Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools

COMMUNITY CATALYST

COI Toolkit on Relations with Sales Representatives

Relations with Sales Representatives

I. Introduction

The pharmaceutical industry invests heavily in marketing directly to prescribers. Spending on pharmaceutical sales representative promotion ("detailing") in 2011 was $6.6 billion, as reported in a survey of firms by IMS, while total promotional spending on prescribers was $10.7 billion, excluding samples.[1]

Primary care physicians and specialists met with pharmaceutical sales representatives (PSRs) an average of twice a month in 2009, according to a national survey.[2] Nearly all nurse practitioners reported having regular contact with PSRs (96 percent) in a 2008 national survey.[3] In 2013, about one in five residents reported turning to sales representatives to learn about drugs, despite policies limiting some activities by PSRs at many academic medical centers.[4]

Physicians who reported interactions with the pharmaceutical industry had a greater propensity to prescribe more expensive brand-name drugs when less expensive generic drugs were available than those physicians who did not have these interactions.[2] A recent systematic review found that in a majority of studies, physicians who received information from PSRs exhibited more frequent prescribing of the promoted drugs, while in no studies did they exhibit less frequent prescribing of these drugs.[5]

PSRs play a key role in complex promotional strategies[6] that may also be illegal. In a long list of multi-million-dollar and even billion-dollar fines imposed by the government on pharmaceutical companies, documents show that half the penalties were for such illegal promotion.[7]

Frequently, information provided by PSRs is biased, incomplete or inaccurate.[8] Given this evidence, why would prescribers meet with them at all? Some argue it is appropriate for prescribers to meet with PSRs because the bias can be overcome and good information gleaned from the presentations. Furthermore, the argument goes, most prescribers will meet with PSRs once they are in practice, therefore it is incumbent on faculty to teach trainees how to interact with them in a controlled setting where misinformation can be detected and discounted.[9]

These arguments do not withstand scrutiny. While quick and easy access to drug information may have been more difficult and time-consuming a decade ago, such is not the case today. Prescribers can subscribe to independent drug bulletins,[10] and there is now almost instantaneous

"Trainees need to understand that pharmaceutical reps are not colleagues, teachers, or pals. Their job is to get you to use their products, whether or not they are the best choice for your patients."

— Jerry Avorn, M.D. Professor of Medicine, Harvard Medical School

access by computer to objective, unbiased information about drugs. Using such sources is more time efficient than meeting with a series of PSRs promoting their products. PSRs are also unlikely to provide information on generic drugs or non-drug alternatives to treatment.

Those who prescribe medications have a professional duty to do what is in the best interest of their patients and be mindful of the finite resources available for health care in general.[11] If meeting with PSRs is detrimental to those goals, then the best role modeling faculty can provide is to decline to meet with PSRs. By doing so, they set high standards of professionalism that can buttress a new physician's decision to forego interactions with PSRs. Indeed, there is some evidence that PSR access to private practices is declining, with approximately 25 percent of physicians now unwilling to see PSRs at any time and 50 percent only by appointment.[12]

While many medical schools and academic medical centers have instituted policies to restrict and regulate the way PSRs interact with faculty, staff, and trainees, few have excluded PSRs completely. We recommend that more should do so.

Medical device sales representatives

Relations with these sales representatives present a different challenge because those individuals are often needed to provide training in the use of the device. However, policies and practices should assure that activities of the device sales representative are confined to training exclusively.

"As a new medical school, we wanted to inculcate COI policies from the beginning to ensure patient safety, garner public trust and protect the integrity of our education."

— Alma B. Littles, MD, Senior Associate Dean, Florida State University College of Medicine

II. Policy Considerations

Exclude pharmaceutical industry sales representatives

Pharmaceutical representatives should not be allowed to meet with faculty, staff, or trainees regardless of location, nor should they be permitted to market their products anywhere inside the medical center and associated clinics and offices.

Supervise medical device sales representatives

Medical device representatives may provide training on devices or equipment, but are excluded from marketing. The training should be arranged by appointment only and closely supervised. Nurse administrators have proved to be good supervisors of such activities by, for instance, controlling access by device representatives to the OR. Vendors should wear an identification badge that clearly identifies them as vendors, and when the training is over, the vendor should leave the medical center.

Restrict interactions if exclusion is not possible

If it is not possible to promulgate policies excluding industry sales representatives, then their activities should be restricted. Vendors should be permitted in the health center by appointment only and should be required to sign in at a designated office where the appointment can be verified. Vendors should wear an identification badge that clearly identifies them as vendors. When the scheduled appointment is over, vendors must sign out and leave the health center premises.

Supervise trainees

Trainee interaction with vendors, if it is allowed to occur, should be viewed as an educational experience and should be supervised by faculty. Supervision should focus on helping the trainee judge the veracity and completeness of the information received from the vendor, while ensuring the trainee receives appropriate information on alternatives, including generic drugs and non-drug therapies, and knows how to evaluate the comparative risks, costs, and benefits of treatment alternatives.

Specify methods to assure compliance and enforcement

Clearly delineate responsibility for overseeing vendor relations in the health center, preferably to a single central office that will oversee all vendor interactions with health center staff. Specify the penalties for violations of the policies, which should include permanent exclusion from the facility by company representatives when there are repeated violations. Have every vendor read the policies and sign a statement attesting to their understanding and acceptance of those policies.

III. Provide Alternative Sources of Information

Clinical pharmacists

Clinical pharmacists can inform prescribers about new drugs, new indications for existing drugs, adverse event warnings, cost information, therapeutic comparisons, and alternative treatments. This information can be shared through online newsletters, emails, departmental presentations, or one-on-one meetings. Clinical pharmacists should be available for formal consultations at the request of prescribers.

Online resources

Prescribers on staff should have immediate access to online resources that can provide objective information on drugs such as *The Medical Letter, Therapeutic Guidelines, Prescrire International (in English), and the BMJ Drugs and Therapeutics Bulletin.*

IV. Examples of Model Policies

UNIVERSITY OF SOUTH DAKOTA SANFORD SCHOOL OF MEDICINE

Industry representatives can not market their products anywhere in the medical center and associated clinics and offices, nor are they permitted to consult with faculty on a professional basis, except for device/equipment training.

FLORIDA STATE UNIVERSITY COLLEGE OF MEDICINE (FSU COM)

Preamble

It is the policy of the FSU COM that pharmaceutical/industry access to students, faculty, and residents, is prohibited on FSU COM property, including regional medical school campuses. However, discussion with representatives for the purpose of obtaining unrestricted educational grants is allowed.

"We engaged our clinical chairs, and showed data to our students, creating a dialogue that moved us in the right direction."

— Janet C. Lindemann, MD, MBA, Dean of Medical Student Education, Sanford School of Medicine, University of South Dakota

This policy applies to all FSU COM full-time faculty and part-time faculty (clerkship directors, clerkship faculty, elective faculty) when performing their duties on FSU COM property.

Site Access
Pharmaceutical/Industry Representatives are not allowed access to faculty, students, residents or staff on FSU COM property, including its regional campuses, except for the purpose of discussing/providing unrestricted educational grants.

LAHEY CLINIC, MASSACHUSETTS *(Access Tightly Regulated)*

Vendor Sales Representative Visits to Lahey Clinic

Registration
At the time of their initial visit to Lahey Clinic, all Vendor sales representatives must first register with the pharmacy administrative assistant in the main pharmacy of the Lahey Clinic facility.

Each Vendor sales representative must sign a registration form indicating that he/she has read and understood the policies governing the conduct of Vendor sales representatives.

Sign-in
Each time a Vendor sales representative visits Lahey Clinic he/she must proceed directly to the Security Department, sign in and procure a temporary visit badge with the date of that visit. The visitor badge must be visible at all times while the Vendor sales representative is on the premises.

Authorized Visits
All visits by Vendor sales representatives to Lahey Clinic personnel must be made on an appointment only basis. Sales representatives must call the person (or administrative assistant) they wish to visit and arrange an appointment time. Appointments should be scheduled before a Vendor sales representative's visit to Lahey Clinic, but if necessary, may be made while on the premises.

Access to Patient Care Areas
Vendor sales representatives are prohibited from entering patient care areas, except that Vendor sales representatives may access patient care areas when (1) access is required for training on new equipment or devices already purchased, or (2) access is required in operating rooms to assist surgeons or to help develop competency with equipment. Vendor sales representatives may not enter patient care areas unless there is disclosure to, and consent by, the patient.

Access to Trainees
Vendor sales representatives may interact with trainees only for educational purposes and under the supervision of Lahey faculty.

V. References

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http://tinyurl.com/AmcModelCoiPolicy

The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.