Reducing Controlled Substances Diversion in Hospitals

California Hospital Association Medication Safety Collaborative Committee
www.calhospital.org/medication-safety-committee

Introduction
The attached road map is intended for acute care settings as a plan to help navigate controlled substance diversion prevention goals. The document provides a recommended framework to coordinate the needed resources and technology for an optimal diversion prevention program. Actions taken pursuant to this framework should be reflected in a standardized set of processes within the organization to ensure that they are maintained.

Some actions are required by law or regulation (and marked with ►) while some may be good recommendations to have in place. Ultimately, each organization is responsible for developing a diversion prevention plan that protects patients from impaired care providers (i.e., to the extent it affects a provider's ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of controlled substances within the organization).

Credits
The committee thanks the Minnesota Department of Health and Minnesota Hospital Association and the Minnesota Drug Diversion Coalition[1] for developing the original document. With their permission, this document builds upon their work and includes California-specific guidance.

Committee Representation
The committee includes representatives from:

- Association of California Nurse Leaders
- California Association of Health Facilities
- California Board of Pharmacy
- California Department of Public Health
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization
- California Medical Association
- California Society of Health System Pharmacists

[1] Minnesota Coalition members are listed at www.health.state.mn.us/patientsafety/drugdiversion/.

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, and others.

Component	Specific Action(s)	Self-Assessment Checklist
Safety Teams / Organizational Structure	1. Organization defines Controlled Substance (CS) Diversion Prevention Program.	1a. The organization has an interdisciplinary team involved in developing and overseeing the CS Diversion Prevention Program. 1b. The CS Diversion Prevention Program includes prevention, detection and investigation. 1c. The CS Diversion Prevention Program is reviewed by the team and updated at least annually. 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas: • Medical Staff • Pharmacy • Nursing • Security • Human Resources • Patient Safety/Risk Management/Compliance • Administration • Legal (as necessary) • Communications (as necessary)
	2. An organizational structure is in place that supports an effective CS Diversion Prevention Program.	2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. 2b. The coordinator(s) has dedicated time to serve in this coordination function. 2c. The organization has a team prepared to respond to suspected CS diversion situations. 2d. The organization has and regularly reviews policies and procedures addressing all aspects of the CS use processes. 2e. The organization regularly reviews policies and procedures to assure compliance with state and federal laws.

	3. Organization proactively collaborates with local law enforcement.	3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss the CS Diversion Prevention Program and establish a communication strategy (including public) prior to CS diversion situations.
	4. Organization fulfills all reporting requirements for diversion or loss of CS.	4a. ►The owner reports to the California Board of Pharmacy within thirty days of discovery of any CS losses, including their amounts and strengths. 4b. ►The DEA registrant or their designee reports any CS theft or significant loss to the DEA within one business day of discovery. 4c. ►The organization follows other applicable requirements. For example, Medicare Conditions of Participation states: "Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate."
Access to Information / Accurate Reporting / Monitoring / Surveillance / Detection System	1. Organization reviews and audits relevant data that could indicate potential CS diversion.	1a. ►The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets and CS "Disposition and Inventory" sheets.
	2. Organization tracks and reviews measures recommended by Medication Safety Committee or other designated groups reporting directly to a Medical Staff Committee.	2a. ►The organization has a process in place to review and analyze CS data on a regular basis. 2b. ►The organization shares findings from the data analysis on a regular basis. 2c. ►There is a process in place to activate a response team that includes a patient care manager, pharmacy, Human Resources (HR) and security when diversion is suspected. 2d. ►The organization has a process in place to contact law enforcement when diversion or theft is suspected.
Facility Expectations	1. Organization communicates the expectation that staff "speak up" when they become aware of an issue related to CS diversion.	1a. ►Senior leadership has clearly communicated that all staff are to speak up and will be supported in speaking up when they become aware of possible diversion. 1b. ►The hospital treats such information as confidential and takes all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.
	2. Organization establishes full disclosure policy.	2a. ►The organization has a clearly defined full disclosure policy and process to communicate to patients/families who are

		affected by CS prevention diversion.
	3. The organization's HR practices support an effective organization-wide CS Diversion Prevention Program.	3a. The organization has established and communicated ways for staff to speak up anonymously (e.g. hot line, paper or electronic submission). 3b. The organization has a process in place to remove an impaired caregiver from patient care. 3c. ►The organization conducts pre-employment background checks for Licensed Independent Practitioners (LIPs) and employees. 3d. A log of staff photographs and signatures are maintained as appropriate. 3e. The organization has a process to manage employee access to CS in a timely fashion when terminated or transferred. 3f. The organization has developed a "for cause" policy for drug testing.
	4. Organization does not allow sharing of pass codes.	4a. ►The organization establishes and enforces a policy of not sharing pass codes such as electronic medical record (EMR), Automated Distribution Machine[2] (ADM) and pharmacy door codes.
Education Staff (and Patients)	1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention.	1a. The CS Diversion Prevention Program team has attended CS diversion prevention and statutory requirements training (e.g. National Association of Drug Diversion Investigators [NADDI], professional associations, licensing boards, state, local and federal law enforcement). 1b. Expectations and supporting education have been incorporated into training for all new staff and LIPs. 1c. Expectations and training include, at a minimum, providing awareness training to know the signs of diversion. 1d. Resources are available to support employees and LIPs, e.g. Employee Assistance Program (EAP) and Health Professional Services Program (HPSP). 1e. The facility requires training on CS policies and

[2] ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed health care facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.

		procedures prior to authorizing staff to have CS access. 1f. The facility provides ongoing staff education at least annually to promote safe handling of CS and CS diversion awareness. 1g. The organization provides patient education on safe medication handling, including potential for diversion.
Storage and Security	1. Organization stores CS and other high-risk items securely, in all settings and circumstances.	1a. ►The organization has a process in place for securing CS (as described in section 2 below) for every setting and circumstance.
	2. Organization has a process in place for securing CS.	2a. Never leave CS unattended. 2b. CS are stored in a locked location (e.g., ADM, ©[3] vault or locked cabinet/drawer/box) at all times. 2c. ADM-managed CS are stored in a location with one CS-type access. For example, users cannot have access to a second type of CS when accessing the intended CS. 2d. Access to CS storage areas is limited to authorized staff. 2e. Non-ADM CS cabinets are secured with a locking device. 2f. ADM and non-ADM access is removed promptly for terminated employees. 2g. Patient-specific CS infusions (e.g., PCA[4], epidural, and continuous infusions) are enclosed in a locked box. 2h. Keys are controlled and accounted for. 2i. Prescription pads and paper are stored in ADM, locked location or under control of an LIP. 2j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area. 2k. Electronic and non-electronic prescriptions comply with state and federal requirements. 2l. CS brought in by a patient that cannot be returned home are inventoried by two authorized health care staff and stored in

[3] Schedule II controlled substance.
[4] Patient-controlled analgesia.

		a locked, limited access area. 2m. CS brought to the hospital for use by the patient (i.e., Patient's Own Medication) is securely stored and accounted for during the hospitalization as well as upon the patient's discharge. It is recommended to have a process in place where patients are contacted after discharge to pick up their CS in storage. CS remaining in the pharmacy and not picked up by the patient after discharge is to be destroyed per the hospital's policies. Preferably, the patient is contacted and asked to pick up their CS.
	3. Organization uses camera surveillance in high-risk areas as appropriate.	3a. Camera surveillance is used in primary CS pharmacy storage area (e.g. narcotics vault).
Procurement	1. Organization effectively and safely handles procurement in the hospital pharmacy.	The organization has a process in place for procuring CS that includes: 1a. ►If the hospital utilizes the controlled substance ordering system (CSOS)[5], then each user must have their own password. Passwords cannot be shared. 1b. ►Excluding radiopharmaceuticals[6], the hospital pharmacy procures all CS. 1c. ►Individuals authorized to order ⓒ-Ⓒ are limited to the DEA registrant and authorized individuals. DEA 222 forms are secured and accessible only to these individuals. 1d. ►Individuals other than the DEA registrant authorized to order CS must have a power of attorney on file to execute the DEA 222 forms as per 21CFR1305.05. 1e. The persons authorized to order CS are not the same persons who receive the CS. 1f. ►All invoices received are signed and have the date when the medications were received. 1g. ►Only a licensed pharmacist or authorized receiving person signs for the controlled substance delivery. 1h. ►If CS are delivered to hospital central receiving, an

[5] An electronic DEA 222 program. DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user. The DEA's CSOS is the preferred method for ⓒCS procurement.

[6] Currently, there is one ⓒradiopharmaceutical: DaTscan™ (Iodine I-123 ioflupane), a cocaine analog indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.

		authorized receiving person signs for the delivery, central receiving transfers CS to the pharmacy within one working day following receipt by the hospital, and then the pharmacist immediately inventories the CS. 1i. ►If CS are delivered to the pharmacy when the pharmacy is closed and pharmacist unavailable, then storage of this delivery must comply with the requirements of California Business and Professions Code 4059.5(f).[7] 1j. ►Any discrepancy between the receipt and the type or quantity of CS actually received is reported to the delivering wholesaler or manufacturer by the next business day after delivery.
Prescribing	1. The organization's ordering/ prescribing practices minimize the risk of CS diversion.	1a. ►CS are prescribed only by licensed authorized prescribers with a DEA registration or institutionally assigned DEA suffix. 1b. ►A valid order from an authorized prescriber exists for all CS administered. 1c. ►CS are not prescribed by an authorized prescriber for him/herself or immediate family members. 1d. Patient-specific CS orders are generated by electronic systems with controlled access except in emergencies in accordance with applicable federal and state laws and rules. 1e. Range orders for CS are minimized.
Preparation & Dispensing	1. The organization's preparation and dispensing practices minimize the risk of CS diversion.	1a. ►Tamper-evident packaging is utilized for CS prepared by pharmacy.[8] 1b. ►CS transported via pneumatic tube are sent via secured transaction. 1c. ►There must be a co-signature for delivery of CS to non-ADM areas. Document chain of custody. 1d. CS are dispensed in single-unit-dose packaging.[9] 1e. Secure, locked, non-transparent medication delivery

[7] See appendix for B&P 4059.5(f) text.
[8] Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.
[9] Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.

		carts/containers are used to deliver CS and accessible only by authorized individuals. 1f. ADMs are utilized in patient care areas for the distribution of CS and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. 1g. Reconciliation is performed on ADM CS dispense transactions for temporary patients to ensure that the CS went to an actual patient.[10] 1h. Bar code scanning is utilized when replenishing ADMs. 1i. A blind count process is used for narcotic vault and ADM distributed CS.[11] 1j. The number of CS on override status in profile ADMs is minimized (e.g. one-time injectables for emergencies only). 1k. Biometric-ID technology is used instead of passwords. If passwords are used, passwords expire on a regular interval.[12] 1l. ADM downtime procedures must be defined to maintain the control, documentation and accountability of CS.
Administration	1. The organization's CS administration practices minimize the risk of CS diversion.	1a. There is a defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 minutes of the end of the procedure). 1b. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered. 1c. ►Only health care providers operating within the scope of their practice may administer CS. 1d. ►CS are removed for one patient at a time from ADMs and/or locked storage areas.

[10] For example, a temporary patient ID may have been used when CS are needed in an emergency and the admission information is not yet transferred to the ADM.

[11] Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.

[12] For example, the ISMP recommends changing passwords every 90 days or less if biometric authentication is not also in use (http://www.ismp.org/selfassessments/ADC/Survey.pdf).

		1e. ►The individual retrieving CS from ADM/locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g. emergencies) and has a policy/process in place to assure chain of custody. 1f. ►All CS are drawn up into syringes that, if not immediately administered, are labeled per institutional policy.
Handling Waste	1. The organization's "waste" handling practices maintain chain of custody to minimize the risk for CS diversion.	Pharmacy: 1a. CS waste from Compounded sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed. Areas outside Pharmacy: 1b. ►Unusable product[13] (UP) CS are to be immediately wasted and witnessed by health care professionals per specific hospital procedures. 1c. All Potentially Reusable Product[14] (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. 1d. The organization has identified the high-risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs. 1e. The organization has identified specific high-risk CS medications (e.g., fentanyl) that are randomly assayed. 1f. The organization has a process to randomly obtain and assay UP CS. For random assays, the UP CS would not be subject to immediate witnessed waste.
	2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.	**Wasting of UP CS:** 2a. ►Approved methods for wasting a CS are defined per federal, state and county laws and regulations. 2b. ►The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except when UP CS are returned to pharmacy for assay. 2c. ►An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.

[13] UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/ beyond use date.

[14] PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow the medication to be re-issued to another patient.

		2d. ►Empty containers of CS (e.g., vials) are discarded in limited access waste containers. 2e. ►Waste containers with trace UP CS are secured to prevent tampering. 2f. ►The pharmacy accounts for manufacturer overfill in injectable containers. All overfill amounts are captured, verified, documented, and wasted accordingly. Controlled substance overfill should be considered unusable product (UP). **PRP Returns:** 2g. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket. 2h. ►All PRP CS returns to pharmacy require chain of custody documentation in the patient care area and in pharmacy **Waste or Reverse Distribution:** 2i. ►DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company. 2j. Expired CS that are quarantined for reverse distribution are properly accounted by way of a log or inventory list. The items sent back via reverse distribution could be reconciled with the reverse distribution log of CS.
Monitoring of CS and Process if Diversion is Suspected	1. Organization removes access to CS if diversion is suspected.	1a. ►All personnel actions (e.g. suspension, terminations and resignations) are promptly communicated to pharmacy so access to CS can be removed. 1b. ►If the hospital becomes aware of an arrest of an employee for illicit use of CS, the hospital immediately conducts its own investigation. The organization assesses whether to suspend, transfer, terminate or take other action (e.g., remove access to CS) against the employee.
	2. Organization regularly monitors CS through inventory, reports and audits.	2a. CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory. Any CS purchases outside of the pharmacy department are tracked. Since the invoice-receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. 2b. Movement of CS throughout the hospital is tracked. For example, reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of

		receipt. 2c. ►CS within an ADM or narcotic vault are inventoried at least monthly. 2d. Non-automated CS storage areas are inventoried at each shift change. 2e. ADM reports are reviewed at least monthly by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. 2f. ADM CS activity is compared to peers with similar staffing responsibilities and FTE appointments. 2g. Transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) is compared to peers. 2h. Patient MAR: amount and quantity administered, is compared to what other caregivers administer on subsequent shifts (without patient change in condition). 2i. Non-ADM CS storage area record of use is compared with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste.
	3. A process is in place to resolve CS discrepancies.	3a. ►CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies that cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours (e.g. metric: unresolved nursing unit CS discrepancies > 24 hours/total nursing unit CS discrepancies should be ≤8 percent). 3b. It is recommended that a pharmacist reconcile CS discrepancies in the ADMs. ►A pharmacist has responsibility for the discrepancy even when a technician performs these duties.
	4. Organization creates standard process to investigate potential diversion cases.	4a. ►There is a standard process in place to investigate potential diversion cases.

Selected Legal References[15]

Federal

21 Code of Federal Regulations Chapter II: Drug Enforcement Administration

Sec. 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) 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; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

Sec. 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission

[15] This is not a comprehensive listing of applicable laws and regulations.

of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Sec. 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

Sec. 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

Sec. 1301.93 Sources of information for employee checks.

DEA recommends that inquiries concerning employees' criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

42 Code of Federal Regulations, State Operations Manual, Appendix A[16]

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs. A-0494

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.
- Facility policies and procedures should minimize scheduled drug diversion.

[16] Bulleted items are from the Interpretive Guidelines for that regulation.

§482.25(b) In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. A-500

- Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.
- The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

§482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area and locked when appropriate. A-0502

- All controlled substances must be locked.

§482.25(b)(2)(ii) Drugs listed in Schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept within a secure area. A-0503

- All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

§482.25(b)(2)(iii) Only authorized personnel may have access to locked areas. A-504

- The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.
- The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored.

§482.25(b)(7) Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate. A-509

- Controlled drug losses are to be reported to appropriate authorities in accordance with State and Federal laws.

State of California

Business and Professions Code

4059.5

> (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.
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> (b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
>
> (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

4081(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept …

4332 Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

Health and Safety Code

11209. (a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

Title 16, Division 17, California State Board of Pharmacy

§1714 Operational Standards and Security

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

§1715.6 Reporting Drug Loss

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

Title 22, Division 5, Licensing & Certification of Health Facilities…, Chapter 1, General Acute Care Hospitals

§70263 Pharmaceutical Services General Requirements

(c)(1) The [pharmacy and therapeutics] committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures.

(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

(q)(10) Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing service and as required by hospital policy.

(q)(11)(A) Drugs listed in Schedules II, III, or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be in the patient's medical record or in a separate log. Such a log shall be retained for at least three years.

§ 70265 Pharmaceutical Service Staff

A pharmacist shall have overall responsibility for the pharmaceutical service. He shall be responsible for the procurement, storage and distribution of all drugs as well as the development, coordination, supervision and review of pharmaceutical services in the hospital.

§70269 Pharmaceutical Service Space

(b) All spaces and areas used for the storage of drugs shall be lockable and accessible to authorized personnel only.