INTRODUCTION

The U.S. Preventive Services Task Force (USPSTF) provides independent, objective, and scientifically rigorous recommendations for clinical preventive services. A primary concern is to avoid even the appearance of members having special interests that might influence their ability to judge evidence and formulate unbiased recommendations. The conflicts of interest policy for the USPSTF is described, as is the formal process by which best practices were incorporated to update the policy. The USPSTF performed a literature review, conducted key informant interviews, and reviewed conflicts of interest policies of ten similar organizations. Important findings included transparency and public accessibility; full disclosure of financial relationships; disclosure of non-financial relationships (that create the potential for bias and compromise a member’s objective judgment); disclosure of family members’ conflicts of interests; and establishment of appropriate reporting periods. Controversies in best practices include the threshold of financial disclosures, ease of access to conflicts of interest policies and declarations, vague definition of non-financial biases, and request for family members’ conflicts of interests (particularly those that are non-financial in nature). The USPSTF conflicts of interest policy includes disclosures for immediate family members, a clear non-financial conflicts of interest definition, long look-back period and application of the policy to prospective members. Conflicts of interest is solicited from all members every 4 months, formally reviewed, adjudicated, and made publicly available. The USPSTF conflicts of interest policy is publicly available as part of the USPSTF Procedure Manual. A continuous improvement process can be applied to conflicts of interest policies to enhance public trust in members of panels, such as the USPSTF, that produce clinical guidelines and recommendations. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

CONFLICTS OF INTEREST IN CLINICAL GUIDELINES: UPDATE OF U.S. PREVENTIVE SERVICES TASK FORCE POLICIES AND PROCEDURES

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The U.S. Preventive Services Task Force (USPSTF) provides independent, objective, and scientifically rigorous recommendations for clinical preventive services. A primary concern is to avoid even the appearance of members having special interests that might influence their ability to judge evidence and formulate unbiased recommendations. The conflicts of interest policy for the USPSTF is described, as is the formal process by which best practices were incorporated to update the policy. The USPSTF performed a literature review, conducted key informant interviews, and reviewed conflicts of interest policies of ten similar organizations. Important findings included transparency and public accessibility; full disclosure of financial relationships; disclosure of non-financial relationships (that create the potential for bias and compromise a member’s objective judgment); disclosure of family members’ conflicts of interests; and establishment of appropriate reporting periods. Controversies in best practices include the threshold of financial disclosures, ease of access to conflicts of interest policies and declarations, vague definition of non-financial biases, and request for family members’ conflicts of interests (particularly those that are non-financial in nature). The USPSTF conflicts of interest policy includes disclosures for immediate family members, a clear non-financial conflicts of interest definition, long look-back period and application of the policy to prospective members. Conflicts of interest is solicited from all members every 4 months, formally reviewed, adjudicated, and made publicly available. The USPSTF conflicts of interest policy is publicly available as part of the USPSTF Procedure Manual. A continuous improvement process can be applied to conflicts of interest policies to enhance public trust in members of panels, such as the USPSTF, that produce clinical guidelines and recommendations. Am J Prev Med 2018;54(1S1):S70–S80. © 2017 American Journal of Preventive Medicine. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
USPSTF recommendation statements are to be accepted and implemented. The National Academy of Medicine defined conflicts of interest (COI) as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” COI can be categorized as financial or intellectual and can influence, directly or indirectly, the ability of an individual to have an open mind and make decisions without implicit or explicit bias. A strong COI policy is essential to protecting public confidence in Task Force recommendations by transparently disclosing interests that could potentially influence the work and decision making of its members and by excluding members who have potentially conflicting interests in a topic from shaping or deciding on a recommendation. Although the USPSTF had an existing COI policy, the USPSTF began updating its COI policy in 2011 to ensure that it met current best practices.

METHODS FOR UPDATING THE U.S. PREVENTIVE SERVICES TASK FORCE CONFLICTS OF INTEREST POLICY

In the fall of 2011, the USPSTF engaged in a comprehensive multistep process to update its existing COI policy. The goal was to understand current trends, best practices, and potential challenges for developing comprehensive COI policies.

To identify potential areas of the policy in need of updating, the USPSTF reviewed recent literature describing current trends and best practices and conducted semi-structured interviews with 14 key informants. Relevant articles were identified through Internet searches and conversations with the Agency for Healthcare Research and Quality staff. Search terms included conflict of interest policies, clinical practice guidelines, and guideline panels, and searches were restricted to articles appearing from 2006 to 2012 to ensure that only the most current practices (at the time of review) were obtained and incorporated in the review. In total, 18 articles were included (Table 1).

Semi-structured interviews were conducted with staff who had been involved in developing and implementing COI policies and procedures at Federal agencies and similar groups that produce guidelines or convene expert panels. These organizations included Agency for Healthcare Research and Quality, American College of Chest Physicians, American College of Physicians, Centers for Medicare and Medicaid Services (CMS), the Community Preventive Services Task Force, Evidence-based Practice Centers, National Academy of Medicine, and NIH. Interviews were also conducted with a consumer group representative, COI researchers, a scientific journal editor, and a former healthcare reporter. The purpose of these interviews was to identify all areas of the USPSTF COI policy that might need updating, to identify perceived challenges in developing and implementing COI policies and procedures, and to gather general advice on this process from individuals who had conducted similar work. An interview guide is available upon request.

The USPSTF also reviewed existing COI policies from ten organizations, including Agency for Healthcare Research and Quality’s National Guideline and Quality Measures Clearinghouses, the American College of Physicians, the American College of Chest Physicians, the American Heart Association, the CMS Coverage and Analysis Group, the Evidence-based Practice Center Program, International Committee of Medical Journal Editors, the National Academies of Sciences, Engineering, and Medicine’s Health and Medicine Division, the Federal Advisory Committee Act, and the NIH Health Lung and Blood Institute. COI policy documents and disclosure forms were provided by key informants. For each policy the USPSTF collected the following information: to whom the policy was applied, types of disclosures that were required, financial thresholds for disclosure, time frame for disclosure, details on implementation of the policy, and transparency requirements.

FINDINGS FROM THE U.S. PREVENTIVE SERVICES TASK FORCE CONFLICTS OF INTEREST REVIEW

Based on the obtained information, the following themes were consistently identified as important areas to consider.

Transparency and Public Accessibility to Conflicts of Interest Policies and Disclosures

Transparency (operating in a way that makes it easy for the public to see what actions are performed) and public accessibility were cited as the most important aspects of respected health organizations’ COI policies. Key informants suggested that the policy should be easily accessible on websites and through links on all USPSTF publications. They also recommended that the policy be regularly updated, reviewed, and managed. The majority of interviewees also supported public access to disclosures of USPSTF members; however, a few respondents were opposed to this because of privacy concerns.

Reviewed literature also recommended that COI policies, including procedures for minimizing the influence of competing interests (e.g., recusal from topic discussions), be made readily accessible to end-users of a guideline. Best practices for managing conflicts favored public access to disclosures and the disclosure
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| James Bell and Associates (2009)² | Best Practices in Conflict of Interest for Comparative Effectiveness Reviews and for Recommendation-Making Panels | - Commissioned by AHRQ to lay the groundwork for an AHRQ-wide approach to COI as a basis for policies adopted by programs within the agency.  
- Identifies five areas that would set the foundation for an AHRQ-wide approach to COI: (1) defining COI, (2) establishing COI policy structure, (3) maintaining public transparency, (4) managing institutional COI, (5) standardizing de minimis thresholds and look-back/look-ahead periods. |
| Boyd and Bero (2006)³   | Improving the Use of Research Evidence in Guideline Development: Managing Conflicts of Interest | - Reviews the existing COI literature to determine optimal strategies for (1) obtaining complete and accurate disclosures; (2) determining when a disclosure constitutes an actual conflict; (3) managing identified conflicts; and (5) enforcing COI policies.  
- Authors found that there is currently little empirical evidence to guide the collection and management of COI information. In the absence of rigorous evidence, the authors draw from specific COI policies and cases to suggest: the use of a specified, detailed, and structured disclosure form; explicit criteria for determining when a disclosure constitutes a COI; a range of management strategies that may be applied to COI on a case-by-case basis; and a policy stipulating that financial ties of members be reported to the public. |
| Brawley et al. (2011)⁴  | New American Cancer Society (ACS) Process for Creating Trustworthy Cancer Screening Guidelines | - Describes ACS’s revised methods to create a more transparent, consistent and rigorous process for developing and communicating guidelines.  
- The new guidelines are aligned with current USPSTF procedures and with National Academy of Medicine principles (described below). The ACS will create a single generalist group for writing the guidelines to avoid undue influence by subspecialists advocating for the use of procedures performed by their subspecialty. It will commission independent systematic evidence reviews and clearly articulate the benefits, limitations, and harms associated with a screening test. Guidelines will be updated at least every 5 years. |
| Guyatt et al. (2010)⁵   | The Vexing Problem of Guidelines and Conflict of Interest: A Potential Solution | - Describes the recently revised COI policy of the ACCP Antithrombotic Guidelines committee.  
- Key elements include the following: (1) placing equal emphasis on intellectual and financial COI; (2) ensuring that chapter lead is a methodologist with no important COI; (3) allowing only panel members without important COI to develop recommendations. |
| National Academy of Medicine (2009)⁶ | Conflict of Interest in Medical Research, Education, and Practice | - Examines financial COI in the field of medicine and recommends steps to improve the disclosure and management of conflicts, including the standardization of disclosure processes and forms across organizations and a national system for the public reporting of payments by pharmaceutical, medical device, and biotechnology companies, which would help facilitate the verification of disclosures.  
- Includes a chapter that examines COI in the development of clinical practice guidelines. The report found considerable differences in the extent to which groups publicly reported their COI policies and/or industry relationships.  
- Given the influence of clinical practice guidelines on physician decisions, quality measures, and health plan coverage, the report recommends that guideline panels, the National Guidelines Clearinghouse, and journals publishing the guidelines provide both COI policies and relevant conflicts of panel members with the guidelines. |
| National Academy of Medicine (2011)⁶ | Clinical Practice Guidelines We Can Trust | - Commissioned to discover the best methods used in developing CPG in order to ensure that organizations have information on approaches that are objective, scientifically valid, and consistent.  
- Eight standards were proposed, including one that focused on management of COI, and covered the following: (1) disclosure of all potential COI before selection for GDG; (2) disclosure of COI to all GDG members; (3) divestment of financial interests before participation; (4) exclusion of members with COI whenever possible. |

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- COI policies were not addressed in this report. |
- 62% of experts reported at least one financial COI. An ethics framework and international policy initiatives may help to identify and manage COI. |
| Lichter et al. (2012)            | Harmonizing Reporting on Potential Conflicts of Interest: A Common Disclosure Process for Health Care and Life Sciences | - Proposes the use of a harmonized disclosure system that, in the face of increasing disclosure requirements, can reduce administrative burden for reporting individuals, including (1) standardized organizational policies for disclosures and (2) standardized format, definitions, and procedures for the collection and maintenance of disclosure information.  
- Specific thresholds for determining significant relationships or conflicts were not addressed in this report. |
| Nelson (2009)                   | Conflicts of interest. Clarity, transparency, action are keys to maintaining trust, avoiding conflicts | - Provides the broad context for the issue of conflicts of interest among healthcare professionals.  
- Urges for complete transparency of disclosures as a means of building public faith in an organization and thwarting any potential misconceptions. |
- Discovered a discrepancy between disclosures made on the USPSTF website versus in journal articles and called these discrepancies "undeclared conflicts of interest." |
- MEDLINE was searched for studies that examined the effect of COI on CPG development and/or recommendations.  
- There are limited data describing the high prevalence of COI among CPG authors. Further research is needed. |
| Norris et al. (2012)            | Conflict of Interest Disclosures for Clinical Practice Guidelines in the National Guideline Clearinghouse | - Reports estimated rates of author COI disclosure and public availability of the disclosure information from a random sample of 250 clinical practice guidelines in the National Guideline Clearinghouse.  
- Found that of 150 CGPs (60%) with author disclosures, 42% of author disclosures were collected but only internally available to members of the guideline organization.  
- Specifies that specific disclosures by guideline panelists should be readily available to end-users. |
| Norris et al. (2012)            | Conflict of Interest Policies for Organizations Producing a Large Number of Clinical Practice Guidelines | - Compares existing COI policies from 17 clinical guideline groups against 2011 National Academy of Medicine standards to identify needed improvements (includes review of the USPSTF policy).  
- Review found wide variation in the COI policies related to types of financial and non-financial COI addressed, financial thresholds, and procedures for maintaining COI information.  
- Reports that none of the organizations met all National Academy of Medicine standards and calls for extensive improvements in COI policies, including a clearer definition of nonfinancial conflicts and the application of the policy to all authors of the systematic review, guideline panelists, and other participants of the development and review process. |

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Drew from existing reviews of COI policies as well as actual policies of select organizations to inform the revision process.  
New policy and procedures for the reporting and management of COI included the review of COI for potential participants and exclusion of participants with unresolvable COI; the inclusion of institution/employer and family member conflicts; and the sharing of disclosures to target audiences (e.g., document users and conference attendees). |
| Scott and Guyatt (2011) | Clinical Practice Guidelines: The Need for Greater Transparency in Formulating Recommendations | Offers key strategies for mitigating conflicts among clinical practice guidelines panelists, specifically: (1) collecting disclosures for all industry-related professional involvement; (2) requiring panelists to indicate specific sections of the draft guidelines for which they may have conflicts; (3) stipulating divestment from companies potentially affected by the guideline recommendation; (4) limiting the drafting of the recommendation to conflict-free members; (5) excluding participants with conflicts from guideline review; and (6) including a description of the COI policy, any funding for the guideline, and relevant financial relationships of the panelists as part of the published guideline. |
| Sniderman and Furberg (2009) | Why guideline making requires reform | Describes limitations in the guideline development process, including the challenge of achieving consensus in guidelines; the lack of independent review; and members’ financial entanglements with industry.  
Supports COI policies that request full disclosure of “present and recent past” financial interests as well as any relationships that may confer financial benefits for the members in the near future. |
| USPSTF (2008) | USPSTF Procedure Manual | Describes former USPSTF COI policy. Task Force members were asked to disclose any information that interfered with their abilities to discuss and/or vote on a specific topic.  
Potential conflicts of interest included financial, professional, intellectual, or other conflicts. |

ACCP, American College of Chest Physicians; ACS, American Cancer Society; AHRQ, Agency for Healthcare Research and Quality; ATS, American Thoracic Society; COI, Conflicts of Interest; CPG, clinical practice guidelines; GDG, guideline development groups; USPSTF, U.S. Preventive Services Task Force.
of financial relationships for public record. The full disclosure of industry relationships, including payments received, was noted as critical for building public trust in an organization. However, a smaller number of sources argued that public disclosure of the conflict did not actually eliminate the conflict and may only unnecessarily taint the reputation of the researcher.

Although public access to COI policies is considered a critical aspect of transparency by experts and other stakeholders, it was not always practiced. Whereas most reviewed COI policies stated they were available online, they were often difficult to locate. Most organizations/agencies also provided access to disclosures through web links on final reports/publications. Some organizations provided the actual disclosure form, whereas others provided more general summaries of disclosures. One organization stated that all COI discussions were confidential and disclosures were not publicized.

Threshold for Financial Disclosures
Financial disclosures are widely defined and vary by organization; they may include professional income, equity, debt, stock options, and intellectual property rights. At the time of review, the threshold for USPSTF financial disclosures was $10,000 per year. The USPSTF found that COI best practices included a lower threshold and some experts recommended eliminating thresholds altogether (i.e., all financial relationships must be disclosed regardless of value). The literature revealed a downward trend in the threshold for financial disclosures, with suggested thresholds between $0 and $1,000. More than half of the reviewed policies had a threshold of $0 whereas the rest were set between $200 and $10,000. Although the reporting thresholds varied, disclosure of financial COI was required by all reviewed organizations and, in a few cases, it was the only disclosure required. As even small payments were shown to compromise objective decision making, those supporting the elimination of de minimis thresholds and disclosure of all financial interests argued that full disclosure is necessary for developing a complete and accurate understanding of an individual’s financial relationships, despite any potential for increased administrative burden on reporting individuals. For example, to increase transparency in healthcare delivery, CMS proposed a final rule in 2010 implementing the CMS Physician Payments Sunshine Act that stipulates a de minimis threshold of $10 or $100 for aggregate payments less than $10.

Disclosure Requirements of Family Members
Understanding the influence of family members’ COI on decision making was another common theme of the review. Of particular importance were the questions of which family members (if any) an individual should be required to provide disclosure information for and at what level of detail. The majority of interviewees raised concerns that family members with financial and non-financial COI could be influential in decision making and should therefore be disclosed. However, concerns regarding the sensitive nature of this topic were raised. For example, asking individuals to disclose COI of family members could be viewed as too intrusive and even offensive. Furthermore, defining the parameters around this type of disclosure was cited as a major challenge. Interviewees struggled with where to draw the line in defining a family member (i.e., spouses, children, siblings, or more extended family). To minimize the burden of disclosure requirements, best practices in the field suggested requiring individuals to report family members’ financial relationships only if (1) they are publicly

Disclosure and Definition of Non-financial Conflicts of Interest
The influence of non-financial COI (e.g., public comments, leadership on a panel, substantial career efforts/interests, advocacy, or policy positions) on the behaviors and recommendations of members of guideline-making groups has gained attention in recent years. Although there is growing acknowledgement that non-financial COI are likely to influence attitudes and behaviors, the definition and measurement of this construct are unclear and further research is needed. Varying descriptions have been used in COI policies to address non-financial COI. For example, non-financial COI may include “competing beliefs, academic institutions, societies, and publications”; “substantial career efforts”; or “important intellectual conflicts of interests,” such as study authorship or grant funding directly related to the topic that creates the potential for bias and compromises a member’s subjective judgment about the recommendation. Addressing the wide definitional variation in non-financial conflicts may allow for more valid and reliable disclosures; however, given the dearth of evidence regarding the magnitude of influence of non-financial interests on decision making by guideline groups, firm guidance on obtaining and managing valid, reliable disclosure information on non-financial interests was lacking. Additionally, the literature discussed the challenges of managing the involvement of intellectually conflicted individuals, who were likely to be experts in the field and may offer insights critical for guideline development. It may be for these reasons that non-financial COI were not included in all reviewed policies and, if they were, the definitions were frequently vague. Most often, non-financial COI were included in a general “other” category.
available or verifiable and (2) “there exists the possibility that the financial relationship will benefit the reporting individual, including if the reporting individual has benefitted in the past.”

Although an increasing number of organizations began including family members in COI policies, there was wide variation in the actual requirements.1,14 Five of the ten COI policies reviewed required COI disclosures by family members, defined as spouses and dependent children, and most disclosures focused only on financial COI.

Establishing Financial Look-Back and Look-Forward Periods
An appropriate look-back period (the time period within which interests must be disclosed), and possibly a look-ahead period, was another common theme that surfaced in the review. However, despite the general support for look-back and look-forward periods, there was no consensus on appropriate time frames for disclosure, and there was no clear evidence that specific look-back and look-forward periods were effective in identifying potential COI during guideline development. Some sources advocated for disclosure of present and recent past relationships as well as those that “[confer] future financial benefit,” but did not offer more concrete reporting periods for consideration.17 Other policies were more prescriptive, requesting disclosure for the previous 5 years or including look-forward periods for pending relationships or those expected in the next 12 months.1

Look-back periods were viewed favorably during the review whereas look-forward periods were viewed with more skepticism, in part because the definition and operationalization of a look-forward period was thought to be confusing to understand and difficult to implement. Overall, trends among leading journals and institutions included a look-back period of more than 3 years and a look-forward period of 1 year, including any financial arrangements in negotiation at the time of disclosure.7

Application of the Conflicts of Interest Policy to Prospective Members
There was scant literature examining the issue of applying COI policies to prospective members of guideline-making groups. A number of interviewees argued that it was very important to apply the policy to potential candidates before their appointment on the panel, as COI was too important a concern to discover only after the individual has become a member. One respondent suggested the COI disclosures should be one of the criteria used to select members.

REVISED U.S. PREVENTIVE SERVICES TASK FORCE POLICY
Drawing from the findings of the USPSTF review, the Task Force worked to incorporate best practices into a revised policy. The revised COI policy is publicly available as part of the USPSTF Procedure Manual.32 The comparisons between the previous and updated policies are summarized in Table 2.

Improved Transparency and Management of Disclosures
The revised USPSTF COI policy addresses all of the themes that were identified in the review and aims to further improve transparency and accountability by providing more detailed direction for how disclosures are managed. Specifically, the following updates were made to improve the transparency and management of disclosures.

As part of the general COI process, all disclosures are reviewed by the USPSTF Chairs to determine whether they are actual COI, based on the nature of the disclosure. For each USPSTF member, the disclosures are reviewed and then assigned one of three levels of potential conflict, each with a set of possible consequences (Level 1: no relevant COI; Level 2: disclosure of a potential bias; Level 3: mitigation required; Table 3).32 Task Force Chairs adjudicate the potential COI and make a determination of possible actions to mitigate the potential conflict on a case-by-case basis in accordance with USPSTF policies. Possible actions to mitigate the potential COI depend on the nature of the COI and its relevance to the particular topic of the recommendation under review. To mitigate Level 3 disclosures, actions vary according to the nature of the conflict, and may include preventing the member from serving as the leader or member on the workgroup of a topic, preventing the member from taking part in all topic activities, including full recusal from discussing or voting on the topic draft or final recommendation.

To ensure transparency and accountability, the USPSTF posts a summary table of any member’s Level 3 disclosures on its website. Level 3 disclosures and resulting recusals are also noted in the published recommendation statements. In addition, International Committee of Medical Journal Editors disclosure forms from USPSTF authors are available for each Recommendation Statement from the journal in which the Recommendation Statement is published, thereby ensuring that the information is publicly available.
Lower Threshold for Financial Disclosures

Following the review, the Task Force chose to lower the financial disclosure threshold to any amount of payment over $0. This was done to maximize transparency and minimize the risk of overlooking potential conflicts. It also simplified reporting, because Task Force members simply list all payments or relationships. Financial relationships include those of USPSTF members, their immediate family members (which include their spouse/partner, dependent children, and parents) and close personal relationships (which include but are not limited to those with whom they are in a romantic or business relationship or those living in the same household). Relevant financial interests include, but are not limited to, stock ownership, an employment or consulting relationship with an entity that could be financially or reputationally affected by a USPSTF decision, participation on an entity’s proprietary governing board or advisory council, research grants, and fees or in-kind payments. Task Force members may be asked to divest of all stocks or stock options and sever relationships with any entities that may result in potential conflicts of interest.

Inclusion of Disclosures for Immediate Family Members and Close Personal Relationships

Although requiring the disclosure of potential COI of family members may be considered intrusive by some, the USPSTF believes it is necessary to achieve maximum transparency. The revised policy now requires all USPSTF members to disclose potential financial and nonfinancial conflicts of immediate family members as well as other close personal relationships (as defined above).

Stronger Definition for Non-financial Conflicts of Interest

Although the review findings suggested that the USPSTF already had a robust non-financial disclosure process in comparison to its peers, USPSTF members felt the definition of non-financial COI could be further clarified. The definition now includes any strongly held beliefs related to a topic area that would make it difficult for a Task Force member to work on a related topic or any relationships with governmental organizations, healthcare organizations, professional societies, or other organizations that may benefit from or be harmed by Task Force
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| 1    | • No financial disclosures of any value  
      • No non-financial disclosures that would impact the judgment of the Task Force member.  
      • Financial interests that do not need to be disclosed:  
        ○ Income from seminars, lectures, teaching engagements, service on advisory committees, or review panels for public entities or nonprofit organizations that do not have a vested interest in the specified topics  
        ○ Diversified mutual or retirement funds  
      • Non-financial interests that do not need to be disclosed:  
        ○ Employment from nonprofit organizations such as government agencies and nonprofit entities that do not have a vested interest in the specified topics  
        ○ General membership in a professional society  
        ○ Attendance at presentations or conferences related to the topic(s) of interest | No action | No disclosure or recusal necessary |
| 2    | • Providing public comments, expert testimony, or participation in speaking bureaus on a relevant topic (excluding speaking engagements on behalf of a product)  
      • Any relevant financial disclosure valued at $1,000 or less  
      • Participation in any governmental organizations; professional societies; or other organizations (as an officer, medical staff, board member, director, expert advisor, or consultant) related to the topic(s) of interest  
      • Serving as editor or deputy editor of an academic journal, book, or website | Information disclosure to Task Force only | Member may participate as primary lead, and may discuss and vote on the topic |
| 3    | • Any relevant financial disclosures valued at more than $1,000  
      • Participation in any proprietary companies (as an officer, medical staff, board member, director, expert advisor, or consultant) related to the topic(s) of interest such that the member would stand to gain financially from a specific outcome of a recommendation statement  
      • Speaking engagements on behalf of a product  
      • If a member has significant non-financial interests in a specific outcome of a recommendation statement  
      • The member has one or more publications or research grants that are likely to be part of the evidence review, and that address key questions in the analytic framework, or that express opinions related to the topic. Whether or not action is needed will depend on the specific content of the publications and/or grants, and the source of funding of any grants. | Possible exclusions from Task Force roles as a result of Level 3 disclosures Include:  
- Member may not serve as primary lead for topic workgroup  
- Member may not serve as primary spokesperson for the topic  
- Member may not serve as a lead on the topic workgroup  
- Recusal from all participation in topic activities | Member may not participate as the primary lead of the topic workgroup specific to the conflict, but may serve as a lead on the topic workgroup and discuss and vote on the topic.  
Member may not participate as the primary spokesperson for the topic specific to the conflict, but may serve as a lead on the topic workgroup and discuss and vote on the topic.  
Member may not participate as a lead in the topic workgroup specific to conflict, but may discuss and vote on the topic.  
Member may not participate as a lead in the topic workgroup specific to conflict and may not discuss or vote on the topic. Member will leave the meeting room for all discussion and voting. Publicly released recommendations will denote the member’s recusal from participation and voting on this topic. |
recommendations. Specifically, non-financial COI include public comments and testimony, leadership role on a panel, substantial career efforts/interests in a specific topic area, published opinions, and advocacy or policy positions. In addition, potential non-financial interests requiring disclosure include any relationships with healthcare organizations, governmental organizations, professional societies, or other organizations that may benefit from or be harmed by USPSTF recommendations.

**Longer Look-back Period**
The USPSTF also increased the look-back period to 3 years from the start of a topic, as 12 months was felt to be too short a period to adequately reflect professional activities that might create potential COI. Two exceptions were made to the 3-year limit. First, the limit on the look-back period was eliminated for scientific publications related to USPSTF topics under review, meaning that any publication published at any time that is related to a USPSTF topic is required to be disclosed. Second, the period of disclosure for research grants received was set at 36 months from the end of the grant period.

**Application of the Conflicts of Interest Policy to Prospective Task Force Members**
The new COI policy was also expanded to apply to potential candidates prior to their appointment on the USPSTF. Prospective members are informed of the COI policy and are required to submit a disclosure form prior to being considered for appointment. The CMS Open-Payments database is also reviewed to ensure that no financial disclosures have been overlooked. Prospective members are interviewed and asked about their COI disclosures before being selected as USPSTF members. Prospective members with significant potential conflicts may be declined on the basis of COI concerns. For example, a prospective member may be employed by an institution that derives its revenue from the sale of particular products that are significantly affected by a USPSTF recommendation. This employment situation would preclude the prospective member from working and voting on that particular recommendation. If a prospective member has multiple potential COIs that may limit his or her ability to participate in multiple topics, membership would not be offered based on the inability of the prospective member to function fully as a productive member of the Task Force. After appointment on the Task Force, current USPSTF members are expected to provide updates of any new COI every 4 months to reflect any changes in their situation.

**CONCLUSIONS**
The integrity of the USPSTF depends on the public’s and clinicians’ confidence in the process the USPSTF uses to formulate its recommendations and minimize bias of its members. Guideline developers must also submit themselves to continuous and rigorous reviews of any potential COI. A recently published special issue of the *Journal of the American Medical Association* on COI highlights progress made and challenges that remain in managing COI. In this special issue, Dr. Harold Sox, a former USPSTF member, identified four main principles of COI management: (1) avoid panelists with COI; (2) use panelists without COI to draft guidelines; (3) involve experts in the discussion of the draft guideline; and (4) restrict the final revisions and voting to panelists without significant COI.23 Currently, the USPSTF follows all of these principles in its COI process, and was cited as an example of a “virtually conflict-free” panel.34

Despite progress in the management of conflicts in health care, there are still areas in which research is needed. The influence of industry on clinicians’ practice patterns needs further examination.35 Innovative studies are needed to examine how financial payments from industry, both large and small, influence the prescribing and utilization patterns of clinicians in their daily practice. Defining and understanding the influence of non-financial COI on individual clinician practice and on guideline panels also warrants more research.

By identifying best practices and standards in the field and updating its COI policy accordingly, the USPSTF demonstrates its commitment to maintaining explicit, transparent, state-of-the-art policies and procedures. For its clinical guidelines to be trustworthy, it is necessary that the USPSTF maintains these standards and procedures and strives to continually update them to ensure the public’s trust.

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