

AMSA PharmFree Scorecard Methodology Work Group

FINAL RECOMMENDATIONS

Policy Domains:

1. Gifts (defined as free items, excluding meals)
2. Meals (including CME and non-CME related meals, whether onsite or offsite)
3. Industry-funded speaking relationships (not ACCME-accredited)
4. Industry-support of accredited CME
5. Attendance of industry-sponsored educational events
6. Industry-supported fellowships
7. Ghostwriting and honorary authorship
8. Consulting and advising relationships for marketing
9. Consulting and advising relationships for research and scientific activities
10. Pharmaceutical samples (teaching hospital scorecard only)
11. Pharmacy and therapeutics committee (teaching hospital scorecard only)
12. Access of pharmaceutical sales representatives to AMCs
13. Access of medical device representatives to AMCs
14. Conflict of interest disclosure
15. Existence of an adequate COI curriculum
16. Extension of COI policies from AMCs to community affiliates
17. Enforcement and Sanctions of Policies (bonus section)

Rating System:

1. *Gifts*

(Defined as any free item, including educational and personal gifts, but excluding meals.)

5=No gifts of any nature or value allowed.

3=Gifts allowed but only if value \leq \$10 (or educational gifts for patient use)

[note: \$10 figure chosen because this is the threshold for disclosure under the Sunshine Act]

2=Gifts allowed but only if value \leq \$100 (or educational gifts for patient and physician use)

[note: \$100 figure chosen because this is the threshold for disclosure under AMA Guidelines]

1=Gifts allowed without restriction (unspecified dollar amount)

2. *Meals*

(Includes both CME and non-CME related meals, whether onsite and offsite)

5=No meals allowed

3=Meals allowed but only if value \leq \$10 or meals are given through unrestricted funds for CME events

1=Meals allowed with no restrictions

3. Industry-funded speaking relationships (not ACCME-accredited)

DECISION TREE NOTE TO GUIDE ANALYSTS: A contract that states presentations will be submitted to the FDA for approval indicate that the presentations are promotional, and not educational no matter what else the policy may state.

5=Faculty not permitted to be on speaker's bureaus or to accept any honorarium or other reimbursement (i.e. travel or hotel stay) to speak at any industry supported non-ACCME accredited events.

4=No participation in speakers bureaus or speaking engagements that are purely commercial but may participate in other industry-funded non-ACCME accredited events as long as the institution conducts a prior review and approval process to ensure that faculty control the content and certify that the content reflects their own independent opinions of topic areas.

3=Participation in speakers bureaus or commercial talks is strongly discouraged but may participate in other industry-funded non-ACCME accredited events as long as the institution conducts a prior review and approval process to ensure that faculty control the content and certify that the content reflects their own independent opinions of topic areas.

2=May participate in speakers bureaus and in other industry-funded non-ACCME accredited events as long as faculty control the content and certify that the content reflects their own independent opinions of topic areas. A contract must be submitted prior to the faculty member engaging in such activities, but no approval is required.

1=No policy.

4. Industry-support of accredited CME

5=In general, CME activities should not be supported by industry. Rare exceptions to this policy are permissible, but must be defined explicitly, eg., industry support may be accepted if the cost of the program would be prohibitively expensive without such support. The only other exception allowed for the highest score would be to create a central, blinded pool of funds from more than one company 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 type of course, course area, department, etc. for which the funding covers. The central office must make those decisions.

3=Support accepted for central, pooled fund to department or division (but not for a specific course); department and division has sole authority in designating courses/topic areas and speakers. Measures are in place to prevent promotional content, such as departments not allowed

to make a profit from programs (ie, funds must be used for educational program only) AND courses must be supported by no less than two companies.

2=Support accepted for specific courses, but measures in place to prevent promotional content, such as departments not allowed to make a profit from programs (ie, funds must be used for educational program only) AND courses must be supported by no less than two companies.

1=Commercial support accepted, with the only stipulation being that they must follow ACCME criteria.

5. Attendance of industry-sponsored educational events

DECISION TREE NOTE TO GUIDE ANALYSTS: This is in regards to passive attendees, not speakers at events.

5= Faculty, students, and trainees should not attend industry-sponsored marketing events or non-ACCME accredited educational events.

4=Attendance allowed but attendees cannot accept reimbursement for travel or other remuneration and they must go through an approval process.

3=Attendance allowed but attendees may not accept reimbursement or other remunerations; however, there is no requirement for a formal approval process.

2= Travel reimbursement is allowed but no other remuneration AND attendees must disclose their financial support to attend this event but does not require a formal approval process.

1=No policy.

6. Industry-supported fellowships

5=Policy does not allow industry support for clinical training of clinical fellows, residents and medical students. However, competitive fellowships strictly for scientific research training managed by the institution are allowed.

3=Industry support for clinical fellowships is allowed, but funds cannot be earmarked to support particular individuals, and industry cannot have a role in selecting recipients.

2=Industry support allowed with institutional approval of release of funds.

1=No policy.

7. Ghostwriting and honorary authorship

5=Ghostwriting and honorary authorship are strictly prohibited. Academic medical faculty and trainees must follow the International Committee of Medical Journal Editors (ICMJE) standards for authorship and contributorship. (The ICMJE authorship standards are based on each author contributing and participating in the work including significant contributions to conception and

design, data collection and analysis, drafting or revising language, and approving final content. COI disclosure forms must be provided for each individual, even in the case of a large, multicenter group leading the project.)

3=Discouraged, but not prohibited

1=No policy

8. *Consulting and advising relationships for marketing (excluding scientific research and speaking)*

(Defined as relationships related specifically to physicians who are hired by a pharmaceutical company to consult and advise in order to increase sales of the company's product. This is different than promotional speaking and may include development of slide sets for promotional talks or working with marketing teams to develop strategies to increase product uptake in a community.)

5=No consulting or advising relationships for marketing allowed.

4=Institution discourages consulting and advising relationships but will allow it only after a review of the contract and a determination that there is no potential conflict of interest between the topic of the marketing consultation and the faculty's clinical or research work.

3=Institution allows marketing consultation but requires a review of the contract to ensure that there are clear deliverables and fee is at fair market value.

2=Institution allows marketing consultation and requires a contract but does not actually review it.

1=Institution places no restrictions on consulting and advising relationships for marketing.

9. *Consulting and advising relationships for research and scientific activities*

(Defined as relationships related specifically to physicians who are hired by a pharmaceutical company to consult and advise on behalf of a research/scientific activity related to drug development.)

5=Contract must be submitted and reviewed by institution to determine there is no potential conflict of interest, the topic of the research consultation and the faculty's clinical work (clear deliverables and fair market value for payments must be identified).

3=Contract must be submitted but no review by institution required.

1=No policy on the management and oversight of relationships.

10. *Pharmaceutical samples (teaching hospital scorecard only)*

DECISION TREE NOTE TO GUIDE ANALYSTS: For teaching hospitals that receive a score of “5”, “4”, or “3” in this domain: policy must encompass academic medical centers or affiliated entities (i.e. both on and off-site clinics).

For teaching hospitals that receive a score of “4” in this domain: policies may allow samples under limited circumstances with the approval of the Pharmacy and Therapeutics (P&T) Committee or policies that incorporate samples into a larger program designed to ensure the availability of brand-name and generic medications to under-insured patients.

5=Institution does not accept samples under any circumstances.

4=Institution accepts samples through narrow circumstances approved by the institution that protect the interests of patients and prevent the use of samples as a marketing tool. (If the circumstances of the specific program are not defined, the policy should define the approvals process). Where there is a specific program in place, the policy must prevent samples from being given directly to physicians by pharmaceutical sales representatives.

3=Institution accepts samples but requires they be distributed through a pharmacy, and not given directly to doctors.

1=Physicians may accept free samples for distribution to patients.

11. Pharmacy and therapeutics committee (teaching hospital scorecard only)

5=Sitting members of the committee cannot have financial relationships with industry. However, committee members may request on an *ad hoc* basis a consultant/discussant who has a COI in order to assist with a specific decision (but this consultant may not vote). The consultant/discussant must disclose all relevant financial relationships.

4= With rare exception, no voting member of a Pharmacy & Therapeutics Committee may have a financial relationship with a pharmaceutical or medical device or diagnostics company. However, as with the above number 5, P & T committees may request on an *ad hoc* basis a consultant/discussant who has such a relationship in order to assist with decisions (but the consultant may not vote or be present at the time of voting). Regardless of voting rights, all P & T committee participants must file periodic financial disclosures.

3=Voting members can have relationships, but must recuse themselves from decisions when they have a relevant COI.

2=Less stringent policies (e.g., just have to disclose) that do not prohibit individuals with conflicts from participating in purchasing decisions (e.g. policies that require members of committees overseeing purchases merely to disclose potential conflicts of interest).

1= No policy, or policy that merely cautions against COI.

12. Access of pharmaceutical sales representatives to AMCs

DECISION TREE NOTE TO GUIDE ANALYSTS: For 5-2 scores, policy must encompass academic medical centers or affiliated entities (i.e. both on and off-site clinics).

5=Pharmaceutical sales representatives should not be allowed access to any faculty or trainees in academic medical centers or affiliated entities (i.e. both on and off-site clinics). However, faculty may invite other industry workers who are not sales representatives for specific discussions that do not involve marketing a specific product.

4=Pharmaceutical representatives are allowed to meet with faculty but only under defined circumstances, including as a requirement that they do not meet in patient care areas, plus other limitations, such as requiring appointments, visible identification, and a requirement that the visit be educational and not promotional in nature.

2=Pharmaceutical representatives are allowed to meet with faculty but only in non-patient care areas. No appointment is necessary.

1=No policy, or a policy that does not substantially limit access.

13. Access of medical device representatives to AMCs

DECISION TREE NOTE TO GUIDE ANALYSTS: For 5 and 2 scores policy must encompass academic medical centers or affiliated entities (i.e. both on and off-site clinics).

5=Medical device representatives are not permitted in any patient care areas, except to provide necessary technical assistance on devices and other equipment already purchased and then only by appointment.

2= Medical device representatives can have access, and there are no measures in place to prevent sales in clinical areas. Registration and invitation required, as well as identification.

1= No policy.

14. Conflict of interest disclosure

DECISION TREE NOTE TO GUIDE ANALYSTS NOTE TO ANALYSTS: This applies to everyone whether or not they have something to disclose (monetary thresholds are not considered for purposes of scoring). Many institutions will set policy in accordance with NIH limits, but we are encouraging institutions to be in line with Open Payments (Sunshine).

For teaching hospital scoring:

5=Internal + two of the three forms of external disclosure required.

4=Internal + one of the three external forms of disclosure required.

2=Internal only

1=No form of disclosure required.

For medical school scoring:

5=Internal + one of the two forms of external disclosure required.

2=Internal only

1=No form of disclosure required.

Internal Disclosure

- Faculty member submits disclosure to institution (detailed form to compliance). This likely already occurs at most institutions and is internal in the sense that the only people seeing the information are the disclosing faculty members and a limited number of staff (such as department heads, compliance staff, etc...)

External Disclosure (three forms for teaching hospitals, two forms for medical schools)

- Passive: Public disclosure on website that mimics Sunshine Act reporting. The quality of this disclosure varies among institutions. It is often disclosed in broad, vague terms, such as “Dr. X discloses receiving between more than \$5000 for consulting and or research in the following companies: ...” It is typically difficult to understand who these relationships might influence specific faculty activities.
- Active to medical students and house staff: Context specific disclosure (i.e. in clinical care, education settings). This is more useful than generic website disclosures. If Dr. X is doing cardiology rounds, he would disclose to his students the relevant disclosure, which is that he earns a certain amount giving promotional talks for the company that makes a particular cardiac drug.
- Active to patients (**exception for med schools, since they will not have a disclosure policy relevant for patients**). Again, more useful than the website for similar reasons. Patients will be unlikely to know which companies make which drugs. This policy would require faculty to give their patients disclosures in a consumer-friendly way, such as “Dr. X is paid by the following companies to give talks about the following products that he may prescribe:”

Less ideal policies would include progressively fewer forms of external disclosure.

15. Existence of an adequate COI curriculum

5=COI curriculum/education is required for medical students, teaching faculty, and house staff (includes residents and fellows), and the curricular content and objectives are consistent with those in the AMSA standards for a “model curriculum.” (The five recommended competencies for medical students include: professionalism and conflict of interest; drug and device development; determining drug and device safety and efficacy; marketing and physician practice; continuing medical education)

4=COI curriculum/education is required but content and objectives are not consistent with those in the AMSA standards for a “model curriculum”.

3=COI curriculum/education is offered but is only required for two out of the three groups of clinicians.

2=COI curriculum/education is offered but is only required for one out of the three groups of clinicians.

1=No COI curriculum/education is offered or required.

16. *Extension of COI policies from AMCs to community affiliates*

5=Policy applies to faculty in all settings, and consequences of non-compliance are made explicit (such as losing an academic appointment).

3=Policy is actively encouraged in all settings, but compliance is voluntary with no consequences for non-compliance.

1=Does not apply outside of the Academic Medical Center and its major affiliated teaching hospitals.

17. *Enforcement and Sanctions of Policies (bonus section)*

NOTE TO ANALYSTS FOR DECISION TREE: This is a bonus section for institutions. They are not penalized for answering “No” but receive 5 additional points for each “Yes”.

(not included in final scoring of policies)

A. Is it clear that there is a party responsible for general oversight to ensure compliance? (Y/N)

B. Is it clear there are sanctions for noncompliance? (Y/N)