

Policy Name: Conflict of Interest Policy Implementation for Quality Measures of American Society of Clinical Oncology
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The American Society of Clinical Oncology (ASCO) is dedicated to conquering cancer through research, education, prevention, and delivery of high-quality patient care. One of the primary ways in which ASCO fulfills this responsibility is through the development of clinical quality measures. Provider and public confidence in these measures depend on the development of measures in a manner designed to minimize actual and perceived conflicts of interest.

Quality measures are developed from an array of sources. In general, ASCO develops quality measures based on priorities set by the Care and Quality Improvement Committee (CQIC) and associated subgroups. ASCO develops measures independently and collaborates with other organizations to develop quality measures applicable to stakeholders of both groups. Quality measures are drafted by Technical Expert Panels (TEPs) and reviewed by the Measures Steering Group (MSG), which reports to the CQIC. Measures used in federal quality reporting programs are reviewed annually or when practice-changing evidence becomes available and are updated as needed.. The following procedures provide strategies for managing potential conflicts of interest (COI) through the stages of measure development in accordance with the principles in ASCO's Policy for Relationships With Companies.¹

I. General Policy

ASCO requires disclosure of relationships with for-profit health care Companies by individuals involved at any stage of the measure development process. As a signatory Society to the Council of Medical Specialty Societies Code for Interactions with Companies² (CMSS Code), ASCO adopts the CMSS Code definition of "Company." A Company is a for-profit entity that develops, produces,

¹ American Society of Clinical Oncology, Policy for Relationships With Companies 2013 JCO2013.49.5002. Available at www.asco.org/rwc.

² Council of Medical Specialty Societies, Code for Interactions with Companies. [CMSS Code for Interactions with Companies - CMSS](#).

markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.

II. Disclosure

ASCO's policy is to promote the development of measures in a manner that minimizes the risk of actual and perceived bias. Disclosure of relationships with Companies is the first step in ASCO's process of evaluating and managing relationships that could result in actual or perceived bias. All prospective members of a TEP, or any other group charged with developing measures will disclose financial interests and other relationships with Companies in accordance with ASCO's Policy for Relationships with Companies. All members of existing Committees and Sub-Committees disclose the same information. Individuals who are not ASCO members but are being considered for appointment to a TEP must also disclose the relationship in accordance with ASCO policy.

Occasionally, an individual may have a relevant indirect or non-financial interest or relationship that is not covered by ASCO's general COI disclosure, such as an intellectual property interest; a strong professional or research opinion; or an outside affiliation. In these situations, the interest should be disclosed to the appropriate ASCO staff member or group leader.

Disclosure reports identifying members' relationships will be available to TEP members during the measure development process. The MSG will have this information available when considering proposed measures for approval.

III. Identifying Affected Companies

Companies with products affected by a quality measure or measure set are considered "affected Companies" for purposes of determining whether a conflict of interest exists in the development of ASCO quality measures. A Company is an "affected Company" if there is a reasonable likelihood of *direct and material regulatory or commercial impact (positive or negative)* on the entity as a result of care being measured. Affected Companies will generally be identified at the time of development of the measure concepts, prior to selection of TEP members, chairs or co-chairs.

An affected Companies list will generally be drafted by an ASCO Measure Development Specialist in consultation with ad hoc experts who will not serve as TEP members. In the event a TEP chair has a non-disqualifying relationship with an affected Company, the affected Company list will be reviewed and approved by the MSG chair. The list of affected Companies should remain consistent throughout measure development and adoption. If changes in the marketplace or in the focus of the measure set make revisions necessary, a modified list may be developed or reviewed by ASCO. The list of Companies affected by a measure set will be made available to prospective TEP Chairs and TEP members and the appropriate committees overseeing measure development. If the list is modified during the development of the measure(s), the TEP composition will be checked to maintain compliance with this Policy.

IV. Measure Development Panels

A. Panel Composition

ASCO's goal is to assemble a diverse and well-qualified group of experts to develop and approve quality measures in a manner that minimizes the risk of actual and perceived bias. Having a relationship with a Company does not necessarily mean an individual is biased or has a conflict of interest. However, ASCO's policy is that certain financial relationships give rise to conflicts of interest that are not capable of being effectively managed and are, in fact, inconsistent with actual and perceived independence. A "Company" means a for-profit business that develops, produces, markets or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions. This definition may change from time to time and will follow the then-current definition of Company in the ASCO Conflict of Interest Policy for Clinical Practice Guidelines. The following criteria render an individual ineligible to participate on a measure TEP:

In the case of measures related to ASCO Guidelines or Guideline Endorsements, an individual is not eligible to serve on a Measure Development Panel TEP if he or she was or would have been ineligible to serve on the guideline panel from which the measure is being derived. In all other instances, decisions about participation on a Panel TEP will be made at the discretion of ASCO and will include, but not be limited to the following.:

- Participates in a speakers' bureau (on any subject) on behalf of an affected Company;
- Is employed by a for-profit healthcare Company, or has been employed by an affected Company at any time during the year prior to appointment to the panel and to continue for one year after the publication of the guideline; or
- Holds a significant ownership interest in an affected Company; or
- Holds a financial or other relationship whether with an affected Company or another interest that, in ASCO's discretion, presents a risk of actual or perceived bias that cannot be effectively managed or could undermine public confidence in the measure.

In all other instances, decisions about participation on a TEP will be made at the discretion of ASCO.

B. Panel Approval of Measures

At meetings, whether in person or via teleconference, TEP recommendations must be adopted by a 75% majority of TEP in attendance, where a simple majority of panel members are present. When the TEP votes electronically, recommendations must be adopted by a 75% majority of the entire TEP. Because of the supermajority voting standard, panel members who have disclosed financial relationships with affected Companies do not need to recuse themselves from discussing and voting on measures on these grounds.

V. Measures Steering Group of the Care and Quality Improvement Committee

Following development and approval by a TEP, measures are reviewed and approved by the MSG.

A. Disclosure

MSG members will generally disclose financial relationships with Companies as described in section II. These disclosures will be compared with the list of affected Companies before a measure is reviewed by the MSG. MSG members' general disclosure reports, identifying relationships with affected Companies, will be available to MSG members prior to MSG discussion and vote of measures under review.

B. Voting

Upon completion of development and testing, measures must be adopted by a 75% majority of the TEP, whether by vote during a meeting or electronically. Measures approved by the developing TEP are then subject to approval by the MSG with a 75% majority vote required to adopt the measure into the ASCO measure library. Because of the supermajority voting standard, MSG members who have disclosed financial relationships with affected Companies at the time of the vote do not need to recuse themselves from discussing and voting on measures on these grounds.

VI. Publication

When ASCO publishes a measure, all disclosures of panel members from the period when measure development work was completed will generally be published concurrently. This Policy is also posted publicly on ASCO's website.

VII. Exceptions

ASCO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt quality measures. If required to achieve this goal, these procedures may be adapted by ASCO on a case-by-case basis to the extent necessary.

VIII. Decisions

Questions about the application of this Policy will be decided by ASCO. ASCO will consider recommendations from the TEP chair or co-chairs and the MSG Chair (unless the question concerns their roles). ASCO decisions can be made by the Chief Medical Officer or the Chief Legal Officer and Executive Vice President, advised by the Ethics Counsel and staff from Performance Measurement, especially the Division Director or lead staff for the MSG. Questions and decisions may concern, for instance, whether an individual is eligible to serve on a panel, or as a panel chair; whether an individual should be recused from voting; or whether an exception is warranted.

IX. Definition of Terms

Term	Definition
Affected Company	Companies with products affected by a measure are considered "affected Companies" for purposes of determining whether a conflict of interest exists in the development of ASCO measures. A Company is an "affected Company" if there is a reasonable likelihood of direct and material regulatory or commercial impact (positive or negative) on the entity as a result of care being measured.
Company	A Company is defined as any for profit entity that develops, produces, markets, sells or re-sells, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions (including but not limited to pharmaceutical, biotechnology, and medical device companies). Entities through which physicians provide clinical services directly to patients are excluded from the definition of "Company."
Speakers Bureau	A compensated role as a presenter for which any of the following criteria are met: (a) a Company has a contractual right to dictate or control the content of the presentation or talk;

	<p>(b) a Company creates the slides or presentation material and has final approval of the content and edits: or (c) the presenter is expected to act as a Company’s agent or spokesperson for the primary purpose of disseminating company or product information. ASCO recognizes that some activities called “speakers’ bureaus” may not meet these criteria and, conversely, that activities may meet these criteria and not be termed “speakers’ bureaus”. ASCO will rely on the judgment and integrity of disclosing individuals to determine whether an activity constitutes a speakers’ bureau under this Policy. This definition of “speakers’ bureau” does not extend to employees of a Company who make presentations as part of their employment.</p>
Significant Ownership	<p>Shares of a publicly traded Company greater than \$50,000 in value or an equity interest in a privately held Company greater than 5% at the time of disclosure. This does not include interests invested in diversified funds whose holdings cannot be controlled by the disclosing individual.</p>