

Chapter I: Institutional Policies and Practices

Academic medical centers should adopt and implement policies that address specific interactions between academic medical personnel and industry and are consistent with recommendations contained in Chapter 2. These policies should reinforce and uphold institutional and individual efforts to promote a learning environment that supports professionalism and eliminates activities that undermine this objective.

NEOUCOM RESPONSE: Agree. Chapter 2 deals with the benefits and pitfalls of the industry funding of medical education.

Academic medical center should make clear to their faculty, students, and staff that, to the extent certain interactions with industry are prohibited within academic medical centers, they are also prohibited off-site.

NEOUCOM RESPONSE: Although we agree, we would like "prohibited" changed to read "strongly discouraged." This better suits the relationship of NEOUCOM to its teaching hospitals.

Our definition of "off-site" is locations away from the NEOUCOM-affiliated hospitals and contracted clinical sites, i.e. a restaurant or a hotel.

All major and limited hospital affiliated sites are considered "on-site."

Similarly, academic medical centers should communicate to off-site training facilities their expectations that the off-site venues will adhere to the standards of the academic center regarding interactions with industry.

NEOUCOM RESPONSE: Agree. Mechanism for communication needs to be defined.

Industry should not invite academic medical center personnel to participate off-site in practices prohibited on-site.

NEOUCOM RESPONSE: Agree in theory but difficult to enforce.

Education for Professionalism: Educational programs should be developed to raise the awareness among students, trainees, and faculty of challenges to professionalism presented by certain interactions with industry and to provide opportunities to help them build critical evaluation skills that reinforce high individual standards, norms and behaviors. Specifically, the Task Force recommends a follow-up on Medical School Objectives Project (MSOP) that focuses on developing learning objectives regarding professionalism and industry interactions.

NEOUCOM RESPONSE: Agree. A NEOUCOM-generated uniform curriculum should be developed for evaluation skills for medical and pharmacy students, residents, and faculty with input from all consortium partners. The curriculum should include education about interacting with pharmaceutical representatives and a basic overview of the processes and disciplines pharmaceuticals play in clinical practice.

CHAPTER 2: BENEFITS AND PITFALLS

Gifts to Individuals: Academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students and trainees of academic medical centers, whether on-site or off-site. Such standards should encompass gifts from equipment and service providers as well as pharmaceutical and device providers.

NEOUCOM RESPONSE: Agree. Gifts of any type can lead to loss of objectivity in decision making.

Pharmaceutical Samples: The distribution of medications in academic medical centers, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.

NEOUCOM RESPONSE: "Central management" defined as central to a geographic site, i.e. each hospital would have its own central management site, as well as NEOUCOM. The Task Force will encourage each major and limited affiliated organization to develop policies and procedures pertaining to the use of samples.

If central management is not thought to be feasible or would interfere with patient access to optimal therapeutics, the academic medical center should carefully consider whether or not there are alternative ways to manage pharmaceutical sample distributions that do not carry the risks to professionalism with which current practices are associated.

NEOUCOM RESPONSE: Agree

Site Access to Pharmaceutical Representatives: To protect patients, patient care areas, work schedules, access by pharmaceutical representatives to individual physicians should be restricted to non-patient care areas and nonpublic areas and should take place only by appointment or invitation of the physician.

NEOUCOM RESPONSE: Agree

Involvement of students and trainees in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.

NEOUCOM RESPONSE: Agree

Academic medical centers should develop mechanisms whereby industry representatives who wish to provide educational information on their products may do so by invitation in faculty-supervised structured settings that provide the opportunity for interaction and critical evaluation. Highly trained industry representatives with M.D., Ph.D. or Pharm.D. degrees would be best suited for transmitting such scientific information in these settings.

NEOUCOM RESPONSE: Agree

Site Access by Device Manufacturer Representatives: Access by device manufacturer representatives to patient care areas should be permitted by academic medical centers only when the representatives are appropriately credentialed by the center and should take place only by appointment or invitation of the physician.

NEOUCOM RESPONSE: Agree

Representatives should not be allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patient, and then only to provide in-service training or assistance on devices and equipment.

NEOUCOM RESPONSE: Agree. Representatives must meet the institution's requirement for "approved" status.

Student interaction with representatives should occur only for educational purposes under faculty supervision.

NEOUCOM RESPONSE: Agree

Continuing Medical Education: Academic medical centers offering CME programs should develop audit mechanisms to assure compliance with the standards of the Accreditation Council for Continuing Medical Education (ACCME), including those with respect to content validation and meals.

NEOUCOM RESPONSE: Agree

Academic medical centers should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.

NEOUCOM RESPONSE: Agree. Please see prior definition of "central."

To the extent that educational programs for physicians are supported by any commercial entity, including pharmaceutical, device, equipment and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards.

NEOUCOM RESPONSE: Agree. The College of Medicine needs to review the policy that permits the Conference Center to allow pharmaceutical companies to host "educational" events in the Center.

Participation in Industry-Supported Programs: With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers' bureaus.

NEOUCOM RESPONSE: Agree

To the extent that academic medical centers choose to allow participation of their faculty and staff in industry-sponsored, FDA-regulated programs, they should develop standards that define appropriate and acceptable involvement.

NEOUCOM RESPONSE: Agree

1. Academic medical centers should require full transparency and disclosure by their personnel to the centers and when participating in such programs; and
2. Academic medical centers should require that payment to academic personnel be only at fair market value.

NEOUCOM RESPONSE: Agree

Academic medical centers should prohibit their faculty, staff, and trainees from:

1. Attending non-accredited industry events billed as continuing medical education
2. Accepting payment for attendance at industry-sponsored meetings; and
3. Accepting personal gifts from industry at such events.

NEOUCOM RESPONSE: Agree with the caveat that "prohibit" be changed to "strongly discouraged."

Industry-Sponsored Scholarships and Other Educational Funds for Trainees: Academic medical centers should establish and implement policies requiring that:

1. All scholarships or other educational funds from industry must be given centrally to the administration of the academic medical center;
2. No *quid pro quo* be involved in any way; and
3. The evaluation and selection of recipients of such funds must be the sole responsibility of the academic medical center or of a nonprofit granting entity, with no involvement by the donor industry.

NEOUCOM RESPONSE: Agree. Refer again to prior definition of "central."

- With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies stating that industry-sponsored food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers.
- Policies should make clear that the same standard of behavior should be met off-site.

NEOUCOM RESPONSE: Agree.

Professional Travel: Academic medical centers should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services.

NEOUCOM RESPONSE: Agree

Ghostwriting: Academic medical centers should prohibit physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry, or otherwise.

NEOUCOM RESPONSE: Agree

Purchasing: Academic medical centers should establish and implement policies that require their personnel with any financial interest (as defined by the medical center's conflict of interest policy or applicable purchasing conflict of interest policy) in any particular manufacturer of pharmaceuticals, devices or equipment, or any provider of services, to disclose such interests according to institutional policies and to recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.

NEOUCOM RESPONSE: Agree

To the extent an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision.

NEOUCOM RESPONSE: Agree

CHAPTER 3: UNMET NEEDS AND OPPORTUNITIES

The Educational Experience: Medical schools and teaching hospitals should design curriculum standards and teaching materials for all phases of medical education – from medical school to residency to continuing medical education – that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics and regulation.

NEOUCOM RESPONSE: Agree. See response Education for Professionalism, Chapter 1.

Content Validation of Continuing Medical Education: The AAMC should collaborate with ACCME to create a process by which CME offerings would be externally spot-reviewed or audited for consistency with applicable guidelines and for the presence of inappropriate influence.

NEOUCOM RESPONSE: Disagree. All CME is well-audited by the ACCME and no further intervention is necessary.

The AAMC should participate with key national medical organizations, such as the AMA, the ACCME, the Society for Academic Continuing Medical Education, and other professional societies in an initiative to define the processes and structure that would best ensure the provision of sound, timely, scientifically objective CME that meets the educational needs of physicians.

NEOUCOM RESPONSE: Agree

Development of Information Portals: The AAMC should convene representatives of academic medicine and industry in a cooperative effort to develop optimal information systems, including Web-based technologies for disseminating information on new products.

NEOUCOM RESPONSE: Agree, exciting proposal. The Task Force feels this will be a most helpful vehicle for transmitting information.

The AAMC should convene an expert panel composed of academic and industry representatives to explore new opportunities and identify best practices in information exchange between academic medicine and industry that are transparent, rely on rigorous evaluation of evidence, and are consistent with standards of professionalism.

NEOUCOM RESPONSE: Agree