

FINANCIAL RELATIONSHIPS BETWEEN VHA HEALTH CARE PROFESSIONALS AND INDUSTRY

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook defines the obligation of VHA health care professionals to avoid or manage financial relationships with industry that may undermine the priority of patient welfare in professional decision-making within VHA.

2. SUMMARY OF CONTENTS/MAJOR CHANGES. This Handbook:

a. Establishes a general requirement for all health care professionals to avoid, or seek guidance in managing financial relationships with industry that may create a conflict of interest.

b. Provides strategies for managing conflicts of interest stemming from financial relationships between industry and those VHA health care professionals who are on Department of Veterans Affairs (VA) decision-making and advisory groups.

c. Enumerates responsibilities of Service Chiefs to ensure that VHA health care professional staff are oriented to the types of financial relationships with industry that pose a potential for conflicts of interest and to reinforce expectations regarding professional norms.

d. Enumerates responsibilities of Designated Education Officers to ensure that VHA trainees are oriented to the types of financial relationships with industry that pose a potential for conflicts of interest and to reinforce expectations regarding professional norms.

e. Requires that as part of the credentialing process, VHA health care professionals certify that they understand that their professional obligation to patients must not be compromised by financial conflicts of interest.

3. RELATED ISSUE. VHA Directive 1004.

4. RESPONSIBLE OFFICE. The National Center for Ethics in Health Care (10E) is responsible for this Handbook. Questions may be addressed to (202) 501-0364.

5. RESCISSIONS. None.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of September 2014.

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CONTENTS

FINANCIAL RELATIONSHIPS BETWEEN VHA HEALTH CARE PROFESSIONALS AND INDUSTRY

PARAGRAPH	PAGE
1. Purpose	1
2. Background	1
3. Definitions	2
4. Scope	4
5. Responsibilities of Each VHA Health Care Professional	5
6. Questions Regarding the Responsibilities for Real-time Verbal Disclosures by Health Care Professionals Who Serve on VHA Decision Making and Advisory Groups	5
7. Questions Regarding the Responsibilities Pertaining to the Management of Conflicts of Interest of Health Care Professionals Who Are Members of VHA Decision-Making or Advisory Groups	8
8. Responsibilities of Chairpersons of Decision-Making and Advisory Groups	9
9. Responsibilities of the Facility Service Chief	10
10. Responsibilities of the VA Designated Education Officers	11
11. Responsibility of the Facility Director with Respect to the Credentialing Process	11
12. References	11

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1. PURPOSE

This Veterans Health Administration (VHA) Handbook defines the obligation of VHA health care professionals to avoid or manage financial relationships with industry that may undermine the priority of patient welfare in professional decision-making within VHA.

2. BACKGROUND

a. All VHA employees have a legal obligation to abide by Federal conflict of interest law (Title 18 United States Code (U.S.C.) 208) and Standards of Ethical Conduct for Employees of the Executive Branch (Title 5 Code of Federal Regulations (CFR) Part 2635). Additionally, these Government ethics laws prohibit a VA employee from using the employee's public office for private gain or participating in official matters that otherwise involve a criminal conflict of interest as defined by those laws or that might give the appearance of such conflict of interest.

b. In addition, VHA health care professionals have a separate professional obligation to place the interests of patients above self-interest. This Handbook establishes requirements that address financial relationships that may be incompatible with this professional obligation. Where appropriate, this Handbook also establishes mechanisms to reinforce existing requirements under Government ethics rules. This Handbook is part of ongoing efforts within VHA to address and manage potential and actual conflicts of interests created by financial relationships between industry and VHA health care professionals.

c. A financial conflict of interest exists when a financial arrangement has the potential to or is perceived to exert inappropriate influence on the integrity of decision making or the professional judgment of health care professionals in the fulfillment of their obligations to patients, and thus damage public trust.

d. Concerns related to financial conflicts of interest have increased as financial relationships between health care professionals and pharmaceutical, biotechnology, medical device, product, equipment, and technology companies have become more ubiquitous and complex (see subpars. 12d, 12e, 12f, 12g, 12h, 12i, 12j, 12k, 12l, 12m, 12n, and 12o).

e. These concerns are based on the effects the relationships may have on the actual or perceived quality of patient care and the independence of professional judgment. Such relationships may entail compensation from industry for services that health care professionals perform as consultants or speakers for those companies as well as investments that health care professionals may have in a company. Compensation may come directly from pharmaceutical, biotechnology, medical device, product, equipment or technology companies or indirectly from proxy medical education or public relations firms, disease advocacy groups, or law firms working on behalf of these companies.

f. Research indicates that individuals are not able to manage their own conflicts of interests. Social science research shows that in situations of conflict of interest “even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias” (see subpars. 12i and 12o). 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” (see subpar. 12i). These effects occur even among individuals who are motivated to be impartial and who have been explicitly instructed about bias (see subpars. 12h and 12k). Thus, prohibitions and strategies for third-party management of conflicts of interest have been proposed and enforced.

g. Even when a financial relationship between a VA health care professional and industry does not correlate with actual compromise of judgment or patient care, the perception that such a relationship can exert inappropriate influence may have a negative impact on the credibility of both the health care professional and the institution.

h. In addition to the obligations set forth in this Handbook, all VA employees are subject to the criminal conflict of interest statutes at 18 U.S.C. Chapter 11, and the Executive Branch Standards of Conduct at 5 CFR Part 2635, which together are commonly referred to as the “Government ethics laws.” Violation of these provisions may be sanctioned by civil and criminal penalties, as well as employment-related discipline such as removal or suspension. Compliance with the provisions in this Handbook does not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. VA Regional Counsels and the Assistant General Counsel for Professional Staff Group III (023), the designated agency ethics official, maintain ethics expertise and provide counseling services to employees related to Government ethics rules. *NOTE: Employees with questions regarding these requirements are encouraged to contact their respective Regional Counsels. Those in VA Central Office should contact the Assistant General Counsel for Professional Staff Group III (023). General guidance on substantive Government ethics matters such as gifts, conflicting financial interests, impartiality, misuse of position, outside activities, and financial disclosure can be found on the [Office of Government Ethics](http://www.usoge.gov) Web site at <http://www.usoge.gov>, and [VA’s Office of General Counsel ethics Web site at: <http://vaww.gc.va.gov/law/employment/Ethics/index.htm>.](http://vaww.gc.va.gov/law/employment/Ethics/index.htm)*

3. DEFINITIONS

a. **Financial Relationship.** For the purposes of this Handbook, a financial relationship is any arrangement between an individual VHA health care professional and pharmaceutical; biotechnology; medical device; product; equipment; and technology companies or their proxy medical education or public relations firms. Financial relationships also include disease advocacy groups; or law firms, that involves monetary or in-kind compensation to the health care professional or non-profit entities that directly or indirectly support the health care professional in ways such as salary, honorarium, consultation fee, or reimbursement; or financial holdings in pharmaceutical, biotechnology, medical device, product, equipment, and technology companies. Compensation may include: money, including low-interest loans, real property, stock options or other equity interest, paid or reimbursed travel and accommodations. Examples include:

(1) Compensation for participation as a member, presenter, moderator, etc., on an industry-funded speakers bureau. **NOTE:** *VHA health care professionals should be aware that representing non-Federal parties before the Government in connection with particular matters is prohibited by criminal conflict of interest law (18 U.S.C. §§ 203, 205). VA employees who receive industry support for presentations made on VA property to VA audiences should consult Regional Counsel in advance to determine whether a proposed activity would fall within the scope of this law.*

(2) Compensation for participation as an advisor, consultant, member, presenter, moderator, etc., on an industry-funded advisory board.

(3) Compensation for participation as an author on an industry-funded publication.

(4) Paid expert witness testimony provided on behalf of industry. **NOTE:** *Serving as an expert witness before a Federal agency or court for a party other than the Government, where the United States is a party or has a direct and substantial interest, is generally prohibited by the Standards of Conduct for Executive Branch Employees.*

(5) Industry-funded education or research grants, honoraria, or low interest loans.

(6) 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.

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

b. **Decision-making or Advisory Group.** A decision-making or advisory group is any group, such as a working group, advisory committee, task force, board, or committee that makes:

(1) Decisions on clinical or technical requirements for major purchasing decisions, or

(2) Recommendations that would have significant implications for major purchasing decisions (e.g., National Leadership Board or Veterans Integrated Service Network (VISN)-level Executive Leadership Boards (ELB), VISN Formulary Committees, VISN Formulary Leaders Committees, Medical Advisory Panel (MAP), Pharmacy and Therapeutics (P&T) Committees, Field Advisory Committees, VA-Department of Defense (DOD) Evidence-Based Practice Work Group), or

(3) Major purchasing decisions. **NOTE:** *Groups chartered under the Federal Advisory Committee Act are not included under this definition.*

c. **Financial Conflict of Interest.** A financial conflict of interest is a financial arrangement that has the potential to or is perceived to exert inappropriate influence on the integrity of

decision making or the professional judgment of health care professionals in the fulfillment of their obligations to patients, and thus damage public trust.

d. **Criminal Conflict of Interest.** Under 18 U.S.C. § 208., a criminal conflict of interest exists when an employee participates personally and substantially in a particular matter, e.g., contract or grant, that would have a direct and predictable effect on the employee's outside financial interest, or the financial interest of the employee's spouse, minor child, general partner, any person/entity whom the employee serves as an officer, director trustee or employee, or any person with whom the employee is negotiating for employment, or with whom the employee has an arrangement for prospective employment.

e. **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 groups working on behalf of such companies.

f. **VHA Health Care Professional.** For the purposes of this Handbook, a VHA health care professional is any full-time, part-time, or without-compensation (WOC) employee of or trainee in VHA who makes treatment recommendations that pertain to commercial products or who is involved in making formulary decisions, developing clinical practice guidelines, institutional policies on care, or in other activities within the health care system that can have a significant effect on the range of treatment options available to patients. These may include physicians, advanced practice nurses, psychologists, physician assistants, pharmacists, other associated health practitioners with prescriptive authority, and certain administrators.

4. SCOPE

The professional obligations of VHA health care professionals must not be compromised by financial relationships with industry. **NOTE:** *Information pertaining to conflicts of interest in research can be found in VHA Handbook 1200.01.* As addressed in this Handbook, VHA health care professionals must:

- a. Avoid or seek guidance in managing actual and potential conflicts of interests;
- b. Follow protocols for disclosure and oversight of such relationships in the context of decision-making and advisory groups; and
- c. Certify in the VHA credentialing process (if applicable) that they understand that their professional obligation to patients must not be compromised by conflicts of interest.

5. RESPONSIBILITIES OF EACH VHA HEALTH CARE PROFESSIONAL

Each VHA health care professional is responsible for:

- a. Avoiding financial relationships with industry that involve actual or potential conflicts of interest and seeking guidance in managing potential or actual conflict of interests. For example,

a clinician or trainee who is offered any type of monetary or in-kind payment or gift by a pharmaceutical company or medical device company needs to consider whether such a payment or gift has the potential to, or could be perceived to, exert inappropriate influence on the individual's professional decision-making or judgment. If it does have such potential, the professional should decline the payment or gift, or seek guidance from their supervisor, Service Chief, VA Designated Education Officer, Designated Agency Ethics Officer, or other appropriate official.

b. Making real-time verbal disclosures of their financial relationships with industry that may have a bearing on the work of the group, when serving as a member of a VA decision-making or advisory group.

c. Completing, if applicable, the VHA credentialing and appraisal process, signing the following statement as part of the process: "I understand that my professional obligations can be compromised by financial conflicts of interest; therefore, I will avoid conflicts or seek guidance in their management."

d. Bringing concerns regarding the potential or actual conflicts of interest of other VA health care professionals, including but not limited to the chairperson of a decision-making or advisory group, to the attention of the person's supervisor, appointing official, or facility leadership.

6. QUESTIONS REGARDING THE RESPONSIBILITIES FOR REAL-TIME VERBAL DISCLOSURES BY HEALTH CARE PROFESSIONALS WHO SERVE ON VHA DECISION MAKING AND ADVISORY GROUPS

a. When and How Often Must Verbal Disclosures Be Made?

(1) Verbal disclosures must be solicited by the chairperson and provided by the members and chairperson:

(a) At the beginning of the first meeting of a decision-making or advisory group and at an appropriate time during that meeting for any late-arriving members.

(b) At the beginning of the first meeting for any subsequently appointed member.

(2) At the beginning of all subsequent meetings of the decision-making or advisory group, the chairperson must remind the members to verbally state any new financial relationships they have with industry that may have a bearing on the work of the decision-making or advisory group.

b. What Is the Scope of Real-Time Verbal Disclosures?

(1) Affiliations requiring disclosure include the financial relationships between the member (not the member's spouse and children) and industry that are pertinent to the particular issues, or companies that are relevant to the work of the decision making or

advisory group. This includes financial relationships that either constitute a conflict of interest or the appearance of a conflict.

(2) Verbal disclosures must include the financial relationships described in subparagraph 6b(1) within the last 12 months and any interviews or negotiations within the last 12 months for employment (including anticipated employment) with an entity that has a financial interest in the matters before the decision making or advisory group.

c. What Form Must Real-Time Verbal Disclosures Take?

(1) Verbal disclosures must include either a negative statement that the member has no financial relationships relevant to the work of the decision making or advisory group or an affirmative statement that the member has a financial relationship, the name of the entity with whom the member has a financial relationship, and the nature of the relationship. Although the amount of compensation or investment may be disclosed, it is not required. Verbal disclosures might take the following forms:

(a) “I do not have any financial relationships with any companies whose work relates to the issues addressed by this committee.”

(b) “I receive compensation from ___(name of company)___ for membership on its speakers bureau.”

(c) “I received compensation from ___(name of company)___ for chairing a committee related to ___(name of drug)___.”

(d) “I received compensation from ___(name of company)___ when I attended a dinner program regarding ___(name of topic)___.”

(e) “I received compensation from ___(name of company)___ for an educational grant pertaining to ___(name of subject)___.”

(f) “I received an in-kind contribution from ___(name of company)___ for a presentation that I gave regarding ___(name of subject)___.”

d. To Whom Do Real-Time Verbal Disclosures Apply?

(1) Real-time verbal disclosures apply to the chairperson of, members of, and non-member Federal employees invited to attend or make a presentation to the following decision making or advisory groups:

(a) MAP.

(b) VISN Formulary Leaders Committees.

(c) VISN Formulary Committees.

- (d) P&T Committees.
- (e) Field Advisory Committees
- (f) VA-DOD Evidence-Based Practice Work Group.
- (g) Clinical Logistics.
- (h) Procurement.
- (i) Technology Assessment.
- (j) National Leadership Board (NLB).
- (k) NLB standing committees.
- (l) VISN-level ELB.
- (m) Additional decision making or advisory groups as determined by VISN Directors or the Principal Deputy Under Secretary for Health.

e. **How must real-time verbal disclosures be recorded in meeting minutes?**

- (1) Sufficient information must be recorded in the meeting minutes to provide a basis for quality review.
 - (2) For the purpose of conflict-of-interest management, meeting minutes need to record:
 - (a) Members present at the meeting.
 - (b) That all participants were asked to provide information on their financial relationships.
 - (c) That a particular individual disclosed a financial relationship with industry.
 - (d) The nature of the financial relationship.
 - (e) The action taken by the chairperson to manage the conflict.

NOTE: For example: “John Doe indicated that he had a potential conflict of interest (honorarium for a one time speaking engagement with X Pharmaceutical Company on selective serotonin uptake inhibitors (SSRIs). He left the room during the discussion and vote on related SSRIs.”

7. QUESTIONS REGARDING THE RESPONSIBILITIES PERTAINING TO THE MANAGEMENT OF CONFLICTS OF INTEREST OF HEALTH CARE PROFESSIONALS WHO ARE MEMBERS OF VHA DECISION MAKING AND ADVISORY GROUPS

a. What Financial Relationships Disqualify Someone From Service on a VA Decision-making or Advisory Group?

(1) Receipt of any compensation for membership on any pharmaceutical company or medical device, product, equipment, or technology manufacturer's speakers bureau or advisory board will disqualify a VHA health care professional from chairing and membership on the following committees: *NOTE: The committee chair should consult with Regional Counsel regarding additional issues under criminal conflict of interest law.*

- (a) MAP.
- (b) VISN Formulary Leaders Committee.
- (c) VISN Formulary Committees.
- (d) P&T Committees.
- (e) VA-DOD Evidence-Based Practice Work Group.
- (f) Clinical Logistics.
- (g) Procurement.
- (h) Technology Assessment.
- (i) NLB.
- (j) NLB standing committees.
- (k) VISN-level ELB.
- (l) Additional decision making or advisory groups as determined by VISN Directors or the Principal Deputy Under Secretary for Health.

b. How Must the Chairperson Manage Member's Financial Relationships with Industry?

(1) The chairperson has authority to manage a members' financial relationships with industry by requiring the member's recusal from both discussion and vote.

(2) The chairperson has authority to review, on a need-to-know basis, the Office of Government Ethics (OEG) Form 450, Confidential Financial Disclosure Report, of decision making or advisory group members and to work with Department Government ethics officials (Regional Counsels or Professional Staff Group III attorneys as appropriate) to address with members any conflicts of interest that need further management.

c. **What Does Recusal Entail?**

(1) Recusal based on a financial relationship with industry entails having someone leave the room for the entire discussion and vote on the relevant matter, not simply recusal from the vote.

(2) Any uncertainty that the chairperson has about a disclosed financial relationship must result in recusal. That is, chairpersons must err on the side of caution when they are uncertain about the potential for a member's financial relationship with industry to present a conflict of interest or to introduce bias.

d. **Who Is Responsible for Managing the Chairperson's Own Conflicts of Interest?**

(1) The chairperson's own financial relationships must be managed according to these protocols, by the chairperson's supervisor or appointing official, e.g., the Chief Consultant, Pharmacy Benefits Management Service (PBM) or Chairperson, MAP, must be consulted to review conflict of interest information for chairpersons of VISN Formulary Committees and facility P&T committees). The chairperson is responsible for bringing the chairperson's own financial relationships with industry to the attention of these officials and informing the decision making or advisory group of decisions and actions taken.

(2) However, decision-making or advisory group members also have a responsibility to bring concerns about the chairperson's financial relationships with industry to the attention of the chairperson's supervisor, appointing official, or facility leadership if the member believes that unresolved issues or questions exist.

8. RESPONSIBILITIES OF CHAIRPERSONS OF DECISION-MAKING AND ADVISORY GROUPS

Chairpersons of decision-making and advisory groups are responsible for:

a. Communicating to nominees to a decision making or advisory group those financial relationships with industry that would disqualify them from service on that group and the procedures for real-time verbal disclosure that will be part of the group's conflict-of-interest process (see para. 6).

b. Clarifying for all members of the decision making or advisory group what a financial relationship is and reminding members on a routine basis about their obligations regarding disclosure and recusal.

- c. Soliciting during meetings a verbal disclosure of members' financial relationships with industry that may have a bearing on the work of the decision-making or advisory group.
- d. Ensuring that meeting minutes reflect sufficient information about those disclosures to provide a basis for quality review and conflict of interest management.
- e. Managing conflicts of interest stemming from financial relationships disclosed by members of the decision making or advisory group.
- f. Consulting with the Designated Ethics Official, when needed, to review the Confidential Financial Disclosure Form 450 of decision making or advisory group members and to address any member conflicts of interest that need further management.
- g. Bringing the chairperson's own financial relationships with industry to the attention of the supervisor or appointing official and informing the decision making or advisory group of decisions and actions taken in response.

9. RESPONSIBILITIES OF THE FACILITY SERVICE CHIEF

Each facility Service Chief is responsible for:

- a. Ensuring that VHA health care professional staff within their area of responsibility are oriented to the types of financial relationships with industry that pose a potential for conflicts of interest.
- b. Conveying to the best of their knowledge to chairpersons of decision making and advisory groups any potential or actual conflicts of interest concerning VHA health care professionals who serve on such groups that may have a bearing on their committee service.
- c. Reinforcing expectations regarding professional norms and conflicts of interest. Actions to accomplish this may include:
 - (1) Reviewing individual prescribing data received from local P&T Committees and using this information as a basis for counseling practitioners on outlier status, including querying practitioners about financial relationships with industry. **NOTE:** *Service Chiefs, in their role as supervisors, have authority to review, on a need-to-know basis, the OGE Form 450 of confidential filers within their service.*
 - (2) Scrutinizing staff requests to use annual leave, administrative absence or leave-without-pay to participate in industry-sponsored events. **NOTE:** *Leave requests to present VA work under a VA title must be submitted and evaluated as requests for administrative absence, not annual leave. Annual leave requests need to be evaluated from the perspective of VA operations, namely whether the absence would adversely affect operation of the service. Further, the Standards of Conduct prohibit employees from accepting compensation for speaking, teaching or writing related to their official duties, which includes presentations that deal in significant part*

with any matter to which the employee is currently assigned or has been assigned in the last year, or any ongoing or announced VA program, policy or operation.

(3) Assessing potential conflicts of interest in staff topic selection for presentations at VA facilities, for example, if the topic could be seen to promote the interests of a company that provides financial support to the staff member.

10. RESPONSIBILITIES OF THE VA DESIGNATED EDUCATION OFFICER

Each VA Designated Education Officer, or designee, is responsible for:

a. Ensuring that trainees are oriented to the types of financial relationships with industry that pose a potential for conflicts of interest.

b. Reinforcing expectations regarding professional norms and conflicts of interest. Actions to accomplish this may include:

(1) Setting and communicating clear expectations regarding trainee access to, and interactions with, industry representatives.

(2) Providing education to trainees regarding potential industry influence on decision making by health care professionals.

(3) Assessing potential conflicts of interest in sponsorship and content of trainee education at VA facilities, for example, if the education could be seen to promote the interests of a commercial entity or to contain biased or selective information.

11. RESPONSIBILITY OF THE FACILITY DIRECTOR WITH RESPECT TO THE CREDENTIALING PROCESS

The Facility Director is responsible for ensuring that the following statement is signed by VHA health care professionals, as part of the VHA credentialing process, at the time a health care professional applies for appointment to the facility and at the time of reappraisal: "I understand that my professional obligations can be compromised by financial conflicts of interest; therefore, I will avoid conflicts or seek guidance in their management."

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