DEPARTMENT: Clinical Operations Group	**POLICY DESCRIPTION:** Pharmacy & Laboratory-Related Dependent Healthcare Professionals
PAGE: 1 of 5	**REPLACES POLICY DATED:** 9/1/13
EFFECTIVE DATE: September 1, 2020	**REFERENCE NUMBER:** COG.MM.004 (formerly CSG.MM.004)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy/procedure applies to healthcare professionals operating within HCA Healthcare hospitals who have responsibility for medication management and to all Pharmacy and Laboratory-related Dependent Healthcare Professionals (DHPs).

PURPOSE: To define Pharmacy and Laboratory-related DHP access to, and interactions with, the Company and its employees.

POLICY:

Pharmacy:

1. Pharmacy-related Tier 2 DHP visits will occur only at a Division or Corporate level.
   a. The Division Director of Pharmacy (DDOP) and/or designee will only work with Institutional Account Executives/Corporate Account Manager/National Sales Representatives.
   b. Pharmacy-related DHPs will not be seen by the DDOP and/or designee without an appointment. Appointments must be made in advance. When scheduling appointments Pharmacy-related DHP will provide their name, company name, phone number, and products to be discussed.

2. Pharmacy-related DHPs from HealthTrust Purchasing Group (HPG) contracted vendors will be seen by HCA Healthcare Division and Corporate staff, and pharmaceuticals will be evaluated in accordance with the Vetting Dependent Healthcare Professionals and Other Non-Employees Policy, COG.PPA.003.

3. Non-HPG contracted Pharmacy-related Tier 2 DHPs will not be seen by HCA Healthcare Division and corporate staff nor will their products be evaluated.
   a. Exceptions are granted only by the DDOP when an HPG contract for that particular product or for a product in the same therapeutic class has not been established.
   b. Vendors without an HPG contract wishing to do business with HCA Healthcare should be referred to the following website for the process for submitting information for evaluation: www.healthtrustpg.com.
   c. Exceptions may be made for situations under an FDA-approved expanded access program for an investigational drug (i.e., “compassionate use,” “Emergency Use,” etc.) based on the needs of the patient.

4. Facility visits by Tier 2 Pharmacy-related DHPs are prohibited unless approved by the DDOP and/or designee. Facility staff or Licensed Independent Practitioners may request a facility visit from a Pharmacy-related Tier 2 DHP by contacting the facility Director of Pharmacy, who will approve the visit in conjunction with the DDOP or designee.

5. Pharmacy-related DHPs who fail to comply with this policy jeopardize DHP status within HCA Healthcare.

a. HCA Healthcare staff observing Pharmacy-related DHPs in the hospital without approval should ask the individual to leave the facility and promptly notify the Director of Pharmacy and Security.
b. The Director of Pharmacy will notify the DDOP of the violation and/it will be logged with HPG, Pharmacy.

Laboratory:

Tier 2 DHP: This Tier includes DHPs providing clinical information and/or instruction to the clinical and laboratory staff of the facility that would impact their delivery of laboratory services or patient care. This includes all sales representatives and their medical science liaisons.

Tier 1 DHP: This Tier includes DHPs providing maintenance or service on Facility laboratory equipment.

Visits pertaining to HCA Healthcare contracted vendors

1. If the vendor is presenting information for new *assays, products and services*
   a. All Facility level requests for new assays must be submitted to the Division Lab Stewardship Core Team for review using the Laboratory New Assay Request Form.
   b. If Division Lab Stewardship Core Team wishes to pursue the assay request, they will submit the request to HCA Healthcare Corporate using the *Laboratory New Assay Request Form*. HCA Healthcare Corporate will review the request and approve or deny the Division proceeding with a vendor visit to further evaluate the assay.
   c. If approved by HCA Healthcare Corporate, the Division Lab Core Team and Supply Chain will coordinate Laboratory-related Tier 2 DHP visit. Division will provide HCA Healthcare Corporate with post-visit feedback on the *Laboratory New Assay Request Form.*
   d. HCA Healthcare Corporate will review the feedback to determine next steps.

2. If the vendor is presenting information for replacement or renewal of products and services
   a. All Laboratory Tier 2 DHP visits for the purpose of replacing/renewing an HPG contracted product must occur at the Division level and should be coordinated through Division Supply Chain.
   b. Division Supply Chain must contact Corporate AVP of Supply Expense Management prior to scheduling Tier 2 DHP visits.

3. If the vendor is presenting information for support of an existing installation
   - Laboratory-related Tier 2 DHP visits for the purpose of supporting an existing installation may occur at the Facility level.

Visits pertaining to non-HCA Healthcare contracted vendor (products, services, assays)

1. Non-HPG contracted Laboratory-related Tier 2 DHP visits will be conducted by Corporate and by appointment request. Tier 2 DHP visits will not be conducted by Division or Facility staff.

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2. HCA Healthcare Requests for laboratory-related Tier 2 DHP visits must be submitted to Corporate by the Division DCMO (or designee) or Division Supply Chain using the *Laboratory New Assay Request Form* or *Laboratory New Product/Service Request Form*.

3. Vendor requests for laboratory-related Tier 2 DHP visits must be requested as follows:
   a. Vendor should be directed to HealthTrustPG.com to complete a Supplier Information Form
   b. Vendors who wish to meet with Corporate Laboratory Services should submit an appointment request to corp.lab@hcahealthcare.com. Vendor must provide their name, company name, phone number and a description of the product or services to be discussed.

Compliance

1. Laboratory-related DHPs who fail to comply with this policy jeopardize DHP status within HCA Healthcare.
   a. HCA Healthcare staff observing Laboratory-related DHPs in the hospital without approval should ask the individual to leave the facility and promptly notify the Laboratory Director and Security.
   b. The Laboratory Director will notify the Division Supply Chain of the violation and/it will be logged with HCA Healthcare.

DEFINITIONS:

1. Non-employee Dependent Healthcare Professionals (DHPs): These are individuals not employed by the facility who are permitted both by law and by the facility to provide patient care services under an approved scope of practice. These individuals may be employed by a contractor, a temporary staffing agency, a privileged practitioner or practitioner group or be directly contracted by a patient for a specific service. DHPs are a subset of all “staff” providing services at the facility, as defined in the Glossary of the Comprehensive Accreditation Manual for Hospitals, published by The Joint Commission (TJC). This concept of staff and the related facility responsibilities is consistent with the requirements of Accreditation Associaton for Ambulatory Health Care, Inc. (AAAHC) and the Centers for Medicare and Medicaid Services (CMS).

2. Tier 2 DHP: An individual who meets the definition of a DHP and who provides clinical services and/or direct hands-on care requiring the involvement and supervision of a member of the clinical staff of the facility (i.e., CNO/CNO designee for the approval of DHP nurses), in the services they provide. This Tier includes DHPs who will provide clinical instruction to the clinical staff of the facility (e.g., vendors providing product instruction to physicians, nurses, or other clinical staff) that would directly impact their delivery of patient care. Vetting and authorization procedures for Tier 2 DHPs shall include administrative approval with oversight by the governing body.

3. Tier 3 DHP: An individual who meets the definition of a DHP and who provides clinical services and/or direct hands-on care requiring the involvement and supervision of a physician or other

licensed independent practitioners (LIP) in the services they provide. As the medical staff oversees patient safety and quality of care provided in association with medical care, a designated medical staff leader shall be responsible for determining the qualifications and competence of Tier 3 DHPs (i.e., medical director of the radiology department for the approval of the DHP radiation physicist). Vetting and authorization procedures for Tier 3 DHPs shall include, in addition to administrative approval, the review and approval by a designated medical staff leader, with oversight by the governing body.

4. Pharmacy and Laboratory Representatives who provide clinical instruction to the staff of the facility that directly impacts the delivery of patient care will be considered a Tier 2 DHP. Tier 2 DHPs include all pharmaceutical and laboratory sales representatives and their medical science liaisons.

5. Tier 1 Non-Employee: This Tier of non-employees may provide services other than patient care services but to do so, would need to enter a safety- or security-sensitive area of the facility. Since a Tier 1 Non-employee does not meet the TJC definition of “staff,” the vetting and authorization procedures are limited to serving the purposes of ensuring safety, security and access control. Processing and approval of Tier 1 Non-Employees shall be done in accordance with the Background Investigations Policy, HR.OP.002, any applicable HCA Healthcare safety and security policies, and the safety and security policies and procedures of the facility as would apply to the services of the Tier 1 Non-Employee. Pharmacy and Laboratory Representatives who provide services exclusive to the operations of the department (i.e., Automated Dispensing Cabinet representatives, wholesaler representatives, pharmaceutical waste, equipment maintenance and service, etc.) will be considered Tier 1 Non-Employee.

6. Clinical Research Associates (a.k.a. “monitors”): Individuals employed by pharmaceutical or laboratory companies who are present for purposes pursuant to their research (i.e., monitoring records, investigational product accountability, site qualification visits etc.) are not considered “sales representatives” and also not considered Tier 2 or Tier 3 DHPs (assuming they are not coming into contact with patients). The facility’s credentialing/privileging policies will determine if they are Tier 1 Non-Employee or considered auditors not subject to the DHP policy.

7. 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.

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REFERENCES:

1. Vendor Relations Policy, EC.028
2. Vetting Dependent Healthcare Professionals and Other Non-Employees Policy, COG.PPA.003
3. Background Investigations Policy, HR.OP.002
4. Vendor/Supplier Facility Relations, ADM-2023
5. The Institute for Safe Medication Practices, Managing Visits from Pharmaceutical Sales Representatives, May 2008