1. GIFTS FROM INDUSTRY

**DEFINITION:**
Gifts are defined as any free item, other than meals, which are covered under domain #2, Meals.

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**NOTES:**
To qualify for a top score of “3”:
- **Prohibited** industry-funded gifts include the following:
  - “Educational gifts” for faculty and trainees, such as textbooks and journal articles or online subscriptions. Policies allowing gifting of textbooks, whether de-identified (i.e. no logos) or not and regardless of how they are given (indirectly via a central office or directly to an individual) score a “2”.
- **Permitted** industry-funded gifts include the following:
  - Institutional gifts to the university.
  - Educational items meant primarily for patient use, such as educational wall charts or anatomic models, or brochures describing medications.
  - Small gifts such as a totebag or water bottle given at a conference where everyone receives the gift as part of the registration fee or orientation packet.
2. MEALS FROM INDUSTRY

**DEFINITION:**
This domain includes both CME and non-CME related meals, whether onsite and/or offsite (includes food and beverage).

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**NOTES**
To qualify for a top score of “3”:
- **Prohibited** industry-funded meals include the following:
  - Any industry-funded food or beverages provided directly to individuals on-site.
  - Industry-funded food or beverages provided off-site as part of a promotional talk (like a dinner program at a restaurant).
  - Meals as part of on- or off-site industry-funded CME courses, unless the meal portion of the program is funded by a non-industry source (such as a medical society, an academic department, the individual participants, etc.).

- **Permitted** industry-funded meals include the following:
  - Industry-funded food or beverages if provided to all participants who register for a legitimate academic conference, such as an annual meeting of a medical specialty society. (For example, this would include snacks and beverages made available in an exhibit hall to all registered participants. It would not include meals available only to participants who choose to attend a specific industry-sponsored lecture taking place at the conference setting.)
  - Industry-funded meals if they are part of a bona fide research or consulting contract.
  - Industry-funded meals (may be on-site in this case) if they are funded by more than one anonymous industry sponsor.
3. INDUSTRY-FUNDED PROMOTIONAL SPEAKING RELATIONSHIPS

Has the institution provided a part (or parts) of the policy that applies to faculty who receive payments from industry for external speaking engagements?

- YES
- NO
  1

Does the policy effectively prevent faculty from being paid by industry to do promotional speaking, or to be on an industry-funded speaker’s bureau? If industry-funded speaking is allowed, an effective policy may ensure the speaking is not promotional in a variety of ways, but for the purposes of the scorecard, the policy must state or clearly imply the following two criteria: (a) The talk is not promotional in nature, but educational; and (b) industry has no role in determining or approving presentation content.

- YES
- NO
  3

Does the policy expect industry-funded speaking relationships to be regulated, but with less stringent limits on content control, compensation, etc.?

- YES
- NO
  2

Does the policy state that there are no limitations on industry-funded speaking or no policy is in place?

- YES
- NO
  1

NOTES:

This domain covers non-ACCME-accredited speaking relationships. Such talks are referred to in various ways, including “speakers bureaus,” “promotional talks,” “peer-to-peer education,” and “lunch and learns.”

Some effective policies include other provisions such as limits on compensation and reimbursement. Regardless of such safeguards, the “a” and “b” requirements above must be met for the policy to score a “3”.

To qualify for a top score of “3”:
  o Industry-funded speaking must be clearly educational as opposed to promotional. Best practice policies may require educational content by using terms such as: “scientific,” “balanced,” or “objective.” For the purposes of the Scorecard, even if the policy does not explicitly state that the talk is not promotional in nature, but instead uses these types of terms, we will assume it is not promotional in nature and that the policy may qualify for a “3” (as long as criteria b, content controlled by speaker, is also present).

To qualify for a “2”:
  o Policies stating that promotional speaking is “discouraged” would score a “2”. In order to score a “3”, the policy must contain terms such as “prohibited” or “not permitted.”
4. INDUSTRY-FUNDED SUPPORT OF ACCME-ACCREDITED CME

Has the institution provided a part (or parts) of the policy that applies to industry-support of ACCME-accredited CME?

**NO** 1

**YES**

Does the policy state that industry funding is not accepted for the support of accredited CME courses except in certain clearly defined circumstances. Examples of permitted exceptions must be defined explicitly and may include:

- The course would be prohibitively expensive/unaffordable to physicians without industry funding, or
- Industry funding can be accepted via a central, undesignated, blinded pool of funds with the central office having sole discretion on how the funds are to be used. For purposes of the Scorecard, a central blinded pool is defined as such: a company cannot suggest or stipulate the specific course or academic program (i.e. department) for which the funding is awarded. The central office must be free to use the funding for whatever educational purposes it chooses.

**YES** 3

**NO**

Does the policy state that commercial support is accepted, but at least one measure is in place to prevent promotional content (in addition to ACCME-accreditation).

**YES** 2

**NO**

Does the policy state that commercial support can be accepted with the only stipulation being that they must follow ACCME criteria?

**YES** 1

**NO**
“ACCME accreditation” is the minimum standard required for accredited courses; however, it alone is not sufficient for either a score of “2” or “3”. As a safeguard against commercially biased courses, ACCME requires that institutions follow their “Standards for Commercial Support”. These standards require disclosure of industry funding, management of existing conflicts of interest (including, for example, review of presentations’ content), and no industry involvement in choosing speakers or creating course content. However, ACCME standards allow companies to designate funding for specific courses, effectively allowing companies to choose to fund courses that will advance their commercial goals.

To qualify for a top score of “3”:

- **Permitted** industry-funded CME includes:
  - Industry funding placed in an unrestricted blind pool of funding in which the funder cannot designate which specific courses or topics can be funded.
  - Industry funding for specialized training requiring expensive equipment that would not be affordable to the institution without such funding.

- **Prohibited** industry-funded CME includes:
  - A process in which the industry funder can designate any of the following: the course, the specific topic, or the receiving department or division within the institution.

To qualify for a “2”:

- **Permitted** industry-funded CME includes:
  - Industry funding that meets ACCME Standards for Commercial Support [add link to these standards here] plus at least one additional measure required to strengthen the firewall between promotional intent and education. Such additional measures may include, but are not limited, to the following:
    - Requiring that more than one company sponsor an event
    - Requiring that all industry funds be overseen and disbursed by a central university-wide CME office (i.e., funds cannot be paid directly from the commercial supporter to divisions or departments)
    - Requiring that physician participants cover some of the cost of the course, such as by paying for their meals, or paying a registration fee
    - Implementing a system of monitoring for commercial bias that is more robust than required by ACCME
5. ATTENDANCE OF INDUSTRY-SPONSORED PROMOTIONAL PROGRAMS

NOTES:

To qualify for a “3”:
- The policy must prohibit or discourage faculty and staff from attending industry-funded events that are not ACCME-accredited and are promotional. (This does not include attendance at national conferences sponsored by medical societies which may provide both accredited CME and non-accredited industry-funded courses.)
- This domain does not apply to speakers at promotional events. Recommendations for promotional speaking policies are covered under domain #3, “industry-funded promotional speaking relationships”.

To qualify for a “2”
- Policies that allow attendance at industry-sponsored events described as “designed to promote evidence-based clinical care and/or advance scientific research and/or designed to enhance the quality of clinical care” do not explicitly prohibit or discourage attendance at promotional activities and therefore score a “2”.
- Some policies state that "Individuals should evaluate carefully their attendance at meetings and conferences that are fully or partially sponsored by Industry because of the potential for perceived or actual Conflict of Interest." However, this does not qualify as a “3” because there is no explicit statement discouraging such attendance.
6. INDUSTRY-FUNDED SCHOLARSHIPS AND AWARDS

DEFINITION:
This domain refers to industry financial support for the travel and registration expenses to attend academic or professional conferences.

NOTES:
To qualify for a top score of “3”:
- **Permitted** industry-support includes:
  - Competitive fellowships awarded by industry strictly for scientific research training, as long as industry has no role in deciding the recipient. Such training usually occurs at the company headquarters or at an academic institution.
  - Industry support for necessary training in medical devices that have been purchased by the institution.
  - Industry support for any travel to any conference or training if it is part of a bona fide consultation agreement.
- **Prohibited** industry-support includes:
  - Accepting money (often termed “scholarships”) from industry to fund medical students or other trainees to attend academic meetings—usually in the form of a single conference, such as an annual meeting of a professional society. If such funding is accepted, but with the requirement that the industry funder have no role in selecting recipients, then the policy would score a “2”.

To qualify for a “2”:
- The policy allows accepting scholarship money from industry only if the industry sponsor has no role in selecting the recipient.
7. GHOSTWRITING AND HONORARY AUTHORSHIP

Has the institution provided a part (or parts) of the policy that applies to ghostwriting and honorary authorship?

If YES, proceed to Is ghostwriting and honorary authorship strictly prohibited?

If NO, proceed to Does the policy discourage, but not prohibit ghostwriting and honorary authorship?

If NO, proceed to Is there no policy in place?

If YES, proceed to 1

If YES, proceed to 3

If NO, proceed to 2

If YES, proceed to 1

NOTES:
To qualify for a top score of “3”:

- Policy may specify “no ghostwriting” or may require that all staff and trainees follow the authorship standards of the International Committee of Medical Journal Editors.

To qualify for a score of “2”:

- When a policy allows publishing articles written by industry sources as long as this participation is disclosed.
8. CONSULTING AND ADVISING RELATIONSHIPS

DEFINITION:
This domain is defined as consulting or advisory relationships with for-profit entities, entered into by a physician outside of his or her duties as an employee of the school or hospital.

Has the institution provided a part (or parts) of the policy that applies to consulting and advising relationships?

YES

NO

Does the policy specify that consulting or advising relationships for purely commercial or marketing purposes are prohibited or actively discouraged? However, consulting or advising relationships for research and scientific activities are allowed without prohibition or discouragement.*

AND requires at least one of the following:
- Prior review of the activity (meaning either prior review of the contract or review of the activity to ensure that there is no potential COI between the activity and the faculty’s research/clinical responsibilities)
- Clear, legitimate deliverables spelled out in the contract
- Fee is at fair market value

YES

NO

Does the institution allow all consulting and advising relationships (research, scientific activities, and commercial and marketing consulting are all allowed) but requires at least one of the following:
- Prior review of the activity (meaning either prior review of the contract or review of the activity to ensure that there is no potential COI between the activity and the faculty’s research/clinical responsibilities)
- Clear, legitimate deliverables spelled out in the contract
- Fee is at fair market value

NO

YES

Does the institution place no restrictions on consulting and advising relationships or is no policy in place?

YES

NO

1

2

3
NOTES:

For Scorecard purposes, “consulting” does not include promotional speaking. Some institutions consider such speaking to be a type of consulting—if so, that part of the policy would not be relevant to this domain, but would be applicable to domain #3, “Industry-funded speaking relationships.”

To qualify for a top score of “3”:

- **Permitted** consulting and advising relationships include:
  - The policy need not explicitly prohibit consultation for marketing purposes. However, best practice policies should use language such as specifying that outside consultation must be for “scientific purposes” or similar terminology.
  - Some scientific consultation may include a marketing component (for example, a researcher helps to develop a novel surgical technology and helps the manufacturer develop content to advertise its features). Such consultation is acceptable under a model policy, because the consulting contract as a whole is primarily for scientific activities.

- **Prohibited or discouraged** consulting or advising relationships include:
  - Consultation which is purely for the purpose of helping the company market a product, with no research or scientific component. (For example, a consultation in which the only deliverable is to review potential print or web advertising to advise on which would most effectively promote a product would not be a best consultation practice in an academic medical center).
9. ACCESS OF PHARMACEUTICAL SALES REPS

Has the institution provided a part (or parts) of the policy that applies to access of pharmaceutical sales representatives to AMCs?

Does the policy prohibit sales representatives to have access to any faculty or trainees in academic medical centers or affiliated clinical entities? However, policy may allow faculty to invite other pharmaceutical representatives for specific discussions that do not involve marketing a specific product.

Does the policy allow pharmaceutical representatives to meet with faculty as long as the following two criteria are met: (a) meetings must take place in non-patient care areas, AND (b) meetings must take place by appointment.

Policy does not substantially limit access or there is no policy in place.

NOTES:

It is common to see other regulatory mechanisms, such as a requirement for sales representatives to wear visible identification. This, however, is not a significant enough item to score a “2”.

“Registering” is not the same as “by appointment.”

To qualify for a top score of “3”:

- Permitted access of pharmaceutical sales representatives includes:
  - The policy can allow faculty or trainee interactions with industry-employed “medical liaisons” or “medical science liaisons” for the purpose of educational exchange.
  - The policy can allow sales representative access to purchasing and formulary committees in order to present information on new products being considered for the formulary.
  - The policy can allow sales representatives on site to deliver samples, as long as it is delivered to a centralized repository and there is no marketing interaction.
10. ACCESS OF MEDICAL DEVICE REPS

Has the institution provided a part (or parts) of the policy that applies to access of medical device representatives to AMCs?

YES  →  NO

Are medical device representatives permitted in patient care areas only for legitimate reasons not related to marketing, such as providing necessary technical assistance and/or training on devices or other equipment already purchased. (Exceptions to the requirement that equipment already be purchased can be made when faculty are involved in legitimate research under a signed contract to research new devices or new uses for approved devices.)

YES  →  NO

Are medical device representatives permitted in patient care areas with no restriction or specification regarding their activities? However, the policy does regulate site access in some way (such as requiring an appointment or registration).

YES  →  NO

Policy does not substantially limit access or there is no policy in place.

YES  →  NO

NOTES:
To qualify for a top score of “3”, policy includes all of the following:

- Requirement that access to patient care access is permitted if the allowed activities of the representative are restricted to those related to technical support or training.
- A “3” policy should effectively prevent medical device representatives from promoting products in patient care areas. However, a policy may not actually state this. It is implied that providing “necessary technical assistance and training on devices and other equipment already purchased” means that promotional marketing is not taking place.
- Policy may allow reps to meet with faculty to “evaluate new purchases of equipment, devices, or related items” along with other “3” scoring criteria. We would not assume this to be marketing.

To qualify for a “2”, the policy is less stringent, but still regulates medical device representative presence in some way. Examples may include requirements that representatives:

- Have an appointment
- Register with the institution before entering a patient care area
- Wear a badge or other identification
- Abide by other policies meant to regulate access
11. CONFLICT OF INTEREST DISCLOSURE

**NOTES:**

- **General**
  - Reporting a COI to a publication does not count as a form of external disclosure; this is pro forma for journals.
  - Public reporting via a public website is not strong enough to meet the external disclosure requirement.

- **Internal Disclosure**
  - This refers to faculty submitting disclosure information to the institution.
  - If a policy states compliance with NIH regulations requiring faculty disclosure of financial relationships of at least $5000, then the policy automatically fulfills the “internal disclosure” requirement.

- **External Disclosure**
  - Trainees/Audiences: Refers to mechanisms such as slides with disclosures during lectures, and verbal disclosures at the beginning of clinical rounds. If a policy requires that faculty disclose financial relationships with “audiences”, then the policy meets this criterion.
  - ACCME disclosure standards to learners during continuing medical education activities are not sufficient to qualify as a form of external disclosure to trainees/students/audiences.
12. EXISTENCE OF AN ADEQUATE COI CURRICULUM FOR MEDICAL STUDENTS

Does the policy make any reference to COI education or curriculum?  

NO 1

YES

Is COI curriculum/education required for medical students? Does the medical school’s curriculum materials that are submitted reflect and cover most of the curricular content and objectives in the AMSA standards for a “model curriculum”?  

YES 3

NO

Does the policy require a COI curriculum/education for medical students, but one that is more limited?  

YES 2

NO

No COI curriculum/education is required for medical students or there is no policy in place.  

YES 1

NO

NOTES:
The policy must relate to medical students as the training audience.

To qualify for a top score of “3”, the policy either states the presence of a curriculum in which the two core competencies listed below are taught, or institution submits curriculum materials that demonstrate this.

1. Understand the effects of industry marketing on physician education and practice, and its relationship to medical professionalism
2. Understand the effects of industry influence on how the efficacy and safety of drugs and devices are demonstrated, regulated, and/or marketed.

On the submission page for the policy documents, there is a question that asks whether or not there is a requirement for COI education in the medical school curriculum. Analysts will use the answer to that question to score the institution because most institutions do not have language within the policy document that states a requirement for a COI curriculum.

To qualify for a “2”:
The policy must mention the curriculum applies to medical students. Policies that require annual COI training for researchers/investigators/faculty, but make no mention of students, do not qualify.
13. EXTENSION OF COI POLICIES TO ADJUNCT/COURTESTY FACULTY AND AFFILIATED HOSPITALS/CLINICS

Has the institution provided a part (or parts) of the policy that applies to extension of COI policies from AMCs to community affiliated institutions and to adjunct faculty?  

YES  →  NO  

Does the institution’s COI policies apply to all employees of the institution, whether full/part-time or volunteer faculty and students/trainees? The policy apply regardless of the site where they are working (i.e.: affiliated institutions, such as off-site clinics and offices, or community hospitals), even if the site itself does not follow the same policy?  

YES  →  NO  

Does the policy apply to, or is actively encouraged, for at least one of the following populations or settings:  
- All employees (full/part-time or volunteer faculty) and students/trainees  
- Applies wherever faculty are working (i.e.: affiliated institution, such as off-site clinics and offices, or community hospitals), even if the site does not have the same policy  

YES  →  NO  

The policy does not apply outside of the academic medical center and its major affiliated teaching hospitals. Or no policy is in place.

NOTES:  
A model policy will state explicitly that COI policies apply no matter where the faculty members or trainees work. Thus, the COI policies of the institution should “follow” faculty and students/trainees wherever they work or rotate. For example, if a medical student’s school prohibits acceptance of industry meals, that student should not accept such meals if offered at a community practice where he or she is doing an outpatient rotation.

A model policy will apply to ALL people in ALL settings. Anything less should score a “2”.

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14. ENFORCEMENT AND SANCTIONS OF POLICIES

Has the institution provided a part (or parts) of the policy that applies to enforcement and sanctions of policies?

YES  NO

1

Does the institution’s COI policy state that there is a party (e.g. the committee or individual to whom violations should be reported) responsible for general oversight to ensure compliance with COI policies AND that there are sanctions for noncompliance (a description of sanctions is not required)?

YES  NO

3

Does the institution’s COI policy state that EITHER there is a party (e.g. the committee or individual to whom violations should be reported) responsible for general oversight to ensure compliance with COI policies OR that there are sanctions for noncompliance (a description of sanctions is not required)?

YES  NO

2

There is no policy in place for enforcement and/or sanctions of policies

YES  NO

1

NOTES:
To qualify for a “3”, the policy must specify both an oversight authority and the existence of consequences for non-compliance.
- Policies that reference compliance with NIH conflict of interest regulations automatically receive a “3” on this domain, because these regulations require oversight and sanctions for non-compliance.
- If a policy specifies penalties for non-compliance without mentioning a specific oversight authority, the policy does not qualify for a “3”, but rather a “2”.