

Supplemental digital content for Chimonas S, Evarts SD, Littlehale SK, Rothman DJ. Managing conflicts of interest in clinical care: The “race to the middle” at U.S. medical schools. Acad Med. 2013;88(10).

Supplemental Digital Table 1

Recommendations from Three Sources for Managing Clinical Conflicts of Interest (CCOIs) at U.S. MD-Granting Medical Schools

Policy area	American Board of Internal Medicine–Institute on Medicine as a Profession, 2006	Association of American Medical Colleges, 2008	Institute of Medicine, 2009
Gifts from industry	Prohibit	Prohibit	Prohibit
Meals provided by industry	Prohibit	Prohibit	Prohibit
Vendor provision of product samples	Central repository	Central repository	Central repository
Vendor access	Register/limit/train	Register/limit/train	Register/limit/train
CCOI policies for pharmacy and therapeutics committees	Members should be conflict-free	Members should be conflict-free	Members should be conflict-free
Industry funding for continuing medical education	Central repository	Central repository	“Reform funding system” (no specific policy proposals)
Consulting agreements	Full transparency	Full transparency	Full transparency
Honoraria	Full transparency	Full transparency	Full transparency
Industry donations for scholarships, fellowships, travel	Central repository	Central repository	Central repository
Faculty authorship on articles ghostwritten by industry employees	Prohibit	Prohibit	Prohibit
Faculty participation in industry-organized speakers’ bureaus	Prohibit	Strongly discourage	Strongly discourage

Supplemental Digital Appendix

Codebook for Assessing Policy Strength

This codebook is designed as a flow chart and is used to assess the strength of each school’s 12 CCOI policy areas:

1. Gifts from Industry
2. Meals from Industry
3. Vendor Access to Medical Center
4. Pharmaceutical Samples from Industry
5. Pharmacy and Therapeutics Committee
6. Continuing Medical Education
7. Consulting for Industry
8. Receipt of Honoraria from Industry
9. Travel Paid for by Industry
10. Industry-Funded Scholarships
11. Ghostwriting
12. Participation in Speakers’ Bureaus

For each policy area, a final score of 3 indicates a stringent policy, a 2 indicates a moderate policy, a 1 indicates a permissive policy, and a 0 indicates that no policy was found for the school. Definitions and notes are provided as needed to clarify any possible ambiguities.

1. GIFTS FROM INDUSTRY

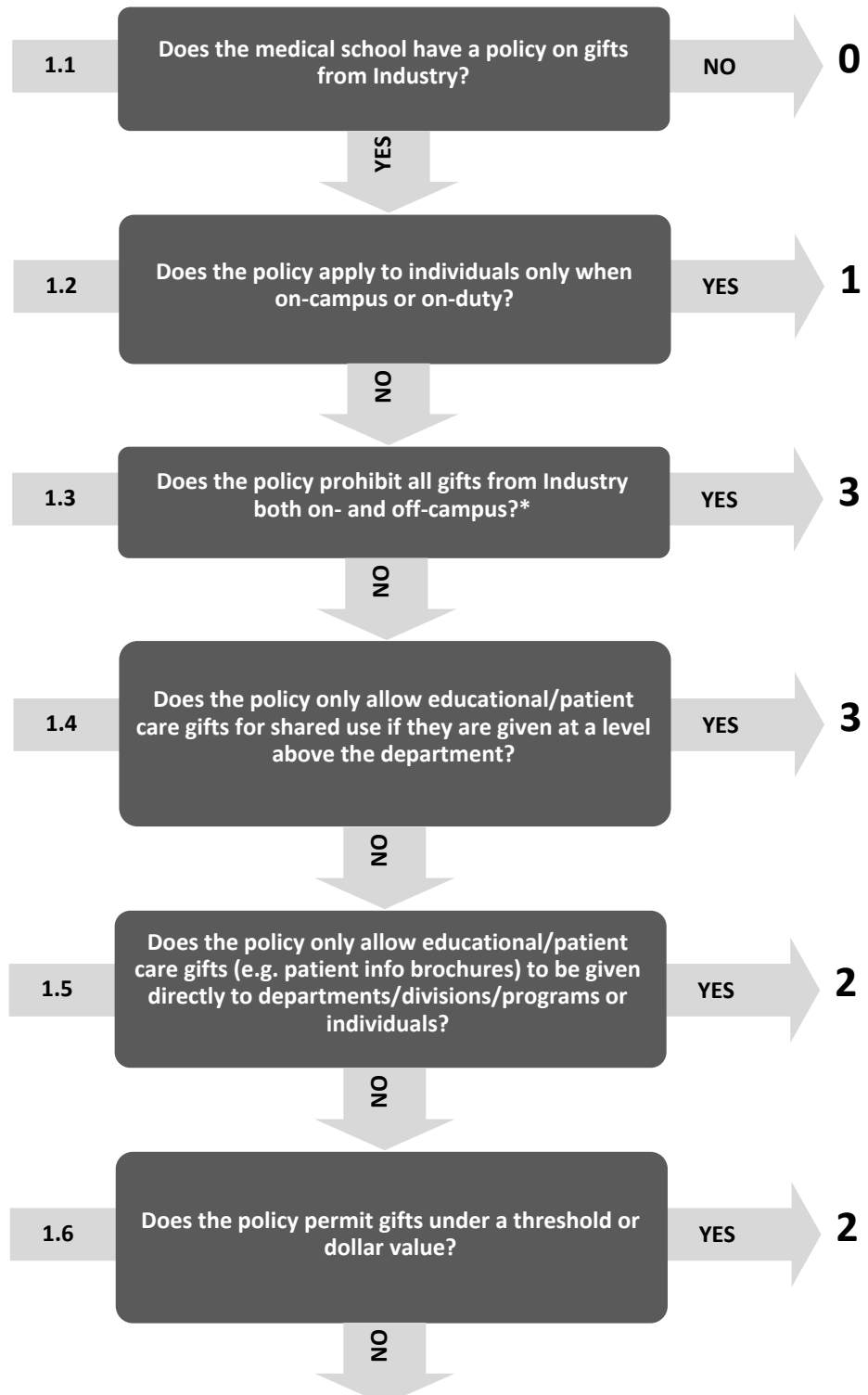
DEFINITION:

Gifts are defined as any item (tangible or intangible) of any value given by Industry to a member of the medical school. It does not include gifts to patients from Industry.

In addition, de minimus gifts (e.g., tote bags) provided to all attendees at off-site conferences are not included in "Gifts" coding.

NOTE:

** If the policy states that all gifts are banned, without elaborating further, it is assumed that it applies to both on- and off-campus gift acceptance.*



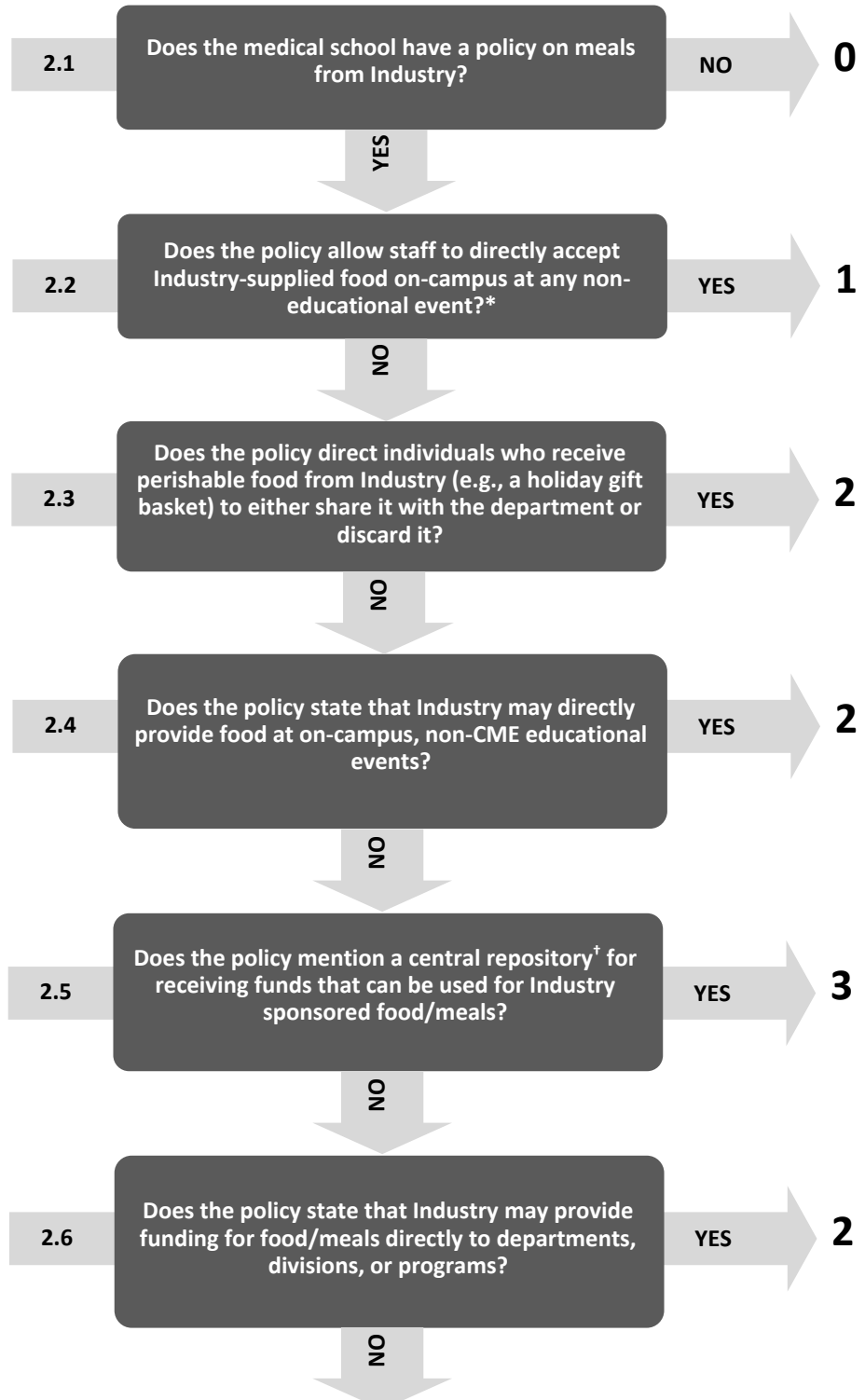
2. MEALS FROM INDUSTRY

DEFINITION:

Meals are defined as any food or beverage supplied by Industry on the property of a medical school. It does not include off-campus meals or meals at on-campus ACCME accredited events.

NOTE:

** Even if the policy provides a dollar limit, if individuals can accept food directly from an Industry representative at on-campus, non-educational events, code the policy area as a 1.
† In this case, a central repository has to be at a higher level than the department.*

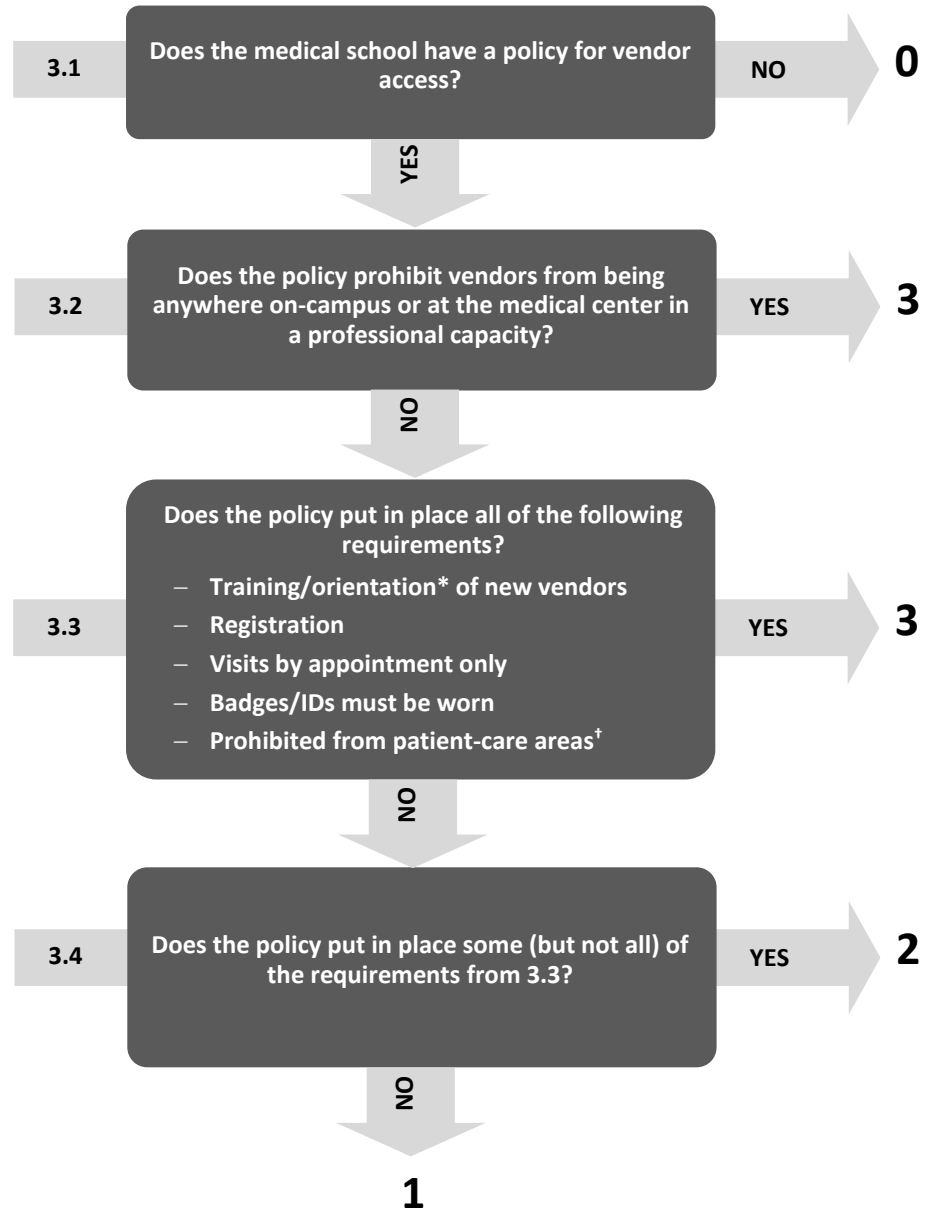


3. VENDOR ACCESS TO MEDICAL CENTER

NOTE:

** Requiring vendors to sign an agreement stating that they have read and are aware of the schools policies is tantamount to training/orientation.*

† The following are excluded from coding Vendor Access: If accompanied by a physician, vendors may enter patient care areas only if it is necessary for patient care (e.g., for training on devices) or unavoidable (e.g., if individuals must pass through such an area on the way to a physician's office).



4. PHARMACEUTICAL SAMPLES FROM INDUSTRY

DEFINITION:

Samples include any product or device that is given by Industry to the provider/hospital free of charge and is intended for distribution to patients or for personal use. For example, “starter packs,” are considered samples.

Demonstration products for patient education and products for evaluation are not treated as “samples.”

EXCEPTIONS:

If the policy provides an exception to an otherwise blanket rule on samples, that exception may be ignored for coding purposes if:

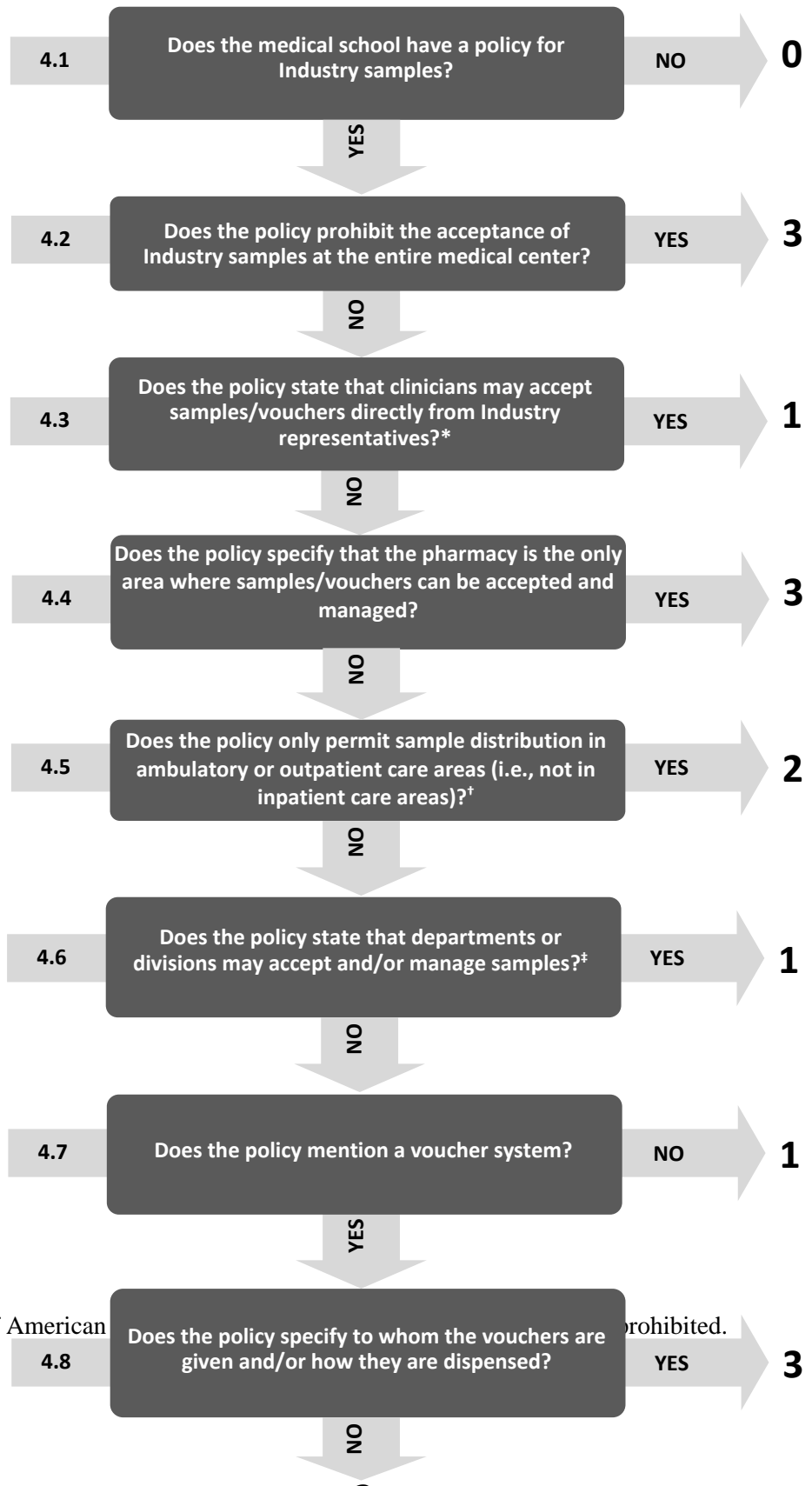
1. Specific clinics/centers are singled out in the policy (e.g., an eye clinic), or
2. The policy requires clinics/other outpatient centers to provide a reason for wanting to accept samples (e.g., for a specific population).

NOTE:

* This does not apply if the policy states that a designated clinician is responsible for accepting samples.

† This is often mentioned when allowing samples for low-income/indigent patients.

‡ Managing samples: If samples are stored and dispensed at the department level, it means that samples are managed at the department level.



5. PHARMACY & THERAPEUTICS COMMITTEE

DEFINITION:

P&T Committees or Formulary Committees are responsible for selecting the hospital formulary's medications and for evaluating their safety and efficacy.

If the policy only mentions how to regulate COI in a university committee, do not code it as P&T. The policy must specifically apply to purchasing, procurement, the formulary, and/or the school of medicine.

For coding purposes, non-voting individuals who provide expert opinion to the committee are excluded from this policy area.

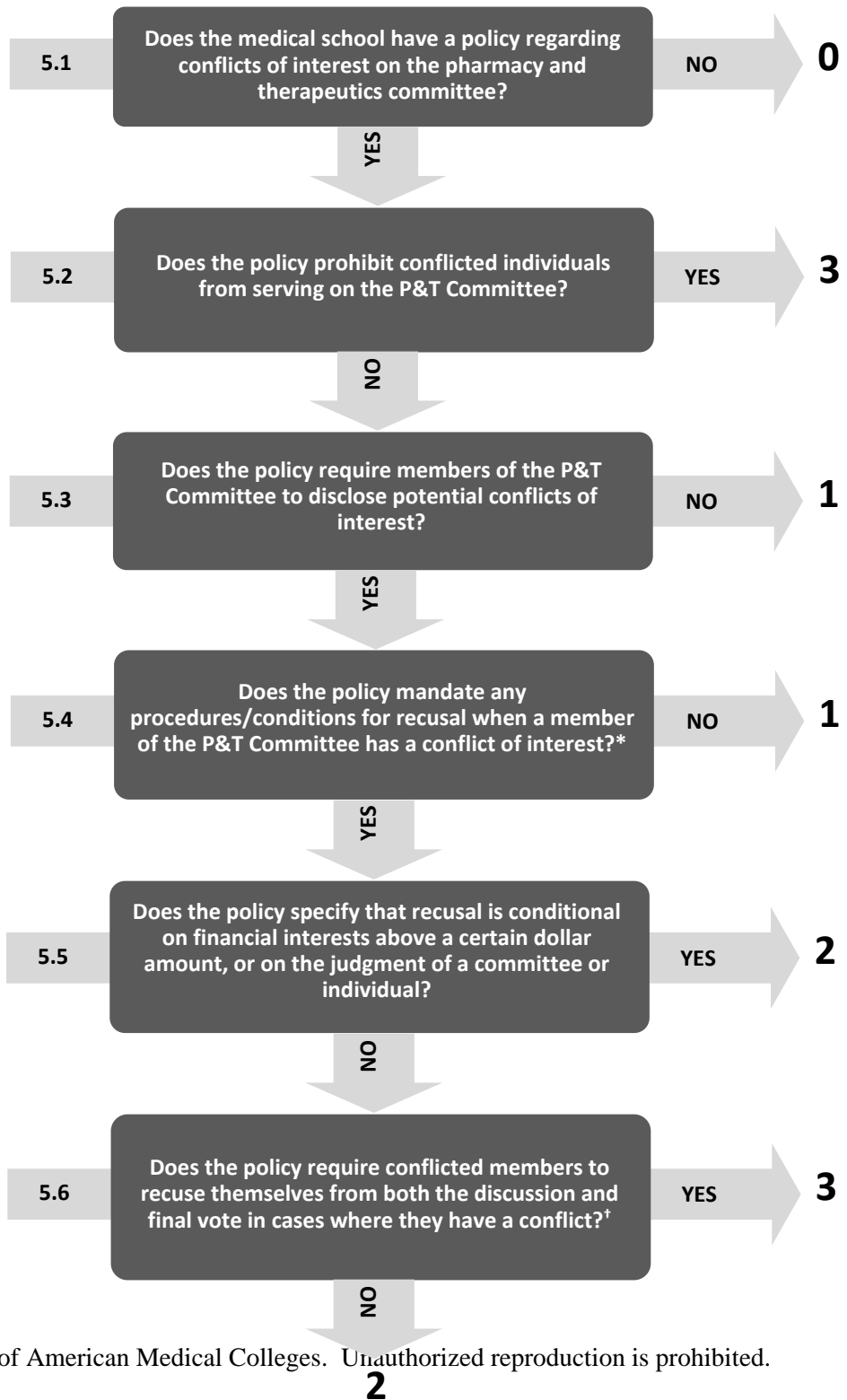
NOTE:

** The policy must only mention that recusal is a possible outcome. It need not state that it will happen or exactly how it will happen.*

† Example policy language for recusal requirements:

Recusal from voting and discussion: "Conflicted individuals are prohibited from participating in the decision"

Recusal only from voting: "Conflicted individuals are prohibited from approving..."



6. CONTINUING MEDICAL EDUCATION

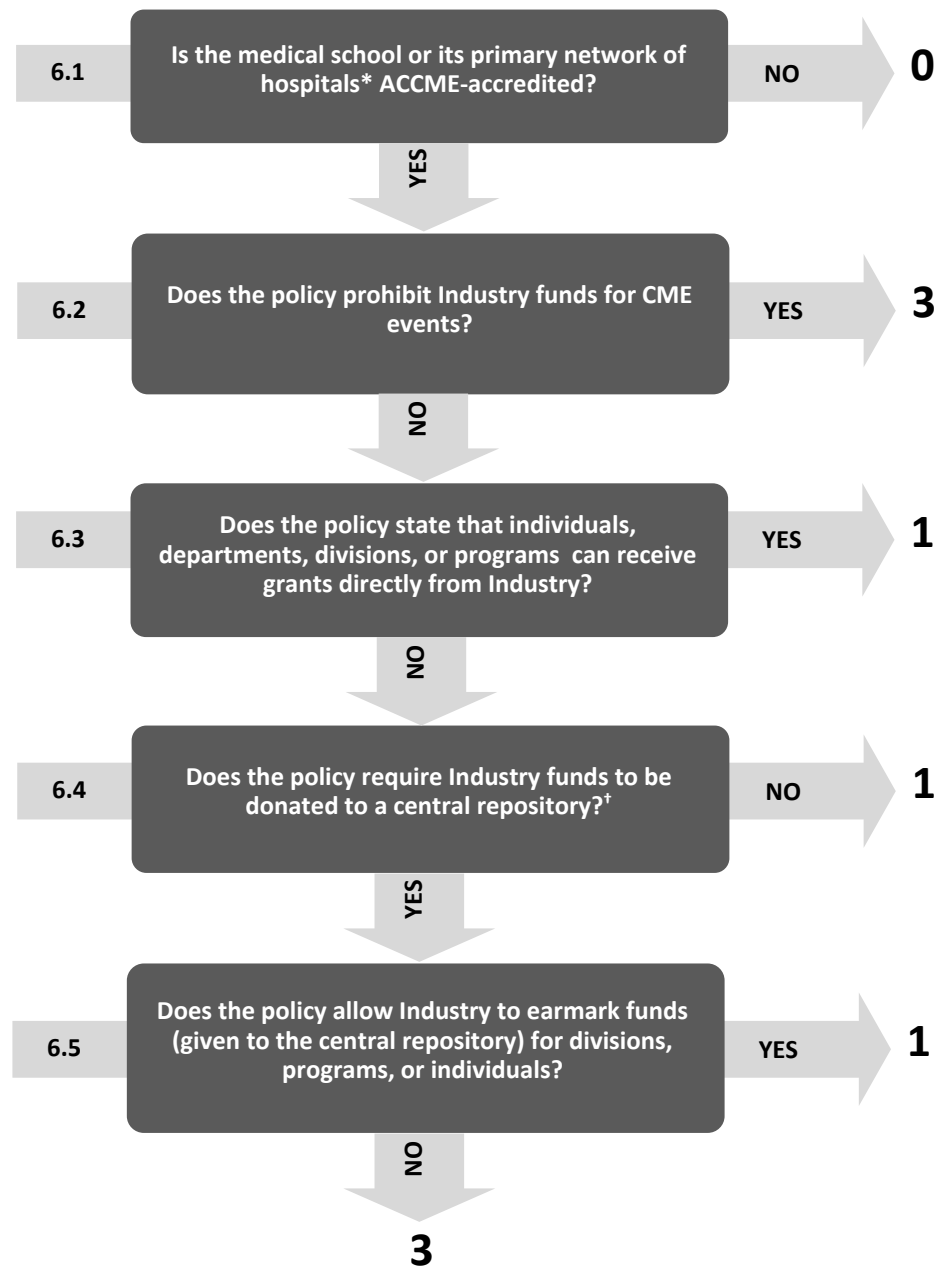
DEFINITION:

For coding purposes, Continuing Medical Education (CME) refers to ACCME-accredited, on-campus CME events hosted or organized by the medical school. Funds received from Industry for CME refers to funds to host and/or organize the events and not those used by faculty, staff, or trainees to attend off-campus CME events.

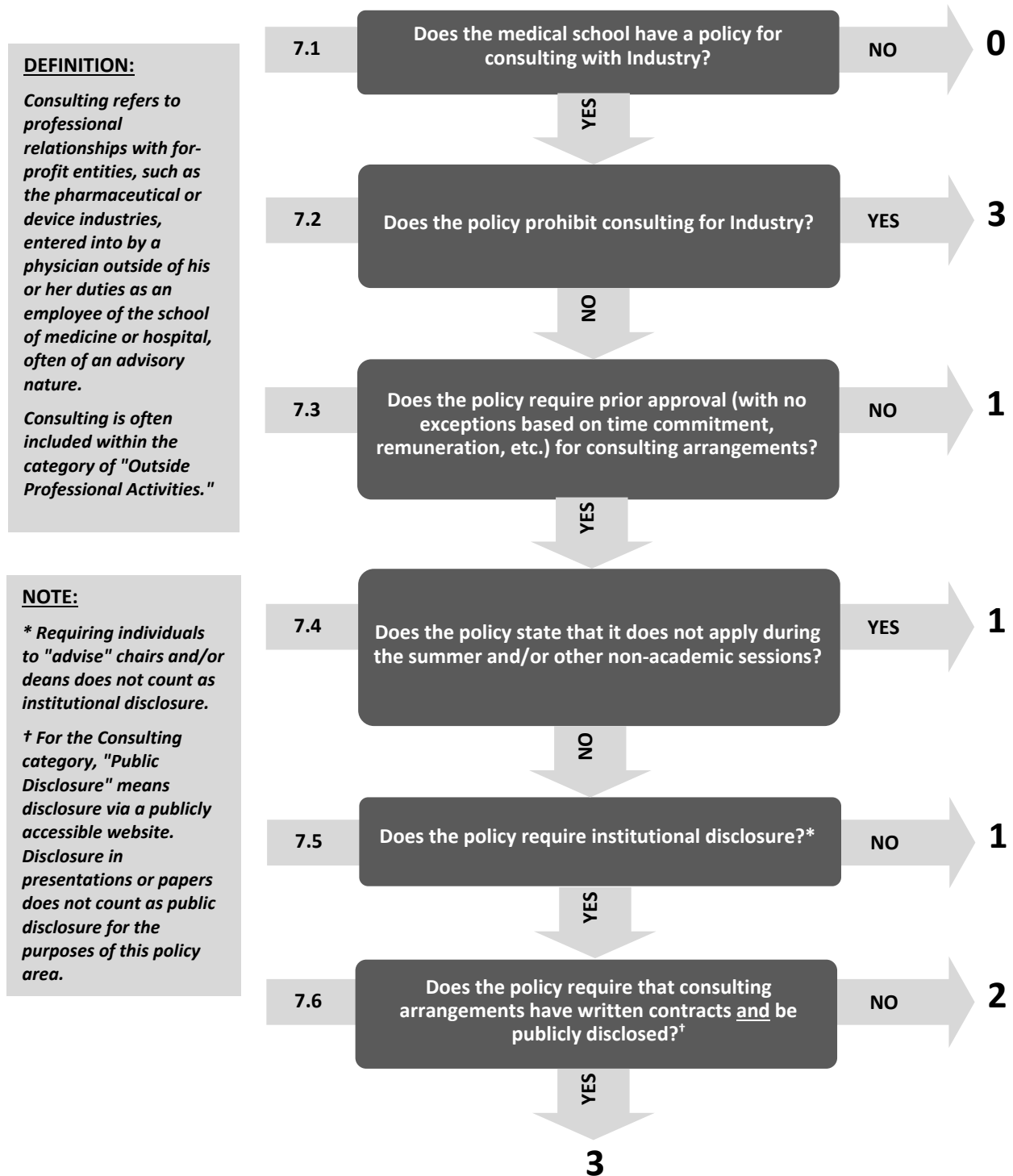
NOTE:

** If the school is not accredited, but the primary network of hospitals (e.g., health system) is accredited, only code as "yes" if the whole network--as opposed to just one hospital--is accredited.*

† A "central repository" means anything above the department level (e.g., the CME office, a "University account," the "School of Medicine foundation," etc.)



7. CONSULTING FOR INDUSTRY



8. RECEIPT OF HONORARIA FROM INDUSTRY

DEFINITION:

Honoraria refers to compensation received from Industry for speaking or presenting at events, meetings, or conferences.

Policies only addressing honoraria for speakers at CME programs organized by the medical school are not applicable to this category.

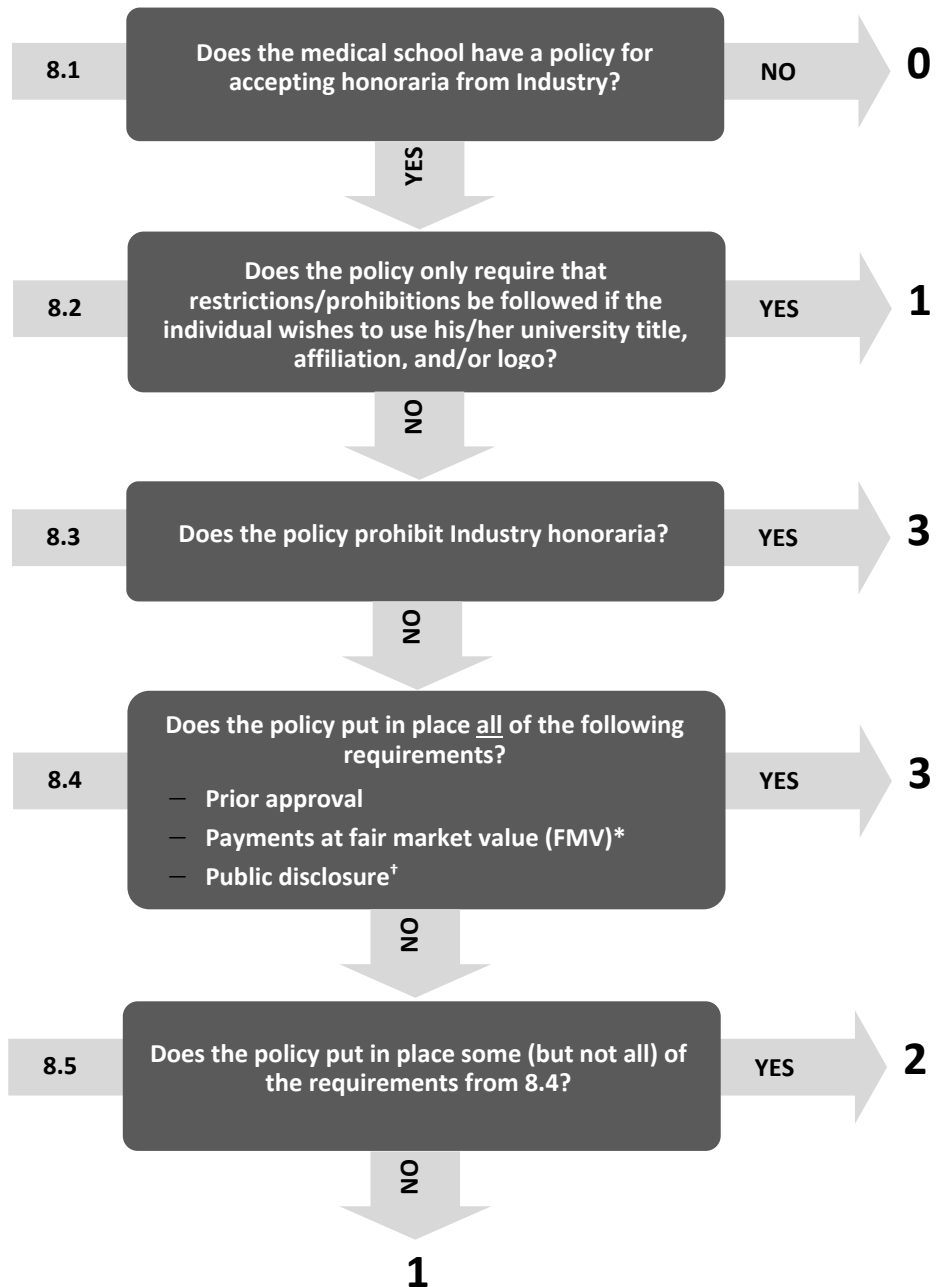
NOTE:

** Examples of phrases synonymous with FMV:*

- Explicit dollar limits*
- "Compensation according to professional standards"*

Phrases that are NOT synonymous with FMV: "reasonable," "modest," "appropriate."

† For the purpose of coding, public disclosure means disclosing Industry funding at the speaking event by the individual speaker.



9. TRAVEL PAID FOR BY INDUSTRY

DEFINITION:

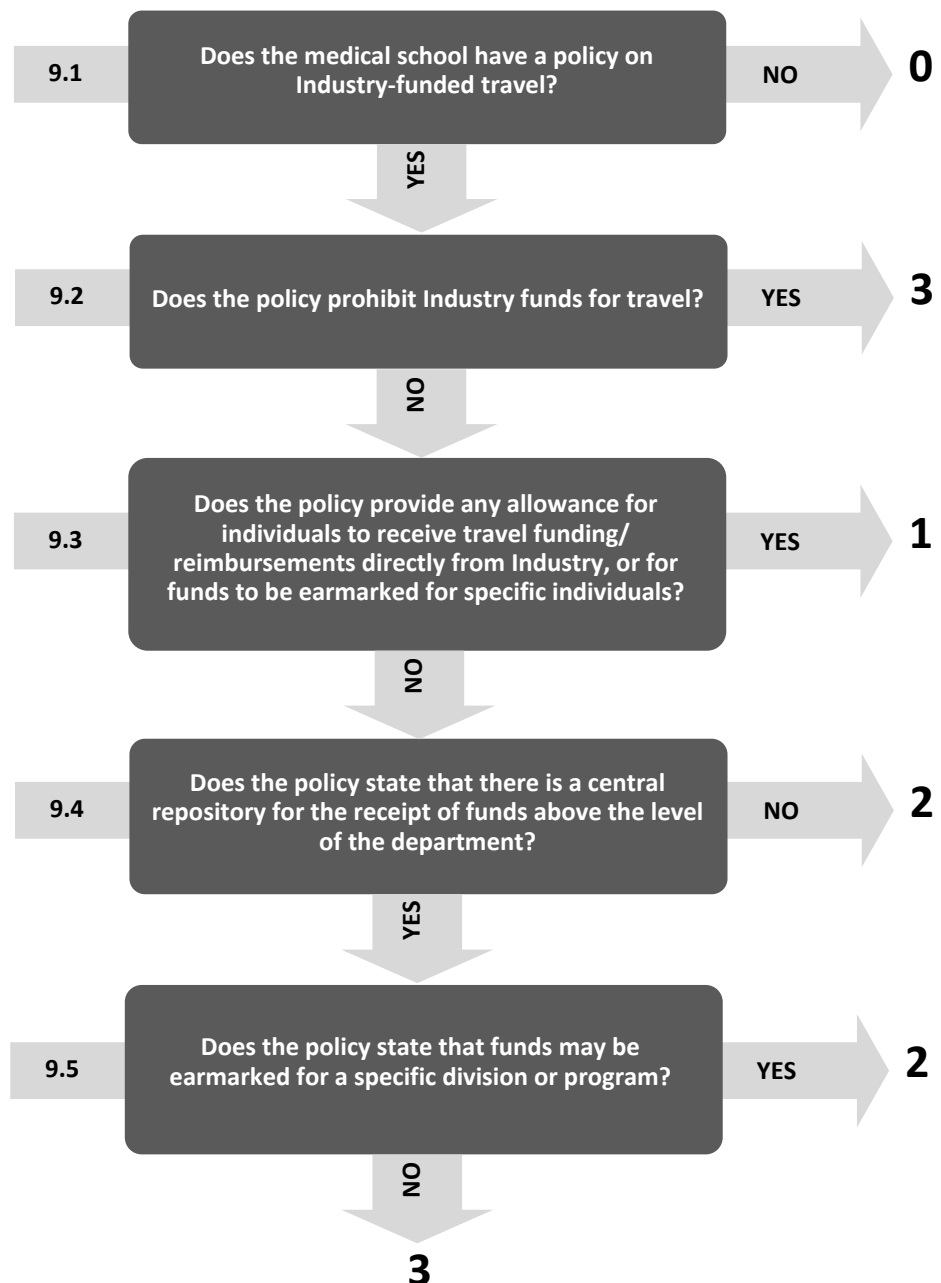
Travel funds are defined as those received from Industry for the purposes of attending educational events, training or education on devices, or other travel not related to outside professional activities. Travel funds related to such activities (e.g., consulting, speaking) are not included in this policy area.

For coding purposes, unless the policy specifies that the following activities are included in a purchasing contract, include in this policy area:

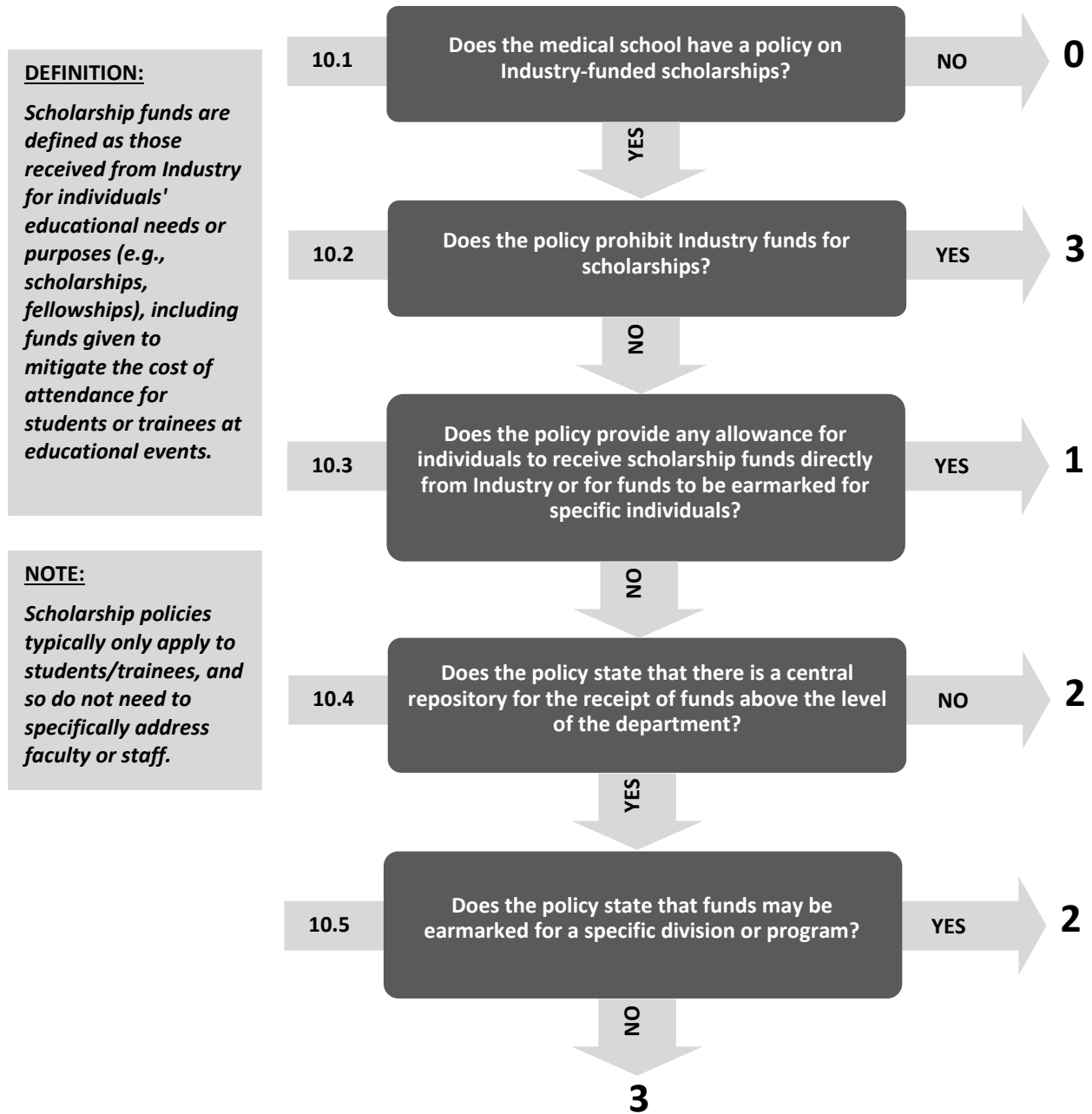
- 1. Vendors pay for individuals to travel to evaluate equipment for purchase, or*
- 2. Vendors pay for individuals to travel for training on a specific piece of equipment.*

NOTE:

If the policy states that personnel may not receive compensation for traveling to meetings, lectures, or conferences, code as travel unless another part of the policy elaborates further on the receipt of travel funds.



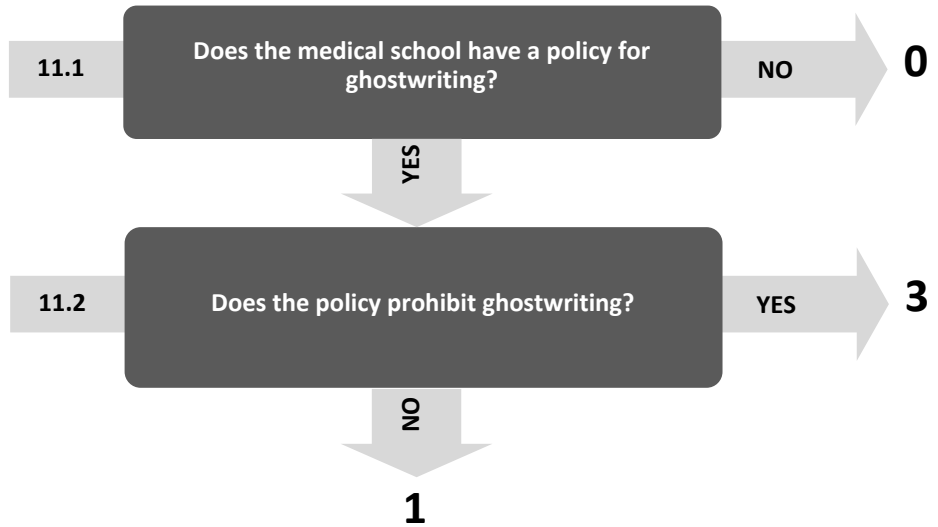
10. INDUSTRY-FUNDED SCHOLARSHIPS



11. GHOSTWRITING

NOTE:

"Discouraging" ghostwriting is not equivalent to banning it.



12. PARTICIPATION IN SPEAKERS’ BUREAUS

