

Controlled Substance Diversion, Detection and Prevention Program

Elements of Best Practice(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
	Legend: CS-Controlled Substances; DEA-Drug Enforcement Administration; ADM-Automated Distribution Machine	
<i>Tier 1 - Essential element and should be in place</i>		
<i>Tier 2 - Recommended element. Progress toward implementation should be made over time</i>		

CORE PRINCIPLES

1	The chain of custody and individual accountability of Controlled Substances (CS) are maintained at all times.	1
2	Organizational policies exist that address all aspects of CS medication use processes. Policies are regularly reviewed and are compliant with federal and state regulations.	1
3	Organizational policies are adhered to by all staff.	1

STORAGE & SECURITY

4	CS are securely stored in a locked location (i.e. ADM, safe, locked cabinet/drawer) at all times unless in the direct physical control of an authorized individual.	1
5	CS that are under the control of an authorized individual are not placed where their view may be obscured or where a distraction may prevent direct observation at all times.	1
6	Access to CS storage areas is minimized and limited to authorized staff.	1
7	CS brought in by a patient that cannot be returned home are inventoried by two authorized healthcare staff, and stored in a locked, limited-access area.	1

PROCUREMENT

8	All CS are obtained from pharmacy.	1
9	Only authorized pharmacy staff can purchase CS.	1
10	The number of individuals authorized to order CS is minimized.	1
11	Separation of duties exist between the ordering and receipt of CS.	1
12	Two individuals count and check-in CS received and confirm that order, invoice, and product-received documentation match.	1
13	CS inventory levels are based upon usage in order to minimize excess stock.	1
14	Automated CS safe technology is utilized.	1
15	Electronic CS Ordering System (CSOS) is utilized (eliminates paper DEA 222 forms).	1
16	A process is in place to identify unusual "peaks" in quantity or frequency of CS ordered.	2
17	All CS procurement paperwork is reviewed for completion and filed according to applicable laws and regulations.	1

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ORDERING / PRESCRIBING

18	CS are ordered only by licensed authorized prescribers with DEA authorization.	1
19	CS orders are generated by electronic systems with controlled access except in emergency situations or when not practical.	1
20	CS are not prescribed by an authorized prescriber for him/herself or an immediate family member.	1
21	Range orders for CS are eliminated.	2

PREPARATION & DISPENSING

22	CS are dispensed in unit dose packaging whenever possible.	1
23	CS waste from Compounded Sterile Product (CSP) preparation area in the pharmacy is collected and randomly assayed.	2
24	ADM technology is utilized in high volume CS pharmacy areas.	2
25	Secure, lockable, non-transparent medication delivery carts / containers are used to deliver CS.	1
26	ADM technology is utilized in patient care areas for the distribution and accountability of CS.	1
27	ADM managed CS are stored in a location with single pocket access.	1
28	Bar code scanning is utilized when replenishing ADM Medstations.	2
29	A "blind count" process is used for all ADM managed CS. (A, see below)	1
30	The number of CS on ADM override status is minimized. (B, see below)	1
31	Bio-ID ADM technology (biometric thumbprint entry) is used instead of passwords.	1
32	CS delivery to non-ADM areas requires co-signature for delivery and return.	1
33	Non-ADM CS cabinets are secured with an electronic lock that requires a user specific code or badge swipe.	2
34	ADM down time procedures are defined to maintain the control, documentation and accountability of CS.	1

ADMINISTRATION

35	A valid order from an authorized prescriber exists for all CS administered.	1
36	CS are only administered by licensed independent practitioners or other licensed or registered health care providers within their scope of practice.	1
37	CS are retrieved from storage areas as close to the time of administration as possible.	1
38	The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.	1
39	CS for one patient at a time are obtained from the ADM / locked storage area.	1
40	The individual retrieving the CS from ADM / locked storage area is also the person that administers the medication.	1
41	All CS drawn up into syringes, if not immediately administered, are labeled per institutional policy and the initials of the individual that drew up the drug are written on the label.	1

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42	Initials on prepared syringes are verified immediately prior to administration to ensure that the syringe has not been switched.	1
43	CS waste from high risk areas (e.g surgical, anesthesia, procedural, high volume) and/or specific high-risk CS medications (e.g. fentanyl) are returned to and reconciled by the pharmacy. Universal precautions are used when handling waste.	1
44	Approved methods for wasting a CS are defined in policy (e.g. squirted into sink, flushed down toilet).	1
45	The wasting of all CS requires an independent witness and documentation, except in situations where waste is being returned to Pharmacy for assay and wasting.	1
46	An individual witnessing CS wasting verifies that the volume / amount being wasted matches the documentation and physically watches the medication being wasted per policy (e.g. squirted into sink, flushed down toilet).	1
47	Patient-specific CS infusions are contained in a locked box utilizing no-port tubing unless under constant surveillance.	2
48	Unused ADM managed CS are returned to a return bin and not to the original ADM pocket.	1
49	All CS returns to the pharmacy require co-signature in the patient care area and in the pharmacy.	1
50	Limited access lock boxes are available in all procedural areas where CS may be left unattended.	1
51	Empty containers of CS (e.g. vials) are discarded in limited-access waste containers (e.g. sharps boxes).	1
52	All CS administered are documented in the medical record.	1

INVENTORY & RECORD KEEPING

53	A perpetual inventory of all CS is maintained.	1
54	ADM managed CS counts are verified each time a CS drawer is accessed.	1
55	ADM managed CS are manually inventoried by two authorized health care providers if a blind count has not been performed within one week.	1
56	ADM CII Safe managed CS are manually inventoried by two licensed or authorized pharmacy providers on a regular basis.	1
57	Non-ADM managed CS are manually inventoried by two authorized health care providers every shift.	1
58	A biennial physical inventory of all CS is completed and documented per DEA requirements.	1

SURVEILLANCE

59	CS waste is randomly tested for content.	1
60	ADM CS discrepancies created by a blind count are resolved by two authorized health care providers within the shift / business day in which these are discovered. A process is in place for investigating discrepancies that are not satisfactorily resolved.	1
61	ADM CS surveillance reports are regularly created and assessed.	1
62	All paper CS "Disposition and Inventory" sheets are reviewed and audited.	1
63	Ordering vs Dispensing vs Administration documentation is audited (electronic preferred).	1

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64	Patient assessment and medication administration documentation is audited on a regular basis.	2
65	Camera surveillance is present in primary CS pharmacy storage area (e.g CS vault).	2
66	Camera surveillance is present in high use CS pharmacy preparation areas.	2
67	Camera surveillance is present in high risk areas (e.g. external return and waste bins) as appropriate and when "for cause" surveillance is required.	2

INVESTIGATION and RESPONSE

68	A 24 hour x 7 days-per-week medication diversion pager or phone number is available to report (anonymously if desired) suspected medication diversion.	1
69	A multidisciplinary "Drug Diversion Response Team," or equivalent, is in place to provide consultation, direction, and oversight for suspected diversion incidents.	1
70	A standardized process exists for interviewing suspected CS diverters.	1
71	Guidelines are in place for the handling of suspected impaired employees and drug testing.	1
72	A defined process is in place for the internal and external reporting of medication diversion incidents.	1

EDUCATION

73	Education on medication diversion and CS policies and procedures is required prior to authorized staff having access to CS.	1
74	An ongoing medication diversion education program is in place to promote the safe handling of CS and awareness of medication diversion.	2

QUALITY IMPROVEMENT

75	A "Medication Diversion Prevention Committee," or equivalent, exists to provide leadership and direction for all medication diversion activities.	2
76	CS diversion incidents are collated, reviewed, and analysed to identify further opportunities for improvement in existing systems.	2
77	A defined process is in place for the ongoing, timely management of employee access to CS when employee is terminated or transferred.	1