

Conflicts of interest: Ad-hoc topic group proposal

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Conflicts of Interest (COI) processes

- COI processes are designed to assure that decisions based on evidence and made by groups working for government, academic institutions or other public-facing organizations that may impact the public are free from the influence of especially special interests (funding), politics and advocacy, or that at the very least, the possibility of influence is transparent
- COI processes have become more complex over the past decade, and are meant to assure that decision-makers in these settings based their votes on evidence, free from other influences

COI processes at the ACHDNC

- Currently COI for Committee members is based only on two assessments:
 - The completed OGE Form 450 Confidential Financial Disclosure Report, reviewed by HRSA staff
 - A personal decision by a specific Committee member based on their own assessment of any potential conflicts for a specific topic vote
- Currently, there is no assessment of potential conflicts for Organizational Representatives

The current COI assessment for the ACHDNC does not reflect the current state of the art methods used by important recommendation groups including:

- The US Preventive Services Task Force (AHRQ)
- The Community Preventive Services Task Force(CDC)
- The National Academies of Sciences, Engineering and Medicine Health and Medicine Division

CPSTF methods

- Prior to the meeting, all voting members review the topics to be voted on and complete a disclosure form that covers:
 - Financial COI
 - Potential business and professional COI
 - Potential intellectual COI
- CDC staff, including the office director, legal advisory, and TF chair and vice chair review COI statements and decide on whether the member should have restricted participation
- Restrictions could include no restrictions and no public disclosure, no restrictions but with public disclosure, participation in discussion restriction from voting, or recusal and restriction from all parts of the topic presentation and discussion
- NOTE that disclosure and actions (decision on restrictions) are SEPARATE: a disclosure may not lead to any restriction

Financial interests (CPSTF)

- Financial conflicts of interest refer to investments or interests in entities that could influence, or give the appearance of influencing, the outcome of a decision
- Entities could be individuals, organizations and corporations, or other groups with established or future business in the matter of a decision
- **A relevant financial interest** (see list below) is a situation in which a committee member has the potential for direct or indirect financial gain or loss related to a recommendation vote
- Members should disclose financial relationships for themselves, their spouse (or close personal relation), and dependent children
- The cutoff is at \$1,000 or greater for the previous 12-month period

Financial interests include:

- Ownership of individual stocks other significant proprietary interests or investments in any third party that could be affected by a decision on a specific topic
- Having an employment, independent contractor, or consulting relationship or other contractual arrangements, whether written or unwritten, with an entity that could be financially or reputationally affected by a decision
- Receiving patents, royalties or licensing fees from a proprietary/private business entity
- Receiving a research grant awarded to you as an individual as a primary investigator, co-investigator, consultant or subcontractor from a proprietary/private business entity or corporate foundation (not Federal or non-profit research grants awarded to an institution)
- Receiving compensation for participation on the governing board or advisory council of a proprietary/private business entity or any other entity including non-profits
- Participating in a speaker's bureau for a proprietary/private business entity
- Receiving honoraria, travel, or gifts from a proprietary/private business entity
- Receiving payment as an expert witness for a plaintiff or a defendant associated with such a proprietary/private business entity
- Receiving compensation for services by parties having a financial interest in the outcome of a decision

Potential Business and Professional interests (CPSTF)

- Business or professional conflicts of interest refer to business or professional relationships or activities not otherwise disclosed as financial that could influence, or give the appearance of influencing, a CPSTF decision
- **A relevant business or professional interest** (see list below) is a situation in which a CPSTF member has the potential for business or professional gain or loss related to a CPSTF finding, e.g., the outcome of a CPSTF decision may positively or negatively affect an organization's ability to receive funding
- CPSTF members should disclose their own business or professional relationships, those of their spouse (or close personal relation), and of dependent children

Potential Business and Professional interests include:

- Public comments and testimony (includes serving as an expert witness) made on behalf of a business or professional organization
- Leadership roles (e.g., in a panel, association, society, journal or certification body)
- Advocacy or policy positions on behalf of an entity
- Disclose relationships with governmental organizations, non-governmental organizations (including non-profits), private organizations, professional societies, or other organizations that you have reason to believe may benefit or be harmed by findings and including serving as a:
 - Board member or Trustee
 - Director
 - Expert Advisor
 - Leadership position in a professional society, including subsection or committee
 - Officer
 - Owner
 - Principal Investigator, Co-Investigator, or Subcontractor on a grant

Potential Intellectual Interests (CPSTF)

- It is recognized that ***potential*** intellectual interests are likely to be numerous because members are chosen for their national reputations on relevant issues and their work may be sufficiently well-known such that different audiences might question the objectivity of the process if such members are known to have taken leadership roles in discussion and even votes on recommendations regarding that topic
- A member may hold strong personal views on the effectiveness of particular interventions and may be unwilling to accept evidence to the contrary; the same holds true for strong moral convictions that could influence a member's scientific opinions.
- Potential intellectual conflicts of interest may be indicated by the following:
 - Membership in a lobbying or advocacy organization
 - Serving as an expert witness
 - Public comments, or other indication of strongly held beliefs
 - Intellectual property rights including books, journals, manuscripts, patents, and copyrights

Organizational representatives

- Should not be held to the same standards as voting members—they are appointed to represent interests including advocacy

However:

- While Organizational Representatives should not have COI-related restrictions, they have special status and access to participation in Committee discussions (as meeting time allows, and at the discretion of the chair)

Proposal:

- Organizational Representatives should annually disclose whether they receive **any** funding from a proprietary/private business entity and include in that disclosure how much and what percentage of their operating budget (if relevant) such funding represents; this information should be available to at least the Committee members

Next steps

- Given the complexity and potential sensitivity of this issue, we should consider creating an ad-hoc topic workgroup to create a proposal to present to the Committee for consideration