




INDUSTRY RELATIONS POLICY	PENNSTATE HERSCHEY  Milton S. Hershey Medical Center
Hospital Administrative Manual	Policy Number: A-89 HAM
Replaces: September, 2012	Effective: November, 2014
Authorized: A. Craig Hillemeier, M.D. Chief Executive Officer Senior Vice President for Health Affairs and Dean, College of Medicine 	
Approved: Alan L. Brechbill Executive Director 	

PURPOSE

To establish guidelines for interactions between industry representatives and PSHMC employees and trainees.

INTRODUCTION:

The relationship between the Penn State Hershey Medical Center (PSHMC) and the pharmaceutical, device, and other health care related industries (INDUSTRY) is complex and multifaceted. Our organization is committed to having responsible interactions with industry representatives in ways that further the core missions of PSHMC. This document outlines a framework for such interactions, contextualized within the organizational mission and values¹.

Because Penn State Hershey Medical Center is committed to delivering the highest quality medical care with the highest levels of integrity and professionalism, physicians and staff are committed to avoid real or perceived conflicts of interest that would compromise our integrity, undermine the public trust, and/or affect medical decisions or judgments. With the growing awareness that the marketing practices of industry influence medical practice and patient care, the following observations and principles inform the PSHMC Industry Relations policy:

1. The primary obligation of health care professionals is to promote the health and well-being of the patients and communities they serve.
2. As such, PSHMC employees, trainees, students, and volunteers should identify and eliminate activities that undermine the performance of this primary obligation.
3. Academic medical centers have an obligation to establish policies that promote professional behaviors and further the importance of patient welfare.
4. There is a growing body of social science literature demonstrating that industry's interactions with physicians affect professional behaviors (1-3).
5. Although many physicians do not believe they are personally susceptible to such influences (4), the evidence shows that physicians are collectively influenced. Physicians' interactions with industry correlate, for example, with their prescribing newer, more costly drugs—whether or not these newer products offer substantial benefit over existing therapies (5, 6).
6. Existing policies do not sufficiently address the potential conflicts of interest that arise from industry's interactions with physicians' (7).

¹ <http://infonet.hmc.psu.edu/facts/summit/vision.htm>

7. Failure to address these concerns threatens to undermine public trust in the medical profession (8, 9).
8. Leaders within academic medicine have called for greater self-regulation of industry interactions at academic medical centers (7), more than 60% of academic medical centers have adopted policies banning gifts and free meals, (AMSA PharmFree Scorecard, American Medical Student Association, 2013 <http://www.amsascorecard.org>), and the AAMC has issued Industry Relations recommendations (10).
9. To promote and enhance the trust of patients and others served by PSHMC, and to support the institutional values of honesty, integrity and excellence, PSHMC's Industry Relations policy aims to establish whether particular kinds of interactions with industry are **permitted, discouraged or prohibited**. The goal is to eliminate conflicts of interest when possible, and reduce and/or manage those that remain.

SCOPE:

This policy is intended to cover interactions that involve marketing of products or services, on-site training, and/or education. It applies to all faculty, staff, residents, students and trainees at PSHMC. Excluded from this policy are interactions with industry concerning clinical or basic science research — with the one exception of academic authorship (discussed below, under Speakers Bureaus and Academic Activities).

CROSS REFERENCES:

While this policy addresses many aspects of industry interaction, it supplements other policies and practices, including:

RA20	Individual Conflict of Interest
A60 HAM	Conflict of Interest Policy
HR80	Private Consulting Practice
A20 HAM	Code of Ethical Behavior
A65 HAM	Vendor Visitation/Solicitation to Clinical/Non-Clinical Work Areas

612 PAM Pharmacy and Therapeutics Committee: Conflict of Interest

DEFINITIONS:

INDUSTRY refers to any company or entity selling goods or services related to health care or the education of health care providers.

GIFTS include, but are not limited to, the following:

- Cash, loans, gift certificates, discounts
- Food, beverage, or entertainment (or vouchers for such items)
- Trinkets (e.g., pens, notepads, clocks, and other office items)
- Professional accoutrements (e.g., calipers, penlights, I.D. holders)
- Books, manuals, models, and other such educational items
- Services
- Drug samples (when given to PSHMC employees or trainees)
- Travel

CONFLICTS OF INTEREST: Financial conflicts of interest occur when reasonable observers could conclude that someone's personal financial interests could conflict with their professional responsibilities to their patients, students, or community. In terms of industry influences, financial conflicts of interest occur when any financial interests in or financial relationships to Industry could cause (or be perceived to cause) physicians, other health care providers, or students to deviate from their professional obligations for economic or other personal gain (7).

MANAGEMENT OF CONFLICT OF INTEREST: In some cases, appropriate management of a conflict of interest will mean eliminating the conflict (e.g., outside relationship or activity) altogether. In other cases, appropriate management may involve careful monitoring and reporting of the activities, allowing activities with value to patients or society to go forward with assurances that the integrity of the individual and institution will be protected. These situations will require careful review, monitoring, and documentation (11).

SPECIFIC ACTIVITIES:

I. Gifts and Compensation

Gifts from industry are a form of marketing intended to create a relationship that can influence decision-making. Though it is hard to know how much any particular decision is influenced by receipt of a gift, the practice has been shown to influence physicians' behavior in the aggregate (3).

- A. As such, industry representatives are prohibited from giving any form of gift to physicians and other faculty, staff, students, and trainees as part of any activity related to their Penn State appointment.
- B. Physicians and other faculty, staff, students, and trainees may not accept any gifts from industry representatives, including meals and gifts of trivial material value, as part of any activity related to their Penn State appointment.
- C. Moving an interaction with industry representatives to an off-campus location in order to avoid these restrictions would be in violation of this policy.
- D. When attending off campus meetings, conferences, etc., as private individuals rather than as Penn State employees, faculty, staff, students, and trainees are discouraged from accepting gifts (which includes meals) from industry representatives.
- E. Gifts containing industry brands and/or logos such as clocks, posters, post-it pads, etc. are marketing tools, and should not be displayed in clinical and teaching areas. Anatomic models or charts that are deemed critical for patient education are permitted, but non-branded versions are preferred.
- F. Employees and trainees may not accept any form of compensation for listening to a promotional presentation ("detailing") by an industry representative.
- G. Employees and trainees may not accept any form of compensation or rebate for prescribing or changing a patient's prescription.
- H. Even if a gift is covered by an exception, staff may not accept a gift if it would undermine the appearance of PSHMC's integrity.²
- I. Any relationships with, or financial interests in, industry must be disclosed to the

² Gifts from Vendors/Business Associates, A73 HAM

University.

II. Food

- A. Industry-sponsored meals in the workplace are not permissible on campus, with the exception of food provided in connection with Accreditation Council for Medical Education (ACCME) accredited programming and in compliance with ACCME guidelines (12).

III. Site Access by Pharmaceutical Representatives

- A. Access to physicians and providers is by faculty invitation and appointment only. Interactions with trainees, students, or staff without faculty invitation and oversight are not permitted. Such interactions are permitted if there is faculty oversight and if the interactions are part of the students' professional education. Interactions are restricted to non-public and non-patient care areas. Pharmaceutical representatives wishing access to the PSHMC campus must register with the Purchasing Department and agree to abide by PSHMC policy A65 HAM³ prior to engaging in any interaction with PSHMC physicians, providers or trainees.
- B. An appointment with one individual or group does not grant permission to meet with other individuals or groups, and upon completion of an appointment, industry representatives must promptly leave the area.
- C. Pharmaceutical representatives who wish to provide educational information on their products may do so by invitation only, in faculty-supervised structured settings that provide the opportunity for interaction and critical evaluation.

IV. Site Access by Device Manufacturer Representatives

- A. Access to physicians and providers is by faculty invitation and appointment only. Interactions with trainees, students, or staff without faculty invitation and oversight are not permitted. Such interactions are permitted if there is faculty oversight and if the interactions are part of the students' professional education. Representatives must be appropriately credentialed and adhere to procedures outlined in policy A65 HAM.
- B. Accepted purposes for physician and provider contact with device manufacturer representatives include:
- Training for new equipment or new procedures with existing equipment
 - Training for a complex procedure requiring technical consultation
 - Product and equipment trials or demonstrations
 - Research and/or field testing of unreleased products or devices
 - Other contacts by approval from the department Chair
- C. Device manufacturer representatives are not permitted to be present during any patient care interaction except under very special circumstances, and then only if there has been prior disclosure to and consent by the patient, and for the purpose of providing in-service training, demonstration, or assistance on devices and equipment.
- D. Additionally, representatives:
- May not touch patients

³ Vendor Visitation/Solicitation to Clinical/Non-Clinical Work Areas A65 HAM

- May not operate any PSHMC equipment or devices, except under extenuating circumstances (e.g. equipment malfunction) or to provide specialized training under the direction of a PSHMC physician
- May not have access to patient records except with HIPAA-compliant prior authorization

V. Other Contact With Industry Representatives

- A. Industry representatives may not attend Grand Rounds, Departmental meetings, or other PSHMC gatherings except by invitation.
- B. Industry representatives may not provide educational materials to PSHMC employees and trainees unless requested by a faculty member. However, upon request, representatives may provide such materials provided they are: 1) peer-reviewed (e.g., journal articles, The Medical Letter, Prescriber's Letter, Cochrane reviews, etc.), and 2) for educational purposes.
- C. Interactions with industry representatives during non-work hours are permitted as long as they are not in violation with other aspects of this policy. However, these interactions are to be viewed with caution, since many such interactions involve marketing tactics intended to influence behavior, which would violate the spirit of this policy.

VI. Financial Support for Educational, Training, and/or Professional Activities

- A. Because Industry support of students and trainees may involve real or perceived conflicts of interest, financial support must be specifically for the purpose of education, training and/or professional activities, and must comply with all of the following provisions:
 - Support is provided to the Department, Institute, or Division, not to individual faculty, trainees, or students
 - Support complies with ACCME Standards for Commercial Support whether or not CME credit is awarded (12)
 - Support is documented for record-keeping purposes
 - Support is fully disclosed
 - The recipient is not subject to any implicit or explicit expectation of providing something in return for the support (i.e., no quid pro quo)
 - No materials carrying a product (or company) name or logo are distributed
- B. Financial support to defray travel/lodging/registration costs for PSHMC employees or trainees to attend educational or professional conferences is permissible, provided that:
 - Funds are given as part of an unrestricted educational grant administered by the Department, Institute, or Division
 - Selection of PSHMC employees or trainees for such support is made by the Department, Institute, or Division without input from the industry sponsor
 - There is no expectation (explicit or implicit) of anything being received in return for such support
- C. Payment to attend a lecture or conference qualifies as a gift, and therefore is not permitted. The same holds true for any payment/compensation for time at

professional meetings.

VII. Academic Presentations and Publications

Paid presentations for the purpose of marketing products on behalf of commercial enterprises (“Industry”) to the public or health care professionals are prohibited.

Presentations sponsored by Industry are permitted, provided that the following conditions are met:

1. The presentation is the work of the speaker;
2. Any Industry-prepared material is identified as such, and not presented as the speaker’s own prepared information;
3. The speaker provides a fair and balanced discussion of the topic;
4. The speaker may be identified using his/her PSHMC academic title during the presentation itself, its introduction, and on invitations to the presentation. However, no reference may be made to the speaker’s PSHMC title or affiliation in any promotional material for the product or company sponsoring the presentation.
5. The speaker states in the presentation and handouts that their presentation does not reflect the views or endorsement of PSH;
6. The speaker’s compensation is not excessive and reflects reasonable market value
7. Any contractual relationship with Industry (including payment and equity) is fully disclosed before or during the presentation.

Failure to adhere to any of the above requirements will be considered a violation of the PSH Industry Relations Policy.

Professional publications must reflect the highest standards of scholarship and integrity of the scientific process. Therefore:

1. Payment from Industry to be named as an author of a peer-reviewed publication without meeting the requirements of authorship (i.e., “ghostwriting”) is strictly prohibited
2. Individuals listed as an author on a manuscript submitted for publication must meet established criteria for authorship as required by major scientific journals. This includes making reasonable efforts to ensure that any article on which one’s name appears as an author was not ghostwritten.

VIII. Consulting with Industry

It is a priority for PSHMC to promote meaningful, productive relationships with industry in order to further shared values and goals. PSHMC acknowledges the value of permitting academic medical center faculty to interact appropriately with industry. Examples of appropriate interaction include faculty participation on industry boards of directors and scientific advisory

boards as well as services provided through professional services agreements and consulting contracts, provided such activities are conducted in full compliance with other policies of the medical center and applicable law, and that compensation reflects the fair market value of the services provided. As such:

- A. PSHMC employees or trainees may serve as consultants, to the extent that such consulting involves legitimate professional activities.
- B. Such activities must be consistent with PSHMC consulting policies⁴, and reimbursement should reflect fair market value.
- C. Participation in activities for marketing purposes such as telephone “interviews,” expert panels, or marketing surveys is prohibited on campus or with the use of Penn State resources including email.

IX. Drug and Product Samples

In accordance with Pharmacy Policy 511 PAM Drug Use: Medication Samples, providing pharmaceutical and product samples to either inpatients or outpatients is not permitted within the Penn State Hershey Medical Center or Health System.

The rationale for the policy includes the following:

- The samples provided are typically the newest (and often most expensive) medications or products that may not be first-line treatment for the presenting medical problem
- Patients started on drug samples are often continued on these medications when lower cost alternatives exist (5, 6, 13)
- Physician prescribing habits can be influenced by the use of samples (14)
- Generic or older/cheaper products are typically not provided
- Direct dispensing by physicians bypasses the services that pharmacists typically provide, thereby increasing the chance of dosing and drug interaction errors, and this can compromise patient safety
- Drug samples are more likely to be distributed to the wealthy and insured (15) than to the poor or uninsured

X. Drug Formularies

- A. PSHMC faculty who serve on the PSHMC Pharmacy & Therapeutics Committee and/or other committees involved in drug or device purchasing decisions should not have financial conflicts of interest involving industries that may benefit from institutional decisions in which they are involved. Such conflicts of interest include:
 - Direct equity ownership in the company
 - Compensation for position on advisory boards
 - Serving as a paid consultant
 - Serving on an industry speaker’s bureau
 - Receiving grants from industry as an individual
- B. If real or perceived conflicts are present, they must be disclosed to the Conflicts of

⁴ Penn State University Policy HR80 Private Consulting Practice

Interest Review Committee, and managed according to the Pharmacy and
Therapeutics Committee Conflict of Interest Policy (PAM 612)

PERSON RESPONSIBLE FOR REVIEW

Chief Medical Officer

Administrator, Support Services Integration

REFERENCES

Analytical Framework - Attachment A

Industry Relations Policy Consensus – Attachment B

Reviewed: 9/12, 11/14

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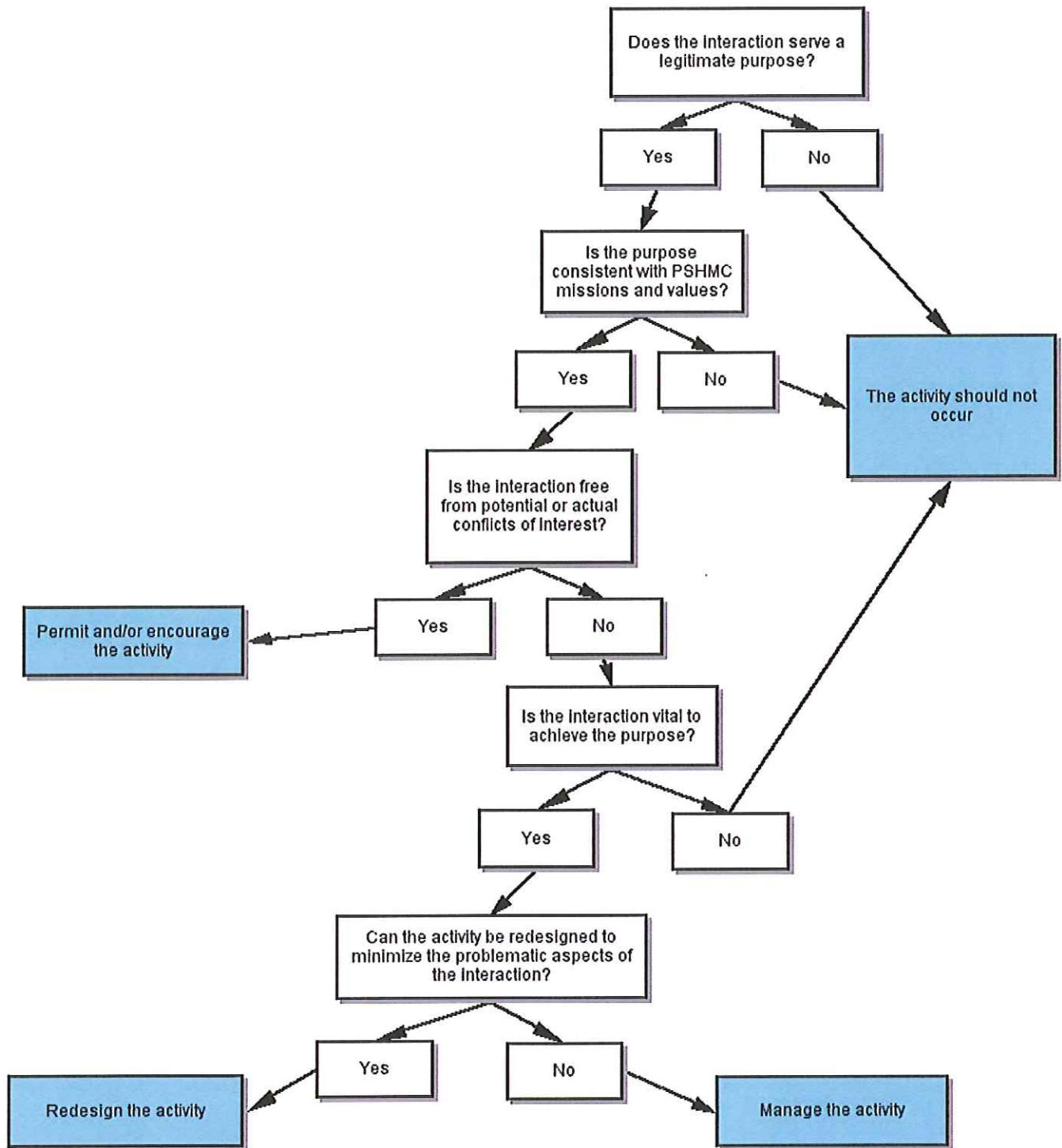
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Attachment A

ANALYTIC FRAMEWORK

In determining whether a particular interaction with industry is appropriate, the following analytic framework has been applied.



Attachment B

Industry Relations Policy Consensus

The following grid represents the collective recommendations of PSHMC Departments and Institutes, in compliance with the 2008 AAMC Task Force on Industry Funding of Medical Education report (1).

	Permit	Discourage	Prohibit
Gifts to Individualsⁱ			
On campus			☐
Off campus		☐	
Industry-sponsored meals in the workplace			☐
Industry-branded merchandise			☐
Compensation for listening to detailing			☐
Compensation or rebate for prescribing a particular medication			☐
Site Access by Pharmaceutical Representativesⁱⁱ	Permit	Discourage	Prohibit
Employee contact with industry representatives at work	☐		
Employee contact after-hours		☐	
Patient contact			☐
Access to medical records			☐
Attending medical conferences or departmental meetings		☐	
Providing educational materials to employees		☐	
Site Access by Device Representatives⁴	Permit	Discourage	Prohibit
In patient care areas	☐		
Patient care interactions	☐		
Access to medical records			☐
Financial Support for Educational, Training, and/or Professional Activities	Permit	Discourage	Prohibit
Support to individuals			☐
Support to Departments or Divisions	☐		
Support to defray travel/lodging/registration	☐		
Payment to attend conference			☐
Marketing Presentations and Ghostwriting	Permit	Discourage	Prohibit
Paid marketing presentations for industry			☐
Payment from industry representatives to serve as an author on an academic article			☐
Participation in ghost written article			☐
Consulting with Industry	Permit	Discourage	Prohibit
Paid consulting with industry	☐		
Participation in marketing activities (phone interviews, expert panels, surveys, etc.)		☐	
Drug or other Product Samples	Permit	Discourage	Prohibit
Establishing a sample closet			☐
Diversion of samples by providers for use by self or families			☐
Selling samples to patients			☐

- 1 Refers to any gift, regardless of value
- 2 Moving an interaction with industry representatives to an off-campus location in order to avoid gift restrictions would be in violation of this policy. When attending off campus meetings, conferences, etc., faculty, staff, students, and trainees are discouraged from accepting gifts (which includes meals) from industry representatives.
- 3 With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines
- 4 Unless critical for patient education and otherwise unavailable (e.g. growth charts, anatomic models, etc).
- 5 Must comply with A-65 HAM
- 6 By faculty invitation and appointment only and restricted to non-patient care areas. Interactions with trainees or staff without faculty invitation and oversight are not permissible.
- 7 Must be in compliance with all other aspects of this policy
- 8 By faculty invitation only
- 9 Only upon employee initiation; should be peer-reviewed
- 10 With proper credentialing and by faculty invitation and appointment only
- 11 Representatives are not allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patients, and then only to provide in-service training or assistance on device equipment
- 12 Must be in the form of unrestricted grant; no quid pro quo
- 13 In the form of unrestricted grants to the Department/Institute/Division and not to individuals
- 14 Must be in compliance with HR80, and compensation should not exceed fair market value
- 15 Should be centrally managed

Bibliography

1. Association of American Medical Colleges. Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council. Washington DC; 2008 June 18-19, 2008.

ⁱ Refers to any gift, regardless of value

ⁱⁱ Must comply with A-65 HAM