DEPARTMENT: Clinical Operations Group - Pharmacy	**POLICY DESCRIPTION**: Controlled Substance Monitoring
PAGE: 1 of 23	**REPLACES POLICY DATED:** 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15, 5/1/18, 10/1/20
EFFECTIVE DATE: November 1, 2023	**REFERENCE NUMBER:** COG.MM.001 (formerly CSG.MM.001 and QM.003)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated facilities including, but not limited to, hospitals, ambulatory surgery centers (ASC), service centers, outpatient imaging centers, all Corporate Departments, Groups, Divisions, Markets, HealthTrust and Parallon. This policy covers all HCA Healthcare employees, healthcare professionals, contractors, and students, as well as those applying for employee positions. HCA Healthcare retail pharmacies, home health services, hospice home care, adult home care, physician practices, and facilities in the United Kingdom are exempt from the requirements of this policy.

PURPOSE:

- Establish controls related to ordering, receiving, prescribing, dispensing, administering, documenting and handling controlled substances.
- Promote patient and colleague safety.
- Define monitoring processes that provide early detection of medication control irregularities.
- Follow federal and state controlled substance laws and regulations in addition to any applicable HCA Healthcare Policies and Procedures.

POLICY:

HCA Healthcare is dedicated to fostering a culture that supports safe and effective patient care and a healthy work environment. HCA Healthcare expects all colleagues, Providers and Graduate Medical Education (GME) Residents to strictly adhere to processes that support the prevention and detection of medication diversion. Colleagues, Providers and Residents are responsible for reading this policy and understanding their role and responsibility in the Medication Diversion Program.

Diversion of medication is a criminal act punishable by local, state and federal authorities and a violation of local and corporate HCA Healthcare employment policy and medical staff bylaws, rules, and regulations. This policy is intended to be used in conjunction with the DEA and State Controlled Substance Diversion and Loss Reporting Policy, COG.MM.006, and the Substance Use in the Workplace Policy, HR.ER.060.

The facility CEO or DEA Registrant designates a facility multidisciplinary Medication Diversion Team (MDT) that is responsible for policy compliance. Each facility's MDT is charged with developing a coordinated and systematic approach to prevent, detect, and report medication diversion. The MDT is responsible for maintaining a medication diversion monitoring and reporting program that discourages diversion and strengthens accountability, rapidly identifies suspected diversion, responds to known or suspected diversion incidents, and continually seeks to improve controls. (References: HCA Healthcare Medication Diversion Program: Hospital Guidebook, HCA Healthcare Medication Diversion Program: ASD Guidebook, and HCA Healthcare: Drug Enforcement Administration (DEA) Guidebook)

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PROCEDURE:

A. Access

1. Eligibility: The following types of colleagues are eligible for access to controlled substances based on their job description, competencies, licensure/certifications and granted clinical privileges by a Company-affiliated facility: Providers**,** GME Residents, RNs, LPN/LVNs, Registered Pharmacists, Pharmacy Technicians, and other qualified colleagues as designated by a Company-affiliated facility, in accordance with State regulations, Bylaws, and policy as applicable.
2. Authorization: Eligible colleague must be granted authorization (whether electronic and/or physical) to access controlled substances. Facilities determine the method(s) to authorize access and document authorization decisions.
    a. Methods for authorizing access:
        i. Role-based authorization: Facility-designated job roles/positions are authorized access based upon role and responsibilities and do not require a Manager/Supervisor to submit an exception-based authorization to trigger provisioning of access.
        ii. Exception-based authorization: Manager/Supervisor with direct knowledge of an eligible colleague's role and/or responsibilities submits an exception-based authorization for access to controlled substances when the individual's job role/position is not included in role-based authorization.
    b. Methods for documenting authorization decision: Decisions to authorize a colleague's access are documented, preferably in a manner that generates Electronic Audit Evidence (EAE).
        i. Hospitals and Acute Care Facilities: Facilities are required to use the electronic Security Access Form (eSAF) Tool to automate workflow/notifications and generate EAE about authorization decisions to provision, modify, and/or de-provision a colleague's access. Facility-designated job roles/positions are setup in the eSAF Tool to trigger automated notification to designated individuals to provision access based upon assignment to a designated job role/position. *Exception: If a facility is not yet using the eSAF Tool (*e.g.*, Acquisition), the Legacy Authorization/Access Form is used.*
        ii. ASCs and non-acute care facilities without the eSAF Tool: The facility establishes a procedure to submit requests and document decisions to provision, modify, and/or de-provision a colleague's access to controlled substances. The procedure defines roles, competencies and approval authority.
3. Revocation: Access can be revoked at any time, including but not limited to suspensions, investigations, policy violations, inactivity, change in job role and termination of employment/contract.

4. Facilities implement reasonable safeguards that allow eligible and authorized colleagues access to controlled substances in accordance with their role, responsibilities, and work assignments, and that deter access to other colleagues without authorized access.
    a. It is recommended that all facility medication storage areas utilize badge access. Reference: Title 42 CFR §482.25(b)(2)(iii) which details authorized access to "locked areas."
    b. Colleague's access is limited to the area(s) needed to perform assigned duties.
    c. Access for traveler, per diem, and other temporary or contract colleague is limited to the designated time period of the contract and/or shift assignment (e.g., charge nurse activates access to ADC at start of each shift).
    d. Automated Dispensing Cabinets (ADCs): BioID is the preferred access method. Passwords to ADCs are configured to meet company standards as outlined in Information Protection & Security Standard: AC.SAC.03 - Password Management.
    e. Keypad and combination locks are changed once a year at a minimum, and in the event of suspected or confirmed diversion; the change is documented appropriately per facility process (e.g. with a work order, MDT meeting minutes, etc.) and reported to the MDT when applicable.
    f. Colleagues with authorized access protect their access to controlled substances including but not limited to: ADCs, locked cabinets, combination locks, badges, passwords, and door lock codes.
    g. In the event a colleague suspects the integrity of their access (electronic or physical) has been compromised, the colleague immediately notifies their supervisor/designee, and the supervisor/designee immediately notifies the MDT.
    h. Colleagues are not allowed to bring items such as book bags, briefcases, duffel bags, purses or any other type of personal bags item into patient care areas. Such items are stored in a locker. If essential personal items are needed, they are brought into the patient care area in a clear bag and kept in plain view at all times.

B. Ordering, Receiving, and Transferring:

Ordering and receiving of controlled substances is performed by different individuals unless mitigating circumstances prevent this from occurring. In such instances, compensating controls are implemented (e.g., additional independent reviews, outside audits). The facility considers limiting the ordering and receiving authority of any controlled substance product to designated staff members, not all Pharmacy Department staff members. Company-affiliated facilities are encouraged to adopt the DEA's Controlled Substance Ordering System (CSOS) process for ordering schedule II controlled substances. As part of CSOS use, both ordering and receiving are done in the drug supplier website where available/applicable.

1. Ordering

   The DEA Registrant, authorized CSOS Coordinator(s), and Powers of Attorney (POA) may apply for CSOS Certificates. Their roles are identified below:

   a. DEA Registrant – This is defined as the physical location and is represented by the individual who last signed/renewed a DEA 224 application.

      i. Henceforth, the term “DEA Registrant” or “Registrant” refers to the aforementioned individual.

         (a) Hospitals: HCA Healthcare affiliates are required to specify the Chief Executive Officer (CEO).

         (b) ASCs: In states that permit the Practice Manager or Administrator of the facility serves as the DEA Registrant. Some states may require the Medical Director.

      ii. Further duties associated with controlled substance ordering/management may be delegated by the Registrant (e.g., CEO, Administrator, Medical Director or Practice Manager) using a POA.

      iii. The DEA Registrant may designate a delegate to perform these duties by executing a POA.

   b. CSOS Coordinator

      i. The role of the CSOS Coordinator may be served by the Registrant.

      ii. If the Registrant does not serve the role of CSOS Coordinator, then the CSOS coordinator may be any individual in the DEA Registrant’s organization and must have his/her CSOS application signed by the Registrant.

      iii. One Principal CSOS Coordinator must be enrolled and only one Alternate CSOS Coordinator may be enrolled in CSOS for any one DEA Registration number.

      iv. Each DEA Registrant identifies a person to hold the DEA number, monitor license renewal, designate those employees eligible to order controlled substances electronically, retain all digital certificates, and to manage these activities.

      v. The Company recommends that the Director of Pharmacy be the CSOS Coordinator for the hospital. The DEA Registrant conveys this responsibility through a POA.

      vi. The CSOS Coordinator submits all required documents to the DEA for issuance of digital signatures to the individuals granted POAs and maintains a copy of each document submitted in a secure area in the pharmacy or a secured location in areas without a pharmacy.

      vii. With the digital signatures, the CSOS Coordinator downloads the digital certificates from the DEA website to the facility-based computer. The digital certificate files, order

acknowledgment files, and receipt acknowledgment files are saved to a secure server with limited access.

viii. The CSOS Coordinator must be enrolled in CSOS before a POA application is processed; however, the CSOS Coordinator and POA applications may be submitted at the same time.

c. POA Designees

i. The Company recommends that a named individual be identified as the primary person to order schedule II controlled substances for the facility (primary designee).

ii. The DEA Registrant or CSOS Coordinator may assume this duty of ordering schedule II controlled substances. Alternatively, the CSOS Coordinator may identify another employee as the primary designee.

iii. The primary designee must have a POA for final authorization to order schedule II controlled substances. For CSOS, a POA must be submitted to the DEA.

iv. Additional staff may also be identified to order schedule II controlled substances in the absence of the primary designee, but the number of POAs will be limited based on the need of the facility. Such 'secondary designees' must also have a POA submitted to the DEA to be fully authorized to submit orders.

v. Facilities follow procedures required by the DEA for revocation of POA/CSOS Coordinator.

2. Receiving

a. Delivery:

i. For hospitals and locations with a Pharmacy Department: Controlled substances are delivered directly to the Pharmacy Department in an area with camera surveillance.

ii. For facilities without a Pharmacy Department (e.g., ASC, Free Standing Emergency Department, etc.): Controlled substance are delivered to a secured designated receiving area.

b. Only authorized personnel identified by the facility are allowed to receive controlled substance orders.

c. The receiving process includes a reconciliation of controlled substances received against the packing slip or invoice accompanying the order as well as the DEA Form 222 or the electronic equivalent, if applicable.

d. The printed invoice is signed and dated by the receiver indicating completion of this phase of receipt of product.

e. With the invoice signed and dated, the receiver or another staff member with receiver access documents receipt of the schedule II controlled substances in the wholesale vendor website system when available. Completion of this activity will allow the receipt record to be downloaded to a designated location for permanent storage. A backup is performed after each schedule II controlled substance receipt.

f. Approval for payment for Accounts Payable is completed by someone other than the authorized receiver. Note: The receiver's signature and dating of the invoice are a separate action from the signing of the invoice by an authorized person approving payment for Accounts Payable.

g. In case of any order discrepancy, shortage or breakage, the drug supplier and facility MDT are notified immediately and the incident is documented on the packing slip/invoice and further review occurs.

h. An inventory system that assures accuracy of all controlled substances is required.

   i. An annual inventory is required. For state controlled substances and non-DEA designated controlled substances, a full manual inventory is conducted. For all federally Scheduled II-V controlled substances on hand, an annual inventory is conducted that is consistent with the requirements for a DEA biennial inventory. Refer to the HCA Healthcare: Drug Enforcement Administration (DEA) Guidebook for inventory requirements and resources. The inventory is signed and dated by the person conducting the inventory. An inventory record includes the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

   ii. All inventory records must be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection.

   iii. Additionally, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

i. The Director of Pharmacy, Administrator or designee maintains the purchasing summary available from drug suppliers, or a written history of all controlled substance purchases made by the facility for the month, sorted by date.

3. Monitoring Procedure

   The Director of Pharmacy, Administrator or designee employs the following methods for monitoring the ordering and receipt of controlled substances.

   a. Check off all DEA Form(s) 222/e222 numbers on Wholesaler Customer Narcotic Purchase Record or Record of Receipt from non-wholesaler purchases against inventory; and

b. Randomly select three deliveries per month and confirm the presence of proper documentation on the DEA Form 222/e222, match units received as documented by invoice and receiving personnel notation on the DEA Form 222/e222, and match units received against the inventory.

4. Record Keeping

a. For all controlled substance orders, the following documents must be saved for at least two years.

i. The completed order form:

(a) In the case of an electronic order, the completed order form as provided by the distributor's software should be saved electronically to the designated location for storage. If the electronic purchase is of a Schedule II drug using CSOS, the order form that should be saved is the one identified by the distributor as the "digital" or "e" form 222. If a suitable completed order form is not made available by the distributor for downloading, due to technological failure or otherwise, the closest available substitute should be saved.

(b) In the case of a non-electronic order, a copy of a document memorializing the order must be saved in the registrant's files. If the order was for a Schedule II drug, that document shall be a copy of the DEA Form 222 submitted by the registrant for the order, and such a document must be kept separate and apart from other records.

ii. The vendor invoice documenting the order: The facility must save a copy of the vendor's invoice for the order. In the case of an electronic order, the invoice should be downloaded and saved along with the order form discussed in paragraph (i). In the case of a non-electronic order, a copy of the invoice should be stored in the registrant's physical files.

iii. Documentation of receipt: The facility must document the actual quantities of controlled substances received from the distributor pursuant to an order. For facilities that have an automated controlled substance vault (e.g., CII Safe), this can be in the form of a C-II Safe Inventory Report. The documentation of receipt should be kept in the same manner and the same location as the "completed order form" referenced above.

b. Additional Procedures for Paper DEA Forms 222:

i. Upon receipt of paper DEA Forms 222 from the Drug Enforcement Agency, the Director of Pharmacy, Administrator or designee records each DEA Form 222 number onto a control log to document all forms received into the facility.

ii. Unused paper DEA Forms 222 are stored in a secured area, (e.g., in the controlled substances vault or a locked drawer) accessible only by individuals authorized to order schedule II controlled substances.

iii. Paper DEA Forms 222 are signed by the authorized agent/attorney only as orders are placed. Blank DEA Forms 222 are never pre-signed in anticipation of future use.

5. Transferring

a. Schedule II controlled substances require a DEA Form 222 for each controlled substance transfer.

b. Schedules III-V controlled substances are documented in writing to show the medication name, dosage form, strength, quantity, and date transferred. Documentation includes the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

c. Non-DEA designated controlled substances are documented in writing to show the medication name, dosage form, strength, quantity, and date transferred. Documentation includes the names, and addresses of the parties involved in the transfer of the controlled substances.

d. Transfer of controlled substances occurs only for the purpose of general dispensing to patients.

e. The receiving facility/Provider must be registered with the DEA.

f. The distribution is recorded by the distributing party and by the receiving party.

g. The total number of dosage units of all controlled substances distributed by the facility/Provider during each calendar year does not exceed five percent of the total number of dosage units of all controlled substances distributed/dispensed by the facility/Provider during the same year.

C. Secure Storage

Controlled substances in patient care areas, pharmacy and/or designated storage areas are maintained in an ADC, locked in a substantially constructed cabinet (hereafter referred to as “locked cabinet”), or mobile storage device. The locked cabinet and mobile storage device are stored in a locked area.

1. Controlled substances requiring refrigeration are double-locked.
2. Controlled substances are not stored in crash carts.
3. Controlled substances are securely stored in a designated ADC or locked cabinet separate from non-controlled medications until the time of administration.

4. Security of ADC (Strap Lock): In addition to the ADC locks provided by the manufacturer, it is recommended that strap locks be placed on any ADC that is not physically attached to a wall.
5. For all areas not utilizing an ADC, in addition to requirements pursuant to Section J. Surveillance and Reporting, reconciliation of controlled substances are verified by two (2) licensed individuals at the end of each case, shift or at close of business, as appropriate.
6. All unused controlled substances are returned to the designated locked return location immediately once deemed not required.
7. Mobile storage devices (e.g., small refrigerators, medication carts, anesthesia carts, epidural carts) containing controlled substances are physically secured, locked when not in use, and stored in a locked area. It is recommended that all medication carts be self-locking.
8. When a procedural room is not staffed by a person with authorized access, all controlled substances are physically secured and locked.
9. Keys to controlled substances (e.g., lock boxes, PCAs, Pyxis keys, substantial secure cabinets) are located in a secure location only accessible by individuals with authorized access.
    a. For hospitals: All keys to controlled substances are managed through the Pharmacy Department. It is prohibited for any colleague to bring keys to ADCs, PCAs or other devices/storage locations, which have been obtained from an outside source (e.g., outside vendor, another facility, etc.) into the facility.
    b. For ASCs: Keys to controlled substances are managed pursuant to the HCA Healthcare Medication Diversion: ASD Program Guidebook.
    c. The existence and current location of all physical keys is determined and an inventory log (paper or electronic) is maintained.
    d. Keys are not to be reproduced or removed from the facility.
    e. If a key is lost, all related locks are re-keyed as soon as possible, if applicable.
    f. ADC keys in hospitals
        i. The Pharmacy Management team retains all physical keys and log to the ADCs in a locked/secured location within the pharmacy.
        ii. The physical keys are only issued to a staff member of the Pharmacy Department at the time of need for the purpose of opening the ADC for department use or maintenance by authorized personnel.
        iii. Pharmacy staff remains with the ADC during the entire time the ADC is unlocked, unless all medications have been removed. At no time is the pharmacy staff to relinquish possession of the key(s) to any other person outside of those staff within the pharmacy authorized to use the key. Keys are not given to maintenance/service personnel.

iv. Pharmacy takes possession immediately of any ADC keys found to be in the possession of anyone other than authorized pharmacy personnel.

10. Any unattended controlled substances or unlabeled medications are immediately reported to the appropriate unit manager, confiscated, appropriately secured, and managed per facility policy. This event is documented and the MDT is notified.
11. Prescription pads and prescription paper are stored in a secured location and controlled based on facility-specific policies and procedures in order to prevent unauthorized prescribing of prescription medications. Printers used for electronically printing prescriptions are secured and inaccessible to unauthorized individuals.
12. A physical inventory of all controlled substances, as defined by definition of this policy, is performed and documented by two (2) authorized individuals at the minimum required frequency. The inventory includes all controlled substances, regardless of whether they were accessed since the previous inventory.
    a. The minimum required frequency for nursing units, procedural areas, and ADCs used exclusively by pharmacy is weekly (including ADCs located in the Pharmacy Department), or for cause. For nursing units, the weekly inventory is completed by the unit's Director/Manager or designee and witnessed by an authorized individual. For ADCs in procedural areas utilized by Anesthesia Providers only, the weekly inventory is completed preferably by an Anesthesia Provider and witnessed by an authorized individual. For ADCs used exclusively by pharmacy, the weekly inventory is completed by pharmacy personnel and witnessed by an authorized individual.
13. The minimum required frequency for Pharmacy Departments and ASCs is once monthly (every 30 days), or for cause. As noted above, ADCs located within a Pharmacy Department are to be inventoried weekly. Expired controlled substances
    a. Expired controlled substances removed from the inventory are placed in a designated expired controlled substances drawer/bin in a locked area separate from non-controlled medications until the time of removal.
    b. Facilities maintain a log of expired controlled substances that is inventoried by two authorized individuals every 30 days.
    c. The total list of expired controlled substances is reconciled at the time of transfer to the reverse distributor. The reconciliation is performed by the person holding a facility DEA Power of Attorney (POA) with the reverse distributor's documentation, including the DEA Form 222 for schedule II controlled substances and the document of schedules III-V controlled substances.

14. Patient-owned Controlled Substances
Patient-owned controlled substances are not stored in the pharmacy or ADCs.

a. Patient-owned controlled substances should be sent home with family members/patient representative, if at all possible. (Refer to facility specific policy for non-controlled patient-owned medications).

b. If patient-owned controlled substances cannot be sent home, the facility has the following options:

i. The facility provides the patient or family member/patient representative with one or more empty mail-back packages to the patient or family member/patient representative to place the medications into the package(s) and seal the package(s) for mailing to the authorized DEA reverse distributor for disposal purposes (no modification of the facility's DEA registration is required). *Any mail-back programs must comport with 21 CFR.1317.70.*

ii. If the facility has a modified DEA registration to become an authorized collector and has placed a collection receptacle at its registered location, then the patient or family member/patient representative may dispose of the patient-owned controlled substances in the facility's collection receptacle.

iii. If there is no authorized person to dispose of the patient-owned controlled substances and it is not feasible to return to the patient, the facility will contact local law enforcement or the local DEA Diversion Field Office for guidance on proper disposal procedure.

a) Unless and until directed otherwise by local law enforcement or the local DEA Diversion Field Office, the controlled substance should be secured and kept separate from the facility's stocks of controlled substances. If the facility has locked locations, the patient-owned controlled substances should be kept in such a locked location, preferably under camera surveillance (i.e. Security storage locker). Wherever stored, patient-owned controlled substances must have a documented chain of custody from the time of receipt to the time of return.

b) Any unclaimed patient-owned controlled substance should be destroyed in accordance with federal, state, local, tribal laws and regulations (refer to the facility specific policy) 30 days after the patient has been discharged.

D. Prescribing

1. Prescribing of controlled substances is limited to a Provider or Advanced Practice Professional (APP) with controlled substance prescribing privileges that have been granted only if the Provider has a verified and current DEA registration with an in-state address, as defined in Compliance

Alert #28. Additionally, a Provider with controlled substance prescribing privileges must have verified and current state controlled substance registration when practicing in a State that requires registration.

2. DEA registration and state controlled substance registration are obtained by each individual Provider. An individual Provider will not be allowed to prescribe controlled substances under a Company-affiliated facility DEA registration. Exception: GME Residents may prescribe controlled substances under a Company-affiliated facility DEA registration in accordance with Use of Institutional and Personal DEA Registration Numbers Policy, GME.001.

E. Preparation, Distribution, Stocking and Dispensing

1. Only authorized colleagues prepare and/or dispense controlled substances.
2. Dispensing samples of controlled substances is prohibited.
3. The authorized colleague who removes the controlled substances from inventory documents the amount removed via computerized system or master log.
4. Controlled substances to be delivered to patient care areas have a printout or form listing the delivery location, item description, and quantity to be delivered. The printout or form is signed by both the person removing and delivering the controlled substances. The delivery person counts and verifies all items prior to delivery.
5. Non-ADC areas: Verification of controlled substances upon delivery is documented by both the person delivering and the person accepting the medication. Documentation of delivery is reconciled, signed, filed, and stored by the Pharmacist, Administrator, or Practice Manager daily. For days/times the pharmacy is closed, this is completed the next day/time the pharmacy is open and covers all days/times in which it was closed.
6. ADC: The authorized staff member stocks the ADC and verifies the inventory count. The verification of delivery occurs electronically (e.g., Pyxis CII Safe Compare Reports). This is reconciled, signed, filed, and stored by the Pharmacist daily. For days/times the pharmacy is closed, this is completed the next day/time the pharmacy is open and covers all days/times in which it was closed.
7. During verification upon delivery, individual controlled substances are inspected to ensure integrity.
8. Kits containing controlled substances have two independent checks prior to dispensing.
9. Manual Dispensing
   a. Floor Stock: Controlled substances distributed to the unit/area and recorded on the Controlled Substance Administration Record (CSAR) matches the items distributed and recorded on the Master Control Dispensing Log.

b. Patient Specific: There is signed documentation of the receipt of controlled substances by the receiving personnel and delivery personnel, which will be maintained in pharmacy. Monitoring is performed on all signed receipts on two random days selected each month to confirm that items/units received match the items dispensed as documented on the pharmacy Master Control Dispensing Log.

10. Automated Dispensing Cabinet (ADC) System Dispensing

a. A process exists for matching controlled substances distributed to the ADCs with the inventory. For example, the quantity of controlled substances distributed to each ADC, as documented in the cabinet system reports, is reconciled with the amount signed out on the Controlled Substance Perpetual Log in the pharmacy vault. Reconciliation of the controlled substances ADC removal report with the ADC loaded/stocked report will suffice. This monitoring is performed on two randomly selected days each month.

b. For Company-affiliated facilities utilizing an automated controlled substance vault, this step is replaced with a daily monitoring process for matching controlled substances distributed from the main inventory to all other locations, including ADC and non-ADC locations. For days/time the pharmacy is closed, this is occurs the next day/time the pharmacy is open and covers all days/time in which it was closed.

F. Administration and Wasting

1. Administration

a. The patient only receives controlled substances procured by the Company-affiliated facility in which the patient is being treated. *Exception: Patients' own medications are only used for cases where the medication is not available from the local wholesaler, non-formulary, or continuation is imperative for patient care.*

b. Controlled substances administered via Patient-Controlled Analgesia (PCA) pumps and epidural pumps are administered in locked systems. Controlled Substance Drips (e.g., Fentanyl, Propofol, etc.) are locked in an IV lock box when not under continuous observation.

c. Documentation of transactions and volume of controlled substances infused per shift/per case is readily available. The documentation process is specifically addressed in the Company-affiliated facility specific policy.

d. Controlled substances are removed by authorized colleague at the time of administration.

e. Controlled substance administration and documentation are completed immediately.

f. Inventory count and integrity verification are performed each time a controlled substance is accessed. *For ASCs: Keys to controlled substances are managed pursuant to the HCA Healthcare Medication Diversion Program: ASD Guidebook.*

i. If the count is incorrect, the colleague creates a discrepancy or equivalent report and follows the steps in Section G. Discrepancies.

ii. If integrity concerns are identified (potential or confirmed), the colleague immediately informs their supervisor and the Pharmacy Department is notified.

g. Chain-of-custody procedures and documentation are utilized when controlled substances are removed by one person and passed to another colleague. This practice is limited and only used in unusual situations. For Company-affiliated hospitals, all chain-of-custody records are sent/accessible to pharmacy. This process is monitored for trends and reported to the MDT. *For ASCs: Keys to controlled substances are managed pursuant to the HCA Healthcare Medication Diversion Program: ASD Guidebook.*

h. Fractionating doses of unit use vials is limited to perioperative and/or procedural areas. Fractionating doses is in compliance with sterile compounding, labeling, and beyond use dating according to regulatory requirements.

i. All controlled substance medication administrations are supported by a Provider order contained in the patient's medical record. STAT or NOW verbal orders issued by the Provider during emergency situations, operative or other procedures (e.g., Endoscopy, cardiac catheterization) are documented in the patient's medical record as soon as possible after the procedure. In such cases, it is recommended that the medication orders be documented as separate events with individual dose orders rather than one event with a totaled dose.

j. Controlled substances that are removed from the ADC via the override functionality are reconciled with a valid medication order within 24 hours.

2. Wasting

a. Any controlled substances packaged in an amount larger than the dose being administered are to have the remaining amount wasted and documented immediately.

b. Wasting of a controlled substance remaining from administration such as a PCA, syringe pump, IV solution and set, used patch, and any other type of infusion, occurs at the end of the medication's use. This is recorded in the ADC, Bar Coded Medication Administration (BCMA), or manual documentation form, per facility policy.

c. Wastage is physically witnessed and documented by two (2) authorized individuals who have access to controlled substances as defined in Section A. Access. Preferably one of the individuals is an HCA Healthcare employee.

d. Methods for wasting controlled substances that are not used for intended purpose are determined by EPA hazardous waste:

i. Partially used EPA hazardous waste controlled substances, during preparing and dispensing, are disposed of via a controlled substance waste disposal system (e.g., Cactus Smart Sink®).

ii. There is a different process for controlled substances that are not EPA hazardous wastes. For these wastes, partially used controlled substances during preparing and dispensing, are sewered, where permitted by state and local water authorities, or disposed of via a controlled substance waste disposal system (e.g., Cactus Smart Sink®).

G. Discrepancies

1. Discrepancies are addressed immediately and appropriately resolved during the shift in which the discrepancy occurred.
   a. The Director/Manager or designated individual of the area is responsible for checking for discrepancies prior to the end of each shift.
   b. Any colleague involved in the discrepancy is available as soon as feasible to assist in the resolution.
2. If the Director/Manager or designated individual is unable to appropriately resolve a discrepancy, the Director of Pharmacy or designee, or Facility Administrator is notified immediately.
3. If investigation does not result in a resolution, the count is corrected by two licensed persons and the event is documented.
4. If resolution does not occur within 24 hours, the notification of occurrence is presented to the DEA Registrant and the MDT is notified.

H. Surgical and Procedural Areas

Note: While the surgical/procedural areas are subject to this entire policy, certain requirements need to be called out for the surgical/procedural areas.

1. The Chief of Anesthesia/designee or ASC Medical Director assumes responsibility for informing all Anesthesia Providers of these rules and their enforcement prior to granting of clinical privileges.
2. The facility-specific process and/or procedures for accessing, handling, wasting, and inventorying controlled substances is followed without exception.
3. If kits are utilized:
   a. Controlled substances (patient-specific kits) dispensed for individual patient use is the preferred method. For ASCs: kits are managed pursuant to the HCA Healthcare Medication Diversion Program: ASD Guidebook.
   b. Sign-out Process for Kits

i. Controlled substance kits are signed out from the ADC, Pharmacy Department, or controlled substance storage area.

ii. When obtaining the controlled substance kit, the Anesthesia Provider verifies the contents of the kit. If the count is incorrect, the user creates a discrepancy or equivalent report to follow the steps in Section G. Discrepancies.

iii. Once signed out, the Anesthesia Provider is responsible for the controlled substance(s).

c. Anesthesia Providers are not permitted to dispense, loan, or exchange controlled substances to another Anesthesiologist Provider from their kit, except in an emergency as defined by Medical Staff Rules and Regulations. Any additional controlled substances needed are checked out from the pharmacy, ADC, or controlled substance storage area.

d. Return Process for Kits

i. The controlled substance kit and the facility-designated form (e.g., Anesthesia Record) are returned to the designated area immediately after use.

ii. Anesthesia Providers verify via signature, date, and time that the contents of the controlled substance kit have been verified and checked against the facility-designated form (e.g., Anesthesia Record).

iii. All discrepancies are resolved during the medication return process.

iv. If a discrepancy cannot be resolved, refer to the steps in Section G. Discrepancies.

4. If controlled substances must be prepared in advance and not administered immediately, they are labeled according to regulatory requirements, locked and secured at all times.
5. Colleagues, Providers and Residents are not allowed to bring items such as book bags, briefcases, duffel bags or any other type of item into surgical/procedural areas. Such items are stored in a locker. If essential personal items are needed, they are brought into the surgical/procedural area in a clear bag and kept in plain view at all times.
6. Chain-of-custody occurs with every hand-off of controlled substances and is documented in the Anesthesia Record or designated location
7. The Provider administering controlled substances is responsible for reconciling all their medication totals (e.g., total administered, amount wasted, and/or amount returned) when applicable.
8. The Provider ending a procedure is responsible for completing final reconciliation of controlled substances used during the procedure.
9. If a discrepancy cannot be resolved, refer to the steps in Section G. Discrepancies.

10. All discrepancies are tracked, using the QI/PI process, by Provider, for trending and identification (as defined by the Medical Executive Committee) and reported to the MDT.
11. Auditing of surgical/procedural areas and locations:
    a. Hospitals: Audits of the controlled substances transactions compared to the anesthesia record are conducted on 2 consecutive full days per month, for a minimum of 20 cases; if 20 cases are not performed in 2 full days, the audit will continue to the third full day, or until a total of 20 cases are complete.
    b. ASCs: Audits of controlled substances are conducted pursuant to the HCA Healthcare Medication Diversion Program: ASD Guidebook.
    c. Audit results are shared with the MDT and the Medical Executive Committee.
    d. If process issues are identified, an action plan is developed.

I. Surveillance and Reporting

1. All suspected, active, and confirmed diversions are reported immediately to the Pharmacist in Charge and DEA Registrant.
2. Facilities and locations without ADCs:
    a. Two (2) authorized individuals who have access to controlled substances reconcile controlled substances in the controlled substance log at the beginning and at the end of each day.
    b. Daily tracking of distributed controlled substances are recorded on a master log utilizing sequentially numbered documents. The master log is reconciled daily. Discrepancies are managed per Section G. Discrepancies.
    c. Monthly tracking:
        i. Hospitals: Each facility performs audits on 2 consecutive full days per month, on a minimum of 20 cases; if 20 cases are not performed in 2 days, the audit will continue on the third full day, or until a total of 20 cases are complete.
        ii. ASCs: Monthly audits are conducted pursuant to the HCA Healthcare Medication Diversion Program: ASD Guidebook
    d. Audit findings are forwarded to the facility person retaining all audit records.
3. Facilities and locations with ADCs
    a. Daily:
        i. The controlled substance discrepancy report is reviewed daily by the pharmacy staff designee. For days/times the pharmacy is closed, the report is reviewed the next day/time the pharmacy is open and covers all days/times in which it was closed.

(a) Unresolved discrepancies are managed per Section G. Discrepancies.

(b) Resolved discrepancies are reviewed for appropriateness of resolution. Inappropriate and questionable resolutions are reported to the MDT and the Director of Pharmacy or designee.

ii. Controlled substances removed utilizing the override functionality are reviewed and reconciled daily by the pharmacy staff designee to ensure the existence of a valid corresponding order. For days/times the pharmacy is closed, the report is reviewed the next day/time the pharmacy is open and covers all days/time in which it was closed. Reconciliation and review includes:

(a) Printing the Profile Override Report from the ADC console.

(b) Ensuring the existence of a valid corresponding order.

(c) Ensuring documentation of the administration, waste, and/or return of the controlled substance is completed.

(d) The Director of Pharmacy or designee signs and dates the report.

(e) The reviewed Profile Override Reports are maintained for a period of one month.

(f) Records older than one month are sent to document storage.

iii. The Dispensing Machine Audit Report is reviewed and reconciled daily by the Nurse Director or Nurse Manager. Findings (reconciled and non-reconciled) are reported to the MDT and the Director of Pharmacy or designee.

iv. The File Variance Report is reviewed daily by Nurse Director/Manager or designee.

(a) File time variances of greater than 30 minutes are reviewed further for appropriateness.

(b) Review findings are reported to the MDT and the Director of Pharmacy or designee.

v. Review of ADC transactions with CII Safe/Pharmacy Vault transactions to verify all CII Safe/ Pharmacy Vault ADC entry and vice versa (including refills/loads/unloads/expired). Discrepancies are managed per Section G. Discrepancies and reported to the MDT. For days/times the pharmacy is closed, the review is completed the next day/time the pharmacy is open and covers all days/times in which it was closed.

b. Weekly:

i. The pharmacy staff designee monitors for compliance of weekly ADC controlled substance inventory.

ii. Weekly ADC controlled substance inventory compliance is reported to the MDT.

c. Monthly:

i. Proactive Diversion Reporting and Reviews for Facilities with Diversion Software are conducted pursuant to the Medication Diversion Program: Hospital Guidebook.

ii. CII Safe/ Pharmacy Vault Monthly Inventory

(a) Inventory is conducted with a witness;

(b) Signatures (both the person conducting inventory and witness) and date of inventory is documented; and

(c) Inventory includes expired controlled substances and all items listed in the Controlled Substance Definition of this policy.

4. The facility-defined QA/PI mechanism is utilized for tracking occurrence reports, based upon colleague. Results are reported to the MDT.

5. Tracking of frequent discrepancies for trending and identification of individuals is ongoing and reported to the Department Head (e.g., Chief of Anesthesia, CMO, or designee) and MDT.

6. Refer to Section I. Surgical/Procedural Areas for additional surveillance guidance specific to surgical/procedural areas.

7. Each facility has a defined process for testing of controlled substances (e.g., waste, returns, and final compounded products):

a. Suspected tampering and unknown medications are tested.

b. Facilities may elect to conduct routine testing of controlled substances.

c. Summary of findings and actions taken are reported to MDT.

J. Monitoring

1. The Division Vice President of Pharmacy Services or their designee assesses facility compliance with the HCA Healthcare Controlled Substance Monitoring Policy twice annually (with an increment of not less than four (4) months between assessments). Every other division assessment is abbreviated and focused on items found to be non-compliant during the previous assessment. Monitoring of policy compliance also occurs through Compliance Process Reviews by the Corporate Ethics & Compliance Department, Continual Survey Readiness Evaluations by the Clinical Operations Group, and Internal Audit as determined necessary. Policy compliance is overseen and enforced by members of the MDT and the facility administration designee.

2. Each facility identifies the controlled substance prescribing laws regarding Providers (including physicians, dentists, podiatrists, APPs and another other licensed professionals with clinical privileges) and ensures state laws are being followed.

K. Required Records:

Facilities maintain the following DEA required records and documents:

1. Prepare and maintain a "DEA Binder" in the facility pharmacy in a location and manner that it is readily retrievable by the Director of Pharmacy and other personnel. Please refer to the HCA Healthcare: Drug Enforcement Agency (DEA) Guidebook for required binder contents.
2. Maintain records of controlled substances stored, dispensed, distributed, transferred, ordered, diverted, lost, and surrendered, including:
   a. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
   b. Power of Attorney authorization to sign order forms
   c. Receipts and/or invoices for schedules II, III, IV, and V controlled substances
3. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
4. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
5. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
6. Reports of Theft or Significant Loss (DEA Form 106), if applicable, in addition to any written reports made pursuant to COG.MM.006 ("DEA and State Controlled Substance Diversion and Loss Reporting Policy").
7. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
8. Records of transfers of controlled substances between pharmacies
9. DEA registration certificate
10. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005, if applicable
11. CSOS digital certificates

DEFINITIONS:

Automated Dispensing Cabinet (ADC): An automated dispensing system that supports decentralized medication management with multiple safety and efficiency features. ADC devices allow medications to be stored near the point of care, while controlling and tracking the distribution and use of medication.

Advanced Practice Professional (APP): Individuals other than members of the Medical Staff who are authorized by law and by the Company-affiliated facility to provide a medical level of care or perform surgical tasks consistent with the Clinical Privileges granted to the APP, but who are required by law and/or the Company-affiliated facility to exercise some or all of those Clinical Privileges pursuant to a

written sponsorship/Supervision/collaborative [CHECK STATE LAW REGARDING REQUIRED NATURE OF RELATIONSHIP] agreement with a Supervising/Collaborating Provider. The categories of Advanced Practice Professionals practicing at the Company-affiliated facility are set forth in Medical Staff Policies.

Anesthesia Providers: Refers to all members of the anesthesia care team who perform anesthesia. Term includes physician anesthesiologist, anesthesiologist assistant, nurse anesthetist, and any other member providing anesthesia care.

Audit: Verification of controlled substance records and procedures for accuracy, completeness, integrity, and compliance with the policy during each step of the controlled substance handling process including, but not limited to, receiving, handling, preparation, transfer, and administration.

Authorized Individual: An eligible colleague who has been granted access (whether electronic and/or physical) to controlled substances in order to complete necessary job functions.

Clinical Privileges or Privileges: The authorization granted by the governing body of the facility (e.g., Board of Trustees) to render specific clinical procedures and patient care services, subject to the provisions of this Policy.

Contract Staff: Refers to individuals employed by a third party under contract to work at an HCA Healthcare facility for a defined period of time.

Controlled Substances: For purposes of this policy, Controlled Substance refers to any medication or other substance identified in Title 21 United States Code Controlled Substances Act (CSA) as schedules II-V (including IIN and IIIN), State and Federal-mandated controlled substances (if applicable), Propofol, additional items deemed necessary by the facility, and any physical item granting access to controlled substances including but not limited to: DEA Forms 222 (paper and electronic), keys, prescription pads, prescription paper, and printers used for electronically printing prescriptions, etc.

Diversion: The term includes any unaccountable loss, theft, and use for unintended purposes, or tampering of a medication. For purposes of this policy, medication diversion is a medical and legal concept involving the transfer of any legally prescribed drug from the individual for whom it was prescribed to another person for any illicit use, including any deviation that removes a prescription drug from its intended path from the manufacturer to the intended patient.

Double-locked: Access to controlled substances requires two physical restrictions from non-authorized individuals. Restrictions include, but are not limited to, a physical key, badge access, username/password, and biometric ID.

Electronic Security Access Form (eSAF) Tool: The application used by Company-affiliated facilities to automate: (1) requests for system access, (2) approval workflow, and (3) notifications to system administrators to grant, modify, and/or remove system access.

DEPARTMENT: Clinical Operations Group - Pharmacy	**POLICY DESCRIPTION**: Controlled Substance Monitoring
PAGE: 22 of 23	**REPLACES POLICY DATED:** 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15, 5/1/18, 10/1/20
EFFECTIVE DATE: November 1, 2023	**REFERENCE NUMBER:** COG.MM.001 (formerly CSG.MM.001 and QM.003)
APPROVED BY: Ethics and Compliance Policy Committee	

Graduate Medical Education (GME) Resident: as used in this policy includes Medical, Podiatry, and Dental Interns, Residents, and Fellows enrolled in:

- Accreditation Council for Graduate Medical Education (ACGME), American Osteopathic Association (AOA), Council on Podiatric Medical Education (CPME), or American Dental Association (ADA) specialty and subspecialty programs operating at HCA Healthcare facilities (whether sponsored by HCA Healthcare or another entity in partnership with HCA Healthcare);
- Fellowship training programs operating at HCA Healthcare facilities (whether sponsored by HCA Healthcare or another entity in partnership with HCA Healthcare) that are not accredited by ACGME accreditation but are approved by HCA Healthcare GME;
- Non-HCA Healthcare ACGME, AOA, CPME, and ADA specialty and subspecialty training programs with residents who are either taking an elective or are assigned a required rotation at an HCA Healthcare facility for which there is a Program Letter of Agreement and/or Educational Affiliation Agreement in place with the facility; and
- Non-HCA Healthcare fellowship training programs that are not accredited by ACGME but are approved by HCA Healthcare GME with residents who are either taking an elective and/or are assigned a required rotation at an HCA Healthcare facility for which there is a Program Letter of Agreement or Educational Affiliation Agreement in place with the facility.

Independent Check: Verification of correct medication, dose, form, route, concentration, quantity, storage, beyond use dating, and integrity of contents by two authorized individuals done independently of one another.

Kits: A container of medications standardized in contents for a specific procedure or patient case. May also refer to electronically established series of medications pulled out of the Automated Dispensing Cabinet (ADC) that constitutes standardized contents for a specific procedure or patient case (e.g., system kit, virtual kit, etc.).

Provider: An individual who has been granted Clinical Privileges and/or Membership by the Board, including, but not limited to, Members of the Medical Staff and Advanced Practice Professionals.

Colleagues: All people providing care, treatment, and services on behalf of a Company-affiliated facility, including those receiving pay (e.g., permanent, temporary, and part-time personnel, as well as contract employees), volunteers and health profession students.

REFERENCES:

1. HCA Healthcare Medication Diversion Program: Hospital Guidebook
2. HCA Healthcare Medication Diversion Program: ASD Guidebook
3. HCA Healthcare: Drug Enforcement Administration (DEA) Guidebook
4. Reporting Compliance Issues and Occurrences to the Corporate Office Policy, EC.025
5. DEA and State Controlled Substance Diversion and Loss Reporting, COG.MM.006

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6. Substance Use in the Workplace (Model Policy), HR.ER.060
7. DEA 21 CFR
8. Information Protection & Security Standard: AC.SAC.03 - Password Management
9. Licensure and Certification Policy, COG.PPA.002
10. COG.PPA.002 Implementation Tool: MEDITECH Procedure to Maintain the Provider Dictionary
11. COG.PPA.002 Implementation Tool: MEDITECH Procedure to Maintain the Provider Dictionary – see Appendix P
12. Use of Institutional and Personal DEA Registration Numbers, GME.001
13. Vetting Dependent Healthcare Professionals and Other Non-Employees, COG.PPA.003
14. Information Confidentiality and Security Agreements Policy, IP.SEC.005
15. E&C Compliance Alert 28
16. AAAHC
17. CMS §416.48 cfc: Pharmaceutical Services
18. CMS §416.48a, Standard: Administration of Drugs
19. CMS Conditions of Participation – §482.23 Nursing Services
20. CMS Conditions of Participation – §482.25 Pharmaceutical Services
21. CMS Conditions of Participation – §482.25 b,2, iii
22. DEA 21 CFR Part 1301
23. Audit Risk Alerts 49, 50, 52
24. The Joint Commission, Comprehensive Accreditation Manual, 2020 Edition
25. ASHP, Guidelines on preventing diversion of controlled substances. 2022.
26. DEA Pharmacist's Manual, 2022 Edition
27. Cactus Smart Sink®