

OVERVIEW:

The Morehouse School of Medicine and Morehouse Medical Associates, Inc. ("MSM") is dedicated to improving the health and well-being of individuals and communities; increasing the diversity of the

development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and trainees also participate in interactions with industry off campus and in scholarly publications. Many aspects of these interactions are positive and important for promoting the educational, clinical and research missions of MSM. However, these interactions must be ethical and cannot create conflicts of interest that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the school.

SCOPE OF POLICY:

This policy applies to all medical staff, faculty, staff, residents, interns, students, and trainees of MSM. While this policy addresses many aspects of Industry interaction, it supplements the existing conflict of interest policies of MSM, particularly as they apply to research conflicts of interest:

- Institutional Conflicts of Interest
- Individual Conflicts of Interest
- Research Conflicts of Interest

In all cases where this policy is more restrictive than other MSM conflict of interest policies, this policy shall control.

This policy applies to interactions with all sales, marketing, or other product-oriented personnel of Industry, including those individuals whose purpose is to provide information to clinicians about companies

journals, textbooks, or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system. Meals or other hospitality funded directly by Industry may not be offered in any facility owned and operated by MSM, except as outlined in subsection 5 below.

MSM personnel may not accept meals or other hospitality funded by Industry, whether on-campus or off-campus, or accept complimentary tickets to sporting or other events or other

been responsibly incorporated into the evidence-based decision making of some individual and group practices. While societal benefits result from the availability of medications at the point of care, pharmaceutical samples are not preferred as often their prior storage and handling are suspect (temperature/humidity control), accountability is generally low (pilferage, diversion, theft), documentation is usually weak (incomplete logs), patient directions and patient information are not provided and/or are inadequate, and pharmacist review/profiling is left incomplete.

Therefore, with limited exceptions, sample medications are not permitted in MSM facilities. As an alternative, pharmaceutical sales representatives should be encouraged to offer voucher programs, which allow patients to get starter supplies of medications through organized distribution channels instead of pharmaceutical samples.

A. Definitions

Drug Samples: Prescription and non-prescription medications which are provided to the sites by pharmaceutical representatives for complimentary distribution to patients, as starter doses.

MSM/MMA Sites: Applicable to all MSM facilities where care is provided to patients.

Pharmaceutical Sales Representatives (PSR): A representative of a pharmaceutical manufacturer who visits the ambulatory care sites for the purpose of soliciting the use of, or providing information about, pharmaceutical products. Representatives who visit MSM facilities for the sole purpose of initiating or monitoring research studies are exempt from these guidelines.

B. Standards

1. Drug samples shall not be made available for use by inpatients.
2. Sample medications are not permitted in MSM facilities except as noted in paragraph 4 below. This includes both patient care and non-patient care areas.
3. Vouchers approved by the MMA Operations Committee ("the Committee") may be distributed by MSM ambulatory care sites in order for patients to receive complimentary starter medications from a pharmacy of their choice. The Committee will determine a formulary of MSM-preferred medications, which then may be available through vouchers. Only vouchers approved by the Committee are permitted to be used by MSM clinicians at MSM facilities.
4. Non-

6. Control of drug samples/vouchers shall be monitored jointly by the Clinical Compliance and Privacy Officer and the MMA Associate Dean for Clinical Affairs.

C. Procedure Actions

1. Participating pharmaceutical companies may distribute the Committee-approved vouchers to MSM/MMA clinics through their sales representatives. These vouchers are for generic medications or brand drugs that are designated as "preferred" by the Committee.
2. PSRs may not distribute non-approved vouchers or coupons within MSM sites, or to MSM clinicians.
3. If a clinic medical director believes there is a clinical need to maintain some physical samples, a request will be made to the Committee, the MMA Associate Dean for Clinical Affairs, and the Clinical Compliance and Privacy Officer using the Special Cause Sample Request Form. If the request is approved, the succeeding steps must be followed:
 - a. A formulary of approved sample products must be approved for the clinic and samples of only those products are permitted at the site.
 - b. The approved products must be reviewed annually by the Associate Dean for Clinical Affairs and the Clinical Compliance and Privacy Officer.
 - c. Samples must be stored in a locked secure area that prohibits unauthorized access or that is under constant supervision or surveillance. PSRs are not authorized to have access to drug sample storage areas.
 - d. Samples are properly stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and safety, according to manufacturer's specifications and law and regulation.
 - e. When samples are received from the manufacturer, they must be recorded on the Sample Drug Log-in Form.
 - f. The sample drugs must be inspected by the Associate Dean for Clinical Affairs or designee monthly, and a copy of this review sent to the Clinical Compliance and Privacy Officer.
 - g. Samples are organized to allow for easy retrieval, yet segregated to prevent medication errors. Storage areas must be routinely inspected to check for expired and deteriorated sample medications; samples stored in the wrong place; drugs that can no longer be identified by name, strength, and expiration date; and other medications that do not belong in that area.
 - h. Samples for prescription drugs are labeled and dispensed according to the same standardized method that MSM uses for non-sample prescription medications.

- i. In the event of a drug recall, the Clinical Compliance and Privacy Officer will notify the clinic. The Associate Dean for Clinical Affairs or designee must review sample inventory and return recalled drugs to the pharmacy.
 - j. When dispensing a sample medication to a patient, the physician must select the drug, dose and quantity of medication to be dispensed. This must be recorded in the patient's medical record. The physician must review the dose-pack and patient label with written instructions prior to the medication being dispensed to the patient.
 - k. The physician may delegate to a medical assistant or nurse the following steps:
 - i. Complete the Sample Drug Sign-Out Log.
 - ii. Complete the Sample Medication Label.
 - iii. Document the patient waiver of a child-proof container
 - iv. Obtain final approval from the physician before dispensing
 - v. Provide patient education regarding the medication
4. The Clinical Compliance and Privacy Officer will inspect the sample medication storage, log, and dispensing process at least annually. If adherence to this policy is not being met, the privilege of maintaining samples will be revoked.

4. Site Access

MSM does not allow use of their facilities or other resources for marketing activities by Industry. MSM always reserves the right to refuse access to their facilities or to limit activities by Industry representatives consistent with their non-profit mission. However, interaction with representatives of Industry is appropriate as it relates to exchange of scientifically valid information and other data, interactions designed to enhance continuity of care for specific patients or patient populations, as well as training intended to advance healthcare and scientific investigation.

To balance these interests, MSM's Procurement Office will develop a registry to assist in the management of site access by Industry representatives for appropriate purposes. Sales or marketing representatives of Industry may access MSM facilities only if the company with which they are associated has registered with the MSM Procurement Office, and they have been specifically invited to meet with an individual healthcare provider or a group of healthcare providers for a particular purpose. Individual physicians or groups of physicians or other healthcare professionals may request a presentation by or other information from a particular company through the MSM Procurement Office or other designated institutional official.

Industry representatives should not be permitted in any patient care area unless each of the following exceptions is met:

- A. The representative is present to provide in-service training on devices and other equipment, including provision of essential guidance on the use of such equipment.
- B. The presence of the representative is expressly requested and approved in advance by a faculty member.

completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the associate dean for graduate medical education. Written documentation of the selection process will be maintained.

b.

