

Hospital of the University of Pennsylvania Clinical Practices of the University of Pennsylvania Clinical Practice Guideline	Number: 1-07-10 Page 1 of 3
SUBJECT: Guidelines for Interactions between Healthcare Professionals and Industry	Effective: 9/27/06

KEY WORDS:

PhRMA
 Drug representatives
 Detail men/women
 Device manufacturers
 Professional behavior
 Organizational ethics
 “Gifts to Physicians from Industry”

SEE ALSO

1-09-07 “Sample Medication Voucher Program”

 #1-12-10 “Organizational Ethics”

 #1-12-41 “Pharmaceutical Company Representative Activity”

 #1-12-H4 “Business Associates”

Purpose:

The purposes of these guidelines are

- to define appropriate interactions of Hospital of the University of Pennsylvania (HUP) and Clinical Practices of the University of Pennsylvania (CPUP) healthcare professionals with the pharmaceutical industry; and
- to minimize undue influence of pharmaceutical and medical device manufacturers’ representatives on the practice patterns of HUP/CPUP professionals.

Healthcare professionals should use objective and evidence-based sources of information to make clinical decisions, rather than information obtained through the marketing efforts of pharmaceutical companies and medical device manufacturers (collectively “Industry”).

Scope:

These guidelines apply to all HUP/CPUP healthcare professionals, including physicians and physicians-in-training, physicians’ assistants, pharmacists, nurses and nurse practitioners, therapists, and any other professionals (collectively “Professionals”) whose clinical decision-making directly affects patient care.

Implementation:

HUP/CPUP Professionals, Department Chairs, Divisional Chiefs and training program directors are responsible for implementation of these guidelines.

Procedure:

A. Meals and Gifts

1. Professionals should not accept gifts, hospitality, services, or subsidies from Industry including but not limited to those for sporting events, entertainment, or any other function not directly related to patient care. Professionals’ spouses or other guests may not have their meals or other expenses paid for by Industry. Educational resources to which all HUP/CPUP Professionals have access (for example, UpToDate online at HUP/CPUP) and unrestricted support for Continuing Medical Education (“CME”) are preferred.
2. Industry representatives may provide educational grants for non-CME programs through departments and divisions only. At the discretion of the Chief or Chair, such support may be used for medical education purposes including honoraria and expenses for extramural lecturers and the provision of modest meals. Support for CME may only be made through educational grants made directly to the Trustees of the University of Pennsylvania/CME. All commercial support grants associated with a CME program must be given with the full knowledge and approval of the University of Pennsylvania School of Medicine (U of Penn SOM) Office of CME. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter and the U of Penn SOM Office of CME. Educational grants should not be made

SUPERSEDES: 7/1/06 Professional_Industry_Guidelines sept 2006.doc	ISSUED BY: /s/ M. Sean Grady, M.D.
	/s/ David W. Kennedy, M.D.

Hospital of the University of Pennsylvania Clinical Practices of the University of Pennsylvania Clinical Practice Guideline	Number: 1-07-10 Page 2 of 3
SUBJECT: Guidelines for Interactions between Healthcare Professionals and Industry	Effective: 9/27/06

or conditioned or related in any way to any pre-existing or future business relationship with the Industry company or any business or other decisions UPHS has or may make relating to the Industry company or its products (including coverage or formulary status decisions). The educational content must be controlled by the Course Director (for a non-CME program) or, by the U of Penn SOM Office of CME (for a CME program), and not by the pharmaceutical company providing the educational grant.

Meals must be accompanied by a legitimate educational program.

B. Industry Contact with HUP/CPUP Professionals

1. Industry will not use the resources of educational or administrative offices of HUP/CPUP clinical departments to inform Professionals of promotional Industry-sponsored events.
2. Announcements of promotional Industry-sponsored events off campus may not be made via any mass mechanism, including UPHS or Penn e-mail, regular mail, e-page, or other mechanism controlled by UPHS, unless the event satisfies the conditions in Section B, Number 1.
3. Educational or administrative offices, including residency and fellowship program offices, may not give promotional Industry representatives e-mail distribution lists or mailing lists to be used for announcement of Industry-sponsored events or meals, unless the event satisfies the conditions in Section B, Number 1.
4. Professionals may not accept compensation for time spent listening to Industry representatives detailing their products.
5. Industry representatives may interact with Professionals in certain designated areas. These are non-patient care areas, including non-patient sections of professionals' offices, and public areas (such as the cafeteria). Professionals may not interact with Industry representatives in patient care areas, including inpatient units, nursing stations, conference rooms of patient care units, physician lounges, patient care areas of outpatient offices, perioperative and operative areas, and the Emergency Department.
6. Industry representatives may not attend Professionals' conferences or reports. Representatives may not see patients, review any part of the medical record (whether in electronic or paper format), go on rounds, or attend surgery without patient authorization or an appropriate Business Associate Agreement (see HIPAA Policy #1-12-H4 regarding Business Associates).
7. Professional staff may not participate in Industry sponsored financially remunerated on-line marketing activities during the work day. This prohibition extends to third party organizations that produce marketing or educational materials for the pharmaceutical industry.

C. Sample Medications

HUP/CPUP Professionals may not accept medication samples from Industry representatives. See HUP/CPUP policy #1-09-07 "Sample Medication Voucher Program in the Clinical Practices of the University of Pennsylvania."

SUPERSEDES: 7/1/06 Professional_Industry_Guidelines sept 2006.doc	ISSUED BY: /s/ M. Sean Grady, M.D.
	/s/ David W. Kennedy, M.D.

Hospital of the University of Pennsylvania Clinical Practices of the University of Pennsylvania Clinical Practice Guideline	Number: 1-07-10 Page 3 of 3
SUBJECT: Guidelines for Interactions between Healthcare Professionals and Industry	Effective: 9/27/06

D. Formulary

Professionals and other staff who participate in decision-making roles regarding the selection of pharmaceuticals, devices and other purchases by HUP and CPUP must not have conflicts of interest. Professionals and other staff members who are consultants but not decision-makers in these processes must actively disclose their significant financial or other relationships with the Industry entity that provides the product and its competitors prior to the Professional or other staff member’s participation in the selection process.

E. Consulting/Travel:

1. HUP/CPUP Professionals should not participate in Industry marketing activities.
2. Professionals may accept reimbursement (of travel, meals and other expense) for presenting research findings at a meeting, presenting on clinical topics or consulting during their “1 day in 7” time (for full time members of the University of Pennsylvania Faculty), provided that the expenses are reasonable in relation to the services provided (fair market value). With regard to reimbursement to HUP/CPUP for enrollment of patients in clinical trials, the amount of reimbursement should cover the direct and indirect costs to the University of Pennsylvania, should be part of the study budget and proportionate to the scientific value of the clinical trial. Professionals may not accept reimbursement to provide lists of patients to Industry (for example, a list of patients taking a certain medication or class of medications).

HUP/CPUP Professionals may not accept funds directly from Industry for the purpose of attending conferences or meetings in a passive capacity, with the exception of trainees as described below. However, a company may pay reasonable reimbursement (of travel and meals) for an investigator to present research findings at a meeting if the company funds the research. In the case of Professionals-in-training or other trainees, conference funds may be donated to a clinical department/division, provided that department faculty (and not the company) chooses the trainee to receive the funds for attending the meeting. For CME-certified activities, reimbursement for travel, lodging, honoraria or personal expenses may not come directly from Industry. U of Penn SOM Office of CME may use funds from the educational grant to reimburse these expenses only for bona fide faculty, employees and volunteers of the provider, joint sponsor, or educational partner.

F. Housestaff Education:

With regard to physicians-in-training, departmental curricula will include discussion and reflection on managing encounters with Industry representatives, and housestaff should be instructed on how promotional activities may influence judgment in prescribing decisions and research activities. Training on the influence of physician-pharmaceutical/Industry representative interactions will be included for housestaff during the first year of HUP/CPUP training programs. Each clinical department or division within HUP/CPUP will educate its Professionals in appropriate prescribing practices at least annually.

SUPERSEDES: 7/1/06 Professional_Industry_Guidelines sept 2006.doc	ISSUED BY: /s/ M. Sean Grady, M.D.
	/s/ David W. Kennedy, M.D.