30 ADC technology is utilized in this work site/patient care area for the distribution and accountability of CS.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.31 There is a process to identify and verify authorized prescribers within either an electronic or manual ordering system.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.32 CS are retrieved from inventory for one patient at a time, and as close to the time of administration as possible, as defined by the organization and appropriate to the care setting.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.33 CS retrieved for a patient is the package size equivalent to, or closest available to, the dose to be administered.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.34 CS infusions are secured in locked infusion pumps, utilizing no-port tubing, unless under constant surveillance (e.g., anesthesia/OR setting).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.35 When CS are drawn up into syringes and not immediately used (select all that apply):

- ☐ Are labeled per organization policy
- ☐ Contains the initials of the HCW who prepared the syringe
- ☐ Kept under direct control of the person preparing the syringe(s) until administration to the patient
- ☐ If sequential doses are administered there is a way to track the dose ordered vs. the dose administered
- ☐ None of these apply

W.36 In areas in which CS are not managed through ADCs, CS disposition and administration records are accurate and include the following information (select all that apply):

- ☐ Date and time administered
- ☐ Medication name
- ☐ Medication strength
- ☐ Dosage form
- ☐ Dose administered
- ☐ Signature of the HCW who administered the dose
- ☐ Amount wasted (if applicable), with cosignature
- ☐ Proof of count verification per shift
- ☐ Signature of HCW who transferred the balance forward when transcribing to a new record
- ☐ None of these apply

W.37 Returns are placed in a one-way, secure return bin and not returned to the original pocket in the ADC.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Waste Controls

W.38 In patient care areas where waste is documented through the ADC, the waste is documented by the person who retrieved and administered the medication and, to the extent possible, in the same device from which the medication was removed.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.39 Procedures require that CS be wasted immediately or as close to the time of administration as possible; there is an established timeframe allowed per policy.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

W.40 The wasting of all CS requires an independent witness to verify the waste and that it matches documentation.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.41 Empty CS containers are discarded in limited-access waste containers that render the waste non-retrievable and waste procedures comply with organizational procedures for waste management.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

W.42 For defined high-risk areas (e.g., pharmacy, surgical, anesthesia, procedural, high volume) and/or specific high-risk CS medications (e.g., fentanyl), waste is witnessed and reconciled with the medication administration record by an authorized HCW.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

PHARMACY-LOCATIONS ONLY

P.01 Which of the following most closely describes your practice location?

- ☐ Anesthesia and surgery/procedural areas
- ☐ Compounding pharmacy (503A/B)
- ☐ Emergency department
- ☐ Hospice unit
- ☐ Long term care
- ☐ Nursing Unit
- ☐ Pharmacy/main vault/central storage location
- ☐ Pharmacy/miscellaneous storage/preparation areas
- ☐ Pharmacy/sterile compounding area/central hub
- ☐ Outpatient surgery/Procedure center
- ☐ Other

P.02 This work location/unit has implemented (select all that apply)

- ☐ Automated dispensing cabinets
- ☐ Manual CS management system

P.03 To proactively identify diversion, variation in purchasing or ordering patterns are regularly monitored by (select all that apply):

- ☐ Comparison of purchase invoices to CS purchase orders and receipt into the pharmacy's perpetual inventory
- ☐ Reconciling invoices to statements or wholesale purchase history reports to detect missing invoices
- ☐ Identifying unusual peaks in quantity or frequency of CS purchases (e.g., quarterly review of purchases over the prior 12–24 months)
- ☐ Wholesaler's ability to flag and notify any unusual peaks in quantity or frequency of CS purchased
- ☐ None of these apply

P.04 Movement of CS throughout the organization is traced, and all transactions are reconciled (e.g., reports match CS vault transactions with receipt into the ADC and/or paper inventory record with nurse signature of receipt).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.05 CS inventory in the pharmacy CS vault is counted at least monthly.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.06 Reports match CS vault transactions with receipt into ADC and/or paper inventory record with signature of receipt.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

Chain of Custody

P.07 Secure, lockable, and tamper-evident delivery containers (e.g., carts, trays, boxes, prescription bags) are used to deliver CS.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.08 Packaging used for transport of CS is designed to be inconspicuous and not draw attention to the contents inside (e.g., opaque containers).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.09 When used, tamper-resistant or tamper-evident mechanism on transport containers are traceable (e.g., plastic tie locks with a unique numerical identifier).

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.10 Environmental services and other support staff are not permitted to have access to central CS storage locations when unattended (e.g., after hours).

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.11 Camera surveillance is present in primary CS pharmacy storage and preparation areas (e.g., CS vault).

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.12 Access to CS storage areas is minimized and limited to authorized staff.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.13 The central pharmacy vault is considered a high-risk location and as such, is supported by automated dispensing technology.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.14 Within pharmacy areas with electronic vault management, CS inventory verification counts are conducted by two rotating, licensed, or otherwise authorized pharmacy providers monthly.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.15 For pharmacies without elecronic vault management, a physical inventory is conducted at least once per month, preferably weekly.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.16 Pharmacy inventory count includes expired and otherwise unusable CSs awaiting disposal or transfer to a reverse distributor.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.17 Procedures are implemented to secure prescription pads and paper, and access is limited to authorized individuals.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.18 Controls are in place to monitor pharmacy inventories for discrepancies within pharmacy for areas with electronic vault management (select all that apply):

- ☐ CS are manually inventoried by two rotating, licensed, or otherwise authorized pharmacy personnel (e.g., pharmacy technicians) monthly
- ☐ At least one of those conducting the inventory is a licensed pharmacist
- ☐ The inventory count includes expired or otherwise unusable CS awaiting disposal or transfer to a reverse distributor
- ☐ None of these apply

P.19 CS pharmacy vault counts managed by ADCs or done manually are verified by a blind count each time a CS drawer, pocket, cabinet, or refrigerator is accessed, except when unit-of-use dispensing technology is deployed.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.20 Inventory verification is conducted for CS managed by ADCs by two authorized HCWs if a blind count has not been performed within one week. CS not managed through ADCs are manually inventoried by two authorized HCWs at the beginning and end of every shift when the area is open for services.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.21 Controls are in place to monitor pharmacy inventories for discrepancies within pharmacy. For pharmacies without electronic vault management, a physical inventory is conducted at least once per month but preferably weekly.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Procurement Controls

P.22 There is a process in place to monitor for a wide variation (e.g., increase) in ordering quantities, frequency of ordering, or unusual products ordered (e.g., bulk bottles when unit-dose is usually stocked).

- ☐ Yes
- ☐ No
- ☐ **Not Applicable**

P.23 An electronic CS ordering system (CSOS) is utilized, eliminating or minimizing use of paper DEA Form 222s.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.24 Separation of duties exists between the ordering and receipt of CS.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.25 Upon receipt of CS, two authorized individuals conduct a visual inspection for package integrity, count, sign (two signatures), and date (packing slip) and confirm that what is received matches what was ordered and invoiced (purchase order and invoice).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.26 There is evidence that a pharmacist or designee reconciles CS received against what is indicated on the delivery ticket or invoice and documents receipt as required. Documentation includes: 1) Receipts are initialed and dated; 2) CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory; and 3) invoices are reconciled to statements or wholesale purchase history reports to detect missing invoices.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.27 There is evidence that a pharmacist or designee reconciles CS received against the invoice: 1) all drug invoices indicate the total number of pages in the invoice, 2) the pharmacist in charge or delegate verifies that drugs detailed in all the pages of an invoice are being received.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.28 To minimize opportunities for CS diversion during repackaging, CS are purchased and dispensed in unit dose packaging whenever possible, and when repackaging is required, it is configured to minimize waste. There are diversion controls in place when CS are repackaged by pharmacy personnel, including separation of duties and chain of custody controls.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Security Controls

P.29 CS managed through ADCs are stored in a location with single pocket or unit of use access when possible.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.30 Barcode-scanning is utilized when replenishing ADCs.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.31 When dispensing, removal from the pharmacy inventory is matched to the refill transaction on the patient care unit to validate that CS reach their destination.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.32 CS returned from nursing units to the return bin of the ADC or to the pharmacy are matched to the CS received by the pharmacy and documented in the perpetual inventory or a return, by pharmacy, to active inventory transaction on the ADC.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.33 Access to DEA 222 forms is limited to authorized individuals and a log is kept that includes (select all that apply):

- ☐ DEA order form number
- ☐ Date the form was received from the DEA
- ☐ Date the form was issued
- ☐ The intials or signature of authorized user
- ☐ The entity the form was issued to
- ☐ Signature of receipt
- ☐ None of these apply

P.34 There is a process to investigate and remedy discrepancies when CS are received in the pharmacy from the wholesaler or other distributor.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.35 Access to CS inventory is limited, with controls to identify (select all that apply):

- ☐ Who accessed the inventory
- ☐ When the inventory was accessed
- ☐ What changes were made to the inventory
- ☐ Readily retrievable audit trail
- ☐ None of these apply

P.36 Is there repackaging of controlled substances?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.36.1 To minimize diversion during repackaging, CS are purchased and dispensed in unit of use packaging whenever possible.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.36.2 Diversion controls are in place when CS are repackaged, and repackaged products are routinely inspected to ensure product integrity.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.37 ADC access to medications for a particular patient is suspended immediately at discharge.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Waste Controls

P.38 All returns to a reverse distributor require that the chain of custody be maintained and that witness of transfer is documented.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

P.39 CS are stocked in as ready-to-use form as possible (e.g., avoiding the use of multidose vials or oral liquids) and in the lowest commercially available units frequently prescribed to patients.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.40 Potentially reusable products issued from ADCs have an auditable verification of return, and returns are inspected for integrity.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.41 Expired or otherwise unusable CS are (select all that apply):

- ☐ Clearly identified as such and stored in a location separate from other medications
- ☐ Properly accounted for with a perpetual inventory list that is regularly verified, as is other CS inventory within the pharmacy
- ☐ Monitored as other CS inventory until return via reverse distributor or destruction and disposal in accordance with legal requirements
- ☐ Not allowed to accumulate (e.g., the frequency of returns and destruction ensures that returns and destruction are done at least quarterly)
- ☐ None of these apply

P.42 CS waste from compounded sterile preparations is documented with a cosignature and randomly assayed at least quarterly.

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

P.43 Unusable CS product are secured to prevent tampering or made otherwise non-retrievable (e.g., use of deactivating, deterring, and solidifying agents.)

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

COMMUNITY PHARMACY

C.1 There are physical access controls, such as secured storage cabinets only accessible by badge or biometric access, to limit and track access by personnel.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.2 The organization has placed cameras in the high-risk areas (select all that apply):

- ☐ Retail location entrance/exits
- ☐ CS storage areas
- ☐ Dispensing and verification areas
- ☐ Will-call
- ☐ Drug take-back receptacles
- ☐ None of these apply

C.3 The organization has placed panic buttons in the high-risk areas (e.g., storage and dispensing locations).

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.4 Required registration and documentation required by the organization is completed and current for special programs (e.g., drug collection receptacle site registration, compliance with the Combat Methamphetamine Epidemic Act of 2005 [CMEA]).

- ☐ Fully Compliant
- ☐ Partially Compliant
- ☐ Not Compliant
- ☐ Not Applicable

C.5 The pharmacy implements a reporting or auditing process that compares CS purchases with utilization to identify discrepancies and trends.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.6 The pharmacy has a system in place to audit documentation of the chain of custody, including dispensing to the patient or their authorized representative.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.7 The pharmacy has established procedures for managing and documenting partial fills of CC.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.8 During nonbusiness hours, CS are stored in an area secured by a physical barrier with security access controls (which may include a locked room within a secured facility) that can only be accessed when authorized pharmacy personnel are present.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.9 The organization has systems in place for documentation and monitoring of (select all that apply):

- ☐ CS inventory adjustments made by pharmacy employees
- ☐ CS prescriptions cancelled and returned to stock
- ☐ CS prescriptions left at will-call (e.g., prescriptions remaining 10 days after being filled)
- ☐ None of these apply

C.10 When dispensing checks are not automated, the quantity dispensed is verified and documented with a second authorized person.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.11 Diversion prevention and monitoring tools are utilized as appropriate to determine the legitimacy of CS prescriptions, including PDMP reporting and checks, in accordance with state requirements.

- ☐ Yes
- ☐ No
- ☐ Not Applicable

C.12 Chain of custody and security is maintained when holding CS prescriptions in the will-call area and when delivering medications to patients, such as with a "meds-to-beds" prescription delivery service, for example, by use of tamper-evident security bags.

- ☐ Yes
- ☐ No
- ☐ Not Applicable