

Policy Regarding Relationships with Pharmaceutical Suppliers, Biotech and Device/Medical Equipment Manufacturers and Other Healthcare Suppliers

1.0 Purpose

The purpose of this policy is to:

- Support USC's standard of maintaining a culture of ethics in its business relations and to minimize conflicts of interest and the appearance of impropriety in our relationships with pharmaceutical companies, biotechnology companies, device and medical equipment manufacturers and other healthcare suppliers ("Industry").
- Provide guidelines for USC Healthcare Providers (defined below) for their interactions with Industry.
- Assist USC Healthcare Providers in exercising independent clinical judgment at all times that is free from influence by relationships with Industry.
- Assist USC Healthcare Providers in complying with federal, state and local laws and regulations, including the federal Anti-Kickback statute.

2.0 Background

USC recognizes that Industry possesses knowledge about the safety and efficacy of pharmaceuticals, medical devices, and medical supplies that may be of value to USC Healthcare Providers and that may benefit their patients. In addition, USC Healthcare Providers may have expertise that is beneficial to Industry. USC also recognizes that relationships with Industry have the potential in certain circumstances to improperly influence, or appear to improperly influence, clinical, purchasing or prescribing decisions. Fundamentally, these interactions must serve legitimate educational, research and clinical purposes, and contribute to better health care for the patients served by USC. Accordingly, USC has developed this policy to provide guidance as to appropriate interactions with Industry.

USC also is required to conduct its business practices in conformity with federal, state and local laws. For example, the federal Anti-kickback statute states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be charged with a felony. Attached here to as **Exhibit A** is a summary of the laws and standards that USC Providers must comply with.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 1 of 16

3.0 Scope

This policy applies to all USC Healthcare Providers, who are defined as:

- University faculty members (including part-time and visiting faculty), staff and other employees (including USC employed residents and fellows), and students who interact with Industry and who have influence over the prescribing, dispensing or purchasing of Industry products or services at USC; and
- The USC affiliated faculty practice plan corporations listed in **Exhibit B**.

For any relationship with Industry that is related to sponsored research, all USC faculty, staff and students must also familiarize themselves and comply with USC's Conflict of Interest in Research policy, a copy of which may be obtained at <http://ooc.usc.edu/ResearchCompliance/ConflictsOfInterest/Policy.cfm>. The policy requires, among other things, that USC faculty, staff and students avoid actual or apparent conflicts of interest and conflicts of commitment that compromise or could have the appearance of compromising the researcher's objectivity or performance relating to the research, and requires that all actual or apparent conflicts of interest be disclosed so that they can be managed, reduced, or eliminated.

4.0 Types of Interactions Covered By this Policy

This policy provides guidelines for the following types of interactions with Industry:

- A. Consulting and Services Arrangements with Industry
- B. Gifts, Free Services and Cash Payments from Industry
- C. Business Courtesies
- D. Education and Conference Scholarships
- E. Unrestricted Grants
- F. Industry Sponsored Research Projects
- G. Training and Education Regarding Use of Medical Devices
- H. Discounts, Free Samples and Other Reductions in Price
- I. Special Rules Relating to Continuing Education (CE) Activity

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 2 of 16

A. Consulting and Service Arrangements with Industry

A.1. This section of the policy covers all consulting,¹ advisory committee, teaching, or other services that USC Healthcare Providers provide to Industry, except for research activities which are addressed in section E, “Industry-Sponsored Research Projects.”

A.2. USC Healthcare Providers may be engaged by Industry to perform professional or consultative services, but only pursuant to a written contract that details the USC Healthcare Provider’s duties and that provides no more than reasonable fair market compensation for necessary services that are actually rendered.

A.3. A USC Healthcare Provider must be careful not to enter into a contract that is, or reasonably appears to be, motivated by any improper purpose, such as to induce the USC Healthcare Provider to change or maintain his or her purchasing or prescribing habits.

A.4. When evaluating a proposal from Industry, a USC Healthcare Provider should consider the following questions:

- What services am I being asked to provide?
- Who is asking me to provide them – with whom did the request originate?
- Are the services necessary?
- Are the services adequately specified in the written contract?
- Will the services be documented?
- Who will review the results of these services on behalf of Industry?
- Does this proposal raise actual or potential conflicts of interest or commitment that require disclosure under the Conflict of Interest and Ethics policy or the Conflicts of Interest in Research policy?²
- If this is consulting outside of USC employment, does it comply with the USC Faculty Handbook and/or USC Employment Policies and Procedures?

¹ USC Healthcare Providers should refer to the USC Faculty Handbook and/or the USC Conflict of Interest in Ethics policy regarding the parameters for outside consulting.

² For guidance regarding disclosable conflicts, please contact the Office of Compliance at 213.740.8258 or the Office of General Counsel at 213.740.7922.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 3 of 16

A.5. The contract between the USC Healthcare Provider and Industry shall be in writing and shall describe Industry's legitimate, commercial need for the services and for the particular individual engaged to provide the services. The contract shall detail the specific duties that the individual will perform and set forth a reasonable fair market value hourly rate for the services.

A.6. The contract shall be signed by an appropriate representative of Industry and a representative from USC or the USC affiliated faculty practice plan corporation, as appropriate. In the event that the consulting work falls within the definition of outside consulting, the contract should be signed by an appropriate representative of Industry and the USC faculty member who will be rendering the consulting services.

A.7. The USC Healthcare Provider shall maintain records of services provided under a contract with Industry to document that actual services were provided in exchange for compensation received from Industry.

A.8. USC Healthcare Providers may accept meals, hospitality, travel and lodging in connection with meetings for consulting or other services, so long as they are of "modest value" and incidental to the consulting or other services provided. See **Exhibit C** for guidelines on establishing "Modest Value".

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 4 of 16

B. Gifts, Free Services and Cash Payments from Industry

B.1. No USC Healthcare Provider should accept any gift from Industry that might inappropriately influence the USC Healthcare Provider's clinical, purchasing or prescribing decisions or create the appearance of impropriety or influence over the provider-patient relationship.³

B.2. USC Healthcare Providers may accept a gift of nominal value from Industry (less than \$50.00 per year from any Industry representative) so long as it primarily benefits patients. Gifts of nominal value could include pens, notepads and other similar small reminder items with company or product logos that have a direct or indirect value to patients. However, no branded Industry items may be utilized in patient care areas.

B.3. No USC Healthcare Provider should accept any item from an Industry representative that is for the individual's personal benefit, such as floral arrangements, artwork, golf balls, sporting bags, or tickets to sporting, musical or other types of entertainment events.

B.4. USC Healthcare Providers only may accept cash or cash equivalents (e.g., gift certificates) as compensation for *bona fide* services in a manner that complies with the above policy guidance pertaining to Consulting.

B.5. Under no circumstances should any USC Healthcare Provider accept any gift or free service, regardless of value, that is in any way intended to influence the Healthcare Provider's clinical decision-making, purchasing or prescribing decisions.

³ USC Healthcare Providers also should refer to USC's Policy regarding Conflicts of Interest and Ethics Policy.

C. Business Courtesies

C.1. Business Meetings/Detailing: USC recognizes that occasionally a USC Healthcare Provider may wish to accept an Industry invitation to attend a lunchtime or dinnertime business meeting, reception or discussion to learn more about the Industry's products or services. Therefore, USC Healthcare Providers shall follow these guidelines in connection with business meetings and detailing/marketing programs:

- USC Healthcare Providers may not solicit or accept any business courtesies⁴ from an Industry representative that are any way intended to inappropriately influence the USC Healthcare Provider's clinical decision-making, purchasing or prescribing practices or otherwise give the reasonable appearance of any improper influence.
- USC Healthcare Providers may attend "working" meals paid for by Industry so long as they are modest in value and occur at venues appropriate for the exchange of information relating to Industry's goods and services or other business-related or educational discussion. See **Exhibit C** for guidelines on what constitutes "modest value."
- No USC Healthcare Provider will accept money or any other remuneration from Industry in exchange for attending any lunch, dinner or reception.
- No USC Healthcare Provider will accept Industry invitations to attend entertainment events for free or at discounted rates, such as plays, sporting events, or golf outings, even where some business may be discussed.
- No USC Healthcare Provider will allow an Industry representative to pay for a spouse or other guest who does not have an independent reason for meeting with Industry.

C.2. Industry-Sponsored Educational/Training Meetings: USC Healthcare Providers may attend meals and receptions in connection with Industry-sponsored educational lectures and training programs containing objective scientific and educational information that will benefit USC patients. USC Healthcare Providers shall follow these guidelines when accepting business courtesies in connection with Industry-sponsored educational and training meetings:

⁴ A business courtesy is a present, gift, hospitality, or favor for which fair market value is not paid by the recipient in a business setting. Business courtesies may include meals, drinks, entertainment, door prizes, honoraria (if not for services), free transportation, promotional items, or free or discounted materials, facilities or equipment.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 6 of 16

- Educational programs sponsored by Industry and related meals or receptions must be structured so as not to improperly influence purchasing or prescribing decisions.
- USC Healthcare Providers' main incentive in attending the presentations, discussions and meals should be to further their knowledge on the subject(s) presented.
- USC Healthcare Providers may attend modest receptions and meals provided by Industry in connection with educational trainings and meetings. The meals and receptions should be incidental and subordinate to the educational content of the meetings or training sessions with most time devoted to education. USC Healthcare Providers may not "dine and dash" (i.e., take food provided by Industry without actually participating in any educational lecture or training program or accept an Industry representative's offer to provide a meal without providing educational content).
- When attending training sessions not located on campus, USC Healthcare Providers may accept reimbursement for reasonable travel, lodging and other expenses of modest value. See **Exhibit C** for guidelines on what constitutes "modest value."
- USC Healthcare Providers should never allow Industry to include spouses or other guests who do not have an independent professional reason for participating in the educational/training program.

C.3 Conference Attendance⁵: USC Healthcare Providers are permitted to attend *bona fide* Industry sponsored conferences and to accept associated meals and receptions at such conferences as long as they are modest and clearly subordinate to the conference goals of promoting objective scientific and educational activities and discourse. USC Healthcare Providers will **not** accept reimbursement from Industry for the seminar registration fee, transportation, lodging, meals or incidentals to defray the costs of attending the conference.

C.4. Conference Lecturer: As a *bona fide* faculty member/lecturer at a conference, a USC Healthcare Provider may accept reasonable reimbursement from Industry for registration fees, transportation, lodging, meals and incidentals to attend that Industry-sponsored conference. In such circumstances, the USC Healthcare Provider must comply with the Accreditation Council for Continuing Medical Education's (ACCME) Standards for Commercial Support⁶, the Accreditation Council for Pharmacy Education⁷ (ACPE) or the American Dental Association⁸ (ADA), as

⁵ USC Healthcare Providers are attending conferences as attendees, and not faculty/lecturers, if they only present a free poster or paper.

⁶ www.accme.org

⁷ www.acpe-accredit.org

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 7 of 16

appropriate, and must ensure that Industry in no way influences the content of the presentation made by the USC Healthcare Provider and that there is appropriate disclosure of any financial ties to Industry.

C.5. A USC Healthcare Provider, whether as attendee or faculty/lecturer, may participate in an Industry-provided meal or reception at a third-party conference if the event complies with the guidelines of the organization sponsoring the conference. The meal or reception should be modest in value and conducive to discussion among the faculty members present and those participating in the event. The amount of time at any such meals or receptions should be clearly subordinate to the amount of time spent at the conference's educational activities.

C.6. A USC Healthcare Provider shall not accept reimbursement for transportation, lodging, meals or incidentals for the cost of his or her spouse or other guest(s).

⁸ www.acda.org

D. Education and Conference Scholarships

D.1. Education Grants: Education grants may provide funding for valuable activities that are important to the University's mission. These activities include but are not limited to sponsorship of grand rounds, journal club, morbidity and mortality conferences, all of which are conducted to further education. USC Healthcare Providers shall comply with the following guidelines when accepting education grants from Industry:

- All education grants received from Industry must be clearly documented in a written agreement signed by all applicable parties.
- USC Healthcare Providers may only consider education grants from Industry for projects that directly benefit USC patients or that advance health policy or education. Research grants are separately addressed in Section F "Sponsored Research Projects."
- Education events conducted by USC or a USC Healthcare Provider using grant funds from Industry must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, Accreditation Council for Pharmacy Education (ACPE), or the American Dental Association (ADA), as appropriate, regardless of whether continuing education credit is awarded or available for the event.
- In general, USC Healthcare Providers should not accept funding for education that originates from Industry's sales and marketing departments or that is offered in connection with the purchase or sale of goods or services. The USC Office of Compliance should be contacted before a USC Healthcare Provider accepts funding for educational or other purposes that originates from Industry's marketing and/or sales departments.
- No funds will inure to the personal benefit of individual Healthcare Providers. All donated funds provided by Industry for education will be applied toward the applicable educational or other earmarked project.
- USC Healthcare Providers will establish and maintain a USC restricted account in accordance with USC policies and Industry requirements for the receipt, management and dispensing of grant monies. Funds from other sources for other purposes will not be commingled with these grant monies.
- USC Healthcare Providers will not accept funds from Industry for any project if Industry requires as a condition of the donation that it approve or influence the materials

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 9 of 16

developed with such funds. This is to avoid any opportunity for Industry to transform a project into a marketing program for Industry's benefit.

- To the extent possible, education grant programs associated with a specific USC Healthcare Provider will be administered by the applicable departmental administrator in such a manner that the USC Healthcare Provider will not know the identity of donors or the amounts donated by Industry. The USC affiliated faculty practice plan corporations or the Department will develop appropriate firewalls to insulate individual Healthcare Providers from potentially being influenced in their purchasing or prescribing decisions by Industry's decision to donate or not to donate.
- The applicable departmental administrator will document the receipt and application of all grant monies. Receipts for purchases will be maintained for each project undertaken at the affiliate or USC level. Excess funds, if any, will be managed in accordance with USC policy.
- Sponsorships and donations by Industry will never be taken into account in awarding contracts or in making purchasing or prescribing decisions.

D.2. Student/Resident/Fellow Scholarships to Conferences: USC recognizes that attendance at educational conferences may further the knowledge of the attendees and benefit USC patients. However, receipt of such funding directly from Industry could inappropriately influence medical or other clinical students, residents, fellows and other healthcare professionals in training, or create the appearance of impropriety. To ensure that healthcare professionals in training are not inappropriately influenced by Industry, the following guidelines shall apply to Industry funding of student/resident/fellow scholarships to educational conferences:

- USC and its affiliated entities may accept financial assistance from Industry for the purpose of permitting medical students, residents, fellows and other healthcare professionals in training to attend major educational, scientific or policy-making meetings of national, regional or specialty medical associations. In all cases, the USC Healthcare Provider must select the particular individuals who will receive the Industry-donated funds with no input from the Industry.
- Funding must be directed by Industry to the University or the faculty practice plan corporation, and not directly to the medical or other clinical student, resident, fellow or other healthcare professional in training to attend an educational conference.
- Offers and requests for funding for such scholarships should not come from or be directed to an Industry company's marketing or sales departments.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 10 of 16

E. Unrestricted Grants

E.1. Unrestricted grants, (e.g., grants not provided for educational or other purposes described in this policy), could have the appearance of inappropriately attempting to influence Healthcare Providers. Healthcare Providers should not accept unrestricted grants. Questions regarding unrestricted grants should be directed to the Office of Compliance.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 11 of 16

F. Industry-Sponsored Research Projects

F.1. All Industry-sponsored research grants must be reviewed and approved by the USC Health Research Association or USC Department of Contracts and Grants, and are subject to USC's research policies generally; see http://policies.usc.edu/faculty_teaching_research.html, and in particular USC's Conflict of Interest in Research policy, a copy of which may be obtained at <http://ooc.usc.edu/ResearchCompliance/ConflictsOfInterest/Policy.cfm>.

F.2. Industry-sponsored research using University space, equipment or personnel, or performed as part of the USC Healthcare Provider's faculty activities, should be conducted through the University of Southern California and not through a faculty practice plan corporation.

F.3. The USC Office of Compliance or Health Research Association should be contacted before any proposed research grant originating from Industry's sales and/or marketing department is accepted.

F.4. The research recipient will independently develop a budget for any such project and will not accept funds in excess of the project budget.

F.5. No donated funds will inure to the personal benefit of a USC Healthcare Provider. All donated funds will be applied toward the applicable research project or otherwise in accordance with USC policy.

F.6. USC Healthcare Providers will establish and maintain a USC restricted account in accordance with USC policies for the receipt, management and dispensing of research grant monies. Funds from other sources will not be commingled with research grant monies.

F.7. USC Healthcare Providers will not accept funds from Industry for any investigator-initiated research project if Industry requires as a condition of the funding that it approve or influence the research design, conduct or right to publish findings that result from these funds.

F.8. USC Healthcare Providers will not accept funds from Industry for any research project if Industry requires as a condition of the funding that it must approve remarks made by the USC Healthcare Provider to media related to the research project. This is to avoid any opportunity for Industry to transform a project into a marketing program for Industry's benefit.

F.9. The applicable departmental administrator will document the receipt and application of all research grant monies. Receipts for purchases will be maintained for each project undertaken at the departmental or USC level. In accordance with USC Policy, any excess funds, if any, will not be used.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 12 of 16

G. Training and Education Regarding the Use of Medical Devices

G1. To ensure that USC Healthcare Providers receive appropriate training free from inappropriate influences over their clinical decision-making, prescribing and purchasing decisions, the following policies shall be followed regarding attendance at medical device manufacturer-sponsored training sessions:

- USC Healthcare Providers may attend programs and events sponsored by manufacturers of clinical devices, so long as they are conducted in settings that are conducive to the effective transmission of knowledge, such as hotel or other commercially available meeting facilities, medical institutions, laboratories or other training facilities. Resort settings are not appropriate settings.
- USC Healthcare Providers may accept reimbursement for reasonable travel, lodging and other expenses of modest value in connection with a training program at an appropriate location. See **Exhibit C** for guidelines on what constitutes “modest value.” A Healthcare Provider should only accept a first or business class airline ticket if there are documented unusual circumstances.
- USC Healthcare Providers attending training programs should only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection with the training program should be subordinate in time and focus to the educational/training purpose(s) of the program.
- Under no circumstances should USC Healthcare Providers allow a medical device company to pay for meals, hospitality, travel or other expenses for their spouses or other guests who do not have a *bona fide* professional interest in the information being provided at the training.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 13 of 16

H. Discounts, Free Samples and Other Reductions in Price

H.1. It is permissible for USC Healthcare Providers to accept discounts and other price reductions on goods or services to the extent the discounts and price reductions comply with the federal Anti-Kickback Law. For further explanation regarding the Anti-Kickback Law, see **Exhibit A**. In addition, it is permissible for USC Healthcare Providers to receive free samples so long as the free samples are not resold, billed for or used for an individual healthcare provider's personal benefit.

H.2. USC Healthcare Providers may only accept a discount that is made at the time they purchase the goods or services or where the terms of any rebate are fixed and set forth in writing at the time of the initial sale of a good or service.

H.3. USC Healthcare Providers who have received a discount must ensure that any invoice, coupon or statement provided by Industry accurately reflects the discounted price.

H.4. USC Healthcare Providers must retain documentation of any discount received from Industry for items or services billed to federal or state health care programs so that such documentation is readily accessible should it be requested by a federal or state health agency.

H.5. Under no circumstances may USC Healthcare Providers charge a patient for a drug sample, or provide a drug sample to a patient, who is covered by a federal or state healthcare program where the cost of the drug is otherwise included within the payment received from the federal or state healthcare program.

H.6. USC Healthcare Providers should never allow the provision of free drug samples to influence their clinical decision-making or purchasing decisions.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 14 of 16

I. Special Rules Relating to Continuing Education Activity

I.1. All education events sponsored by the University of Southern California or a USC Healthcare Provider must comply with the ACCME Standards for Commercial Support, the Accreditation Council for Pharmacy Education (ACPE) or the American Dental Association, as appropriate.

I.2. If a USC Healthcare Provider speaks at an event at which CE credits are offered, or is presenting as *bona fide* faculty at any other event, the USC Healthcare Provider shall comply with the ACCME Standards for Commercial Support. USC Healthcare Providers should familiarize themselves with these standards, which require, among other things:

- Faculty **independence** in determining the content of the presentation.
- **Disclosure** of relevant faculty financial relationships.
- **Disclosure** of sources of support for the CME activity.

I.3. The ACCME Standards do not apply to presentations at Industry-sponsored events where the clear purpose of the event is to market the Industry's product(s), and not to provide medical education of general interest. In these circumstances, Industry may ask the faculty member to use Industry's slide deck or other presentation materials.⁹ While such activities are not prohibited by this Policy, USC Healthcare Providers should carefully consider whether a particular activity has the potential to compromise, or to appear to compromise, their best clinical judgment. At a minimum, all relevant financial relationships should be disclosed at the outset of any such presentation.

I.4. USC Healthcare Providers should not endorse off-label uses of an FDA-approved drug or device when using Industry's slide deck or presentation materials, or otherwise receive compensation from Industry for any such endorsement.

⁹ USC Healthcare Providers should refer to USC's Conflict of Interest and Ethics policy as well, particularly its limitations on endorsements.

5.0. **Enforcement**

Sanctions for violations of this policy for faculty will be in accordance with all provisions of the policies contained in the Faculty Handbook. Sanctions for violations of this policy for staff will in accordance with all provisions of the policies contained in the Staff Hiring and Employment policies. Sanctions for violations of this policy for students will be in accordance with all provisions of the policies contained in SCampus. Any disciplinary action against a faculty member or a non-faculty employee under this policy must take into account the scale of the offense, the individual's intent, and the degree of wrongdoing.

Issued by: Chrysostomos L. Nikias, Provost and Senior Vice President for Academic Affairs
Todd R. Dickey, Senior Vice President for Administration

Date issued: January 15, 2008

University of Southern California
Page 16 of 16

EXHIBIT A

Summary of Applicable Law and Standards

It is USC policy to ensure that all interactions with Industry are conducted in conformity with the federal Anti-Kickback Law, in addition to other applicable federal, state and local laws. Generally, the Anti-Kickback Law prohibits paying or receiving anything of value, for which one purpose is to induce the receiver to use, recommend or purchase any products or services that may be paid for by Medicare, Medi-Cal or any other state or federal health care program. Violations of the law are punishable by up to five years in prison, criminal fines up to \$25,000, administrative civil money penalties up to \$50,000, and exclusion from participation in federal health care programs

USC policy is informed by the voluntary guidelines developed by the American Medical Association (Ethical Opinion E-8.061), the Pharmaceutical Research and Manufacturers of America “Code of Interactions with Health Care Professionals” (“PhRMA Code”), the Advanced Medical Technology Association’s “Code of Ethics on Interactions with Health Care Professionals” (“AdvaMed Code”), the Office of the Inspector General’s (“OIG”) “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”) and the ACCME Standards for Commercial Support (“ACCME Standards”).

In particular, USC seeks to comply with the general principles set forth in the OIG Compliance Guidance and to ensure that no interactions with Industry have the potential to improperly influence clinical decision-making, inappropriately increase Medicare/Medicaid or other insurance costs, increase the risk of overutilization of health care services, or create patient safety or quality of care concerns.

Shown below are links to the voluntary guidelines and government guidance noted above:

American Medical Association Ethical Opinion E-8.061
See <http://www.ama-assn.org/ama/pub/category/8484.html>

PhRMA Code
See <http://www.phrma.org/files/PhRMA%20Code.pdf>

AdvaMed Code
See http://www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf

OIG Compliance Program Guidance for Pharmaceutical Manufacturers
See <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

ACCME Standards for Commercial Support
See http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

Medicare Anti-Kickback Statute
http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00001320---a007b.html

EXHIBIT B

The following are the USC affiliated faculty practice plan corporations that are “Healthcare Providers” under this policy*

USC Obstetricians and Gynecologists, Inc.
USC Family Medicine, Inc.
USC Radiation Oncology Associates, Inc.
USC Imaging Associates, Inc.
USC Radiology Associates, Inc.
USC Head and Neck Group, Inc.
USC Neurologists, Inc.
USC Cardiothoracic Surgeons, Inc.
USC Internal Medicine, Inc.
Doheny Eye Medical Group, Inc.
USC Orthopaedic Surgery Associates, Inc.
USCAN Anesthesiology Medical Group, Inc.
USC Urological Associates, Inc.
USC Neurosurgeons, Inc.
USC Surgeons, Inc.
University Pathology Associates, Inc.
USC Psychiatry & Psychology Associates, Inc.
USC Colorectal Surgeons, Inc.
USC Emergency Medicine Associates, Inc.
USC Occupational Therapy Associates, Inc.
USC Physical Therapy Associates, Inc.
USC Care Medical Group, Inc.

* Schools and departments that are not faculty practice plan corporations but who interact with Industry, including but not limited to, Dentistry, Pharmacy and Student Health, are subject to the same obligations as the faculty practice plan corporations under this Policy.

EXHIBIT C

Specific Guidelines for establishing “Modest Value” in Meals, Travel and Lodging

For USC-related activities, “Modest Value” is defined by the USC Expenditure Manual, “Modest value” means modest by local standards, but in no event may exceed the following : (1) for out-of-town travel, the maximum value of meals, hospitality, travel (exclusive of plane fare) and lodging should not exceed the maximum rate of USC travel reimbursement for actual expenses, which is currently set at \$350 per day (*see* USC Expenditure Manual <http://policies.usc.edu/policies/expmanual010106.pdf>); and (2) if only certain individual items provided, lodging should not exceed \$250/night, breakfast \$15, lunch \$35, and dinner \$75.

For non-USC related activities, we recommend utilizing the USC definition of “modest value” along with the additional guidance provided below:

- *Lodging in Expensive Cities.* For travel to more expensive cities (*e.g.*, New York, Boston and certain foreign cities), the maximum lodging per night may exceed \$250. To determine the maximum allowable, go to www.fodors.com. Click on the “hotels” tab and navigate to the city in question. Click on the box marked “price.” The highest price range for that city will be indicated as “Over \$x”. The maximum lodging per night for that city would then be \$x. For example, the maximum lodging per night using this procedure for 2006 was \$475 for New York, \$350 for Chicago, and \$325 for Boston and Los Angeles. For these cities, the maximum value of meals, hospitality, travel and lodging would be \$350 per day plus the amount by which the maximum lodging per night exceeds \$250.
- *Meals, Travel, Lodging and Other Incidentals beyond the Above Norms.* Meals, hospitality, travel and lodging outside these norms would not be incidental to the work involved under the consulting or other service contract. Such benefits are permitted only if treated as extra compensation that, combined with monetary compensation, is still fair market value for services provided by the USC Healthcare Provider.
- *Plane Fare.* First or business class tickets to such meetings are permitted only if: (i) treated as extra compensation that, combined with monetary compensation, is still fair market value for services provided by the USC Healthcare Provider, or (ii) as otherwise permitted by USC policy
- *Locations of Meetings.* Meetings should take place at appropriate venues, such as conference hotels or other commercial meeting spaces, rather than at resorts.
- *Meals, Travel, Lodging must be Incidental.* Meals, receptions and other hospitality are permitted so long as they constitute only an incidental part of any meetings for consulting services. For example, in connection with an all day meeting, a one-hour reception or meal would be acceptable. However, it

would not be appropriate for an “all day meeting” to consist of only three hours of lectures or meetings followed by an afternoon of golf or other entertainment at a resort paid for by Industry. In this case, the hospitality provided to the USC Healthcare Provider would not be incidental to the work involved under the consulting or other service contract. Such benefits are permitted only if treated as extra compensation that, combined with monetary compensation, is still fair market value for services provided by the USC Healthcare Provider.