DEPARTMENT: Clinical Operations Group (COG)	**POLICY DESCRIPTION:** Controlled Substance State Licensing and DEA Registration Policy
PAGE: 1 of 5	**REPLACES POLICY DATED:**
EFFECTIVE DATE: June 1, 2022	**REFERENCE NUMBER:** COG.RAS.006
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE:

HCA Holdings, Inc. (the "Company") and all of its Affiliates operating in the United States including, but not limited to, hospitals, ambulatory surgery centers ("ASCs"), provider-based Emergency Departments ("PBEDs"), free standing Emergency Departments ("FSEDs"), outpatient imaging centers, and departments of hospitals ("HCA Healthcare Affiliates"). "

This policy covers all Company employees, healthcare professionals, contractors, and students.

HCA Healthcare retail pharmacies, home health agencies, hospice agencies, adult home care, physician practices, and facilities in the United Kingdom are exempt from the requirements of this policy.

PURPOSE:

- Establish controls related to obtaining appropriate state licensure and Drug Enforcement Administration (DEA) registrations prior to engaging in any activities related to controlled substances (including but not limited to, ordering, receiving, storing, dispensing, administering, or transferring).
- Promote patient safety.
- Follow federal and state controlled substance laws and regulations in addition to any applicable Company Policies and Procedures.

POLICY:

Authorization Required to Operate: Before engaging in any activities related to controlled substances (including but not limited to, ordering, receiving, storing, dispensing, administering, or transferring), a facility must be properly licensed under applicable state and federal laws. Proper licensure includes:

1) an Institutional Practitioner (Hospital/Clinic) DEA Registration; and
2) any applicable state licenses (including, if applicable, controlled substance permits).

For purposes of this policy, "facility" refers to any building where controlled substances are ordered, received, stored, dispensed, administered, or transferred, regardless of whether the building is its own department or part of a larger department located across multiple buildings. If you have questions about whether your facility or any facility, building, or department associated with a main hospital has the appropriate DEA Registration and applicable state licensure, please contact:

1) the Company facility and/or division Operations Counsel; and
2) the Clinical Operations Group Regulatory Accreditation Services department for guidance.

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PROCEDURE:

A. **Introduction:**

1. The process for obtaining appropriate licensing and registration can be lengthy. The application process for state licensing varies, but may take up to six months or more. The subsequent DEA registration process may take an additional month or longer.
2. For new facilities, state licensing and DEA registration should be obtained well in advance of the opening date of the facility.

B. **State Licensing:**

1. Review state licensing statutes, regulations, and guidance, and consult with the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department, in order to determine whether each facility managed by your hospital is required to have its own separate medical facility and/or state board of pharmacy licenses. State requirements vary, so each facility must be familiar with the requirements in its state. For instance, some states allow multiple related facilities to operate under a single state pharmacy license issued to a hospital if the hospital is supplying the drugs to the facilities; other states require that the facilities obtain separate pharmacy licenses. Each facility must ensure that it is covered by a current state medical facility and pharmacy license, if needed, and that the information on the licenses is accurate and up to date. This must be confirmed *prior* to opening any new facility.
2. Obtaining a State License:
   a. There are certain prerequisites to obtaining a DEA registration, including obtaining a state pharmacy license and/or controlled substance permit that is required by state law. The application process for obtaining the necessary authorizations under state law varies, but can take up to six months or more.
   b. Requirements for state licenses vary. Be sure to follow the requirements for your state closely, as errors or omissions can significantly delay the process. If you have any questions regarding the requirements for your state or need assistance, do not hesitate to consult with the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department.

C. **DEA Registration**

1. There are two types of DEA Registrations:
   a. Individual Practitioner means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense, administer or prescribe a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or

an institutional practitioner.

b. Institutional Practitioner means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

2. This policy applies to **Institutional Practitioner** registrations and describes the process of obtaining that registration on behalf of an HCA Healthcare Affiliate rather than an individual. Each facility that is required to have its own DEA registration must ensure that the registration is current, and that the information on the registration is accurate and up to date. New facilities must ensure that they have obtained any applicable DEA registration *prior* to opening.

3. Determining if a Separate DEA Registration is Required: DEA regulations require each "principal place of business" to have its own DEA registration in order to order, receive, store, dispense, administer or transfer controlled substances. "Principal place of business" is not clearly defined in DEA's regulations or any guidance. In some cases, the DEA allows multiple buildings that are part of a single "campus" or hospital system to operate under a common DEA registration; in other cases, it may not. The DEA considers many factors in determining whether a separate registration is required. In general, when opening a new facility, you should assume that a separate registration is required for every building where a controlled substance is ordered, received, stored, dispensed, administered, or transferred.

   a. Each main hospital would generally be considered a "principal place of business" and therefore should have its own DEA registration.

   b. In some circumstances, separate buildings associated with the main hospital may need a separate registration. This is a legal determination that requires input from the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department. Further guidance is set forth below.

   c. Separate DEA Registration Likely Not Required:

      i. A separate DEA registration is usually not required for any building that is physically connected to the main hospital (i.e., contiguous), so long as the main hospital is properly registered with the DEA, both the hospital and connected building are managed under a common operating legal entity, and state law allows the hospital and connected building to operate under a single state pharmacy license.

      ii. Registration is not required for a building that does not order, receive, store, dispense, administer, or transfer controlled substances.

      iii. A facility's determination that it does not need a separate DEA registration must be

approved by the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department.

d. Separate DEA Registration May Be Required:

i. A separate DEA registration may be required for any building associated with a main hospital that is not located on the same "contiguous campus" as the main hospital, or that is located on the same campus as the main hospital but is not physically connected to the main hospital.

ii. For these buildings, consult with the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department for guidance on whether a separate DEA registration should be obtained. In doing so, please provide the following information:

1) A map showing the building's location and the main hospital's location (e.g., a campus map, or a Google map of the relevant area).
2) A description of the building's location in relation to the main hospital.
3) A description of how the main hospital is accessed from the building (e.g., by walking through an indoor hallway connecting the buildings; by walking across a parking lot; by driving 1 mile down the road; etc.).
4) A description of any intervening buildings, roads, parking lots, etc., between the building and the main hospital.
5) A description of the owners (or lessees) of all relevant buildings and the operating legal entities for each building.

D. **Obtaining a DEA Registration**

1. Apply for a new DEA Registration online at the U.S. Department of Justice Diversion Control Division. Most facilities will utilize DEA Form 224 and specify "Hospital/Clinic" as the application type, but if you are not certain, consult with the Company facility, division Operations Counsel, and/or the Clinical Operations Group Regulatory Accreditation Services department. Unless advised differently by the Company facility and/or division Operations Counsel, do not apply for the DEA registration until the facility has the proper state license.

2. Online DEA Registration Steps and Required Information:

a. Business Information: Name of Business, Address, Tax ID, and Phone Number.
b. Activity: Business Activity and Drug Schedule Information.
c. State License(s): It is mandatory to provide State medical and/or controlled substance licenses/registrations. Failure to provide valid and active state licenses will cause DEA to declare the application defective and it will be withdrawn without refund.
d. Background Information: Information pertaining to controlled substances in the

applicant's background.

e. Payment: Payment is made online.
f. Signature: eSignature should be that of the Registrant.
g. Confirmation: Applicants will confirm the entered information, make corrections if needed, and electronically submit the application and a submission confirmation will be presented. Applicants will be able to print copies for their records. Make sure to save the confirmation electronically and email to the Company facility and/or division Operations Counsel and the Clinical Operations Group Regulatory Accreditation Services department.

3. For HCA Healthcare-affiliated facilities, the individual applicant for all Institutional DEA Registrations is the Chief Executive Officer (CEO).
4. DEA may conduct pre-registration facility inspections to ensure adequate controls are in place for diversion prevention. Contact the Company facility and/or division Operations Counsel, in consultation with the Clinical Operations Group Regulatory Accreditation Services department, if DEA requests to schedule an inspection.

E. **Verification of Registration and License**

1. Note: DEA sometimes sends the registration by mail, but not always. It is important to check the online account regularly to see whether DEA has issued the registration.
2. New facilities must send a copy of the required DEA registration and state license to the Company facility and/or division Operations Counsel, in addition to the Clinical Operations Group Regulatory Accreditation Services department, prior to opening.
3. Existing facilities currently in operation must periodically re-verify that their DEA registration and applicable state license(s) are current. The HCA Healthcare Clinical Operations Group will provide instructions regarding how verification must be completed.

REFERENCES:

1. Code of Federal Regulations, Title 21
2. U.S. Department of Justice, DEA Diversion Control Division website: https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s1