Assessment Tool for Physician-Industry Relationships

In the July-August 2009 issue of *Health Progress*, Michael Panicola, Ph.D., corporate vice president, ethics, SSM Health Care, and Ron Hamel, Ph.D., senior director, ethics, Catholic Health Association, published an article titled, "Industry-Physician Relationships: A Call for Greater Distance" (pp. 62-68). The article described the need for a change in these relationships based on evidence from various sources as well as SSM Health Care's efforts to bring about such a change. At the time of publication, SSMHC had not yet developed its recommendations. Those recommendations appear below. What follows immediately below is a description of the process with links to tools that were used in the process. The process and the tools may be of use to other systems that wish to address this issue.

The Process

As SSMHC's corporate vice president for ethics, Panicola was asked to look into the issue of industry-physician relationships after it became a matter of intense public interest in light of several events. These included Senator Charles Grassley's (R-IA) 2008 investigation that uncovered major financial conflicts of interest among several prominent academic physicians; the introduction of the Physician Payments Sunshine Act of 2009 by Senators Grassley and Herb Kohl (D-WI); news reports of lawsuits and huge settlements/fines by pharmaceutical and device makers; and a substantial body of research showing that industry payments and gifts, even of nominal value, impact physician judgment, adversely affect patient care, and contribute to the growing problems of the American health care system.

To review the overall issue of industry-physician relationships in more depth, please see the *Health Progress* article.

After researching the issue, SSMHC believed it was necessary to strengthen its current policy governing industry (or vendor)-employee relationships, including those of employed physicians.. In light of the impact on physicians, administration engaged in dialogue with physicians rather than dictating policy to them. To this end, three distinct physician groups provided input: the physician advisory group, the physician leadership committee, and the physician leadership team. Within the groups, there was overwhelming support for exploring the issue further through the formation of a task force comprised of physician leaders representative of all SSM markets.

Task force members agreed to meet together to review current SSMHC policy and to work toward consensus on any recommended changes to that policy. In preparation for the meeting, which was conducted via conference call on May 8, 2009, participants received a simple tool with these directions:

> Complete the "proposed policy changes" column in the attached grid utilizing input from your physician colleagues, which you were asked to obtain in previous emails, as well as your own experiences/reflections. When completing, ask yourself, "Is SSMHC's current policy related to the item under consideration adequate?" If yes, simply write no change necessary. If no, suggest what the policy related to that item should be (e.g., for gifts, SSMHC should have a zero-dollar limit meaning all gifts from industry should be banned). If SSMHC's policy is silent on a particular item, you will obviously need to suggest what it should be.

To review the tool — the "Pre-Conference Call Task Force Grid" — used by the task-force members in the preparatory phase, please click here to view Document A.

For the conference call itself, a streamlined and simplified tool was used for comparison purposes prior to discussing recommendations and working toward consensus. Unlike

the previous tool, this tool included just-released recommendations of the Institute of Medicine as outlined in its April 28, 2009 report entitled, *Conflict of Interest in Medical Research, Education, and Practice*.

To review the tool — "Task Force Discussion Tool" used by the task-force during the conference call, please click here to view Document B.

Recommendations:
During the conference call, the task force members identified several areas of the current SSMHC policy that needed to be strengthened in light of the present circumstances and other items that needed to be added to the policy. The recommendations of the task force that were developed in May 2009 appear below. SSMHC's policy will go into effect on October 1, 2009.

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Item	SSM Task-Force Recommendations
Gifts	
a) Food/beverages in workplace	a) no, zero-dollar limit
b) Pens, mugs, notepads, etc.	b) no, zero-dollar limit
c) Tickets to cultural/sports events	c) no, zero-dollar limit
d) Restaurant dinners/trips	d) no, zero-dollar limit
Reimbursements	
a) Admission to CM meetings	a) no, zero-dollar limit
b) Travel and meeting expenses	b) no, zero-dollar limit
c) Compensation for time at meetings	c) no, zero-dollar limit
Payments	
a) Cash/cash equivalents	a) no, zero-dollar limit
b) Consulting	b) consulting acceptable provided contract with specific tasks outlined and pay commensurate with work; employed physicians must get approval from supervisor for consulting arrangements and make appropriate disclosures; non-employed must disclose if in a position of influence and/or leadership role (e.g., P&T committee, formulary committee)
c) Honoraria	c) yes, reasonable compensation to present "own" material — can't be a voice for industry
d) Advisory board	d) no payment, done on voluntarily basis . . . can receive reasonable compensation for travel, lodging, meals for participation in meetings . . . should not participate in advisory boards if have significant COIs
e) Clinical research	e) yes, but only for direct costs related to research . . . researchers with financial stake in outcome are prohibited from conducting clinical trials on human subjects
f) Speaker bureaus	f) physicians may not participate in, or receive compensation for, talks given through a *speakers bureau* or similar frequent speaker arrangements if: (a) the events do not meet the criteria of Section 6; *or* (b) if the content of the lectures given is provided by industry or is subject to *any* form of prior approval by either representatives of industry or event planners contracted by industry; *or* (c) the content of the presentation is not based on the best available scientific evidence; *or* (d) the company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Assessment Tool for Physician-Industry Relationships *(Continued)*

Item	SSM Task-Force Recommendations
f) Speaker bureaus	Section 6 criteria: (a) the activity is designed to promote evidence-bassed clinical care and/or advance scientific research; (b) the financial support of industry is prominently disclosed; (C) if the SSM representative is an attendee, industry does not pay attendees' travel and attendance expenses; (d) attendees do not receive gifts or other compensation for attendance; (e) meals provided are modest (i.e., the value of which is comparable to the Standard Meal Allowance as specified by the United States Internal Revenue Service) and consistent with the educational or scientific purpose of the event.
g) Ghostwriting	g) no
Education a) Industry-sponsored CME	a) Industry can sponsor CME programs provided that industry's support is for legitimate educational purposes and all such programs are negotiated through and executed by the CME office or its equivalent in each entity
b) Industry support for scholarships, fellowships, or other support of students, residents, trainees	b) Entities that participate in graduate medical education are required to establish a process whereby industry funds for scholarships, fellowships, or other such support are given to and distributed by the foundation or its equivalent in each entity
Site Access for Industry Reps	a) Expectation is that access to physicians <u>should be</u> restricted through mechanisms developed by each entity and visits by industry representatives should only occur at the physicians' express invitation . . . visits should occur during non-patient care time . . . no reps involved in marketing activities in patient-traffic areas
Drug and Device Samples	a) The long-term goal is to work toward a voucher system with centralized distribution office . . . for now, all entities need to require that samples should generally be reserved for indigent patients or for limited short-term therapeutic trials in these or other patients but <u>not</u> for routine maintenance . . . no personal use of drug samples by physicians and her/his family • set time line . . . 6 months to implement voucher system and no samples allowed if not in place — allowances for change management, education campaign • develop work-group to report back to come up with staged implementation
Disclosure of Conflicts of Interest	a) Require disclosure of COIs for <u>all</u> medical staff physicians during appointment and reappointment process — no minimum dollar threshold and disclosures will be reported on public website . . . every committee within an SSM operating entity should require and obtain disclosures of COI annually at the beginning of each year and committee members must recuse themselves when they have COIs that could interfere or influence their decision making • review COI disclosure policies and forms we currently have in place

Next Steps:
Moving forward, the task force has developed and agreed to the following plan.

1. Revise the applicable Corporate Responsibility Process (CRP) guideline in light of the task force's recommendations. Vet this draft guideline with the CRP Steering Team.
2. Review the draft CRP guideline with system management for its input.
3. Develop a PowerPoint program for physicians to review the draft guideline and seek their input on it, pointing out items that are not negotiable (e.g., gifts and payments) and those that are or are at least flexible and allow for local interpretation (e.g., site access and samples) **Click here to access the PowerPoint presentation.**
4. Conduct physician feedback sessions at each entity and with physician groups through the VP for Medical Affairs other physician leaders, etc. Submit feedback to Corporate Vice-President, Ethics.
5. Hold a systemwide physician task force conference call to review the feedback and revise recommendations as needed.
6. Revise the draft guideline in light of task force's recommendations and get approval for final guideline from appropriate persons/groups.
7. Synch the guideline requirements and content with other applicable policies, forms, etc.
8. Develop a communication plan for rolling out the guidelines and implement.

Editor's Note: We are grateful to SSMHC and to Mike Panicola for sharing these resources with the ministry.