SCOPE: All Company-affiliated facilities including, but not limited to, hospitals, ambulatory surgery centers (ASC), physician practices, service centers, outpatient imaging centers, all Corporate Departments, Groups, Divisions, Markets, HealthTrust and Parallon. This policy covers all HCA employees, healthcare professionals, contractors, and students, as well as those applying for employee positions.

PURPOSE:
- Establish controls related to ordering, receiving, prescribing, dispensing, administering, and documenting controlled substances.
- Promote patient 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 Policies and Procedures.

POLICY: HCA is dedicated to fostering a culture that supports safe and effective patient care and a healthy work environment. HCA expects all workforce members, Licensed Independent Practitioners (LIPs), Advanced Practice Professionals (APPs) and Graduate Medical Education (GME) Residents to strictly adhere to processes that support the prevention of medication diversion. Workforce members, LIPs, APPs, and Residents are responsible for reading this policy and understanding their role in preventing medication diversion.

Diversion of medication is a criminal act punishable by local, state and federal authorities and a violation of local and corporate HCA 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, CSG.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. (Reference: HCA Medication Diversion Control Program: Hospital Guidebook)

DEFINITIONS:

Automated Dispensing Cabinet (ADC): An automated dispensing system which 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): An individual who provides direct patient care services in the Hospital under a defined degree of supervision, exercising judgment within the areas of documented professional competence and consistent with applicable law. For purposes of this Policy, the categories of individuals to be considered as an APP are physician assistants (PA), certified registered nurse anesthetists (CRNA), anesthesiology assistants (AA), certified nurse midwives (CNM), clinical...
psychologists (Ph.D.), advanced registered nurse practitioners (ARNP), clinical nurse specialists (CNS), and any other individual recognized by the State and the facility as a mid-level provider performing a medical level of services.

**Anesthesiologists**: Refers to all members of the anesthesia care team who perform anesthesia. Term includes physician anesthesiologist, anesthesiologist assistants, 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 workforce member who has been granted access (whether electronic and/or physical) to controlled substances in order to complete necessary job functions.

**Clinical Privileges**: The permission granted by the governing body of a Company-affiliated facility to appropriately licensed individuals to render specifically delineated professional, diagnostic, admitting, therapeutic, medical, surgical, psychological, dental, or podiatry services with the approval of the Board.

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

**Controlled Substances**: Within HCA, DEA Controlled Dangerous Substances listed in Schedule II – V, (including 2N and 3N) are controlled along with State or Federal-mandated controlled substances (if applicable), and additional items deemed necessary by the facility. HCA requires Propofol to be designated as a controlled substance in every facility. For purposes of this policy, Controlled Substances refers to any medication or other substance identified in Title 21 United States Code Controlled Substances Act (CSA), Propofol, and any physical item granting access to controlled substances including, keys, prescription pads, prescription paper, printers used for electronically printing prescriptions, etc.

**Credentialing Processing Center (CPC)**: Three centers established by Parallon Business Solutions to handle the administrative aspects of information gathering and data verification for physicians, other licensed independent practitioners, and advanced practice professionals who wish to be considered for appointment, reappointment, and/or clinical privileges at HCA-affiliated facilities per a facility Service Level Agreement.

**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.

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 facilities (whether sponsored by HCA or another entity in partnership with HCA);
- Fellowship training programs operating at HCA facilities (whether sponsored by HCA or another entity in partnership with HCA) that are not accredited by ACGME accreditation but are approved by HCA GME;
- Non-HCA 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 facility for which there is a Program Letter of Agreement and/or Educational Affiliation Agreement in place with the facility; and
- Non-HCA fellowship training programs that are not accredited by ACGME but are approved by HCA GME with residents who are either taking an elective and/or are assigned a required rotation at an HCA 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, 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 a series of medications pulled out of the Automated Dispensing Cabinet (ADC) that constitutes standardized contents for a specific procedure or patient case.

Licensed Independent Practitioner (LIP): An individual who is permitted by applicable State law(s) to provide patient care services without direction or supervision, within the scope of the individual’s license. These are individuals who are designated by the State and by the facility to provide patient care independently. For purposes of this Policy, the categories of individuals to be considered an LIP include, but are not limited to physicians (MD or DO), maxillofacial/oral surgeons (DMD), dentists (DDS), podiatrists (DPM), optometrists (OD), licensed clinical psychologists, and any other individual recognized by the State and the facility as an individual independently performing a medical level of services. LIP possesses a valid DEA registration specific to the State of which the facility is located and a State controlled substance registration is applicable.

Workforce Members: 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. The definition of staff does not include licensed independent practitioners who are not paid staff or who are not contract employees. (May be subject to individual organization additions of specific staff.)
DEPARTMENT: Clinical Services Group - Pharmacy  
POLICY DESCRIPTION: Controlled Substance Monitoring  
PAGE: 4 of 18  
REPLACES POLICY DATED: 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15  
EFFECTIVE DATE: May 1, 2018  
REFERENCE NUMBER: CSG.MM.001 (formerly QM.003)  
APPROVED BY: Ethics and Compliance Policy Committee

PROCEDURE:

A. Access
1. Eligibility: The following types of workforce members are eligible for access to controlled substances based on their job description, competencies, licensure/certifications and granted clinical privileges by a Company-affiliated facility: LIPs, APPs, GME Residents, RNs, LPN/LVN, Registered Pharmacists, Pharmacy Technicians, and other qualified workforce members as designated by a Company-Affiliated facility.
2. Authorization: Eligible workforce member 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 workforce member’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 workforce member’s access are documented, preferably in a manner that generates Electronic Audit Evidence (EAE).
      i. electronic Security Access Form (eSAF) Tool: Facilities are encouraged to use the eSAF Tool to automate workflow/notifications and generate EAE about authorization decisions to provision, modify, and/or deprovision a workforce member’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.
      ii. Legacy Authorization/Access Form: If a facility is not yet using the eSAF Tool, refer to the HCA Medication Diversion Control Program: Hospital Guidebook that includes a Sample Authorization/Access Form.
3. Revocation: Access can be revoked at any time, including but not limited to suspensions, investigations, policy violations, and termination of employment/contract.
4. Facilities implement reasonable safeguards that allow eligible and authorized workforce members access to controlled substances in accordance with their role, responsibilities, and work assignments and that deter access to other workforce members without authorized access.
   a. It is recommended that all facility medication storage areas utilize badge access. Reference: 482.25(b)(2)(iii) which details authorized access to “locked areas.”
   b. Workforce members’ access is limited to the area(s) needed to perform assigned duties.
   c. Access for traveler, per diem, and other temporary or contract workforce members is limited to the designated time period of the contract and/or shift assignment.
d. Passwords for Automated Dispensing Cabinets (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 with a work order.

f. Workforce members 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 workforce member suspects the integrity of their access (electronic or physical) has been compromised, the workforce member immediately notifies their supervisor/designee, and the supervisor/designee immediately notifies the MDT.

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 C-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 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.
         c) Physician Practices: An individual practitioner will be designated.
      ii. Further duties associated with controlled substance ordering/management may be delegated by the Registrant 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. Only one Principal CSOS Coordinator and one Alternate CSOS Coordinator may be enrolled in CSOS for any one DEA Registration number.
### Controlled Substance Monitoring

**Policy Description**

- **DEPARTMENT:** Clinical Services Group - Pharmacy
- **POLICY DESCRIPTION:** Controlled Substance Monitoring
- **PAGE:** 6 of 18
- **REPLACES POLICY DATED:** 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15
- **EFFECTIVE DATE:** May 1, 2018
- **REFERENCE NUMBER:** CSG.MM.001 (formerly QM.003)
- **APPROVED BY:** Ethics and Compliance Policy Committee

#### 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 C-II controlled substances for the facility (primary designee).
- ii. The DEA Registrant or CSOS Coordinator may assume this duty of ordering C-II controlled substances. Alternatively, the CSOS Coordinator may identify another employee as the primary designee.
- iii. The primary designee must have a POA submitted to the DEA for final authorization to order C-II controlled substances.
- iv. Additional staff may also be identified to order C-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. Controlled substances are delivered directly to the Pharmacy Department in an area with camera surveillance. In areas that are not under camera surveillance, the receiving area is accessible only to those authorized to handle controlled substances.
- 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 ordering form, 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 POA access documents receipt of the C-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 C-II controlled substance receipt into the facility pharmacy.

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. HCA Accounting Policy Guide (APG #07) requires at minimum an annual inventory. For controlled and non-DEA designated controlled substances, a full manual inventory is conducted. The inventory is signed and dated by the person conducting the inventory. This annual inventory can be used for the DEA biennial inventory requirement.

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

- a. Check off all DEA Form 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, and match units received against the inventory.

4. Record Keeping

- a. For all controlled substance purchases the following four documents are saved electronically to the designated location for permanent storage.

  - i. e222: When placing the CSOS order requisition (electronic 222) print and save the form to the server before closing out.

  - ii. Receipt of Invoice: When product is received in CSOS print and save the Receipt of Invoice to the server.

  - iii. Vendor Invoice: Save a copy of the vendor invoice to the server.

  - iv. C-II Safe Inventory Report - Only applicable for facilities that have an automated controlled substances vault (C-II safe).

- b. Upon receipt of DEA Form 222 ordering forms from the Drug Enforcement Agency, the Pharmacy Director or designee records each DEA Form 222 number onto a control log to document all forms received into the facility. Unused DEA 222 forms are stored in a secured area, (e.g., in the controlled substances vault or a locked drawer) accessible only by individuals authorized to order C-II controlled substances.
c. DEA Form 222 ordering forms are signed by the authorized agent/attorney only as orders are placed. Blank DEA Form 222 ordering forms 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. Schedule 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/practitioner 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/practitioner 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/practitioner 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, 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. For physician practices where two (2) licensed individuals are not staffed, controlled substances are reconciled by two individuals, at least one of whom is licensed.
   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. The existence and current location of all physical keys is determined and an inventory log is maintained.
   b. Keys are not to be reproduced or removed from the facility or from a physician’s office practice.
   c. If a key is lost, all related locks are re-keyed as soon as possible, if applicable.
   d. ADC keys
      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 and keys for controlled substances is performed at a minimum of once monthly in the pharmacy, ASDs, and physician practices and once weekly on the nursing units, or for cause. The weekly nursing inventory is completed by the unit’s Nurse Manager/Supervisor or designee. The inventory is completed for all controlled substances, including those that were not accessed via ADC during that time frame, and the inventory documented. Inventories are conducted and documented by two (2) authorized individuals.

13. 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 by the person holding a DEA Power of Attorney (POA) with the DEA-222 form provided by the reverse distributor, who sends the expired controlled substances for destruction.
**DEPARTMENT:** Clinical Services Group - Pharmacy  
**POLICY DESCRIPTION:** Controlled Substance Monitoring

**PAGE:** 10 of 18  
**REPLACES POLICY DATED:** 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15

**EFFECTIVE DATE:** May 1, 2018  
**REFERENCE NUMBER:** CSG.MM.001 (formerly QM.003)

**APPROVED BY:** Ethics and Compliance Policy Committee

<table>
<thead>
<tr>
<th>14. Patient-owned Controlled Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Medications are sent home with family members/patient representative, if at all possible. (Refer to facility specific policy for non-controlled patient-owned medications)</td>
</tr>
<tr>
<td>a. Patient-owned controlled substances not sent home are logged and kept in a locked location or ADC. Patient-owned controlled substances have a documented chain of custody from the time of receipt to the time of return. (See Medication Diversion Control Program: Hospital Guidebook – Sample Patient Medication Storage Log).</td>
</tr>
<tr>
<td>b. Logging the patient’s controlled substances consists of counting and verifying the controlled substances by the patient/patient’s representative and a licensed workforce member. If patient/patient’s representative is unavailable, two licensed workforce members count and verify the medications.</td>
</tr>
<tr>
<td>c. Patient-owned controlled substances are placed in a sealed tamper-evident bag before transporting to the locked location or ADC.</td>
</tr>
<tr>
<td>d. If patient-owned controlled substances cannot be returned to the patient, they are held and destroyed within 30 days post-discharge with the appropriate documentation (refer to the facility specific policy).</td>
</tr>
<tr>
<td>e. If patient-owned controlled substances are secured in locations other than pharmacy, the facility-specific policy addresses a process for pharmacy notification and sending patient-owned controlled substances to the pharmacy for destruction.</td>
</tr>
</tbody>
</table>

**D. Prescribing**

Prescribing of controlled substances is limited to a Licensed Independent Practitioner (LIP) or Advanced Practice Professional (APP) with controlled substance prescribing privileges that have been granted only if the practitioner has a verified and current DEA registration with an in-state address, as defined in Compliance Alert #28. Additionally, an LIP or APP with controlled substance prescribing privileges must have verified and current state controlled substance registration when practicing in a State that requires registration.

**E. Medical Staff Members and/or Practitioners Granted Clinical Privileges**

1. Hospitals and ASCs have medical staff bylaws or a policy that specifies the requirements for an LIP or APP with controlled substance prescribing privileges to have a verified and current DEA registration with an in-state address, as defined in Compliance Alert #28. Additionally, an LIP or APP with controlled substance prescribing privileges has verified and current state controlled substance registration when practicing in a state that requires it.

2. Designated facility workforce members (e.g., medical staff services department, human resources department, an authorized centralized credentials verification service, or other designation) verify the DEA registration and State controlled substance registration with the primary source agency that issued the registration.
   a. DEA registration is verified through the National Technical Information Service (NTIS) website: [http://www.deanumber.com/](http://www.deanumber.com/).
   b. State controlled substance registration is verified with the appropriate State agency.

3. Primary source verifications of DEA registration and state controlled substance registration, if applicable, is done at the following times:
   a. At the time of an initial request for privileges, including temporary privileges.
b. Prior to the expiration date(s) so that verification can be completed by the expiration date(s).

c. At the time a registration is reinstated, such as after it expired and was renewed, or after a practitioner transferred the registration to another state, and then requested it to be reinstated for the facility’s state.

d. Registration is re-verified from the primary source at the time of reappointment.

e. Registration is re-verified from the primary source when new controlled substance prescribing privileges, or an increase in controlled substance prescribing privileges, are requested.

4. A practitioner whose registration cannot be verified through primary source verification (i.e., through NTIS for DEA) by the expiration date(s) will have controlled substance prescribing privileges suspended until the primary source verification can be completed.

5. A secondary source of information (i.e., the paper copy of registration from the practitioner) will not be accepted.

6. There are no grace periods. Registration is recognized only when primary source is verified. Registration will be considered expired on the date of expiration.

7. Primary source verification of DEA registration and state controlled substance registration includes the following:
   a. Confirmation of registration number;
   b. Confirmation of date verified and the expiration date;
   c. Confirmation of in-state registration for DEA registration (reference Compliance Alert #28); and
   d. Confirmation of the authorized schedules of controlled substances match the prescribing privileges of the practitioner.

8. If the practitioner is an APP, the following will also be confirmed before controlled substance prescribing privileges are granted:
   a. That the scope of State licensure for the APP allows prescribing controlled substances in the schedules requested (note: check state laws and regulations).
   b. That if the APP is allowed to prescribe only under LIP supervision, and/or with a collaborative practice agreement, and/or with approved protocols, then confirmation has been made to ensure this is in place (i.e., the agreement or protocol is on file in the APP’s credentials file at the facility).
   c. That if the APP is allowed to prescribe only under LIP supervision, then the supervising LIP has a verified and current in-state DEA registration and State controlled substance registration for the schedules of controlled substances to be prescribed by the APP.

9. If DEA registration or state controlled substance registration cannot be verified as outlined above, then prescribing privileges for controlled substances will not be granted or continued. The medical staff bylaws or medical staff policy are followed regarding privileging actions to be taken.

10. DEA registration and state controlled substance registration are obtained by each individual practitioner. An individual practitioner will not be allowed to prescribe controlled substances under a hospital’s DEA registration. GME Residents may prescribe controlled substances under a hospitals’ DEA registration in accordance with Use of Institutional and Personal DEA Registration Numbers Policy, GME.001.
11. When DEA registration and state controlled substance registration (when required) is confirmed through primary source verification, and controlled substance prescribing privileges are granted, the information regarding registration is entered into the MIS Provider Dictionary, and flags are set in the Meditech pharmacy module to alert pharmacists prior to dispensing the controlled substance if the order is not authorized.

12. The Medical Staff Office immediately updates the MIS Provider Dictionary (or any health information management system provider dictionary utilized by the facility) with DEA registration and state controlled substance registration information when that information changes. “Immediately” is defined as the same business day as notification of a change.

F. Preparation, Distribution, Stocking and Dispensing

1. Only authorized workforce members prepare and/or dispense controlled substances.
2. Dispensing samples of controlled substances is prohibited.
3. The authorized workforce member who removes the controlled substances from inventory documents the amount removed via computerized system or master log.
4. All items 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.
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.
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.
### G. Administration and Wasting

#### 1. Administration

- a. The patient only receives controlled substances procured by the 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. Facilities evaluate other controlled substances on the floor for consideration of a locking mechanism such as an intra venous lock box.

- 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 facility specific policy.

- d. Controlled substances are removed by authorized workforce member 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. If the count is incorrect, the workforce member creates a discrepancy or equivalent report and follows the steps in Section H. Discrepancies.

- g. Chain-of-custody procedures and documentation are utilized when controlled substances are removed by one person and passed to another healthcare provider. This practice is limited and only used in unusual situations. For hospitals, all chain-of-custody records are sent/accessible to Pharmacy. This process is monitored for trends and reported to the MDT.

- 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 (e.g., remaining PCA, syringe pump, IV solution, and used folded fentanyl patch) 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 employee.

d. Partially used controlled substances, during preparing and dispensing, are sewer, where permitted by state and local water authorities, or disposed of via a controlled substance waste disposal system (e.g., Cactus Smart Sink®).

H. Discrepancies

1. Discrepancies are addressed immediately and appropriately resolved during the shift in which the discrepancy occurred.
   a. The Manager or designated facility employee of the area is responsible for checking for discrepancies prior to the end of each shift.
   b. Any personnel involved in the discrepancy is available as soon as feasible to assist in the resolution.

2. If the Manager is unable to appropriately resolve a discrepancy, the Director of Pharmacy or designee, Facility Administrator, or Division Director of Quality Management (for physician practices) 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 (e.g., Chief Executive Officer, Physician Services Group AVP of Quality, or Facility Administrator).

I. Surgical/Procedure 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 anesthesiologists of these rules and their enforcement prior to granting of clinical privileges.

2. The facility-specific process and/or procedures for accessing, handling, and wasting controlled substances is followed without exception.

3. If kits are utilized:
   a. Controlled substances (patient-specific kits) are dispensed for individual patient use. Anesthesiologist-specific kits are acceptable, but not preferred.
   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 anesthesiologist 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 H. Discrepancies.
iii. Once signed out, the anesthesiologist is responsible for the controlled substance(s).

c. Anesthesiologists are not permitted to dispense, loan, or exchange controlled substance(s) to other anesthesiologists 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. Anesthesiologists 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 H. Discrepancies.

4. Controlled substances prepared in advance and not administered immediately are labeled according to regulatory requirements.

5. Controlled substances prepared in advance for the next patient are locked and secured at all times.

6. Workforce members, LIPs, APPs, 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.

7. Chain-of-custody occurs with every hand-off of controlled substances and is documented in the Anesthesia Record or designated location. (See Medication Diversion Control Program: Hospital Guidebook – Sample Controlled Substance Handoff Form)

8. The workforce member administering controlled substances is responsible for reconciling all their medication totals (e.g., total administered, amount wasted, and/or amount returned, when applicable).

9. The practitioner ending a procedure is responsible for completing final reconciliation of controlled substances used during the procedure.

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. Audits of the controlled substances transactions compared to the anesthesia record are conducted on two consecutive full days per month, for a minimum of twenty cases; if twenty cases are not performed in two full days, the audit will continue to the third full day, or until a total of twenty cases is complete.
   b. Audit results are shared with the MDT and Quarterly Medical Staff Meetings.
   c. If process issues are identified, an action plan is developed.

**J. 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 H. Discrepancies.
   c. Monthly tracking: Each facility performs audits on two consecutive full days per month, on a minimum of twenty cases; if twenty cases are not performed in two days, the audit will continue on the third full day, or until a total of twenty cases is complete.
   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. Unresolved discrepancies are managed per Section H. Discrepancies.
   b. 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. 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 Pharmacy Director 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 Manager(s). Discrepancies are managed per Section H. Discrepancies.
   iv. The File Variance Report is reviewed daily by BCMA Coordinator and Nurse Manager(s).
      a) File time variances of greater than 30 minutes are reviewed further for appropriateness.
      b) Review findings are reported to 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 H. Discrepancies.
   b. Weekly:
      i. The pharmacy staff designee monitors for compliance of weekly ADC controlled substance inventory by nursing.
   c. Monthly:
      i. Proactive Diversion Reporting and Reviews for Facilities with Diversion Software are conducted pursuant to the Medication Diversion Control Program: Hospital Guidebook.
      ii. CII Safe/Pharmacy Vault Monthly Inventory
         a) Inventory is conducted with a witness;
         b) Signature and date of inventory is documented; and
### DEPARTMENT: Clinical Services Group - Pharmacy
### POLICY DESCRIPTION: Controlled Substance Monitoring

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<th>REPLACES POLICY DATED: 3/1/08, 5/31/10, 5/1/11, 11/1/11, 9/1/15</th>
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<tr>
<td>EFFECTIVE DATE: May 1, 2018</td>
<td>REFERENCE NUMBER: CSG.MM.001 (formerly QM.003)</td>
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<tr>
<td>APPROVED BY: Ethics and Compliance Policy Committee</td>
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</tbody>
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#### 4. The facility-defined QA/PI mechanism is utilized for tracking occurrence reports, based upon workforce member. 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.

#### K. Monitoring

Monitoring of the HCA Medication Diversion Prevention Policy occurs bi-annually (with an increment of not less than 4 months between audits) by the Division Directors of Pharmacy or their designee. Auditing of policy compliance also occurs through Compliance Process Reviews by the Corporate Ethics & Compliance Department, Quality Review System Surveys by the Clinical Services Group, and Internal Audit as determined necessary.

1. Policy compliance is overseen and enforced by members of the MDT and the facility administration designee.
2. Each facility identifies the laws regarding APPs and controlled substance prescribing and ensures the state laws are being followed.

#### L. Required Records:

Facilities maintain the following records and documents:

1. Official order forms (DEA Form 222 and e222)
2. Power of Attorney authorization to sign order forms
3. Receipts and invoices for controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories
5. Records of controlled substances transferred
6. Report of Theft or Loss (DEA Form 106)
7. DEA registration certificate
8. CSOS digital certificates

#### REFERENCES:

1. HCA Medication Diversion Control Program: Hospital Guidebook
2. Reporting Compliance Issues and Occurrences to the Corporate Office Policy, EC.025
3. DEA and State Controlled Substance Diversion and Loss Reporting, CSG.MM.006
4. Substance Use in the Workplace (Model Policy), HR.ER.060
5. DEA 21 CFR 1304.02(g)
6. Information Protection & Security Standard: AC.SAC.03 - Password Management
7. Licensure and Certification Policy, CSG.QS.002
8. CSG.QS.002 Implementation Tool: Procedure to Maintain the MEDITECH 5.6 MIS Provider Dictionary
9. CSG.QS.002 Implementation Tool: Provider Dictionary Appendix P: Electronic Prescribing of Controlled and Non-Controlled Substances
10. Use of Institutional and Personal DEA Registration Numbers, GME.001
11. Vetting Dependent Healthcare Professionals and Other Non-Employees, CSG.QS.003
12. Information Confidentiality and Security Agreements Policy, IP.SEC.005
13. E&C Alert #28
14. AAAHC
15. CMS §416.48 cfc: Pharmaceutical Services
16. CMS §416.48a, Standard: Administration of Drugs
17. CMS Conditions of Participation – §482.23 Nursing Services
18. CMS Conditions of Participation – §482.25 Pharmaceutical Services
19. CMS Conditions of Participation -§482.25 b,2, iii
20. DEA 21 CFR Part 1301
21. Audit Risk Alerts #49, 50, 52
24. Cactus Smart Sink®