Recognizing and Avoiding Financial Conflicts of Interest – A Professional Staff Activity Concerning Financial Relationships Between Health Care Professionals and Industry

OVERVIEW

The goals of the activity are to:

1. Familiarize clinical staff and trainees with the VHA policy on Financial Relationships Between Health Care Professionals and Industry
2. Explain the ethical justification for this conflict of interest policy
3. Give health care professionals a clear way to talk about conflict of interest
4. Summarize VHA employees’ responsibilities related to financial conflicts of interest with industry

Learning objectives:
At the end of this activity, participants will be able to accomplish all of the following objectives:

- Describe their responsibilities under VHA Handbook 1004.07
- Summarize the evidence that supports conflict of interest policies
- Identify a possible conflict of interest
- Identify the correct response to a possible conflict of interest
- Disclose or seek guidance about a conflict

Session Timing:

1. 30-40 minutes
   a. Overview of conflicts of interest and policy (slides 1-11): 10 minutes
   b. Scenarios (slides 12 and 13): 12-15 minutes
   c. Recap and references (slides 14-1): 3 minutes

Materials:

1. Handouts:
   a. Avoiding Financial Conflict of Interest with Industry
   b. Interactive Exercise
2. Slides with speaker’s notes
3. References
Facilitator Notes:
Before the training, the facilitator should print out and package the handouts together for the participants. Notes are included in the presentation about when participants should refer to the worksheets. References are included for later study.
Handout: Avoiding Financial Conflict of Interest

All VA employees have a duty to abide by Federal conflict of interest law, also called "government ethics". Under the law, VA employees are prohibited from using their public office for private gain or participating in official matters that otherwise involve a criminal conflict of interest or give the appearance of such conflict of interest. If you have more questions about government ethics law, you can consult a Government Ethics Official in the VA Office of General Counsel.

In addition to government ethics obligations, VHA health care professionals have a separate professional obligation to place the interests of patients above self-interest, including financial self-interest. These responsibilities are summarized below. If you have more questions about ethical obligations of health care professionals, you can consult VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, Frequently Asked Questions: Financial Relationships Between VHA Health Care Professionals and Industry, or you can contact the National Center for Ethics in Health Care.

To whom does the policy apply? This policy applies to VHA Health Care Professionals, defined as full-time, part-time, or without compensation VHA employees and trainees who engage in activities within the health care system that can have a significant effect on the range of treatment options available to patients. These activities include recommending medical devices and prescribing drugs to individual patients.

What kinds of relationships are covered? The relationships covered are financial relationships with industry. "Industry" includes pharmaceutical companies, biotechnology companies, medical device, product, equipment, and technology companies, and proxy medical education, publishing, public relations firms, disease advocacy groups, and law firms working on behalf of such companies. A financial relationship can arise from your acceptance of any financial compensation or fee for any purpose, including research and education grants. It also includes in-kind offers such as food, entertainment, complimentary tickets or registration and travel expenses. Some frequently encountered examples of financial relationships include:

- Compensation for participation as a member, presenter, moderator, etc., on an industry-funded speakers bureau.
- Compensation for participation as an advisor, consultant, member, presenter, moderator, etc., on an industry-funded advisory board.
- Compensation for participation as an author on an industry-funded publication.
- Paid expert witness testimony provided on behalf of industry.
- Industry-funded education or research grants, honoraria, or low interest loans.
- Compensation for a paid role (Medical Director, Board Member, Resident or Trainee Representative, etc.) on a pharmaceutical, biotechnology, medical device, product, equipment, or technology company or their proxies.
Handout: Avoiding Financial Conflict of Interest (2)

- Compensation for participation as developer, speaker, moderator, attendee, etc., of industry-funded Continuing Medical Education (CME) (whether accredited, unaccredited, certified or non-certified) or other industry-sponsored programs, such as lectures, dinner meetings, or teleconferences.

What are your responsibilities?

1. Recognize that in completing the VHA credentialing processes, you have affirmed that you understand your obligations and responsibilities to avoid or manage financial conflicts of interest.

2. Avoid or manage financial relationships that may cause a conflict. If you realize that you may have a conflict of interest due to the offer of a gift or compensation, it is your responsibility to either refuse the offer, or seek guidance from your supervisor, Service Chief, Deputy Ethics Official in the Office of General Counsel, or other appropriate official.

3. Bring concerns about the financial relationships or conflicts of other health care professionals to the attention of appropriate officials.

4. If you to sit on a VHA decision-making committee, you must disclose your financial relationships with industry

When should you seek guidance? As soon as you become aware that there is a conflict of interest, or may be the perception of a conflict of interest. For example, a clinician or trainee who is offered any type of monetary or in-kind payment or gift by a pharmaceutical or medical device company is encountering a potential conflict of interest

How should you seek guidance? Be clear, be direct, and disclose as much information as you have — without all the information, you may not receive accurate advice. Seek guidance from your supervisor, Service Chief, Deputy Ethics Official in the Office of General Counsel, or other appropriate official.

If you are approached about a relationship, an offer, or a gift that may constitute a conflict of Interest, take the following steps:

- Speak to your supervisor
- Contact an Ethics Official with VA Office of General Counsel
- If you are unsure about the relationship, avoid it!

If you discover that you have a conflict of interest

- Speak to your supervisor and tell him or her:
  - What you want to talk about
  - What strikes you as a potential conflict
  - What kind of advice/guidance you need
1. You are a VA oncologist and have a patient with a rare form of cancer that you think would be best treated with a biologic drug that isn't on the VHA formulary. A course of treatment with this novel drug costs $300,000. You are about to place the order for the off-formulary prescription when you realize that you may have a conflict of interest because the drug is produced by the company that employs your husband.

Is this a conflict of interest?
What details are important?
What would you do about it?

2. You are a VA orthopedic surgeon. One of your responsibilities is to recommend implantable medical devices to your patients. In your role at the Academic Affiliate, you conduct research with a grant from a medical device company and you notice, when considering devices for one of your patients, that the device you work on is one of the approved devices appropriate to treat your patient’s condition. You think it is the best option for this patient.

Is this a conflict of interest?
What would you do about it?
What details are important?

Use this space to explain what concerns you about your relationship with the device company and your VA responsibilities:
I am worried about:

The details of my relationship [time, duties, compensation] are as follows:

I would like your help deciding:
SLIDE DECK OUTLINE

(not for the facilitator are listed in italics, to separate them from the suggested script.)

Slide 1

Financial Conflict of Interest with Industry

Welcome everyone.

Today we’ll be talking about financial conflicts of interest between physicians and industry.

We’ll talk about why they matter and what they are.

We will also discuss what to do if you find yourself approached by a company, or think that a relationship you are already a part of may constitute a conflict.

We'll also consider two real-world scenarios to test and expand our knowledge.

Let’s get started.

Slide 2

Why Conflicts Matter, Ethically:

Conflicts of interest, even the perception of conflicts, have widespread repercussions:

Financial relationships with industry may compromise health care providers’ professional objectivity and integrity, and undermine their ethical obligation to put the interests of patients first.

A conflict of interest may result in:

- Harm to individual patient welfare, or groups of patients
- A conflict of commitment, i.e. commitment to an outside relationship taking a physician’s time away from patient care
- Bias, loss of objectivity and integrity, and departure from professional standards
- A loss of trust in you and your fellow health care professionals, and a loss of public trust in VA

(References are included in the last 2 slides of this presentation).
Pharmaceutical and medical device companies spend a great deal of money to try to influence physicians, here are a few examples from the medical and academic literature of how companies do this.

- Ghostwriting peer-reviewed articles for physicians. This practice, often managed by a company’s marketing department, subtly shapes the medical literature and how clinicians perceive health conditions and treatments.

- It is estimated that in 2012, the pharmaceutical industry spent about 15 billion dollars on drug detailing to prescribers. Officially, the goal of drug detailers is to provide information, answer questions and deliver samples. More accurately, their goal is to change prescribing practices to benefit specific drugs.

- In the well-known case surrounding off-label uses of gabapentin, the company illegally promoted off-label use through payments to physicians and others for advisory board memberships, consultancies, meetings, accredited continuing medical education events by third-party vendors, cultivated clinical thought leaders, and paid medical communication companies to develop and publish medical articles. The company admitted guilt in the case and paid 430 million dollars in relation to civil and criminal liability.

Most Individuals Can’t Recognize or Manage their Own Conflicts of Interest

If you are thinking, not a problem, I’m not influenced by pharmaceutical reps, or free lunches, consider the following:

- Physicians routinely underestimate the effect of conflicts, assuming that they are invulnerable to bias, with 61% of respondents in one study believing that their own relationships did not affect their decision making, but only 16% believed the same of their colleagues.

You can see the breakdown on these beliefs in the graph, showing the difference in physicians’ beliefs about their bias and the bias of others.
It Is Genuinely Difficult to be Objective

- Even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias. Self-interest changes how individuals seek out and weigh the information on which they later base their choices when they have a stake in the outcome, even among individuals who are motivated to be impartial and who have been explicitly instructed about bias.

- Rationalizations that allow for accepting gifts and positions (a sense of entitlement to gifts due to hard work and feelings that one is invulnerable to bias) both work on the unconscious level.

- One study asked medical residents to rate various industry gifts in terms of appropriateness. In the graph here, you can see the percentage of residents who rated a gift as inappropriate and also reported accepting at least one of those gifts (n being the number of residents who reported that the gift was inappropriate).

You may not consciously experience bias, or consciously act out of self-interest, but it is important to be on guard and aware of the possibility, given the real harm that conflicts of interest can do to you and your fellow health care professionals, patients, VA and the public.

Disclosing a conflict is not a cure-all either: research shows that physicians give more biased advice after disclosing conflicts (known as moral licensing) and patients feel pressure not to reject the advice of a physician who discloses a conflict for fear of insinuating bias on the part of the physician.

Impact of Conflict of Interest on Physician Behavior

Studies have also shown that conflicts of interest have real effects on physician behavior, in a variety of ways:

- Gifts of less than $20 are shown to affect physicians

- Industry sponsored research is 3.6 times more likely to reach conclusions favorable to industry than non-sponsored studies

- Physicians who accepted money from a drug company are 19 times more likely to request formulary additions from that company than physicians who didn’t take money.
A meta-analysis of physician industry contact and prescribing practices found an association between industry exposure and higher prescribing frequency, higher costs, or lower prescribing quality.21

Again, these potential impacts affect physician behavior, what is prescribed and implanted in patients, and published information about the efficacy of treatments.

**Slide 7**

What Kinds of Relationships Could Constitute a Conflict?

So what kind of relationships should we be looking out for? Well, a conflict of interest is any relationship that may lead you to put your own personal gain, or a close family member’s personal gain above your duty to your patients.

For example:

- Membership on a pharmaceutical company’s Speaker's Bureau
- Compensation for speaking at an event for a third party educational group tied to a pharmaceutical or medical device company
- Agreeing to collaborate with an industry physician on a research project, either as an active partner, or in an advisory role
- Attending an industry-sponsored or industry proxy group-sponsored dinner for leading physicians
- Dinner lectures featuring faculty speakers
- Funding for Travel to a CME conference

Any of these relationships could lead a physician to place their own financial gain, or the relationship itself above their duty to their patients.

**Slide 8**

Conflict of Interest Policies Are Common Across Health Care

VA isn’t the only organization with a policy in place on financial conflicts of interest. Medical organizations, such as the AMA, medical Schools, and academic medical centers all have policies that address conflicts of interest.
So what are your responsibilities under VA Policy?

One, Recognize that in completing the VHA credentialing processes, you have affirmed that you understand your obligations and responsibilities to avoid or manage financial conflicts of interest.

Two, Avoid conflict of interests or relationships that give the appearance of a conflict

Three, Disclose or seek guidance about relationships you think may be a conflict or may develop into a conflict

Four, Bring concerns about the financial relationships or conflicts of other health care professionals to the attention of appropriate officials.

Five, If you to sit on a VHA decision-making committee, you must disclose your financial relationships with industry.

So what should you do if you’re approached about a relationship, offer or gift that you think may pose a conflict of interest?

Consider declining the offer, and thus avoiding the conflict of interest or perception of a conflict. If you are unsure about the relationship, you can just say no.

You can also speak with your supervisor about it and seek their advice.

If you think the relationship could violate government ethics rules, you should contact your Designated Agency Ethics Official, in VHA, this is the Ethics Specialty Team in the Office of Government ethics, (GovernmentEthics@va.gov), or your regional counsel.

In the course of your work it may become clear that a relationship you’re already involved in may pose a conflict of interest (as we’ll see the upcoming scenarios). If you discover that you have a conflict,
you should speak to your supervisor about it and they can advise you about what course of action to take.

It's important though that you give your supervisor enough information, and present it clearly enough, so that they can give you good advice. So when you go to meet with them, make sure that you have the following information ready:

1. What you want to talk about
2. What strikes you as a conflict
3. What kind of advice/guidance you need

## Slide 12

### Scenario 1

Let’s consider a scenario to bring these ideas into focus. Consider the situation on the screen (or on your worksheet), read it over and when you are finished, answer the three questions you see here: Is this a conflict? What are the important details? And what would you do about it if you were in the oncologist’s position?

Your worksheet includes a copy of this scenario and spaces to fill in this information.

[Give the group a minute to read the scenario, and another few minutes to answer the questions, checking in with them when it seems like they're done. Ask for volunteers to give their suggested answers. A suggested answer is also provided below—though keep in mind that this scenario, like many conflict dilemmas, has other possible outcomes]

--Suggested Answers:

1. Yes, this scenario poses at least an appearance of a conflict of interest. The oncologist’s immediate family member could stand to profit from her prescribing the drug to her patient. The appearance is made more significant by the extreme high cost of the drug treatment.

2. The nature of the familial relationship is important (immediate) as would be more detail about the husband’s position and terms of compensation with the company. (e.g. Is he an officer of the company, does he participate in profit sharing?) The cost of the drug is also key here. A routinely priced prescription would be less likely to appear to be a financial benefit even if the physician made an off-formulary recommendation. The potential conflict is tempered by the fact that this case involves treatment for only one patient and not a large national contract for an ongoing supply of the medication. The clinician would need to confer with the DAEO and share information about her husband’s employment terms to explore whether an actual conflict of interest exists. It is important to determine if the husband (and therefore the employee) will receive a direct and predictable financial benefit from the doctor’s actions. Although it is unlikely this can
be shown for most spouses in these circumstances, it is always a good idea to lay the
facts before counsel and have them decide whether an actual conflict exists according
to the law.

3. The oncologist can and should discuss the case with her service chief, who could
provide an objective medical opinion about the appropriateness of the recommended
treatment for this patient. If such potential conflicts have the potential to arise again in
the future, they might also discuss establishing a regular process of review for her
treatment recommendations when she is suggesting drugs from her husband’s
company. With such reviews, she would be able to avoid the appearance of a conflict of
interest as well as remove any unconscious bias she may have in favor of drugs from
her husband’s company. One approach would be to request an e-consult from another
physician and accept that individual’s treatment recommendation to present to the
patient.

---

**Slide 13**

**Scenario 2**

Let’s consider a second scenario, answering the
questions above. You can again go to your worksheet
for the scenario and the questions.

[Give the group a minute to read the scenario, and
another few minutes to answer the questions,
checking in with them when it seems like they’re done.

Ask for volunteers to give their suggested answers. A suggested answer is also
provided below—though keep in mind that this scenario, like many conflict dilemmas,
has other possible outcomes]

---

**Suggested Answer**

1. Yes this poses a potential conflict, though it is a bit tenuous. Your work as an
academic benefits from the grant from the device company, but you would not stand to
directly and predictably benefit financially from the implantation or increased
implantation of medical devices. This device is also already included in a national
contract so you wouldn’t be asking for a special use for this device. However, the
greater concern is that your familiarity with the product, and your attachment to it may
cause you to select it over other devices that would be better suited to your patient.

2. The relationship here, beneficiary of the medical device company’s grant, familiarity
with the device, but not stock ownership is the key detail here. Again, the surgeon’s
relationship stands to bias him toward the device, possibly at the expense of the
patient’s well-being.

3. This is another situation in which you should seek a second opinion, either from your
service chief or a colleague,. You should know that disclosure of the conflict may
backfire here, as colleagues might agree with your assessment in order not to suggest
an unprofessional bias. Another option is to discuss your concerns with your service
chief and ask him or her to monitor your selection of medical devices over the long term
compared to the practice of your colleagues in VA. Such scrutiny is routine in VA for prescription drug use to try to identify outliers who may have a bias toward particular drugs. A long-term comparative analysis of your treatment practices could reveal an unconscious bias on your part. If this exists, you and your service chief could work to remove the bias by routinely involving other clinicians in decision making about the best treatment option to offer a patient. The other option if a bias is shown is to give up the grant from the device manufacturer.

4. The concern here is that the surgeon might not select the best device for his patient, due to an unconscious bias based on his relationship with the device and the company. Thus, it would interfere with the surgeon’s duty to put the interests of his patients above his own.

Slide 14

Recap

Let’s recap:

The main thing that we should take away from today is that it’s our responsibility to avoid financial conflicts of interest.

You are responsible for bringing potential conflicts to the attention of your supervisor or the Designated Agency Ethics Official or both if there’s a relationship you’re unsure about. And when you seek advice, make sure you are very clear about the details of the situation, raise your concerns, and ask specifically how you should respond to the situation.

VHA asks that you seek advice because it can be difficult for any individual to recognize and manage their own bias. By seeking advice from someone who doesn’t have the potential bias you hold, you can test your own decision making and unspoken assumptions. In this way, VHA’s goal is to help you avoid any real or perceived bias, allowing you to avoid potential legal or reputational jeopardy as well as to protect VA from the same. Most importantly, it helps to ensure VHA patients are receiving care based on their best interests, not your best interests or the best interests of a company with which you have a financial relationship.

Slide 15

References

The next two slides are the slides with references from the medical literature from the first few slides.

[These references are also reproduced below in the section “Slide References”]
If you need more information, you can see the NCEHC website for information and FAQs about the Conflict of Interest policy and other topics. If you need guidance about a conflict or possible conflict, here also is the information for the Office of Government Ethics ethics specialty team.
Guidelines

American Medical Association: “Patients must be able to trust that their physicians have based treatment recommendations on the physician’s independent professional judgment and knowledge of the patient’s unique circumstances. Gifts from industry can undermine physicians’ objectivity and put at risk physicians’ ability to fulfill their primary professional commitment to serve patients' interests.”

To preserve patient-physician trust and public confidence, physicians should: decline any cash gifts from an entity with a direct interest in treatment recommendations; decline any gifts for which reciprocity is expected. In-kind gifts are allowed when the gift will directly benefit patients (including education) and is of “minimal value.”

Academic institutions may accept special funding to support students’, residents’, and fellows’ participation in professional meetings provided “the program identifies recipients based on independent institutional criteria” and funds are distributed “without specific attribution to sponsors.” (Council on Ethical and Judicial Affairs, Amendment to “Gifts to Physicians from Industry,” 2013)

American Medical Student Association (AMSA): The AMSA Scorecard ranks medical schools in 14 areas focused on conflict of interest policies related to industry marketing and education (not covering basic and clinical research). The scorecard is extremely detailed, including information on gifts of meals, as well as access of sales reps for pharmaceuticals and medical devices. The scorecard seems to reward the most rigorous, strictest policies—while recognizing that no school will get a perfect score. http://amsascorecard.org/methodology

The Pew Charitable Trusts: A panel convened in 2012 to update the list of best practices from the Association of American Medical Colleges for medical center policies on conflict of interest. The Pew Charitable Trusts’ Recommendations for Best Practices in Conflicts of Interest Policies for Academic Medical Centers includes recommendations in 15 areas. The recommendations are meant to maintain the integrity of medical practice, education and training, while not restricting research or study. http://www.pewtrusts.org/en/research-and-analysis/reports/0001/01/01/conflictsofinterest-policies-for-academic-medical-centers

Resources from the National Center for Ethics in Health Care

Training Module for Health Care Professionals - Financial Relationships Between Health Care Professionals and Industry: Training Designed to Help You Understand the Requirements and Standards in VHA Handbook 1004.07 - This self-directed training module is for health care professionals whose decisions can influence the range of treatment options available to patients. It is appropriate for both clinical and non-clinical staff.

Frequently Asked Questions: Financial Relationships Between VHA Health Care Professionals and Industry - ten-page document features information to assist health care providers in clarifying issues regarding financial relationships with pharmaceutical,
biotechnology, medical device, product, equipment, or technology companies or their proxies.

**Verbal Disclosure Script for Chair** - One-page sample script for chairpersons of VHA decision making and advisory groups, as required by VHA Handbook 1004.07, for real-time verbal disclosure of financial relationships with industry.

**Verbal Disclosure Information for Members** - Two-page information sheet for members of VHA decision making and advisory groups about the kinds of financial relationships that must be disclosed; offers samples of verbal disclosure scripts.

**Compensation to Health Care Professionals from the Pharmaceutical Industry** (NEC Report February 2006)

**National Ethics Committee Report: Compensation to Health Care Professionals from the Pharmaceutical Industry** (NET Summary February 2006)

**Gifts to Health Care Professionals from the Pharmaceutical Industry** (NEC Report October 2003)

**National Ethics Committee Report: Gifts to Health Care Professionals from the Pharmaceutical Industry** (NET Summary January 2004)

**Slide References**


7. Sah S., 486.


11. Dana J, Loewenstein G.


13. Dana J, Loewenstein G.


15. Sah, S. 484.


17. Steinman MA, Shlipak MG, McPhee SJ. 554.


