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April 7, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Attn: ACO Legal Issues
Mail Stop C5-15-12
Baltimore, MD 21244-1850

**Re: Transparency Reports and Reporting of Physician Ownership or Investment Interests
(Affordable Care Act Section 6002)**

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to submit comments in response to the questions posed by the Centers for Medicare and Medicaid Services (CMS) regarding the implementation of Sec. 6002 of the Affordable Care Act (ACA), Transparency Reports and Reporting of Physician Ownership or Investment Interests. The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to furnish input to CMS in advance of the release of a notice of proposed rulemaking.

ACC policies involving relationships with industry

The ACC and the ACC Foundation (ACCF) are committed to the highest ethical standards. The ACC believes that relationships with members of industry provide value when such relationships are ethically structured and managed. Moreover, the College's relationships with industry are transparent and such industry support has no influence on educational or scientific content. The ACC adheres to strict guidelines regarding its relationships with industry and the funding it receives to carry out its mission to advocate for improved quality cardiovascular care and to promote science, workforce development, diversity, medical education and lifelong learning. As such, the College is transparent in disclosing its funding sources. The ACC annually reports sources of industry support and displays this information on its website, www.cardiosource.org.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

As a leader among medical specialty societies, the ACC has long recognized the concerns regarding physician relationships with industry and has been a proponent of transparency regarding industry payments to physicians. In 2008 the ACC convened a forum that brought together leaders from Congress, industry and medicine to discuss these concerns and the need for transparency in these relationships. As a result of this discussion, the College developed a series of best practices, as well as policy governing the ACC's relationships with industry, *Principles for Relationships with Industry*, which regulates the ACC's interactions with industry in nine key areas of operation: advertising, charitable donations, clinical document development, continuing medical education, exposition, governance, government grants and foundation support, registries and sponsorship.

Clinical documents

These policies address not only ACC's direct relationships with industry, but also the relationships of ACC leaders and the authors of clinical documents developed through the ACCF. Clinical documents published in 2009 and beyond are governed by the detailed policy located at <http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx>. The ACCF requires individuals interested in participating in writing committees to disclose all relationships with industry and other entities involved in the production, marketing, distribution or reselling of healthcare goods, services, advice or information consumed by patients, investors and/or physicians. This may include relationships with government entities as well as not-for-profit institutions and organizations. From this information, the College then determines what is relevant to the individual document. According to ACCF's official policy, relevant relationships include:

- Relationships or interests that relate to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document
- The company/entity (with whom the relationship exists) makes a drug, drug class or device addressed in the document or makes a competing drug or device addressed in the document
- The person or a member of the person's household has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the document.

When commissioning a Writing Committee, ACCF requires that the Writing Committee Chair plus 50% of the members have no relevant relationships. Members with relevant RWI are not permitted to draft text or recommendations or vote on recommendations pertaining to their relevant relationships. Additionally, the ACCF collects and discloses information pertaining to relationships with industry for peer reviewers. Relationships deemed to be relevant to the document for both authors and reviewers are published in the document. In the spirit of full disclosure, *all* reported healthcare relationships with industry and other entities for authors and the members of the document oversight group – including those deemed not to be relevant to the document – are posted on the [ACC website](#). Each clinical document published in the *Journal of American College of Cardiology* links directly to the ACCF's policy on relationships, in addition to the online comprehensive information.

Relationships with industry are not defined solely by monetary gain. Individuals may have still have relationships with industry, even though they are not compensated directly. In fact, the ACC defines seven categories for reporting relationships with industry:

- Consultant
- Speakers' Bureau

- Ownership/Partnership/Principal
- Personal Research
- Salary
- Institutional or Organizational
- Expert Witness

The full definitions for each of these categories are attached herein. Given that organizations or institutions may be the recipient of the financial gain, for the purposes of writing committees, the ACC considers the relationships of an individual's employing institution or organization to be relevant if the individual has decision-making authority. For example, if an individual's institution is recruiting patients for a trial and the individual is a sub-investigator or co-investigator and/or if the individual is a Chief of Cardiology and therefore has fiscal authority and/or direct decision-making responsibility (such as support for research grants, fellowships, grand rounds, and institutional supplies), those relationships must be reported to the ACC.

Educational programming

It is important to note that while the ACCF has adopted its own detailed policy governing the development of clinical documents and writing committees, the ACCF is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education (CME) credits. As such, the ACCF is bound by the requirements set by the ACCME regarding relationships with industry as they relate to educational programming. These policies are detailed in the [*ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*](#). Specifically, any industry funding for educational programming is paid to the accredited CME provider, who is required to "make all decisions regarding the disposition and disbursement of commercial support." In addition to the ACCME Standards for Commercial Support guidance, ACCF assesses any real or perceived conflicts of interest with its faculty, planners, managers and staff who are in a position to control the content of CME-credited activities. All potential conflicts that may be identified through a required disclosure mechanism, are thoroughly vetted through a process that includes course directors and appropriate peer review by education committee members and/or external reviewers, for fair balance, scientific objectivity and validity, and patient care and safety recommendations. Additionally, "A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as a condition of contributing funds or service." These requirements and others are imposed to ensure that CME-certified activities are independent of any direct or indirect influence from commercial grantors. The ACC encourages CMS to refer to the ACCME Standards as the Agency develops the regulations pertaining to Sec. 6002 of the ACA. This will provide consistency and continuity across the physician community. In turn, it will help physicians to understand what information it is that needs to be disclosed and where potential conflicts of interest might exist, as opposed to mere relationships with industry.

Public reporting of relationships with industry

While the ACC strongly supports transparency in physician and physician organization relationships with industry, the College believes that it is critical this information be placed into the proper context. The ACC believes that the mere existence of a relationship does not create a conflict of interest, and yet many have garnered publicity by arguing that this is the case. However, in so doing, they ignore the expertise of these individuals that often times cannot be found elsewhere. Especially in esoteric areas of science and medicine, the individuals engaged in

research funded by industry may be the foremost experts in that field. To prevent them from participating in discussions of the issue or the development of clinical documents could be detrimental to the scientific underpinnings of the discussion or the documents. The ACC agrees that a relationship exists in such a case and participation does need to be limited (ACC policy prohibits the individual from drafting or voting on the recommendation and/or corresponding text where the particular section relates to that product or a competing product); however, the individual's expertise is invaluable to the preceding discussion. Instead of removing the individual from participation entirely, disclosure of the relationship and its nature helps to inform the context in which the other participants place the information and opinions offered by the expert. Explaining this to the public is critical to their understanding of the disclosures and the effect that these relationships may have on the patient-physician relationship. The ACC urges CMS to work with physician organizations to develop materials explaining the relevance of appropriate physician relationships with industry.

Additionally, it is important to furnish the public with information pertaining to the relevance of relationships. While there has been an increase in sub-specialization within medicine, this does not necessarily translate into narrow fields of research for clinical investigators and trialists. A physician may be conducting research funded by a company on one product and prescribe a product treating an unrelated disease or condition to a patient. Thus, it is important that these distinctions are explained to consumers who may have little or no understanding of these relationships. Medical specialty societies such as ACC have grappled with these discussions and the ramifications of physician relationships with industry for a number of years now. Because of this, they have the best understanding of the intricacies and are best able to put these relationships into the proper context.

Not only does the ACC support publicly disclosing physician relationships with industry, but the College believes it is critical that this information be made publicly available in a format understandable by the average consumer. As mentioned above, the relationships with industry of authors and peer reviewers of ACC's clinical documents are publicly disclosed upon publication of the document. They are presented in table format. Each table contains a column for each of the seven categories detailed above and the relevant information pertaining to each author in each. This simple presentation allows the reader to easily determine if relevant relationships exist. Additionally, the ACC categorizes the relationships as significant, modest or no financial relationship. Even situations where no financial relationship exists, but some other type does, are listed in the table. For instance, service on a relevant FDA panel would be listed, even though no financial relationship exists with industry as a result of that service. The ACC believes that this relationship is relevant because of the influence the individual may have on a particular product.

Today's consumers are technologically savvy and experienced at manipulating large volumes of data. CMS should present the data in a way that allows consumers to do just that: search and reconfigure the data to locate the information they seek. Thus, **the ACC supports the development of a database that provides consumers the opportunity to search for their particular physician or physician's employer, as well as particular manufacturer and the various categories of payments.** CMS should also include the relevant relationship dates in the database. This will help consumers determine the relevance of the particular relationship on any given date. Additionally, links to the various definitions and educational material should be easily accessible from the database. The information should be updated regularly and the date of each disclosure prominent.

Submission and correction of information

Under the ACC's policies on relationships with industry, the College collects a great deal of information pertaining to members relationships. As such, we have experience in this area. The ACC has created an electronic form that provides information about the policies and definitions along the way to enable physicians to ensure that they are submitting the correct information. This form is available at <https://services.acc.org/Disclosure/login.aspx?ReturnUrl=%2fDisclosure%2fDefault.aspx>. The information entered into this database is then populated on a standard form and furnished as needed.

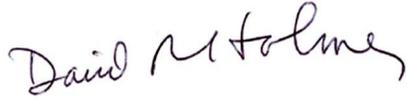
There is, however, a key difference between the ACC's data collection requirements and those of CMS. The ACA does require that the information pertaining to relationships be reported by industry, rather than physicians. Because industry will be doing the actual reporting and submitting vast amounts of data at one time, the ACC would encourage CMS to allow for batch submission of this information, making it easier and less burdensome to transmit this information.

In addition to requiring the information be reported to CMS by industry, the ACA also requires that physicians, and not just industry, be given the opportunity to correct the information before it is made available to the public. The ACC encourages CMS to provide physicians with access to the information at least 60 days before it is made available to the public. The early access should be electronic and easy to use. Access to each individual's report should be granted using the physician's NPI and password. The information should be updated and made available for review on a regular basis with a pre-determined schedule to enable physicians to ensure accuracy. Not only should physicians have access to these early reports, but their practice administrative staff should be able to assist with the review of this information for accuracy and correction. Physician practice staff is generally intimately familiar with the relationships their physicians have with industry and the related financial relationships. These individuals are critical resources for physicians, ensuring that physicians are able to focus on patient care, rather than the day-to-day running of the practice.

It is critical that the information pertaining to physician relationships with industry reported to CMS be accurate, given the wide variety of uses for this information. After all, it will not only be the average consumer relying on this information. Researchers, guidelines developers, hosts for continuing education programs and others may use this information to make determinations on a variety of issues. Once information becomes public, it becomes challenging to correct misinformation and misperceptions. Given the potential harm that may result from the publication of incorrect information in this database, the ACC urges CMS to create a formal appeals process for correcting information reported in the database. This process should allow for the electronic filing of appeals and submission of supporting documentation. In the event of an appeal by a physician, CMS should delay in releasing the information until a formal determination can be made regarding the accuracy of the information.

The ACC appreciates the opportunity to provide CMS with feedback pertaining to the future regulations implementing Sec. 6002 of the ACA and would welcome the opportunity to discuss this feedback further. We look forward to working with CMS on this and future issues. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,



David R. Holmes, Jr., M.D., F.A.C.C.
President

Cc: Jack Lewin, M.D. – CEO, ACC