



## MOUNT SINAI SOUTH NASSAU POLICY & PROCEDURE

<b>POLICY TITLE:</b>	Acceptance and/or Solicitation of Gifts or Benefits From Vendors		
<b>POLICY NUMBER:</b>	OF-ADM-276	<b>LAST REVIEWED DATE:</b>	01/2020
<b>POLICY CATEGORY/MANUAL:</b>	Compliance Hospital-wide Policies		
<b>CROSS REFERENCE:</b>	Conflicts of Interest and Related Party Transactions (OF-ADM-277), Acceptance of Gifts From Patients (OF-ADM-275) No Solicitation Policy (Employee Handbook), Pharmaceutical Sales Representatives Policy Reference #9015, Compliance with Anti-Referral Laws Policy		

### **PURPOSE:**

The purpose of this policy is to provide guidance regarding appropriate practices for the acceptance and solicitation of gifts or benefits from Vendors in order to ensure compliance with all applicable federal and state laws and the Mount Sinai South Nassau (the “**Hospital’s**”) Code of Conduct. Gifts from patients or their families are addressed in the hospital-wide policy OF-ADM-275 “Acceptance of Gifts From Patients”.

### **DEFINITIONS:**

1. **Personnel:** “**Personnel**” include employees, management, board members, physicians, physician extenders, contracted staff, volunteers, students, consultants and Other Agents.
2. **Vendors:** “**Vendors**” include all vendors, suppliers, consultants, other care providers, educational institutions, payers, physician owned distributorships, and other third parties (including, but not limited to, pharmaceutical manufacturers) seeking to do, or currently engaged in, business or in competition with the Hospital.
3. **Other Agents:** “**Other Agents**” of the Hospital include educational institutions (including students), other care providers, payers and other third parties.
4. **Relative:** A “**Relative**” of an individual means (i) his or her spouse, or domestic partner, as defined under New York Public Health Law § 2994-a, (ii) his or her ancestors, brothers and sisters (whether whole or half-blood), children (whether natural or adopted), grandchildren, great-grandchildren; or (iii) the spouse or domestic partner of his or her brothers, sisters, children, grandchildren, and great-grandchildren.

### **POLICY:**

It is the Hospital’s policy that Personnel may not accept or solicit from a Vendor a gift or benefit given as a result of the Personnel’s position or association with the Hospital and intended for that individual’s personal use. While offers of gifts benefits, donations, compensation, travel

expenses or grants may serve an important and beneficial function, they may, in some circumstances, violate the federal and state Anti-Kickback Statutes.

The guiding principle of this Policy is simple: Hospital Personnel may not be involved with gifts or benefits that are undertaken: (i) in return for or to induce referrals, or (ii) in return for or to induce the purchasing, leasing, ordering or arranging (or the recommending of any of the foregoing) any good, item or service.

The federal Anti-Kickback Statute makes it a crime for anyone to knowingly and willfully solicit, receive, offer or pay any remuneration directly or indirectly (including bribes, rebates, kickbacks, cash or in-kind payments) in return for referring an individual for services under any Federal Health Care Program or in return for purchasing, leasing or ordering any goods, facility services or item paid for under any Federal Health Care Program. The statute has been interpreted to mean that if even one purpose of the transaction is to induce referrals or an advantage for the person offering the remuneration, it is a violation of the statute even if it is not the sole purpose of the transaction. The New York State laws prohibit medical assistance providers, who furnish services under Medicaid, from soliciting or receiving any payment or other consideration for the referral of services for which Medicaid payments are made.

Violations of the federal and state anti-kickback laws may result in significant fines, imprisonment and exclusion from federal and state reimbursement programs; therefore, it is imperative that inappropriate and appropriate practices are distinguished and Personnel seek guidance if they are unsure about the propriety of a particular situation.

This policy is not intended to address the extension of gifts to and receipt of gifts from patients or patients' family members. For further guidance on this topic, please see the Hospital's Policy "Acceptance of Gifts" (OF-ADM-275)

To the extent that you have any question or concern regarding the applicability of this Policy to a particular circumstance, you are required to contact the Compliance Officer.

A failure to follow this Policy may result in disciplinary action in accordance with the terms of our Compliance Program.

#### **A. General Guidelines**

To assist personnel in understanding and complying with this Policy, the following guidelines must be observed:

- I. Personnel are strictly prohibited from soliciting any gifts or benefits of any kind from any person or entity, either individually or on behalf of the Hospital, with the exception of authorized solicitation for fundraising purposes.
- II. Personnel are strictly prohibited from offering or giving any gifts or benefits to government employees or officials.
- III. Personnel may never offer, pay or receive gifts or benefits that in any way take into account the volume or value of referrals, purchases, or other business generated between the parties.

- IV. Personnel may never accept gifts or benefits in exchange for prescribing certain products, services or drugs, or that are intended to induce referrals or otherwise generate business.
- V. Personnel may never accept gifts or benefits that could be perceived as an attempt to interfere with their professional judgment.
- VI. Gifts or benefits to Relatives of Hospital Personnel from a vendor or other agent of the Hospital are not permitted.

**B. Interactions with Vendors**

**I. Educational Presentations by Vendor Representatives**

Presentations and discussions by industry representatives on Hospital premises, during working hours are allowable as long as the information provided is educational in nature and is not solely intended to sell a product or service. Vendors may purchase booth space at a Hospital sponsored Vendor fair as long as the opportunity to purchase booth space is offered consistently and equally among the Vendors and documentation of such is maintained. However, single booths/tables outside of Hospital sponsored meetings, such as Grand Rounds, are not allowable.

- 1.) Accompanying Meals – Meals are allowed in conjunction with an educational presentation as long as the following criteria are met:
  - a.) the meal is modest,
  - b.) the meal is occasional,
  - c.) the meal is held on Hospital premises,
  - d.) the meal is not offered as a take-out (e.g., a company representative drops off lunch for a department without providing an educational presentation).
- 2.) Educational Items – It is appropriate for Vendors to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value ) and do not have value to healthcare professionals outside of their professional responsibilities. For example, an anatomical model for use in an examination room is acceptable, but a tablet or other electronic device that may have independent value to a healthcare professional outside of the work environment is not appropriate.

“Branded” items that are non-educational, such as pens, notepads, mugs and similar “reminder” items containing company logos are not appropriate.

Gifts and gratuities of nominal value, such as flowers, cookies or candy that a Vendor may provide during the Holiday Season are acceptable.

In addition, as stated in the Hospital's policy "Acceptance of Gifts from Patients" (OF-ADM-275), gifts of cash or cash equivalents are strictly prohibited. Cash equivalents include, but are not limited to, checks, gift certificates, gift cards and stocks.

II. **Fundraising Events** – Vendors may be solicited for gifts and donations for fundraising events so long as the solicitation:

- a.) is for a charitable, academic or educational event organized, sponsored or approved by the Hospital's Development Office (e.g., the annual golf outing, annual hospital fundraiser, or 5K Walk and Health Fair);
- b.) is made to all Vendors in the community and not limited to those currently doing, or seeking to do, business with the Hospital;
- c.) clearly indicates that an affirmative or negative response will not factor into the Vendor selection determination; and
- d.) is not originating from Materials Management due to the nature and functionality of the department.

III. **Entertainment and Recreation/Business Related Meals** –

Unless otherwise provided in this policy or specifically authorized by the Compliance Officer, Personnel may not accept Vendor invitations to entertainment or recreational events, (e.g., Broadway shows, vacation resorts, sporting events, or other similar activities.)

- a.) In some instances, a Vendor, in the course of doing business, may offer to go off-site to lunch or dinner. It is not appropriate to accept such invitations from a *health care related company's* field sales representatives and/or their immediate managers. Participation in such business entertainment would be permissible if:
  - i. the invitation is from a senior business executive of the health related company (i.e., not the sales representative or his or her immediate manager);
  - ii. there is an actual academic, educational or business purpose for the entertainment (e.g., business is actually being discussed);
  - iii. the meal is not part of an entertainment or recreational event;
  - iv. the meal is modest as judged by local standards;

- v. the meal is not offered for the purpose of influencing the business behavior of the recipient; and
  - vi. the meal is provided in a manner that is conducive to informal conversation.
- b.) Personnel may accept occasional business lunches and dinners from vendors who are *not engaged in health care related businesses* (for example, an accounting firm) for which there is little risk of violating the anti-referral laws.
- IV. **Hospital Fundraising/Networking Events** – Vendors required to comply with Advamed and Pharma Codes may not individually invite Hospital personnel to attend Hospital-sponsored fundraising events such as the annual hospital fundraiser, Annual Golf Tournament or other Hospital sponsored networking events. For example, if a Vendor purchases a table at a Hospital fundraising event, the Vendor may donate any unused portion of its purchase to the Hospital, not to an individual associated with the Hospital. The Development Office will distribute such tickets to Personnel.
- V. **Other Networking Events** – Personnel may attend other networking events sponsored by professional associations (e.g., the Health Care Financial Management Association, American Hospital Association, American Health Information Management Association).
- VI. **Educational or Professional Meetings** – Direct financial support to Personnel from Vendors for educational or professional meetings (such as those that provide continuing education credits) is not allowed.

The Hospital may accept an offer from a Vendor to underwrite or subsidize the costs of an educational conference or professional meeting that the Hospital is sponsoring as long as:

- a.) the subsidy is paid directly to the applicable Hospital department. In no event should a subsidy ever be paid directly to Personnel or Other Agent of the Hospital attending the conference or meeting;
- b.) the subsidy is for the cost of the conference or meeting only. Compensation or reimbursement cannot be accepted for travel, lodging and meal expenses if the Personnel's or Other Agent's role at the conference is solely as an attendee (see below Section VII for speaking engagements);
- c.) a Request for Seminars/Conferences is completed in accordance with Hospital policy (OF-ADM-209) and any other department specific procedures are met;

- d.) the selection of individuals attending the conference or meeting is made by the Hospital and there is documentation of such selection criteria; and
- e.) the Hospital remains responsible for selection of the content, faculty, educational methods, materials, and venue.

*Note: The Hospital may accept reimbursement from the Vendor for actual travel, lodging or meal expenses that are reasonably incurred (e.g., moderate meals and lodging) as part of a site visit or to evaluate equipment or products that the Hospital is considering purchasing. Prior review and approval from the Compliance Department is required.*

- VII. **Speaker Programs** – Salaried employees of the Hospital are permitted to accept reimbursement for travel, lodging and meal expenses to attend a conference or meeting if the individual lectures, makes a presentation, moderates or participates in a panel.

Salaried employees of the Hospital who participate in Vendor-sponsored programs intended to train speakers (e.g., to help educate and inform other health care professionals about the benefits, risks and appropriate uses of Vendor products) are permitted to accept reasonable compensation for their time, considering the value of the type of services provided and to accept reimbursement for reasonable travel, lodging and meal expenses. Such compensation and reimbursement should only be accepted when

(1) the participants receive extensive training on the Vendor company's products or other specific topic to be presented in compliance with FDA regulatory requirements for communications (if applicable);

(2) this training will result in the participants providing a valuable service to the Vendor; and

(3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section VIII below).

- a.) In no way can a speaking engagement be an inducement or reward for endorsing a particular product or service from the Vendor.
- b.) Any compensation or reimbursement must be reasonable and based on fair market value.
- c.) In addition, all compensation and reimbursement for speaking engagements must be reported annually on the "Conflicts of Interest and Related Party Transactions" disclosure form (OF-ADM-277).
- d.) Not provided during working hours (when the individual is already compensated by the Hospital.)

Speaker training sessions should be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.

This policy may not include all circumstances. For questions regarding speaking programs, please consult with the Compliance Officer.

VIII. **Consulting Services** – Personnel may participate in bona fide consulting arrangements with Vendors (e.g., based on their expertise or knowledge of a specific therapeutic area) and accept reasonable compensation for their advisory services and reimbursement for travel, lodging and meal expenses incurred as part of providing those services. The following factors support the existence of a bona fide consulting arrangement:

- a.) a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- b.) the compensation or reimbursement is reasonable and based on fair market value;
- c.) the venue and circumstances of any meeting are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues; and
- d.) in no way can a consulting engagement be an inducement or reward for endorsing a particular product or service from the Vendor.
- e.) Not provided during working hours (when the individual is already compensated by the Hospital.)

IX. **Solicitation** – The distribution of material or solicitation of Personnel or patients Hospital property (both inside and outside) by Vendors is strictly prohibited and is further described in the Hospital’s Employee Handbook. The only exceptions to the policy regarding solicitations are functions and activities of the Hospital and its associated organizations that are previously approved.

- a.) **Maternity Gift Bags** – Hospital policy prohibits the practice of giving gift bags to maternity patients at discharge that were not previously approved by the Department Director.
- b.) **Educational Materials** – Vendor supplied materials intended to provide patient assistance and education must be previously approved by the Department Director. (e.g. new diabetic insulin educational materials and starter kits)
- c.) **Literature** – that is provided by a Vendor in order to inform patients about a product or service is permitted only in patient waiting areas, cannot be

directly distributed to patients and must have prior approval by the Department Director.

- d.) ID Badges – Staff are prohibited from using ID badge holders or lanyards that display a Vendor’s logo. Only the approved Mount Sinai South Nassau ID badge may be displayed and employees may not wear any articles of personal adornment which advertise or sponsor any person or thing unless such items are issued or authorized by the President/CEO of the Hospital. Please see policy OF-HR-157 “Employee Dress Code”

**C. Review and Reporting of Vendor Offers or Invitations**

- I. Any Personnel or Other Agent of the Hospital who receives an offer or invitation of a gift or benefit from a Vendor should disclose the situation, in writing, to his/her supervisor. If the supervisor has any doubts as to the acceptance of the offer or invitation, he/she should contact the Compliance Officer. Appendix A of this policy provides some examples of situations involving the offering of gifts and benefits from Vendors. Acceptance of gifts, compensation, etc. should be disclosed in the annual Disclosure Statement as per the Hospital Policy “Conflicts of Interest and Related Party Transactions” (OF-ADM-277)
- II. All educational presentations by vendors in which a meal is provided, any educational items or equipment/supplies that are provided free of cost, any sample products exceeding 90 day supply, any device or DME “loaned” for a trial period exceeding 90 days, or any other gifts or donations made by a vendor to the Hospital must be reported to the Compliance department by the department manager or director and included on the annual Conflict of Interest Disclosure Statement.
  - a.) For educational sessions, the report must include the following:
    - i. a copy of the sign-in sheet with names of attendees and date of presentation,
    - ii. a copy of any educational material distributed,
    - iii. the type of meal provided, and
    - iv. any other relevant documentation.
  - b.) For educational items, equipment, supplies or other gifts or donations provided free of cost, the report must include the following:
    - i. the name of the vendor and contact information,
    - ii. the type of item(s), supplies or equipment received
    - iii. the dollar value of each item, supply or equipment, and/or

- iv. any other relevant documentation.
- c.) For samples over 90 day supply or use of sample equipment over 90 days
  - i. If accepted personally, include on the annual Conflict of Interest Disclosure Statement.
  - ii. If accepted on behalf of the Hospital, report to the Compliance Office.

The Compliance department will track all reports received from the department manager or director and use the information to compare annually against the payments listed under the Hospital’s name on the CMS Open Payments website.

The Open Payments law requires CMS to collect and display information reported by applicable manufacturers and group purchasing organizations about the payments and other transfers of value these organizations have made to physicians and teaching hospitals.

Please see Appendix B for further guidance on both reportable and non-reportable information under the CMS Open Payments regulation.

**REGULATORY STANDARDS:**

The Federal Anti-Kickback Statute (42U.S.C.§1320a-7b(b)), the New York State Anti-kickback Law (Social Services Law § 366-d); CMS Open Payments Regulations (42 CFR Parts 402 and 403, 78 Federal Register 9458 [February 13, 2013], 79 Federal Register 67758 [November 13, 2014]).

**REVIEWS/APPROVALS:**

Original Approval	11/09 Oversight Committee
Reviewed and Approved	6/13 Oversight Committee
Reviewed and Approved	11/14 Oversight Committee
Reviewed and Approved	5/15 Oversight Committee
Reviewed without revisions	5/17
Reviewed and Approved	1/18 Oversight Committee
Reviewed and Approved	01/2020 Oversight Committee

## APPENDIX A

\*\* Note: The below is not intended to be an all-inclusive list of situations. If there are any questions as to the acceptance of a gift or benefit from a Vendor, contact your Supervisor or the Compliance Office. \*\*Examples of Unacceptable & Acceptable Vendor Interaction Practices

Unacceptable		A Vendor drops off lunch to a department as a thank you for being a loyal customer.
Acceptable		A Vendor presents an educational session to a department and brings sandwiches for the staff to eat during the session.
Unacceptable		A Vendor provides a gift card to a staff member as a thank you during the Holiday Season.
Acceptable		A Vendor provides a box of cookies to a staff member as a thank you during the Holiday Season.
Unacceptable		A Vendor provides a patient care unit with a tablet or other electronic device to keep in the staff area.
Acceptable		A Vendor provides a patient care unit with an anatomical poster to hang in the staff area.
Unacceptable		A Vendor gives tickets to a sporting event as a thank you to the manager of a department that they just signed a service contract with.
Acceptable		A Vendor raffles tickets to a sporting event during a professional function open to all participants, and an employee wins the tickets.
Unacceptable		A Vendor provides a staff member with two tickets to the Annual Hospital fundraising event.
Acceptable		A Vendor purchases tickets for a table at Hospital fundraising event such as the Annual Hospital fundraising event, and donates several tickets back to the Hospital for the Hospital to choose which Personnel it will offer the tickets.
Unacceptable		A staff member is invited by a Vendor to attend an educational seminar and the Vendor will pay for the cost of the attendance, travel, lodging and meal expenses.
Acceptable		A Vendor offers to subsidize an educational seminar sponsored by the Hospital and the Hospital chooses the employee that will attend and will benefit the hospital most from the information provided.

## **APPENDIX B**

### **Items that are reportable under the CMS Open Payments Regulation**

- Travel & lodging (including the specific destination)
- Compensation for serving as faculty or as a speaker for an accredited or certified Continuing Education (CE) program
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program
- Compensation for services other than consulting, including serving as faculty at an event other than a CE program
- Ownership or investment interest (current/prospective)
- Space rental or facility fees (Teaching Hospital only)
- The loan of devices or limited quantities of medical supplies for evaluation/demonstration of over 90 days.
- Consulting fee
- Education
- Research
- Charitable Contribution
- Honoraria
- Gifts
- Entertainment
- Food and beverage
- Grants

### **Items that are Excluded from reporting under the CMS Open Payments Regulation**

- Payments or transfer of value made solely in the context of an existing personal relationship (e.g., one spouse who works for a manufacturer giving a gift to their spouse who is a Physician)
- Payments or transfer of value less than \$10 when the total value for the year is less than or equal to \$100 (This amount to be adjusted in accordance with the consumer price index and published by CMS annually)
- Educational materials that directly benefit patients or are intended for patient use such as patient education materials and anatomical models, but excluding journal articles and textbooks.
- Discounts and rebates
- The loan of devices or limited quantities of medical supplies for evaluation/demonstration of 90 days or less average daily use
- Dividends or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund
- Payments or transfer of value to a physician for services with respect to a civil or criminal action or administrative proceeding or arbitration (e.g., as an expert witness)

- Items and services provided under a contractual warranty, service or maintenance agreement (so long as the contract warranty specifies the terms prior to expiration and the terms do not change)
- Product samples (including coupons and vouchers that can be used by patients to obtain samples) where there is an agreement in writing that the products will be provided to patients
- Payments or transfer of value (e.g., product samples, coupons, or vouchers) received by a physician when he or she is a patient or a subject in a research study
- Payments or transfer of value for the provision of health care services directly paid to a manufacturer's employees or their family or provided through the manufacturer's self-insured plan (e.g., on-site clinic)
- Payments or transfer of value for licensed nonmedical professional services (e.g., a physician-attorney paid only for legal services)
- In-kind items for the provision of charity care (this includes items given to covered recipients who are unable to pay, or for whom payment would be a significant hardship)