KING'S DAUGHTERS MEDICAL CENTER | **ADMINISTRATIVE POLICY**

POLICY AND PROCEDURE | **EFFECTIVE DATE: 4/29/22**

SUPERSEDES: 7/30/18; 6/11/18; 3/4/16; 08/02/04; 11/1/03
Reviewed Date: 8/18/21; 6/20/12

FILE: SECTION F (5) | **SUBJECT: SALES REPRESENTATIVES IN THE MEDICAL CENTER**

POLICY:

I. Medical service representatives (representatives) may visit the facility in conjunction with their duties. Representatives are guests of the Medical Center and as such may provide services in accordance with accepted rules of conduct within the facility. Representatives are required to fulfill requirements as set forth below.

II. Representatives will limit their visits to providing information and servicing the account.

PROCEDURE:

1.1 Sales Rep Access Levels.

Level I Access: Access to facility, but NO access to clinical or patient care areas. Does NOT consult with patient care staff or clinicians. Does NOT operate equipment or provide technical assistance. Visits less than 3 times per year (more frequent visitors classified as LEVEL II). **COVID-19 Vaccination Requirement for vendors/sales representatives:** Representatives/Vendors who meet Level 1 Access definition but are present within the hospital more than once per month are required to provide documentation of compliance with the CMS COVID-19 vaccination requirement for health care providers and suppliers, as described in the CMS Omnibus COVID-19 Health Care Staff Vaccination Rule. **Examples:** Maintenance/construction workers who are working in the hospital on projects that are projected to take 2 weeks or longer to complete.

Level II Access: Access to patient care environments EXCLUDING sterile or restricted areas. Includes vendor and supplier sales representatives that interact with providers. Includes Durable Medical Equipment (DME) providers, medical device sales, pharmacy sales, and lab/radiology/diagnostic representatives (Reps) and frequent LEVEL I vendors. **Examples:** Pharmaceutical representatives, Medical device representatives, Vendors conducting education / in-services. **Level II Access and Level III Access**: Representatives/Vendors who meet Level II and III Access definition are required to provide documentation of compliance with the CMS COVID-19 vaccination requirement for health care providers and suppliers, as described in the CMS Omnibus COVID-19 Health Care Staff Vaccination Rule.

Level III Access: Access to patient care environments INCLUDING sterile or restricted areas. Attends and/or observes patient procedures. Resource for physicians and medical professionals concerning equipment operation, calibration, etc. This is the highest level of credentialing and will require you to submit the most documents.

1.2 **<u>*Documentation</u>**.

Required Documentation	LEVEL I	LEVEL II	LEVEL III
Completed KDMC Sales Rep Data Sheet	✔	✔	✔
Completed Employer-Level Verification Sheet	✔	✔	✔
Proof of a current TB skin test / PPD record		✔	✔
Proof of a current influenza immunization, or elect to wear mask	✔	✔	✔
Proof of a Hepatitis B vaccination			✔
Proof of COVID-19 vaccination or approved exemption information	✔	✔	✔
Signed Code of Conduct and Compliance Training Attestation		✔	✔
Signed KDMC Acknowledgement and Release from Liability Form	✔	✔	✔
Signed KDMC Pharmacy Guidelines Acknowledgement (required only of pharmaceutical reps)		✔	
Payment of Annual Fee		✔	✔
KDMC Issued Vendor Badge	✔	✔	✔

1.2.1 All sales representatives must complete the Sales Representative Data Sheet and comply with all requirements within the vendor management program: (Attachment A).

1.2.2 All sales representatives must complete the Acknowledgment and Release from Liability form (Attachment B).

1.2.3 All Pharmaceutical sales representatives must sign the Medical Service Representatives Pharmacy Addendum (Attachment C).

1.2.4 All sales representatives must present verification of Employment, a Criminal Background Check, Sex Offender Registry check, Drug Screen, Training outlining their expertise about the applicable products they represent or complete Employer Verification Sheet – (Attachment D).

1.2.5 All sales representatives must present verification of a current influenza immunization, or elect to wear mask during Flu Season as noted in KDMC Flu Policy.

1.2.6 All sales representatives must complete the General Code of Conduct and Compliance and submit a signed Code of Conduct and Compliance Training Attestation. (Attachment E)

1.2.7 All sales representatives seeking Level II and/or Level III Access must present current documentation of an annual TB skin test.

1.2.8 All sales representatives seeking Level III Access must present current documentation of a Hepatitis B vaccination.

1.2.9 *All vendor representatives must present verification of COVID-19 vaccination records or have an approved exemption from their employer as per KDHS COVID-19 Vaccination Program Policy. (Section: I (62)).

2 KDMC's Policies and Procedures.

2.1 All sales representatives must review and be knowledgeable about KDMC's policies and procedures related to fire and electrical safety as well as patient confidentiality.

2.1 As a prerequisite, all vendors must follow the medical centers policy regarding vendor credentialing, requirements, behavior and expectations.

2.1.1 All sales representatives will be given informational material for which they will be responsible to follow while a visitor at KDMC.

2.1.2 Any sales representative who fails to comply with the requirements of this policy and/or fails to familiarize her/ himself with the applicable policies and procedures will not be permitted in the Medical Center.

2.2 **Other.**

2.2.1 Breaks may be taken in staff lounge. Sales representatives are not permitted in physician's lounge

2.2.2 All sales representatives should have an appointment.

2.2.3 Sales Representatives should only utilize OPEN Parking.

Clinical Department Responsibilities:

3 Arrival of Sales Representative.

3.1 *As stated above, after receiving a badge, supply sales representatives must sign in and out at the vendor liaison office when using the Ashland campus and KDOH security desk when calling on Kings Daughters Ohio. Representatives will not permitted to share or loan out their Vendor ID badge. Pharmaceutical representatives must report to the pharmacy prior to visiting any other areas of the medical center (see attachment B).

3.1.1 Verify that the sales representative is wearing the applicable name badge.

3.1.2 Assure that the sales representative follows KDMC procedures regarding proper attire, aseptic technique and standard precautions.

3.1.3 If a sales representative arrives at the medical center to present new equipment, prior to use of the new equipment, the approval of the Director of Materials Management as well as an ad hoc committee must be obtained.

3.1.4 KDHS Biomedical department before used on patients must inspect equipment.

4 Consignment

5.1 All items to be consigned must have a completed, signed agreement on file in the Materials Management office. Any additions or deletions to the consigned items must be presented to and approved by Surgical Services and Materials Management prior to implementation.

4.1.1 Prior to removing consignment products from the facility, the vendor and a KDMC team member will inventory the outgoing products.

4.1.2 Vendors are responsible for shipment of replacements into inventory. Refilling and rotation of the stock will be the sole responsibility of the vendor.

4.1.3 Vendor/Representative is responsible for maintaining and validating consignment on a weekly basis.

4.1.4 All vendors are required to submit Bill-Only invoices within 7 days of case date or be subjected to a potential 10% decrease in total invoice per week.

5 Loaner Instrument Sets

5.1 Surgeon requiring loaner instrumentation is responsible for initially contacting vendor to confirm availability of the loaner instruments and written Instructions For Use (IFU).

5.2 *KDMC does not pay loaner or rental fees unless vendor received prior approval from a Surgical Service Manager. Approval must also be submitted to Purchasing when requesting Bill only PO.

5.3 KDMC does not pay for freight associated with shipping of loaner equipment.

5.4 All loaned instruments are considered non-sterile.

5.5 Vendor/Representative is responsible to ensure that loaner instruments arrive at KDMC at least two (2) business days prior to scheduled case.

5.5.1 First time vendor loaned sets require three (3) business days for in servicing, inspecting and processing. In emergent situations, the

required time constraint may be waived and processing will be expedited at the discretion of the Central Sterile Supervisor/Manager.

5.5.2 All loaner trays will be delivered and logged in with Central Sterile supervisor or designee. Documentation including date and time of arrival, weight of trays, signature of vendor and CSS staff receiving trays and name and number of trays will be recorded on an inventory loaner form.

5.5.3 Vendor will provide the manufacturer's tray content list and Food and Drug Administration (FDA) approved written IFU. Vendor will provide in-servicing to CSS staff for any loaner tray upon request.

5.5.4 KDMC will not accept contaminated, broken or defective instruments. If procedure should be cancelled or delayed due to ill-prepared instrumentation, the vendor will accept responsibility for lost revenues.

5.5.5 *Trays will be weighed upon delivery. The weight of any tray is not to exceed twenty (25) pounds.

5.5.6 Trays will be tagged by the vendor with date, surgeon and procedure and placed in the designated area prior to processing.

5.5.7 The vendor will remove loaner instrumentation from the facility within two (2) business days after use. Any trays not removed within this timeframe may be shipped to the company at their own risk and expense.

5.5.7.1 Inventory loaner sheets will be maintained in CSS for verification that all components were accounted for at arrival, assembly, decontamination and return.

5.5.7.2 Limited storage for instrument sets frequently used by KDMC will be made available.

6 **During Procedure.**

6.1 *With the exception of representatives who are essential to preforming the procedure, representatives have no "hands on" contact with patients and cannot operate equipment. All participation must be limited to verbal guidance only.

6.1.1 Sales representatives are to leave immediately after the procedure.

6.1.2 Circulators will verify all supplies brought in by the sales representatives.

6.1.3 Sales representatives in the procedure area are to wear lead aprons and thyroid shields whenever x-ray or fluoro is being used, or leave the exposure area. It is the responsibility of the sales representatives and his or her company to provide and maintain x-ray badges. KDMC is not responsible for any exposure.

7 **Disciplinary action.**

7.1 Sales representatives are to conduct themselves in accordance with KDMC policies and procedures. Vendors will adhere to all applicable KDMC policies and will be subject to a progressive discipline plan for policy non-compliance.

7.2 KDMC will follow progressive discipline in the order set forth below.

7.2.1 First infraction will result in a letter of reprimand from the procedural area manager.

7.2.2 Copies of this letter will be sent to the Director of Surgical Services, CMO, Materials Management, the vendor and vendor's immediate supervisor.

7.2.3 Second infraction will result in the loss of visitation privileges for six (6) months.

7.2.4 Third infraction will result in loss of visitation privileges permanently.

7.2.5 Vendors who have lost privileges and are found conducting business on KDMC premises will be subject to prosecution

7.2.6 KDMC may deviate from this progression on a case-by-case basis depending on the nature and or severity of the issue at hand.

7.2.7 Dissemination of false or misleading product information will be grounds for immediate and permanent suspension of privileges.

7.3 Consent: The patient will be informed of the proposed presence of a sales representative in their procedure at the discretion of the physician.

7.4 KDMC does not reimburse vendors for trialed product.

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President/CEO

Attachments:
- A Vendor Sales Rep Data Sheet
- B Acknowledgment and Release from Liability
- C Medical Service Representatives Pharmacy Addendum

D Employer-Level Verification Sheet
E General Compliance Training Attestation Form

Attachment A

Vendor Representative Credentialing Data Sheet

KING'S DAUGHTERS

Date	Date of Birth:	
First Name	Last Name	
Phone (Cell)	Phone (Home)	
Email Address		
Home Address		
City	State	Zip Code
Company		
Position / Title		
Products Covered		
Area's Covered		
Phone # of Company		
Address of Company		
City	State	Zip Code
Name of Immediate Supervisor		
Phone # of Immediate Supervisor		
Email Address of Immediate Supervisor		

Do you represent Implantable Products or Tissue? □ Yes □ No

Access Level Requesting Please Check appropriate Box.

LEVEL I

Vendor Representative Managers
Access to facility, but *NO* access to clinical or patient care areas
Does *NOT* consult with patient care staff or clinicians
Does *NOT* operate equipment or provide technical assistance
Visits less than 3 times per year (more frequent visitors classified as LEVEL II)

LEVEL II

Tech Support and Sales Vendor Reps
Access to patient care environments *EXCLUDING* sterile or restricted areas
Includes vendor and supplier sales representatives that interact with providers
Includes DME providers, medical device sales, pharmacy sales, and lab/radiology/diagnostic reps
or frequent LEVEL I vendors

LEVEL III

Clinical Support and Sales Vendors
Access to patient care environments *INCLUDING* sterile or restricted areas
Attends and/or observes patient procedures
Resource for physicians and medical professionals concerning equipment operation, calibration,

Attachment B

KING'S DAUGHTERS HEALTH SYSTEM

ACKNOWLEDGMENT AND RELEASE FROM LIABILITY

I _____ (First & Last Name) hereby confirm that I am a sales representative with _____ (company name) and that I am on the premises to promote the purchase, sale and use of _____(product name).

I acknowledge and understand that while King's Daughters Medical Center will strive to provide a safe and secure environment and that my presence at the facility will be that of an invitee. As such, I will have any and all rights and remedies associated with such status. In accordance with my status as an invitee, I hereby release King's Daughters Medical Center, its agents, employees and physicians from any and all liability for injuries that may occur as a result of open and obvious hazards on the premises.

Additional, I hereby release King's Daughters Medical Center, its agents, employees and physicians from any and all liability for injuries that may occur in connection with activities that exceed the duty of care owed to me as an invitee. I understand and agree that my presence on the premises and in the facility is for my own business benefit as well as that of the Medical Center, and as such, I may be permitted to enter areas that are not open to the general public. I understand and agree that in areas such as these, my status is not that of an invitee, and I assume any and all risks associated with my presence in these areas. Specifically, I hereby release King's Daughters Medical Center, its agents, employees and physicians from any and all injuries that may occur as a result of my involvement or participation in medical, radiological and surgical procedures. Further, I specifically release King's Daughters Medical Center, its agents, employees and physicians from any and all liability associated with any type of exposure that may occur in connection with a procedure and acknowledge that King's Daughters Medical Center is not responsible for any injury that might occur as a result. Notwithstanding the foregoing, King's Daughters Medical Center will make every effort to provide a safe environment, as provided for its own employees.

I acknowledge and understand that King's Daughters Medical Center shall have the right to remove, limit or completely prohibit my presence in the facility or my participation or involvement in a procedure if, in its sole discretion, it finds my presence, health, actions or performance is detrimental to patient well-being or safety or the therapeutic or other business function of the department.

I further acknowledge receipt and understanding of King's Daughters Medical Center's policies and procedures related to fire and electrical safety as well as the Medical Center's Privacy Policy and I agree to adhere to the terms thereof. I further agree that King's Daughters Medical Center has a right to rely on my representations with respect to my understanding of the above-referenced policies and procedures.

_____

_____ Date

Signature of Sales Representative

_____

Company

ATTACHMENT C

MEDICAL SERVICE REPRESENTATIVES
PHARMACY ADDENDUM

Medical service representatives (sales representatives) may visit the facility in conjunction with their duties. Representatives are guests of the facility and as such may provide services in accordance with the accepted code of conduct within the facility.

Representatives MUST report to the Pharmacy Department prior to visiting other areas each time they enter the facility. They shall limit their visits to providing information and servicing their account. The Director of Pharmacy and the Clinical Manager shall see representatives by appointment only. Representatives must contact the pharmacy to arrange appointments with other departments within the Medical Center.

Solicitations, displays, and distribution of samples or other promotional materials in the medical center are prohibited without prior approval from the pharmacy. Medications that are not on formulary cannot be displayed or promoted within the facility.

I acknowledge that I have received a copy of the Pharmacy guidelines for Medical Sales Representatives. I have read and understand the above and agree to cooperate.

_____
Signature

_____
Company Represented

_____
Date

Attachment D

EMPLOYER VERIFICATION SHEET

(To be completed by Supervising Manager of Representative servicing account of King's Daughters Medical Center and affiliates)

Supervising Manager Name

Supervising Manager Phone _____

Supervising Manager Email _____

Company Name _____

Representative Name _____

_____

Liability Insurance Carrier
Policy Number
Policy Expiration Date _____
_____
_____

Is representative a current employee?

_____

Upon hire, was a background check performed for the vendor representative, specific to criminal background check and sex offender registry?

_____

Has the representative received training concerning the product(s) or service(s) provided to King's Daughters Medical Center?

_____

Has the representative received training concerning blood-borne pathogens?

_____

Has the representative received training concerning Operating Room protocol and sterile procedures?

_____

Supervising Manager Name

_____

Supervising Manager Signature _____ Date _____

Attachment E

CODE OF CONDUCT CERTIFICATION AND INITIAL GENERAL TRAINING ATTESTATION

Instructions: Complete the information below, sign the form, date the form, check the boxes, and return to your King's Daughters Medical Center contact.

Printed Name:_____
Specialty/Company _____
Supervisor: _____
Date_____ , 20_____

- ☐ I have received, read and understand the Code of Conduct.
- ☐ I certify that on the date below I completed the mandatory two (2) hour Initial General Compliance Training session which included education on KDMC's Corporate Integrity Agreement, KDMC's compliance policies and procedures, Code of Conduct, reporting requirements for suspected violations of any Federal healthcare program and KDMC's own Policies and Procedures. Based upon this education I agree:
- ☐ To abide by the Code of Conduct, the compliance program policies and procedures and the Medical Center policies and procedures.
- ☐ I agree to comply with all Federal health care program requirements.
- ☐ I understand it is my obligation to promptly report any suspected violations of any Federal health care program requirements, the Code of Conduct, or of the Medical Center's own policies and procedures.
- ☐ I understand that failure to comply with the Code of Conduct and compliance program policies and procedures may lead to disciplinary actions.
- ☐ I understand and agree to abide by the obligations set forth in the Corporate Integrity Agreement.

_____
Signature