

# OFFICE OF THE GENERAL COUNSEL: USF REGULATIONS

## NOTICE OF PROPOSED REGULATION

DATE: SEPTEMBER 21, 2011

<b>Regulation No:</b>	<b>Title:</b>
USF 9.019	<b>Limiting Conflicts of Interest in Interactions With the Pharmaceutical, Medical Device and Biotechnology Industries.</b>

### Summary

Board of Governors Regulation 1.001 authorizes each Board of Trustees to provide for the establishment of the personnel program for all the employees of the University which may include, but is not limited to, ethical obligations and conflicts of interest, restrictive covenants, disciplinary actions, complaints, appeals and grievance procedures, and separation and termination from employment.

The federal *Accountable Care Act* generally imposes reporting obligations and the avoidance of conflicts of interest on health care providers as of January 2012. This Regulation is proposed by USF Health College of Medicine to adopt best practices in these arenas and to facilitate USF Health compliance with the federal legislation.

The proposed regulation has been thoroughly reviewed and discussed among appropriate faculty, staff and student groups. Two town hall meetings were held for open and general discussion.

This regulation will be reviewed by the Health Sciences Advisory Council (10-6-11) and by the USF Health Workgroup (10-20-11) and the full Board of Trustees (12-15-11).

The proposed Regulation follows:

**(End of Summary)**

**AUTHORITY TO ADOPT/AMEND/REPEAL:** Art. IX, Sec. 7, Fla. Constitution; Fla. Board of Governors Regulation 1.001.

**UNIVERSITY OFFICIAL INITIATING PROPOSED REGULATION:** Stephen K. Klasko, MD, MBA, Vice President/CEO for USF Health, Dean, USF College of Medicine.

**WRITTEN COMMENTS CONCERNING THIS PROPOSED REGULATION MAY BE SUBMITTED WITHIN 14 DAYS AFTER THE POSTING DATE OF THIS NOTICE TO:**

Dee Brown, Agency Clerk  
Office of the General Counsel

University of South Florida System  
4202 East Fowler Avenue, Suite CGS 301  
Tampa, FL 33620-4301  
Phone: (813) 974-7150; FAX: 813-974-5236; E-MAIL: [USFLEGAL@ADMIN.USF.EDU](mailto:USFLEGAL@ADMIN.USF.EDU)

1 **UNIVERSITY OF SOUTH FLORIDA SYSTEM REGULATION**

2 **9.019—Limiting Conflicts of Interest in Interactions With the Pharmaceutical, Medical**  
3 **Device, and Biotechnology Industries.**

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5 (1) **Definitions.** The following definitions apply to this Regulation:

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7 (a) “COM” means the University of South Florida, College of Medicine.

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9 (b) “COM personnel” means any employee or appointee of the University of South  
10 Florida (whether full-time, part-time or courtesy, compensated or uncompensated),  
11 including but not limited to any Faculty, Administration, Staff and Temporary employee,  
12 who has a COM appointment and/or assignment; the term also includes COM medical  
13 students, graduate students, and postgraduate physicians-in-training.

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15 (c) “Industry” means the pharmaceutical, medical device, and biotechnology  
16 industries and their representatives.

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18 (2) **Introduction.** COM personnel must devote particular attention to potential  
19 conflicts of interest in any interactions with Industry in order to protect the integrity of  
20 professional judgments and to preserve public trust in physicians, researchers, and academic  
21 medical institutions. At the same time, there are many legitimate, important and necessary  
22 interactions between COM personnel and Industry. Therefore, the COM has established this  
23 Regulation to define the boundaries regarding acceptable interactions with Industry and to  
24 provide mechanisms to monitor these interactions.

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**(3) Applicability of Regulation.** This Regulation applies to all COM personnel. This Regulation is supplemental to and does not supersede any other applicable University of South Florida (USF) regulations and policies, including without limitation USF Regulations 10.206 and 10.107 regarding Ethical Obligations, Conflicts of Interest and Outside Activities.

**(4) General Statement of Regulation.**

(a) The goal of this Regulation is to increase transparency with regard to Industry interactions and to eliminate or mitigate conflicts of interest created by these interactions. All interactions between COM personnel and Industry must be consistent with this Regulation.

(b) All COM personnel are expected to become familiar with and adhere to this Regulation. COM personnel should consult with the COM's Associate Dean for Faculty & Academic Affairs with any questions or to obtain further guidance. COM personnel ultimately are individually accountable for their actions.

**(5) Gifts and Individual Financial Relationships with Industry.**

(a) Gifts. The COM recognizes that the acceptance of gifts, even in modest amounts, can exert influence on the recipients' behavior, which may affect patients.

48 Accordingly, COM personnel may not accept gifts from Industry regardless of the monetary  
49 value of the gift unless such a gift is specifically allowed under certain narrow  
50 circumstances as provided by this Regulation. A “gift” is anything accepted by COM  
51 personnel, or by another person on behalf of the COM personnel, when equal or greater  
52 payment is not given within 90 days of receipt. Gifts include, transportation, lodging,  
53 parking, membership dues, admission fees, flowers, personal services, preferential rates or  
54 terms on a debt, loan, goods or services, forgiveness of a debt, and the use of real property.

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56 (b) Meals.

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58 1. COM personnel may not accept on-site meals or any other gifts of food for  
59 themselves or others if sponsored, catered, or provided by Industry, unless such meals are  
60 specifically allowed under certain narrow circumstances as provided by this Regulation.  
61 Industry funding for meals or in-kind contributions of food or beverages may not be  
62 accepted for COM Departmental meetings, retreats or social events. In general, acceptance  
63 of meals provided by Industry at off-site locations is discouraged except for certain prior  
64 approved meetings conducted by sponsors of clinical research at investigator meetings when  
65 launching a new study or reviewing an existing sponsored study. Such meetings related to  
66 research or the development and/or initiation of clinical trials, or a new study when  
67 conducted by sponsors of clinical research provide education, discussion, and training directly  
68 related to the specific protocol requirements and the attendance at these investigator meetings by  
69 the principal investigator and his/her study staff is an important mechanism to document that the  
70 site at USF Health has the appropriate training and experience to conduct the study. In this

71 narrow instance with prior approval by the Dean of the College of Medicine/Designee the  
72 industry sponsor may provide transportation, lodging and meals for attendees at the investigator  
73 meetings.

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75 2. As a limited exception to the foregoing, food supplied by Industry in conjunction  
76 with a Continuing Medical Education (CME) event is allowed if such provision of food  
77 complies with Accreditation Council for Continuing Medical Education (ACCME)  
78 standards and guidelines.

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80 3. Industry may support the educational mission of the COM by providing  
81 unrestricted educational grants or gifts which will be placed in an appropriate USF or USF  
82 Foundation account as controlled by or accessible to the Senior Vice President, USF Health,  
83 the COM or its Departments and monitored/distributed pursuant to USF and/or USF  
84 Foundation regulations, policies and procedures.

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86 (c) Consulting Relationships.

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88 1. The COM recognizes that COM personnel may be sought after as consultants to  
89 Industry and that such relationships can lead to innovation and improvements in medical and  
90 surgical products, and can ultimately promote advances in patient care. At a Department's  
91 option, such consulting duties may be assigned (in lieu of outside activity) by the  
92 Department Chair with all revenue accruing to be paid directly to the Department for the  
93 support of Departmental programs and the COM personnel in accordance with USF

94 Regulation. However, such consulting relationships must not: (a) interfere with University  
95 duties; (b) compromise professional ethics; (c) have elements that may be construed by the  
96 government as an illegal kickback; or (d) be used as a vehicle for direct payment to faculty  
97 aimed at convincing them to use an Industry company's products.

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99 2. Accordingly, outside consulting relationships with Industry are permitted  
100 (except for COM Departments providing such consultation services as a part of  
101 Departmental assigned activity) under the following conditions:

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103 a. The relationships must be disclosed via the outside activity reporting process  
104 (Reporting Outside Activities Database - ROAD) prior to engaging in the outside activity;  
105 and approved by the Department Chair, unless other arrangements are made with the  
106 Department Chair to conduct the activity as part of the COM personnel's Departmental  
107 assignment; and

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109 b. The COM personnel must submit a request for annual leave if the participation  
110 will take place during University business hours (Monday-Friday, 8am-5pm) or during  
111 periods when scheduled for on-call duties; and

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113 c. The relationship must be described in a formal written contract which documents  
114 the specific, legitimate tasks and deliverables, and payment for services must be  
115 commensurate with the tasks performed considering the faculty member's specialty,  
116 expertise, experience, and regional/nation/international reputation.

117 d. A copy of the final, fully-executed contract must be submitted to (i) the  
118 Department Chair for the Department file, and (ii) the COM's Office of Faculty Affairs.

119  
120 3. On occasion, an Industry company will ask for a release letter from the  
121 University indicating that the University has approved the consulting activity in question.  
122 The COM personnel may provide the approved outside activity report form in response to  
123 such requests.

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125 4. In accordance with USF System Policy 0-309, COM personnel who participate in  
126 a USF System Research Project involving the Industry company with whom the consulting  
127 relationship is proposed must disclose whether the individual or the individual's Immediate  
128 Family has a Reportable Financial Interest or Relationship in the USF System Research Project  
129 through the eCOI Disclosure system: <https://arc.research.usf.edu/Prod>.

130  
131 5. Outside employment, consulting activities, and financial interests of COM  
132 personnel may be disallowed if they result in conflicts with the employee's duties,  
133 responsibilities, and obligations to the COM as set forth in University of South Florida  
134 regulations and policies. It is the responsibility of the COM personnel to ensure that no  
135 consulting or employment agreement that he or she enters into violates any University of  
136 South Florida regulations and policies as well as state and federal laws.

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140 (d) Industry-Funded Speaking Relationships.

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142 1. The COM recognizes that COM personnel may be sought after as speakers to  
143 present information relevant to an Industry company's products, and recognizes that such  
144 speaking opportunities may serve to provide necessary scientific and educational  
145 information to the medical and health care provider community. The COM recognizes that  
146 COM personnel spend time and effort apart from their assigned COM duties in preparing for  
147 such presentations, and that compensation by the Industry company for the COM  
148 personnel's time may be offered. The COM also recognizes that speaking relationships  
149 must not function as de facto gifts from Industry or marketing of Industry products.

150

151 2. COM personnel participation as speakers on behalf of an Industry company  
152 relative to its products must be conducted as an approved outside activity. The COM  
153 personnel must disclose the activity via the outside activity reporting process (Reporting  
154 Outside Activities Database - ROAD) prior to engaging in the outside activity. Approval  
155 will not be unreasonably withheld, but will be dependent upon whether the COM personnel  
156 are meeting his or her Departmental assignments/expectations. Speaking engagements will  
157 only be allowed for one year (12 months) but may be renewed using the procedure as  
158 described above. The COM personnel must also submit a request for annual leave if the  
159 participation will take place during University business hours (8am-5pm, Monday-Friday)  
160 or during periods when scheduled for on-call duties.

161

162 3. Payment to the COM personnel must be commensurate with the tasks performed

163 considering the COM personnel's specialty, expertise, experience, and  
164 regional/national/international reputation. The gathering where the information is presented  
165 must be primarily dedicated to informing healthcare professionals about a product or  
166 treatment, providing scientific information, and promoting educational discourse on the  
167 topic presented. The venue must be conducive to informational communication and any  
168 meals (a) are reasonable as judged by local standards; (b) are not part of an entertainment or  
169 recreational event; and (c) are provided in a manner conducive to informational  
170 communication. In addition, inclusion of the COM personnel's spouse or other guest in a  
171 meal accompanying an informational presentation made by or on behalf of an Industry  
172 company is not appropriate.

173

174 4. The COM personnel shall be responsible to retain full control of the educational  
175 content and ensure the ethical and scientific integrity of the information he/she presents.  
176 The content of the presentation/speech should be produced by and/or fully vetted for  
177 scientific accuracy by the faculty member. The Departmental Chair or Center Director  
178 reserves the right to review all content for appropriateness.

179

180 5. If an industry engagement requires that a faculty member must as a condition of  
181 the engagement use industry prepared presentation materials on drug products, then the  
182 presentation and audiovisual materials must follow pharmaceutical guidelines and present  
183 information on the FDA-approved use of the drug product and may not promote the "off-  
184 label" use of a drug product. Speakers and their materials should clearly identify the company

185 that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the  
186 company, and that the speaker is presenting information that is consistent with FDA guidelines.<sup>1</sup>

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188 6. Participation in an Industry-sponsored speaker's bureau may create a conflict of  
189 interest for the COM personnel if he/she is invited to speak on a similar topic for a  
190 professional meeting certified for CPE (continuing professional education) credit unless  
191 such CPE activity is conducted in association with or on behalf of activities of the Health  
192 Professional Conferencing Corporation (HPCC).

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194 7. The COM shall not sponsor or host any Industry speaker's bureau activities.

195

196 (e) Disclosure.

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198 1. COM personnel wishing to engage in activities or hold financial interests that are  
199 required to be reported under University of South Florida Regulations 10.206 and 10.107  
200 have an obligation to disclose and receive approval prior to engaging in these activities and  
201 to assure that such activities do not infringe upon their responsibilities and obligations to the  
202 COM and to the University of South Florida. Each COM personnel is responsible for  
203 complying with the regulations and laws concerning outside activities and financial  
204 interests.

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206 2. COM personnel engaging in outside activities must take reasonable precautions  
207 to ensure that the outside employer or other recipient of services understands that he or she

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<sup>1</sup> [http://www.phrma.org/sites/default/files/108/phrma\\_marketing\\_code\\_2008.pdf](http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf) Section 7

208 is engaging in the activities as an individual and not on behalf of the COM or the University  
209 of South Florida. COM personnel may not use the University's resources, including its  
210 name or addresses, without express written approval from an administrator designated by  
211 the University of South Florida President to approve such use. A request for the use of  
212 University resources must be submitted pursuant to the University of South Florida  
213 Regulations 10.206 or 10.107.

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215 3. COM personnel disclosures of outside activities are to be reported via the  
216 Reporting Outside Activities Database (ROAD) which is to be reviewed by the Department  
217 Chair or immediate supervisor and forwarded to the COM Dean or the COM Dean's  
218 designee for authorization. This report should be completed and filed prior to such time as  
219 the outside activity or financial interest begins and at the beginning of each fiscal year. If a  
220 material change in the information presented occurs during the year, a new report must be  
221 submitted. All reports associated with continuing outside employment/activity must be  
222 renewed on a fiscal year basis. The report shall include the amount of financial  
223 compensation for the outside employment/activity.

224

225 4. COM faculty who present formal lectures to students or residents of the  
226 University of South Florida must disclose any and all outside activities, financial interests or  
227 personal relationships with Industry that are pertinent to the lecture subject at each  
228 presentation.

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230 5. All reports of outside activities by COM faculty at the University of South  
231 Florida are open to the public under Florida law. This information is publicly available via  
232 the COM's website. Additionally, COM personnel are expected to take appropriate steps to  
233 disclose their financial ties with Industry to patients when such a relationship might  
234 represent an apparent conflict of interest.

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236 6. Annual Attestation. COM faculty, residents and staff who have no outside  
237 activities or financial interests to report are required to provide an annual attestation to that  
238 effect.

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240 **(6) Pharmaceutical Samples and Certain Medically Necessary Devices.**

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242 (a) COM personnel may not directly accept pharmaceutical samples from Industry  
243 except under certain narrow circumstances approved by the COM that protect the interests  
244 of patients and prevent the use of samples as a marketing tool. Pharmaceutical sales  
245 representatives are prohibited from giving samples directly to physicians, except at the  
246 COM clinical site for control and dispensing as provided by this Regulation. The COM and  
247 COM personnel shall not accept remuneration of any kind for either receiving or dispensing  
248 sample medications. COM personnel shall not accept sample medications for personal use,  
249 and are not authorized to request, take or dispense sample medications without a written  
250 order of a licensed practitioner legally authorized to prescribe medications.

251  
252 (b) Pharmaceutical samples can benefit patient care by allowing patients to try a

253 medication for effectiveness and absence of side effects prior to incurring a related cost, and  
254 by expediting the patient's medical intervention. With these benefits comes responsibility  
255 for managing the medications to ensure security of medication inventory, prevent dispensing  
256 of expired medications, and recording of all dispensed medications in the respective patient  
257 records.

258  
259 (c) Sample medications are to be signed for by a physician and stored in a locked  
260 central location within the COM clinical site and with the COM's designated  
261 pharmacy/clinic manager responsible for security of access. Any Schedule II or III  
262 medications are to be kept in a separate locked storage space/cabinet. Sample medications  
263 may be dispensed only under the written order of a licensed practitioner legally authorized  
264 to prescribe medications, and must be recorded in the patient's medical record along with  
265 the corresponding written order for the medication. The medical record documentation  
266 should include the order date, medication and quantity dispensed; and dosing instructions,  
267 which should be provided to the patient. Sample medications are to be checked by the  
268 designated clinic manager for expiration dates on a monthly basis. Expired medications are  
269 to be disposed of as hazardous waste and not distributed or dispensed for use by anyone.  
270 The medication inventory is to be updated whenever medications are received, dispensed or  
271 disposed of. Certain dermatological sample preparations in the dermatology clinical area  
272 such as skin crèmes, ointments, gels, treatments, and emollients under 30 g total or 30 cc total  
273 per package and non-prescription elective and/or cosmetic agents are exempt from the inventory  
274 control accountability enumerated above.

275

276 (d) Authorized sample devices for patient use are listed on an annually updated clinic  
277 list approved by the Dean of the College of Medicine. Devices to be considered for  
278 approval must be commonly utilized for patient care for intensive care management such as,  
279 but not limited to, glucose meters utilized in diabetes care management.

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281 1. Receipt of such devices from a device representative are to be signed for by a  
282 physician/designee and must be stored in a locked central location within the COM clinical  
283 site.

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285 2. The COM's clinic manager or designee shall be responsible for security and/or  
286 access in accordance with the policy for use of such devices together with the accompanying  
287 continuing care supplies which are to be used for initiation of management as authorized by  
288 the patient's third party carrier or for humanitarian reasons may be provided to patients  
289 otherwise unable to pay or unable to obtain the initial device and necessary supplies.

290

291 3. Sample supplies, if initially dispensed for the convenience of the patient at  
292 initiation of care management, must be dispensed under the written order of a licensed  
293 practitioner legally authorized to prescribe medications or devices and must be recorded in  
294 the patient's medical record along with the corresponding written order for the supplies.

295 The medical record documentation should also include the initial order date, specific  
296 supplies, and quantity dispensed as well as instructions for use and the frequency of use;  
297 appropriate documentation and instruction should also be provided to the patient by a  
298 member of the care coordination team. The inventory of sample supplies with a date of

299 expiration must be checked periodically by the designated clinic manager and destroyed if  
300 the expiration date is exceeded.

301

302 **(7) Purchasing and Formularies.**

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304 (a) COM personnel engaged in University purchasing are subject to the provisions  
305 of the University of South Florida's regulation and applicable state and federal law  
306 regarding the disclosure of outside activities, financial interests and conflict of interest. In  
307 addition, formulary committees and committees overseeing purchases of medical devices  
308 shall exclude those who have financial relationships with Industry from voting on applicable  
309 purchases. Expert clinicians may advise such committees provided that all conflicts of  
310 interest are disclosed.

311

312 (b) An approved disclosure form must be attached to each applicable Requisition to  
313 Purchase from an enterprise in which COM personnel has a material financial or managerial  
314 interest. If there is a requisition prepared to purchase from an enterprise in which a COM  
315 personnel has a material interest, the COM personnel with the interest cannot approve the  
316 requisition. If the purchase is allowed under state law, the approval of the COM personnel's  
317 supervisor will be required when an outside interest exists regardless of whether the  
318 proposed purchases fall under the sole source, emergency, or special purchasing categories.

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322 **(8) Industry Representatives (Including Sales and Device Representatives)**

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324 (a) Industry representatives are required to schedule an appointment to meet with a  
325 COM personnel for educational purposes relative to the representative's company's  
326 products, and must limit their interaction to only that COM personnel. Industry  
327 representatives are required to check in at a designated area to sign in as a visitor at a USF  
328 Health/COM site; receive a visitor pass to be worn throughout their visit; and return the  
329 visitor pass upon signing out when leaving the site. On their initial visit to a USF  
330 Health/COM site, Industry representatives are to be notified of this Regulation and other  
331 applicable USF Health/COM policies, standards, and procedures and sign an agreement  
332 acknowledging their commitment to comply with such. An Industry representative's failure  
333 to comply with these registration and other Regulation requirements can result in penalties  
334 including denial of any future access.

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336 (b) Industry representatives are not allowed access to patients or Protected Health  
337 Information (PHI) unless authorized by the treating physician and patient for involvement in  
338 patient care in accordance with appropriate patient consent or in accordance with an  
339 IRB/Privacy Board approved research authorization or waiver. Pharmaceutical  
340 representatives shall not have access to patient information nor be allowed to observe  
341 examinations or therapeutic discussions of patients. Except as allowed above, device  
342 representative's access to patient information, examinations, and therapeutic discussion shall  
343 be limited to only that which is necessary for appropriate education of the medical staff  
344 during planned or active use of the represented device.

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(c) Educational materials or product information that may be useful to patients may be directly accepted by the physician and designated clinic staff. Industry representatives are not permitted to place educational material in patient care areas or waiting areas. Any educational sessions presented by Industry representatives are to be held away from patient care areas wherein PHI is not viewed or heard.

**(9) Education.**

(a) On-Site Educational Activities.

1. Teaching Aids/Books/Devices/Educational Materials/Equipment. COM personnel are generally not permitted to directly accept books, instruments, equipment, or teaching aids from Industry. Industry may support the educational mission of the COM by providing unrestricted educational grants or gifts of the above listed items to the COM under the conditions stated in this section. Such unrestricted grant or gift funds will be placed in an appropriate USF or USF Foundation account as controlled by or accessible to the Senior Vice President, USF Health, the COM or its Departments and monitored/distributed pursuant to USF and/or USF Foundation regulations, policies and procedures. Additionally, educational materials may be donated by Industry to the COM for use by COM personnel and students provided such materials are preapproved in advance by the COM's Vice Dean for Educational Affairs or Dean and have no branding beyond a logo on the cover or device. Such materials must not be distributed directly by industry to individual COM faculty, residents, staff, students, and patients.

368 2. Educational Presentations. Industry representatives are allowed to provide  
369 educational materials and presentations to medical students and postgraduate physicians in-  
370 training only if the interaction is approved by the Vice Dean for Educational Affairs (for  
371 medical students) or the relevant residency program director (for residents) subject to the  
372 following conditions:

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374 a. Interactions must only involve presentation of published literature and FDA  
375 approved indications.

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377 b. Time allowed for open questions shall be not greater than 10% of the allocated  
378 presentation time.

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380 c. The Industry representative may not provide promotional items to any medical  
381 students or resident physicians, regardless of value, nor gifts such as meals, food, and  
382 beverages except as authorized under the specific provisions of paragraph (5) (b) 3 above.

383  
384 3. Other On-Site Educational Activities. COM personnel may engage in  
385 educational activities onsite in conjunction with Industry under the conditions set forth in  
386 this section. CME courses must conform to Accreditation Council for Continuing Medical  
387 Education (ACCME) standards and must be processed through and approved by the USF  
388 Health Office of Continuing Professional Development (OCPD). Any non-CME  
389 educational activities that involve the participation of Industry shall be conducted in  
390 accordance with this Regulation and in such a manner as to ensure that Industry-

391 participation is fully disclosed.

392

393 (b) Payment for Travel or Attendance at Off-Site Lectures and Meetings.

394 COM personnel may not accept payments from Industry to attend off-site lectures or

395 meetings except under the following limited circumstances: (i) for legitimate reimbursement

396 for travel to provide contractual services to Industry pursuant to an approved consulting

397 activity or other approved outside activity; (ii) to view capital equipment *in situ* if the

398 equipment is being considered for purchase or for training in the use of equipment, in which

399 cases travel should be reimbursed through and in compliance with University policies; or

400 (iii) to participate in meetings directly related to ongoing sponsored research in which case

401 travel should be reimbursed through and in compliance with University policies.

402 Unrestricted grants from Industry to the institution may be used in part to support travel for

403 COM personnel attending professional meetings; however, the decision to use gift funds for

404 travel expenses will be made at the discretion of the applicable COM Department Chair and

405 the COM Dean. A Department Chair's use of funds for his/her own travel must be approved

406 in advance by the COM Dean. Students and trainees may accept travel funds from scientific

407 societies, whether or not Industry is the source of the funds, provided the society and/or

408 COM Department control the selection of the recipient of travel support.

409

410 (c) Industry Support for Scholarships/Fellowships and Funds for Trainees. COM

411 personnel may not accept scholarships or fellowships to support training initiatives directly

412 from Industry; however, scholarship and fellowship funds may be provided to USF or the

413 USF Foundation and placed in accounts controlled by or accessible to the Senior Vice

414 President, USF Health, the COM or its Departments, as appropriate to support these  
415 initiatives. There shall be no *quid pro quo* associated with such funding, and recipients of  
416 scholarships and fellowships shall be chosen by the COM/Department and not by Industry.

417

418 **(10) Relations with Industry Representatives in Publications.**

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420 The professional presentations, books, articles, reports, or other materials, oral or written, of  
421 COM personnel must have appropriate authorship attribution. COM personnel may not  
422 submit material(s) for publication (or for consideration for publication) in professional  
423 works as their own created product if those material(s) are primarily created by another  
424 person such as but not limited to employees of any Industry company. Such conduct may be  
425 referred for consideration as research misconduct (possible plagiarism) under USF System  
426 Policy 0-301, Misconduct in Research.

427

428 **(11) Medical School Curriculum.**

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430 The COM Curriculum Committee shall ensure that COM medical students are trained to  
431 understand the importance of federal, state, and institutional conflict of interest laws, rules,  
432 policies and procedures, and how Industry promotion can influence clinical judgment.

433

434 **(12) Enforcement and Penalties.**

435

436 COM directors, department chairs and immediate supervisors are responsible for reviewing

437 disclosures and for ascertaining that COM personnel and activity under their supervision are  
438 in compliance with this Regulation and initiating enforcement and corrective action to  
439 address any instance of non-compliance with this Regulation. COM personnel who fail to  
440 abide by the provisions of this Regulation are subject to appropriate disciplinary action in  
441 accordance with University regulations. Examples of sanctions are: disallowance or limiting  
442 outside activities, changes in assignment, limitations on research activities, fines, reduction  
443 in pay, demotion, written reprimand, suspension without pay, and termination for cause.

444

445 **(13) Annual Review and Revision.**

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447 The COM Faculty Council, USF COM Chapter of the American Medical Student  
448 Association representatives, and the administration of the College of Medicine will review  
449 this document annually to revise and propose changes as may be both appropriate and  
450 necessary as this is envisioned to be a dynamic shared governance regulation consistent with  
451 professionalism standards for the COM and the University.

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454 *Authority: Art. IX, Sec. 7, Fla. Constitution; Fla. Board of Governors Regulation 1.001.*

455 *History—New XX-XX-11.*