At all times, the residency and Fellowship programs at Carolinas HealthCare System Northeast will follow these Carolinas HealthCare System policies:

1. Carolinas HealthCare System Pharmaceutical Sales Representatives. (ADM 200.09)
2. Carolinas HealthCare System Materials Management Sales Representative Access. (MM 300.13)

At the discretion of the Chair of Education, Pharmaceutical companies will be allowed to cater breakfast or lunch at resident conferences.

Mark D. Robinson, MD  
DIO, Chair of Education  
Cabarrus Family Medicine Residency  

1/20/17  
Date

Phyllis Wingate  
Division President  
Carolinas HealthCare System NorthEast  

1/20/17  
Date
CAROLINAS HEALTHCARE SYSTEM

Category: Administration
Procedure: Pharmaceutical Sales Representatives
Number: ADM 200.09
Date of Issue: 05/01
Reviewed / Revised: 07/16

PHARMACEUTICAL SALES REPRESENTATIVES

SUMMARY STATEMENT

To provide guidance and structure to the pharmaceutical purchasing process, adhere to federal regulations and provide for a safe work environment.

POLICY

Pharmacy Director, Managers or designee, and Department Managers, under the auspices of Carolinas Healthcare System Pharmacy Services, Materials Management, Corporate Relations and Corporate Compliance, are responsible for oversight and enforcement of departmental policies, procedures and guidelines specific to Pharmaceutical Sales Representatives.

Pharmaceutical Sales Representatives visiting any of the System facilities shall be advised of, and adhere to the Carolinas HealthCare System Pharmaceutical Sales Representative Policy as outlined herein. This policy applies to Acute Care, Long Term Care, and Ambulatory Clinics owned, operated, or managed by Carolinas HealthCare System which include, but are not limited to, the following:

Carolinas Medical Center Campus¹
CMC Clinics
CMC – Mercy
CHS – Pineville
CHS – University
CHS – Lincoln
CHS – NorthEast
CHS – Union
CHS – Stanly
CHS – Cleveland
CHS – Kings Mtn

CMC Rx Retail
CarolinaCARE
Behavioral Health
Carolinas Rehabilitation
Long Term Care

PROCEDURE

1. The Pharmacy Director / Manager or designee will ensure Pharmaceutical sales representatives have a signed copy of the Pharmaceutical Sales Representative Attestation Form on file in each facility’s pharmacy prior to visitation of that facility.

¹ Includes all locations on the Carolinas Medical Center Campus such as Medical Education Building, Cannon Research, etc.
2. Pharmaceutical sales representatives must register with the Pharmacy prior to visiting a facility or campus. At Carolinas Medical Center (CMC) only, registration of the pharmaceutical sales representatives will occur at Guest Services (3rd floor) and/or Corporate Relations (Medical Education Building).

3. Policy violation can result in loss of privileges at all Carolinas HealthCare System facilities, as determined by CHS Pharmacy and/or Corporate Compliance, which means the violator(s) will no longer be allowed on Carolinas HealthCare System premises. Violations may also be reported to any federal agency or entity involved in monitoring or regulating pharmaceutical and biomedical device products. The violation letters will be sent and monitored by the Assistant Vice President of Pharmacy or designee.

4. The Pharmacy will verify scheduled appointments and distribute the Carolinas HealthCare System authorized ID badge to pharmaceutical sales representatives with approved business at the facility or campus. At CMC only, the verification and ID badge distribution will occur at Guest Services and/or Corporate Relations. Pharmaceutical sales representatives without verified appointments will not be allowed access to Carolinas HealthCare System facilities or campuses.

5. Pharmaceutical Sales Representative must display at all times, the Carolinas HealthCare System authorized ID badge, while on a Carolinas HealthCare System facility or campus. Badges will be dated with the day of approved appointment and the area(s) they are approved to visit and used for that day only. Failure to observe this procedure can result in loss of privileges.

6. The Pharmaceutical Sales Representative must limit pharmaceutical detailing to medications approved for formulary and indications/specifics as determined by the Carolinas HealthCare System medical staff and the Pharmacy.

7. The Pharmaceutical Sales Representative will have limited access, may leave approved promotional articles with appropriate personnel but not allowed in the following areas:
   - Physician lounges
   - Resident lounges or sleeping areas
   - Nursing lounges
   - Pharmacy lounges
   - Laboratories

8. The Pharmaceutical Sales Representatives will be prohibited in detailing of pharmaceuticals in the following areas, unless otherwise approved by Pharmacy:
   - Patient care areas
   - Emergency Department
   - Medical Library
   - Lobbies (exception is approved display in Medical Education building at CMC)
   - Cafeteria
   - Common hallways
• Parking lots & doorways
• Restrooms, showers and changing areas

9. Pharmaceutical Sales Representatives making rounds in any patient care area, observing patient procedures, viewing / accessing any written, verbal or computerized patient information is prohibited.

10. The Pharmacy will review and authorize requests for pharmaceutical company sponsored educational offerings for Carolinas HealthCare System facilities / sites and facilitate advertising for the event. No unapproved educational offerings are permitted at Carolinas HealthCare System facilities or campuses. Advertising for unapproved educational offerings for events being held off Carolinas HealthCare System campuses will not be displayed at Carolinas HealthCare System.

11. Samples must be delivered to the Pharmacy for disposition to authorized areas. (See Pharmacy Sample Policy & Procedure to identify authorized areas). Controlled substance samples are prohibited.

12. Information regarding new drug approvals will be presented to the Director of Clinical Pharmacy Services for inclusion in Carolinas HealthCare System medication evaluation programs as clinically indicated. The detailing and promoting of new drugs is prohibited until approval by the Pharmacy, the Pharmacy and Therapeutic Committee, and the Medical Executive Committee.

13. All pharmaceutical contracting activities will be forwarded by the Pharmacy to the appropriate member of the Materials Management Department to conduct the bidding process according to approved guidelines.

14. Parking

• Sales representatives will be required to park in the parking lots or decks designated for Carolinas HealthCare System visitors only.

• Any vehicles parked inappropriately (e.g. in any patient, employee, or physician lot) will be ticketed and / or towed according to Carolinas HealthCare System policy.

APPROVALS

<table>
<thead>
<tr>
<th>Policy Coordinator</th>
<th>Robert Carta, Vice President, Pharmacy Services</th>
</tr>
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<tbody>
<tr>
<td>Policy Approvers</td>
<td>Scott Leighty, Senior Vice President, Corporate Operations</td>
</tr>
<tr>
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<td>John Knox, Executive Vice President &amp; Chief Administrative Officer</td>
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</tbody>
</table>
To our professional medical sales and service representatives:

When doing business with the Carolinas HealthCare System, it is expected that you and your company understand and adhere to our policies. The Pharmaceutical Sales Representatives Policy and Procedure outlines the standards of behavior expected by representatives doing business with Carolinas HealthCare System. If you have further questions regarding business ethics related to any business activity please refer to the brochure, A System of Integrity, or contact the Department of Corporate Compliance or Corporate Relations.

It is our commitment to comply with all FDA regulations and requirements. It is our intent to comply with the guidelines endorsed by the American Medical Association (AMA) and the Accreditation Council of Continuing Medical Education (ACCME). Medical staff working with medical sales and service representatives are required to sign a Conflict of Interest disclosure form in certain circumstances when working with external representatives or agents.

Please sign this form below indicating that you have read and are familiar with The Pharmaceutical Sales Representatives Policy and Procedure and A System of Integrity. A signed copy of this form must be on file at any Carolinas HealthCare System facility’s pharmacy visited by a representative or agent.

Company: ____________________________________________

____________________________________________________
Supervisor Name  ____________________________________

____________________________________________________
Pharmaceutical Sales Representative Name  _____________

____________________________________________________
Email Address  ______________________________________

____________________________________________________
Regional Manager Name  ____________________________

____________________________________________________
Date  ____________________________________________

ADM 200.09, revised 07/16
CAROLINAS HEALTHCARE SYSTEM

Category: Materials Resource Management
Policy: Materials Resource Management Sales Representative Access
Number: MM 300.13
Date of Issue: 06/06
Reviewed / Revised: 05/15

MATERIALS RESOURCE MANAGEMENT SALES REPRESENTATIVE ACCESS

SUMMARY STATEMENT

Materials, device, and equipment representatives will only access Carolinas HealthCare System facilities with the appropriate approval and appointments. They will be expected to follow all Carolinas HealthCare System policies and procedures relating to the confidentiality and safety of all patients, employees, and medical staff of Carolinas HealthCare System while visiting any campus.

POLICY

While making sales calls/appointments in facilities owned, operated, or managed by Carolinas HealthCare System, materials, device, equipment and services sales representatives ("sales representatives") offering materials, devices, or equipment will adhere to the guidelines developed by Materials Resource Management.

System of Integrity

The Carolinas HealthCare System operates under a Corporate Compliance Program referred to as the System of Integrity. This System is described in a booklet entitled The System of Integrity. It describes the code of conduct for CHS employees and those doing business with CHS. Vendor Representatives are expected to conduct themselves in accordance with this System in any dealings with Carolinas HealthCare System and in dealings with individuals affiliated with Carolinas HealthCare System.

This policy is specific to the following facilities. These facilities will be referred to in the body of this policy as "covered" facilities (Other CHS facilities may have modified the procedures):

All CHS owned facilities

PROCEDURE

A. Appointments

1. All sales representatives will be required to make advance appointments with Materials Resource Management or the appropriate department manager before calling on personnel within the facilities covered with this policy.

2. Sales representatives must register with Guest Services or Materials Resource Management (or other specified area) upon arrival to a covered facility or campus before going to the department.
3. Sales representatives without verifiable appointments will not be allowed to access a covered facility or campus.

4. Managers are not to meet with any sales representative who does not have a verifiable appointment within their departments.

B. Access Point

1. All sales representatives with a verifiable appointment at a covered facility between the hours of 8:00 a.m. and 5:00 p.m. are required to check in with Guest Services or Materials Resource Management (or other specified area) at that facility. Sales representatives will be required to sign a log book, pick up their identification badge, and sign the Materials Resource Management Sales Representative Attestation Form (if a signed copy is not on file).

2. When a sales representative is required to be in a covered facility outside of normal business hours, that sales representative should forward proof of the appointment to Materials Resource Management before 5:00 p.m. the day before/day of the appointment. The sales representative badge can be forwarded to the department where the appointment will take place.

3. Guest Services or Materials Resource Management (or other specified area) will verify scheduled appointments upon check-in by the sales representative and distribute an authorized ID badge to each sales representative with approved business at the covered facility.

C. Identification

1. The Carolinas HealthCare System authorized ID badge and the sales representative’s company badge must be displayed at all times while at any covered facility or campus.

2. Badges will be dated with the day of approved appointment and must be returned to Guest Services or Materials Resource Management (or other specified area) after the appointment.

3. If the appointment extends beyond 5:00 p.m., the badge should be given to the department manager (or designee) to be returned the following business day.

4. Sales representatives will be required to obtain a new badge upon each visit to a facility.

   a. Certain sales representatives may be given permanent badges at the discretion of the department manager or director based on a need for routine emergency access to the department.

   b. Each sales representative with a permanent badge will still be required to adhere to all other elements of this policy and procedure.
c. If a sales representative presents at a covered facility without this badge, he or she must follow the same check-in process as the other sales representatives and will receive a badge for the day of the appointment.

D. Limitations and Access

1. Sales representatives may not publicly market, sell, make offers/proposals, or in any way detail their materials, devices, or equipment.

   a. Such sales oriented behaviors are specifically prohibited in patient care areas, the Emergency Department, Medical Library, lobbies, cafeteria or dining areas, common hallways, parking lots, doorways, restrooms, showers, and changing areas. Note: these activities are allowed in the approved vendor display in Medical Education building at CMC.

   b. Marketing, selling, making offers/proposals or in any way detailing materials, devices, or equipment will be limited to products approved for the Materials Resource Management formulary of materials, devices and equipment as determined by Product Standardization Teams.

2. Without specific approval by Materials Resource Management or the department manager, sales representatives will not be allowed access to any patient care area, physician lounges, resident lounges or sleeping areas, nursing lounges, pharmacy lounges, or laboratories.

3. Sales representatives will not be authorized to make rounds in any patient care area, observe patient procedures, or view or access any written, verbal or computerized patient information with the following exceptions:

   a. Requests for presence of a sales representative in a clinical area (e.g. patient care unit, operating room, etc.) may be made by a physician or a service coordinator (or designee) and should be made to the appropriate manager or director.

   b. Arrangements must be made at least 24 hours prior to a regularly scheduled procedure or at the discretion of the department manager or director.

   c. After appropriate authorization, the sales representative is permitted to provide verbal, technical assistance for his/her product. They are not allowed to perform any other tasks.

4. Use of Wireless communication devices - two-way radios, cellular and cordless telephones, CB radios, ham radios, walkie-talkies, and other wireless devices used for communication purposes is prohibited within CHS facilities. Exceptions must be approved in writing by the CHS Communications Department.

E. Parking

1. Sales representatives will be required to park in the parking lots or decks designated for Carolinas HealthCare System visitors.
2. Any vehicles parked inappropriately will be ticketed and/or towed according to Carolinas HealthCare System policy.

F. Loading and Unloading

1. Each facility will have specific areas designated for loading and unloading pharmaceuticals, materials, devices, and equipment. Sales representatives should inquire as to the location of these areas before visiting the facility.

2. Sales representatives who load or unload in non-designated areas will be instructed to move to the proper area.

3. Samples of materials or devices must be delivered to Materials Resource Management for disposition to authorized areas.

4. Sales representatives will not leave boxes or other containers in public parking areas. All waste should be disposed of according to Carolinas HealthCare System policy.

G. Equipment

1. All equipment brought to a facility must be certified by that facility's Clinical Engineering Department and must meet established facility and departmental Infection Control standards prior to use in a department.

2. Evaluation of equipment must be approved in writing by Materials Resource Management.

3. Information regarding new product and equipment approvals will be presented to a CHS Director of Materials Resource Management for inclusion in CHS evaluation programs as indicated.

H. Educational Offerings

1. All educational offerings sponsored by, materials, device, and equipment sales representatives taking place in any covered facility or campus must be reviewed and approved by Materials Resource Management.

2. Advertising for approved educational offerings will be coordinated by Materials Resource Management.

3. No unapproved educational offerings are permitted at covered facilities or campuses. Advertising for unapproved educational offerings for events being held off campus will not be displayed at any covered facility.

I. The Materials Resource Management Director of Contracts or other authorized Materials Resource Management Director will conduct all contracting activities using the approved bid process.
J. Enforcement / Compliance

1. Failure to comply with these procedures will result in loss of privileges at covered facilities.

2. Sales representatives must have a signed copy of the Materials Resource Management Sales Representative Attestation Form on file in each facility prior to visiting that facility.

3. Sales representatives will be required to attend an orientation session to review the policy and sign the attestation and to be educated on safety procedures and other relevant information. These sessions will be offered on a quarterly basis.

4. Violation of the policy will result in loss of privileges at all covered facilities, as determined by Materials Resource Management and/or Corporate Compliance, which means the violator(s) will no longer be allowed on Carolinas HealthCare System premises. Violations may also be reported to any federal agency or entity involved in monitoring or regulating medical materials, equipment, and biomedical device products.

5. Employees should notify their direct supervisor of any sales representative without proper identification or who is found in an area that is off-limits.

6. Names of any sales representatives who breach this policy should be forwarded immediately to the Vice President of Materials Resource Management.

K. Employee Responsibilities

1. CHS employees are required to follow this policy by requiring sales representatives to secure appointments through Materials Resource Management and to report any violation of this policy to Materials Resource Management. CHS employees who violate this policy will be reported to the appropriate, responsible Vice President for appropriate action.

2. CHS employees should not meet with sales representatives who do not have an appointment with them or with someone in the same department.

3. If there is an emergency requirement to meet with a representative, Guest Services should be notified of the appointment. If the need is after hours, the appointment and the need for the appointment should be documented.

APPROVALS

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<thead>
<tr>
<th>Policy Coordinator</th>
<th>David Boyce, Vice President, Materials Resource Management</th>
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<tbody>
<tr>
<td>Policy Approvers</td>
<td>Jim Olsen, Senior Vice President, Materials Resource Management</td>
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</table>
CAROLINAS HEALTHCARE SYSTEM
MATERIALS RESOURCE MANAGEMENT SALES REPRESENTATIVES
POLICY ACKNOWLEDGEMENT AND AGREEMENT

I have received a copy of the policy. I understand and agree to comply with all parts of the policy. I have also received, read and understand the *System of Integrity*.

Vendor Signature: ______________________

Company Name: ______________________

Date: ______________________

MM 300.13, revised 05/15