Statement for the Record

of the

American Medical Association

to the

Special Committee on Aging
United States Senate

RE: Roundtable on the Physician Payments Sunshine Act September 12, 2012

Presented by: Jeremy A. Lazarus, MD

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The American Medical Association (AMA) appreciates the opportunity to provide its views and to discuss with other stakeholders the thematic issues surrounding the implementation of the Physician Payment Sunshine Act (Sunshine Act) provisions of the Patient Protection and Affordable Care Act (ACA). We commend Chairman Kohl, Ranking Member Corker, Senator Grassley, and members of the Committee for convening this Roundtable to ensure impacted stakeholders and the agency charged with the implementation of the Sunshine Act, the Centers for Medicare & Medicaid Services (CMS), have the opportunity to fully discuss key areas of concern related to the implementation of the Sunshine Act. Below we have outlined areas of concern in the proposed rule as well as recommended modifications to ensure that the final rule comports with the statute as well as congressional intent. We look forward to working with CMS and other stakeholders in order to streamline the regulatory burden, ensure accurate and fair reporting, and allow adequate time to conduct outreach and education on the final rule to physicians.

Background

In brief, the AMA supports efforts to increase transparency. To that end, the AMA worked with Congress on the Sunshine Act and we supported the final version of the legislation after important modifications were made to minimize the regulatory and paperwork burden on physicians, to safeguard physician due process rights, and ultimately to provide an accurate and meaningful picture of physician-industry interactions.

The Sunshine Act modifications ultimately reflected a considered decision to avoid a "boil the ocean" approach to transparency reporting that would create more questions than answers, increase disputes, and impose a substantial administrative burden.

It is important to note, however, that while not all transfers are subject to reporting under the Sunshine Act, the AMA provides ethical guidance that covers all transfers—including indirect ones.

The AMA was founded with the purpose of establishing ethical standards for all physicians. First developed in 1847, the AMA *Code of Medical Ethics* (AMA *Code*) undergoes continual revision, guided by the AMA Council on Ethical and Judicial Affairs (CEJA). The opinions contained in the AMA *Code* establish core standards of conduct for the medical profession that address relevant issues in medical practice. The AMA *Code* constitutes the most comprehensive source of ethical guidance for physicians and serves as the primary compendium of medical professional ethical statements in the United States.

The AMA believes that physician relationships with industry should be transparent, meaningfully independent, and focused on benefits to patients. The AMA supports providing information that physicians and the public need to make informed, critical judgments about physician-industry relationships. In addition, the AMA supports practices that ensure that a physician's clinical judgments are objective and evidence based and that a physician's interactions with industry are transparent.

In previous testimony before the Committee in 2007, we outlined the AMA's clear ethical guidelines that govern physician interaction with industry. In brief, based on the AMA *Principles of Medical Ethics* (*Principles*) and the AMA *Code*, physicians' responsibility to their patients is paramount. This means that physicians must not place their own financial interests above the welfare of their patients and their medical recommendations must not be inappropriately influenced by financial considerations. We are including an overview of relevant AMA policy on the topic. In 2011, the AMA's House of Delegates, a deliberative body comprised of representatives from state medical associations and medical specialty societies, adopted ethics policy on Financial Relationships with Industry in Continuing Medical Education proposed by CEJA. CEJA's report on this matter identified the core ethical principles of transparency, independence, and accountability. The report's recommendations provide practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust. A copy of the report is attached.

The AMA, along with other stakeholders in the medical profession, continues to take appropriate measures to reduce the actual or perceived conflicts-of-interest that might arise from industry transfers of value to physicians, in order to safeguard the delivery of quality health care based on the best available science, thus earning and maintaining the trust of patients.

The focus of the roundtable is on the implementation of the Sunshine Act; however, the Sunshine Act does not set ethical standards for the medical profession nor does it codify fraud and abuse or program integrity laws. The AMA is concerned to the extent that the Sunshine Act requirements are characterized as establishing ethical standards governing conflict of interests, for example, and/or designed to identify fraud and abuse. **While the transparency reporting undoubtedly could provide information in some cases on transfers that violate professional ethical codes or even federal and state fraud and abuse laws, the purpose of the Sunshine Act registry is not to supplant the role of the profession in regulating ethical conduct or to create new fraud and abuse laws.**

There is a danger in conflating these issues since it could lead to a public perception that most, if not all, transparency reports are prima facie evidence of unethical or illegal behavior. This perception has the potential to chill beneficial collaboration and information exchange between physicians and industry. For example, we would not want a stigma associated with industry-physician collaborations that facilitate the clinical application of knowledge we are rapidly gleaning about the human genome. New technologies and discoveries such as molecular pathology diagnostics have the potential to revolutionize the practice of medicine as we know it. Physician decisions are heavily dependent on the quality of the scientific information available, provided to them, in part, by industry and federal regulators. There remains a need for interactions between physicians and industry to ensure the free flow of valid scientific information. When the information is accurate and complete, physicians have the necessary tools to make the right treatment decisions. If information is not properly provided by industry, or if physicians never receive such information, necessary and appropriate medical care can be jeopardized.

Areas of Concern with the Proposed Rule

The AMA submitted a sign-on comment letter to the Sunshine Act proposed rule along with 49 medical specialty societies and 43 state medical associations. The sign-on comment letter is attached. In addition, the AMA joined a sign-on letter submitted by national organizations involved in Continuing Medical Education (CME) in the United States, including Accreditation of CME Providers, granting of CME Credit for CME activities, and fulfillment of the responsibility of the Profession of Medicine to self-regulate in the arena of CME. The sign-on comment letter is also attached. The following five areas provide a high level summary of the AMA's concerns and recommended changes to the proposed rule.

CMS is Required to Publish Accurate Transparency Reports.

CMS has proposed a process that is unlikely to ensure accurate reporting or a reasonable opportunity to correct false, misleading, or inaccurate reports by severely limiting the ability of physicians to review and challenge incorrect reports. The proposed rule does not require manufacturers to provide physicians with the option of an ongoing opportunity to check reports nor does it indicate that the agency or some other independent third party will arbitrate disputes between physicians and manufacturers. In

addition, the agency proposes to severely restrict the ability of physicians to challenge reports with a compressed 45 day window once a year even though the statute provides that 45 days is the minimum amount of time allotted to challenge the reports before these reports are made public. **We oppose limiting a physician's ability to challenge the accuracy of reports to the "current" and prior reporting year within a compressed 45-day window each year.** There is no statutory support for this provision and it is inconsistent with the Congress' intent to ensure such reports are accurate. **The ACA provides that before a report is made public, physicians are to have 45 days to review and submit corrections, at a minimum. This does not apply to corrections after the reports are made public. Congress intended that disputes would not delay publication, but never provided that all disputes were to be compressed into a 45-day once a year period. The rule as proposed would deny physicians substantive and procedural due process rights.**

In light of the current state of technology, **industry has the capability to allow for real-time updates and modification of reports. Instead of compressing the challenge period into a short period of time that could require significant allocation of staff resources during this condensed period, it is reasonable to require manufacturers and CMS to allow modification and correction of reports on an ongoing basis as part of their normal workflow. In sum, the statute does not establish a maximum 45-day window in which to challenge the accuracy of transparency reports and we do not support CMS imposing such an arbitrary limitation on the due process rights of physicians.**

We strongly urge CMS to re-structure the process that the agency has outlined and require industry to provide physicians with ongoing access to reports and establish a neutral arbiter to resolve disputes. The proposed rule opens the door to the real possibility that a large number of physicians could become the victims of false, inaccurate, or misleading reporting and suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood.

CMS is Not Authorized by Statute to Expand Reporting to Indirect Transfers (Not Otherwise Specified in Statute)

Although the statute limits reporting to direct payments/transfers of value to physicians except in carefully specified circumstances, CMS has expanded the category of transfers subject to reporting to a broad category of indirect transfers. The current statute contains a number of differences from the original bills S. 2029, *"Physician Payments Sunshine Act of 2007"* and H.R. 5605, "*Physician Payments Sunshine Act of 2008.*" The original bills would have explicitly required that manufacturers report a payment or other transfers of value made "directly, indirectly, or through an agent, subsidiary, or other third party." This language was not included in the ACA version of the Sunshine Act. A new subsection was added once the original language was struck in order to capture when reporting on indirect payments and transfers would be required. These situations include those instances where manufacturers are transferring payment or value to a third party at

the request of the physician or designated on behalf of the physician. This closes an obvious potential loophole to avoid reporting. The purpose was not to create a back door by which a vast, complicated, and confusing number of transfers with questionable relevance would be added to the reporting requirement. The proposed regulation would impose a significant paperwork burden while obscuring significant interactions between industry and physicians.

Certified Continuing Medical Education (CME) is Excluded from Reporting by Statute

CMS has proposed reporting standards that will include indirect transfers that occur through certified CME even though the statutory language does not support such an interpretation. The AMA agrees that other educational activities including those that are characterized as CME (but which are not certified) could be subject to reporting as there could be direct transfers of value to individual physicians and industry could control and/or influence the content of the educational materials. **Certified CME is independent and manufacturers have no control or input into the content, the speakers, or the attendees. In light of the foregoing, certified CME is not covered by the Sunshine Act and CMS should make this clear.** The law includes a broad category of educational activities that are subject to reporting.

We urge CMS to exclude from reporting certified CME as this is a reasonable interpretation of the statute as well as the legislative history. As discussed above, earlier versions of the Sunshine Act, S. 2029 and H.R. 5605, required reporting on a far larger universe of transfers/payments including all indirect transfers/payments and for "participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar." The statute does not include a reference to CME and limits the universe of indirect transfers/payments that are reportable. The statutory language is clear and certified CME does not involve transfers that trigger reporting.

CMS is Required to Ensure Accurate Attribution and Is Not Allowed to Use Estimates

CMS has proposed attributing a transfer of value/payment to a physician even when a physician did not receive value directly (and even in some instances indirectly) based on employment, affiliation, or association with an entity or person that did receive a direct transfer. The ACA provides for actual transfers of value to a covered physician, not estimates. CMS' proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with the changes to the legislation as reflected in the final statute. **Congress did not direct CMS to develop reports that provide an approximation of the value transferred by manufacturers to physicians nor did Congress intend that transfers of value made by manufacturers to an organization or entity that employ physicians would be attributed to a physician without regard to whether they received the transfer, requested the transfer, or it**

was designated on their behalf. CMS has proposed that where an organization receives a payment or transfer of value, it will be apportioned among the physicians in the organization or institution. This, of course, could result in grossly misleading reporting. Physicians employed by a large organization or institution could have funding and transfers imputed to their report that they cannot reject, did not receive directly (or even indirectly), and for which they have no knowledge so they are unable to effectively challenge it. We also strongly oppose CMS' proposal to attribute to a physician transfers of value or payment that are made to other individuals where the physician personally did not request the transfer, it was not designated on their behalf, and they did not receive it. **CMS is required to direct manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on their behalf.**

The Proposed Rule Imposes a Significant Paperwork Burden on Physicians

CMS has underestimated the paperwork requirements of ensuring that industry accurately reports transfers. The process as outlined in the proposed regulation imposes ongoing and time intensive paperwork obligations on physicians if the proposed rule remains unchanged when CMS issues a final regulation. CMS has provided a very limited estimate and analysis of the burden associated with the information collection requirements for physicians. While we strongly believe this estimate would be alleviated by requiring industry to provide ongoing physician access to reports, the current proposed rule would impose a paperwork burden on <u>all</u> physicians who will need to maintain ongoing records of every activity they engage in so they are able to ensure accurate reporting. This is not an overstatement given the large universe of indirect reporting requirements contained in the proposed rule. We believe that CMS has greatly underestimated the amount of time physicians would need to review cumulative reports and to challenge them before they were posted given the resources physicians would likely need to dispute inaccurate, false, and misleading reports.

The AMA appreciates the opportunity to provide our views to the Special Committee on Aging and we look forward to working with CMS and other stakeholders to promote the goal of transparency in a meaningful manner.

AMA Policy Overview

AMA believes that relationships with industry should be transparent, meaningfully independent, and focused on benefits to patients, including

- providing the information physicians and the public need to make informed, critical judgments about physician-industry relationships
- ensuring that physician's clinical judgments are objective and evidence based
- monitoring interactions with industry to help ensure transparency and independence

AMA has supported efforts to promote public transparency in the interactions between industry and physicians.

The AMA continues to strongly support certified CME which ensures that industry does not influence the content of continuing education for physicians as well supports access to independent information about drugs and devices (so called "independent physician education or academic detailing).

The AMA has recently adopted policy specifically concerning the Affordable Care Act Physician Payment Sunshine Act provisions:

> That our AMA (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by CMS; and, (2) recommend to CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database. Substitute Resolution 223, Physician Payment Sunshine, A-12.

AMA policies cover issues in physician-industry relationship across clinical practice, medical research, and physician education

Clinical practice

- E-5.075 and D-315.988, address access to patients' medical records and physician prescribing data[1]
- E-8.047, provides guidance for physicians when industry representatives are present during clinical care, e.g., technical assistance in the use of devices[2]
- E-8.061, requires physicians to decline inappropriate gifts from industry, such as payments to defray costs of participating in continuing medical education or token consulting or advisory arrangements[3]
- H-410.953, sets out ethical principles for the design of clinical practice guidelines[4]

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[1] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-5.075.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-315.988.HTM

[2] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.047.HTM

[3] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.061.HTM

Medical research

- E-8.031 and E-8.0315, provide guidance for managing conflicts of interest in biomedical research, such as disclosing financial relationships to prospective subjects and avoiding compromising financial interests with the sponsor concurrent with involvement in research (e.g., purchase of stock)[5]

- H-460.914, calls for transparent, responsible reporting of clinical trials[6]

- D-460.979, urges AMA to collaborate with industry to develop guidelines for open scientific communication[7]

Physician education

- E-9.0115 and E-9.011, provide guidance re financial relationships with industry in the context of continuing medical education[8]

- D-295.955, addresses educating medical students about industry[9]

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[4] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-410.953.HTM

[5] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.031.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-8.0315.HTM

[6] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-460.914.HTM

[7] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-460.979.HTM

[8] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-9.0115.HTM; https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fE-9.011.HTM

[9] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-295.955.HTM

AMA POLICY

The HOD adopted policy specifically concerning the Affordable Care Act Physician Payment Sunshine Act provisions:

> That our AMA (1) continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by CMS; and, (2) recommend to CMS that a physician comment section be included on the "Physician Payments Sunshine Act" public database. Substitute Resolution 223, Physician Payment Sunshine, A-12.

Clinical practice

E-5.075 and D-315.988, address access to patients' medical records and physician prescribing data

E-5.075 Confidentiality: Disclosure of Records to Data Collection Companies
Data collection from computerized or other patient records for marketing purposes raises serious ethical concerns. In some cases, firms have sought to amass information on physicians' prescribing practices on behalf of pharmaceutical houses for marketing purposes. Often, physicians are offered incentives such as computer hardware and software packages in return for agreeing to such an arrangement. They may be told that data-collecting software does not capture patients' names. These arrangements may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must give their permission after being fully informed about the purpose of such disclosures. If permission is not obtained, physicians violate patient confidentiality by sharing specific and intimate information from patients' records with commercial interests. Arrangements of this kind may also violate Opinion 8.061, "Gifts to Physicians From Industry." Finally, these arrangements may harm the integrity of the patient-physician relationship. The trust that is fundamental to this relationship is based on the principle that the physicians are the agents first and foremost of their patients. (I, II, IV) Issued June 1994; Updated June 1998.

D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry
Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOs and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data. (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05; Reaffirmation A-09; Reaffirmed: Res. 233, A-11)

E-8.047, provides guidance for physicians when industry representatives are present during clinical care, e.g., technical assistance in the use of devices

E-8.047 Industry Representatives in Clinical Settings
Manufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians.
Because of their obligation to protect their patients, physicians must strive to prevent industry representatives from breaching patient privacy and confidentiality, and seek to verify that they are properly credentialed and do not exceed the bounds of their training. Physicians may fulfill these obligations by satisfying themselves that the facility has suitable mechanisms in place to accomplish these functions.
Physicians or their designees must disclose to patients the anticipated presence and roles of industry representatives during clinical encounters, and obtain patients' approval. This requires neither disclosure of the representative's specific identity nor a formal informed consent process. (I, IV, V) Issued November 2007 based on the report "Industry Representatives in Clinical Settings," adopted June 2007.

E-8.061, requires physicians to decline inappropriate gifts from industry, such as payments to defray costs of participating in continuing medical education or token consulting or advisory arrangement

E-8.061 Gifts to Physicians from Industry
Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines: (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members. (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads). (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made. (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference. (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be

accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses. (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations. (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II)
Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501); Updated June 1996 and June 1998.

Clarification of Opinion 8.061
Scope Opinion 8.061, "Gifts to Physicians from Industry," is intended to provide ethical guidance to physicians. Other parties involved in the health care sector, including the pharmaceutical, devices, and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.

The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

General Questions (a) Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?

"Industry" includes all "proprietary health-related entities that might create a conflict of interest."

Guideline 1 Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or for use by family members.

(a) May physicians accept gram stain test kits, stethoscopes, or other diagnostic equipment?

Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.

(b) May companies invite physicians to a dinner with a speaker and donate $100 to a charity or medical school on behalf of the physician?

There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician-and one that the physician might have ordinarily felt obligated to make a contribution to-receives financial support as a result of the physician's decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician's input, there would seem to be little problem with the arrangement.

(c) May contributions to a professional society's general fund be accepted from industry?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(d) When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?

First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of $100 are permissible. When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker other than a sales representative of the company. Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

(e) May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

(f) May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of education options?

This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

(g) May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical textbooks are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, ie, for the selection by the physician from an exclusively medical textbook catalogue, would not seem to be materially different. The issue is whether the gift certificate

gives the recipient such control as to make the certificate similar to cash. As with charitable donations, preselection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

(h) May physicians accept drug samples or other free pharmaceuticals for personal use or use by family members?

The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance, and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion 8.19, "Self-Treatment or Treatment of Immediate Family Members." It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.

(i) May companies invite physicians to a dinner with a speaker and offer them a large number of gifts from which to choose one?

In general, the greater the freedom of choice given to the physician, the more the offer seems like cash. A large number of gifts presented to physicians who attend a dinner would therefore be inappropriate.

There is no precise way of deciding an appropriate upper limit on the amount of choice that is acceptable. However, it is important that a specific limit be chosen to ensure clarity in the guidelines. A limit of eight has been chosen because it permits flexibility but prevents undue freedom of choice. Each of the choices must have a value to the physicians of no more than $100.

(j) May physicians charge for their time with industry representatives or otherwise receive material compensation for participation in a detail visit?
Guideline 1 states that gifts in the form of cash payments should not be accepted. Also, Guideline 6 makes clear that, in the context of the industry-physician relationship, only physicians who provide genuine services may receive reasonable compensation. When considering the time a physician spends with an industry representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an industry representative.

Guideline 2 Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

(a) May physicians, individually or through their practice group, accept electronic equipment, such as hand held devices or computers, intended to facilitate their ability to receive detail information electronically?
Although Guideline 2 recognizes that gifts related to a physician' s practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.

Guideline 3 The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and

educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4 Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(a) Are conference subsidies from the educational division of a company covered by the guidelines?

Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division, or some other section of the company.

(b) May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?
Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 5 Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(a) If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria?
This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment, and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In

cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

(b) If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?
If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

(c) May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

(d) If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the National Institute of Health (NIH) conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

(e) How can a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

(f) May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

(g) Do the restrictions on travel, lodging, and meals apply to educational programs run by medical schools, professional societies, or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt

that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest.")

(h) May company funds be used for travel expenses and honoraria for bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."
Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

(i) May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

(j) When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(k) May continuing medical education conferences be held in the Bahamas, Europe, or South America?

There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

(l) May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?

In general, no. If a physician is presenting as an independent expert at a CME event, both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 5d) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.

(m) What kinds of social events during conferences and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a

substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, eg, inexpensive boat rides, barbecues, entertainment that draws on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

(n) May a company rent an expensive entertainment complex for a evening during a medical conference and invite the physicians attending the conference?

No. The guidelines permit only modest hospitality.

(o) If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

No. Mere interactive exchange would not constitute genuine consulting services.

(p) If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay for the costs of the meals for spouses?

If a meal falls within the guidelines, then the physician's spouse may be included.

(q) May companies donate funds to sponsor a professional society's charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

(r) If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

Guideline 6 Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

(a) When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?

Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

(b) What is meant by "carefully selected educational conferences?"

The intent of Guideline 6 is to ensure that financial hardship does not prevent students, residents, and fellows from attending major educational conferences. For example, we did not want to deny cardiology fellows the opportunity to attend the annual scientific meeting of the American College of Cardiology or orthopedic surgery residents the opportunity to attend the annual scientific meeting of the American Academy of Orthopedic Surgeons. However, it was not the intent of the guideline to permit reimbursement of travel expenses in other circumstances, such as when conferences or symposia are designed specifically for students, residents, or fellows. Funds are limited to travel and lodging expenses for attendance at major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Guideline 7 No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

(a) May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

(b) May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?

No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

(c) How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

Issued 1992. Updated December 2000, June 2002, and June 2004 (Food and Drug Law Journal, 2001;56(1):27-40).

H-410.953, sets out ethical principles for the design of clinical practice guidelines

H-410.953 Ethical Considerations in the Development of Medical Practice Guidelines
Medical practice guidelines help inform physician judgment and decision making by physicians and patients. Practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically

credible product of development processes that are rigorous, independent, transparent, and accountable.
To that end, the development or updating of medical practice guidelines should meet the following expectations:
1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.
6. Guidelines are subject to rigorous, independent peer review.
7. Clear statements of methodology, conflict of interest policy and procedures, and disclosures of panel members' conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public.
8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations. (BOT Rep. 2, A-11)

Medical research

E-8.031 and E-8.0315, provide guidance for managing conflicts of interest in biomedical research, such as disclosing financial relationships to prospective subjects and avoiding compromising financial interests with the sponsor concurrent with involvement in research (e.g., purchase of stock)

E-8.031 Conflicts of Interest: Biomedical Research

Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity. All medical centers should develop specific guidelines for their clinical staff on conflicts of interest. These guidelines should include the following rules: (1) once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company's stock until the involvement ends and the results of the research are published or otherwise disseminated to the public; (2) any remuneration received by the researcher from the company whose product is being studied must

be commensurate with the efforts of the researcher on behalf of the company; and (3) clinical investigators should disclose any material ties to companies whose products they are investigating, including financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties. The disclosures should be made in writing to the medical center where the research is conducted, organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. Other types of publications, such as a letters to the editor, should also include an explanatory statement that discloses any potential conflict of interest. In addition, medical centers should form review committees to examine disclosures by clinical staff about financial associations with commercial corporations. (II, IV) Issued March 1992 based on the report "Conflicts of Interest in Biomedical Research," adopted December 1989 (JAMA. 1990; 263: 2790-2793); Updated June 1999 based on the report "Conflicts of Interest: Biomedical Research," adopted December 1998.

E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials

As the biotechnology and pharmaceutical industries continue to expand research activities and funding of clinical trials, and as increasing numbers of physicians both within and outside academic health centers become involved in partnerships with industry to perform these activities, greater safeguards against conflicts of interest are needed to ensure the integrity of the research and to protect the welfare of human subjects. Physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from incentives to conduct trials and to recruit subjects. In particular, physicians involved in clinical research should heed the following guidelines: (1) Physicians should agree to participate as investigators in clinical trials only when it relates to their scope of practice and area of medical expertise. They should have adequate training in the conduct of research and should participate only in protocols which they are satisfied are scientifically sound. (2) Physicians should be familiar with the ethics of research and should agree to participate in trials only if they are satisfied that an Institutional Review Board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations. (3) When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator. This is best achieved when someone other than the treating physician obtains the participant's informed consent to participate in the trial. This individual should be protected from the pressures of financial incentives, as described in the following section. (4) Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, "Fee Splitting: Referral to Health Care Facilities," it is unethical for physicians to accept payment solely for referring patients to research studies. (5) Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research. Also, a physician should not bill a third party payer when he or she has received funds from a sponsor to cover the additional expenses related to conducting the trial. (6) The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in any written informed consent. (7) When entering into a contract to perform research, physicians should ensure themselves that the presentation or

publication of results will not be unduly delayed or otherwise obstructed by the sponsoring company. (II, V) Issued June 2001 based on the report "Managing Conflicts of Interest in the Conduct of Clinical Trials," adopted December 2000 (JAMA. 2002; 287: 78-84).

H-460.914, calls for transparent, responsible reporting of clinical trials[10]

H-460.914 Influence of Funding Source on Outcome, Validity, and Reliability of Pharmaceutical Research
Our AMA: (1) policy is that all medical journal editors and authors should adhere to the revised CONSORT (Consolidated Standards for Reporting of Trials Group) Statement and Uniform Requirements for Manuscripts Submitted to Biomedical Journals; (2) recommends that (a) the Department of Health and Human Services establish a comprehensive registry for all clinical trials conducted in the United States; (b) every clinical trial should have a unique identifier; and (c) all results from registered clinical trials be made publicly available through either publication or an electronic data-repository; and (3) urges that Institutional Review Boards consider registration of clinical trials to an existing registry as condition of approval. (CSA Rep. 10, A-04)

D-460.979, urges AMA to collaborate with industry to develop guidelines for open scientific communication

Physicians and Clinical Trials
Our AMA will (1) work with the Pharmaceutical Research and Manufacturers of America, the American Academy of Pharmaceutical Physicians, and all other appropriate organizations to develop guidelines that would eliminate the use of restrictive covenants or clauses that interfere with scientific communication in agreements between pharmaceutical companies or manufacturers of medical instruments, equipment and devices, and physician researchers; and (2) take all appropriate action to protect the rights of physician researchers to present, publish and disseminate data from clinical trials. (Res. 610, I-04)

Physician education

E-9.0115 and E-9.011, provide guidance re financial relationships with industry in the context of continuing medical education

E-9.0115 Financial Relationships with Industry in Continuing Medical Education
In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of

[10] https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-460.914.HTM

professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities. Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.
(b) provide the information physician-learners need to make critical judgments about an educational activity, including:
(i) the source(s) and nature of commercial support for the activity; and/or
(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
(iii) what steps have been taken to mitigate the potential influence of financial relationships.
(c) protect the independence of educational activities by:
(i) ensuring independent, prospective assessment of educational needs and priorities;
(ii) adhering to a transparent process for prospectively determining when industry support is needed;
(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;
(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and
(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review. (I, V) Issued November 2011 based on the report "Financial Relationships with Industry in Continuing Medical Education," adopted June 2011.

E-9.011 Continuing Medical Education

Physicians should strive to further their medical education throughout their careers, for only by participating in continuing medical education (CME) can they continue to serve patients to the best of their abilities and live up to professional standards of excellence. Fulfillment of mandatory state CME requirements does not necessarily fulfill the physician's ethical obligation to maintain his or her medical expertise.

Attendees. Guidelines for physicians attending a CME conference or activity are as follows: (1) The physician choosing among CME activities should assess their educational value and select

only those activities which are of high quality and appropriate for the physician's educational needs. When selecting formal CME activities, the physician should, at a minimum, choose only those activities that (a) are offered by sponsors accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), or a state medical society; (b) contain information on subjects relevant to the physician's needs; (c) are responsibly conducted by qualified faculty; (d) conform to Opinion 8.061, "Gifts to Physicians from Industry." (2) The educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference. (3) Physicians should claim credit commensurate with only the actual time spent attending a CME activity or in studying a CME enduring material. (4) Attending promotional activities put on by industry or their designees is not unethical as long as the conference conforms to Opinion 8.061, "Gifts to Physicians from Industry," and is clearly identified as promotional to all participants. Faculty. Guidelines for physicians serving as presenters, moderators, or other faculty at a CME conference are as follows: (1) Physicians serving as presenters, moderators, or other faculty at a CME conference should ensure that (a) research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner; (b) the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry. Faculty may, however, use scientific data generated from industry-sponsored research, and they may also accept technical assistance from industry in preparing slides or other presentation materials, as long as this assistance is of only nominal monetary value and the company has no input in the actual content of the material. (2) When invited to present at non-CME activities that are primarily promotional, faculty should avoid participation unless the activity is clearly identified as promotional in its program announcements and other advertising. (3) All conflicts of interest or biases, such as a financial connection to a particular commercial firm or product, should be disclosed by faculty members to the activity's sponsor and to the audience. Faculty may accept reasonable honoraria and reimbursement for expenses in accordance with Opinion 8.061, "Gifts to Physicians from Industry."

Sponsors. Guidelines for physicians involved in the sponsorship of CME activities are as follows: (1) Physicians involved in the sponsorship of CME activities should ensure that (a) the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand; (b) representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations. Funding from industry or others may be accepted in accordance with Opinion 8.061, "Gifts to Physicians from Industry." (2) Sponsors should not promote CME activities in a way that encourages attendees to violate the guidelines of the Council on Ethical and Judicial Affairs, including Opinion 8.061, "Gifts to Physicians from Industry," or the principles established for the AMA's Physician Recognition Award. CME activities should be developed and promoted consistent with guideline 2 for Attendees. (3) Any non-CME activity that is primarily promotional must be identified as such to faculty and participants, both in its advertising and at the conference itself. (4) The entity presenting the program should not profit unfairly or charge a fee which is excessive for the content and length of the program. (5) The program, content, duration, and ancillary activities should be consistent with the ideals of the AMA CME program. (I, V) Issued December 1993; Updated June 1996.

D-295.955, addresses educating medical students about industry

D-295.955 Educating Medical Students about the Pharmaceutical Industry

Our AMA will strongly encourage medical schools to include: (1) unbiased curricula concerning the impact of direct-to-consumer marketing practices employed by the pharmaceutical industry as they relate to the physician-patient relationship; and (2) unbiased information in their curricula concerning the pharmaceutical industry regarding (a) the cost of research and development for new medications, (b) the cost of promoting and advertising new medications, (c) the proportion of (a) and (b) in comparison to their overall expenditures, and (d) the basic principles in the decision making process involved in prescribing medications, specifically using evidence based medicine to compare outcomes and cost effectiveness of generic versus proprietary medications of the same class. (Res. 303, A-05)

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-11)
Financial Relationships with Industry in Continuing Medical Education
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public. The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

This report examines financial relationships between medicine and industry in the specific context of continuing medical education. It summarizes the ethical foundations of medicine's obligation to ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. The report analyzes the ethical challenges that can be posed when physicians who organize, teach in, or serve other roles in continuing medical education have financial relationships with companies that have a direct interest in physicians' recommendations and illustrates strategies for mitigating the potential of such financial relationships to influence professional education in undesired ways. It identifies core ethical principles of transparency, independence, and accountability and provides practical ethical guidance to maintain the independence and integrity of continuing professional education and promote public trust.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-11

Subject: Financial Relationships with Industry in Continuing Medical Education

Presented by: John W. McMahon, Sr., MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Patricia L. Austin, MD, Chair)

Relationships between medicine and industry—such as pharmaceutical, biotechnology, and medical device companies—have driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public.[1,2] The interests and obligations of medicine and industry diverge in important ways, however. An increasingly urgent challenge for both partners is to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they each take clear, effective action to avoid relationships that could undermine public trust.

As relationships between medicine and industry have evolved, major national organizations, such as the Institute of Medicine (IOM)[3] and the Association of American Medical Colleges (AAMC)[4,5,6] have explored the challenges that these relationships can pose in research, clinical care, education, and beyond. Key stakeholders, including (among others) the Accreditation Council for Continuing Medical Education (ACCME),[7] the Council of Medical Specialty Societies (CMSS),[8] and the Pharmaceutical Research and Manufacturers Association (PhRMA)[9] have developed guidance to help their constituents sustain appropriate, productive, and professional interactions.

The American Medical Association was founded on the vision that as medical professionals, physicians should represent the highest standards of competence, integrity, and professionalism. This report carries that vision forward. It examines ethical aspects of medicine-industry relationships in continuing medical education (CME), explores ethical challenges that can be posed by financial relationships from the perspective of physicians, and provides guidance for members of the medical profession who attend or who organize, teach in, or serve other roles in CME.

The Council on Ethical and Judicial Affairs recognizes that pharmaceutical, biotechnology, and medical device companies are not the only entities with which financial relationships can raise concerns. CEJA likewise recognizes that CME is not the only domain of potential concern. However, narrowing our focus to CME allows us to explore the complex considerations at stake in a manageable context and to provide practical ethical guidance on issues that increasingly challenge physicians as professionals.

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

LIFELONG LEARNING & MEDICINE'S DUTY TO EDUCATE

> *Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*
>
> — Edmund Pellegrino[10]

The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[10,11,12] The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship. To sustain that commitment, medicine must ensure that physicians acquire and maintain the knowledge, skills, and values that are central to the healing profession. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate practitioners.[13,14]

The special moral character of the interaction between patient and physician arises from the need—illness or the prevention of illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients' lives. Patients entrust to physicians the care of their bodies and the protection of sensitive information revealed in confidence for the purpose of seeking healing. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine's status as a caring and competent profession. Thus medicine's ethical duty to educate cannot be delegated to others.

Individual physicians have an ethical obligation to dedicate themselves to "continue to study, apply, and advance scientific knowledge" and to "maintain a commitment to medical education."[15] As professionals, practicing physicians are expected to commit themselves to lifelong learning and to maintain their clinical knowledge and skills through CME and other professional development activities.[16] That commitment is reflected not only in ethical expectations and standards, but also in requirements for licensure and specialty certification, as well as hospital credentialing.

Physicians and the patients who rely on them must be confident that treatment recommendations and clinical decisions are well informed and reflect up-to-date knowledge and practice. CME activities that are pedagogically sound, scientifically grounded, and clinically relevant are essential to ensure that physicians can provide the high quality of care their patients deserve. To achieve these goals, medicine has an ethical obligation to ensure that the profession independently sets the agenda and defines the goals of physician education; controls what subject matter is taught; determines physicians' educational needs; and takes steps to ensure the independence of educational content and of those who teach it. The importance of doing so may extend well beyond continuing education—as one commentary noted, "[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career."[17]

CONTINUING MEDICAL EDUCATION

Continuing medical education today takes place in an environment that includes "promotional" activities, "certified CME," and noncertified CME. Promotional activities lie outside the scope of the present analysis and recommendations. As defined by the Food and Drug Administration (FDA), these are activities developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or

service. They are governed by the labeling and advertising provisions of the Food, Drug, and Cosmetic Act,[18,19] and may constitute protected commercial speech.

"Certified CME" refers to educational activities developed and implemented in compliance with the certification requirements of the American Medical Association Physician Recognition Award (PRA) CME Credit System or the accrediting policies of the American Academy of Family Physicians or American Osteopathic Association.[20] Certified CME meets the requirements for Category 1 credit under AMA's PRA program, including compliance with Accreditation Council for Continuing Medical Education (ACCME) standards and with relevant AMA ethics policy.[21]

Beyond these formal categories lie activities designed to inform and educate practicing physicians that are neither promotion nor certified CME. These other activities may or may not be commercially supported, may or may not voluntarily adhere to AMA policy or ACCME Standards for Commercial Support℠ (even if they are not formally certified or offered by formally accredited providers), and may or may not be recognized by licensing bodies or credentialing boards as fulfilling CME requirements.

Physician involvement is critical in CME. Individually and collectively, physicians play key roles in educating their peers, as teachers, content developers, organizers of CME, or in other capacities.

Financial Relationships with Industry in CME

In the context of continuing medical education, relationships with industry that may pose challenges for the independence and objectivity of physician education include not only direct industry support of CME activities, but also financial relationships between industry and individual physicians involved in CME as faculty, content developers, or in other capacities.

Industry support for CME has declined in recent years, but commercial funding still accounts for approximately 40 percent of overall CME-related revenue, ranging from less than one percent to just over 60 percent across accredited CME providers.[22] A growing number of accredited providers—20 percent as of July 2009—no longer accepts any commercial support at all.[23]

Industry support helps to meet the costs of CME activities in the face of uncertain funding from other sources[24] and may help make CME more accessible, especially for physicians in resource-poor communities.[25] Industry engagement and support can be especially helpful in ensuring affordable CME when educational activities need high cost, sophisticated, rapidly evolving technology or devices. Along with lower costs, industry support may encourage greater participation than would otherwise be the case by providing amenities. As yet there is no peer-reviewed evidence to support or to refute the effect of industry funding on accessibility of or participation in CME activities.[26]

However, there is growing concern within and outside medicine that industry funding for CME could have undesirable effects, including potentially biasing content toward funders' products and influencing the overall range of topics covered.[27,28,29,30] Importantly, where patients' health and public trust are concerned, the perception of bias, even if mistaken, can be as potentially damaging as the existence of actual bias.

Influence, Evidence & Ethics

Whether or how financial relationships influence CME activities or the overall CME curriculum is an important question. But answering this empirical question cannot resolve the core ethical

challenge, no matter what the evidence should prove to be. Physicians are entrusted with the interests of patients. Where trust is central, the *appearance* of influence or bias can be as damaging as actual influence. Empirical evidence alone is not enough to overcome public skepticism. Even evidence that undesired consequences have not occurred cannot be expected by itself to restore confidence when trust has been compromised.

The available data neither support nor disprove that financial relationships influence CME. Standards have been established to address concerns about possible influence in CME, such as the ACCME Standards for Commercial Support.[SM] The efficacy of those standards or other processes to address the potential for industry influence on content or the overall range of CME topics is difficult to determine. Several recent studies have suggested that the great majority of physicians attending CME activities do not perceive bias in the content of those activities, based on their responses to questions about bias on standard evaluations of CME activities.[31,32,33] As the authors themselves note, these studies are subject to limitations, such as the "insensitivity of simple 'yes/no' questions to assess learners' perceptions of bias."[33, cf. 32, cp., 34]

Other research indicates that individual physicians, like everyone else, are subject to influence, even if they are not aware of how industry support of a CME activity could affect their clinical decisions.[35,36,37,38,39] Further, a recent review of the relevant literature found that although there is clear evidence that CME influences physicians' prescribing practices, the question of what effect changes in prescribing have on actual patient outcomes has not specifically been studied.[39]

To maintain productive relationships with industry that benefit patients and to sustain the trust on which the patient-physician relationship and public confidence in the profession depend, medicine must take steps to safeguard the independence and integrity of physician education.

ENSURING THE INDEPENDENCE & INTEGRITY OF CME

CEJA recognizes that competing interests are a fact of life for everyone, including but not limited to physicians. For physicians, however, even very modest potential or perceived competing interests can put trust at risk. As individuals and as a profession, physicians have a responsibility to protect the quality of professional education and the reputation of medicine. While competing interests cannot be eliminated entirely, prudent judgments can be made about how to minimize potential influence and prevent or reduce undesired consequences.

Minimizing the Opportunity for Influence

Physicians should aspire to avoid the potential for influence or the chance that confidence in the integrity and independence of their professional education could be diminished. Avoiding entirely situations in which there is potential for influence has the virtue of ethical clarity and practical simplicity. CME that is free of financial relationships with companies that have direct interests in physicians' recommendations strongly underscores medicine's defining professional commitment to independence and fidelity to patients. Avoiding such relationships also has the practical advantage of eliminating the administrative and resource costs that must otherwise be devoted to mitigating influence,[40] costs that may be particularly challenging for smaller CME providers.[25]

In their roles as CME providers, content developers, and faculty, physicians should strive to avoid financial relationships with industry. The Institute of Medicine has called for development of a new system of funding CME that is free of industry influence.[3] Medicine should cultivate alternative sources of support, should design and conduct educational activities so as to reduce costs, and should insist that content developers and faculty members not have problematic ties with

industry to ensure independent, unbiased, high quality educational programming that best meets physicians' needs and is accessible and affordable for all practitioners.

Changing the terms of financial relationships likewise can help minimize the potential for influence. For example, physicians who have decision-making authority in organizations that provide CME could set an upper limit on how great a proportion of the organization's income derives from industry support to ensure that the organization does not become overly reliant on commercial funding. Asking physicians who teach in or develop content for a CME activity to refrain from accepting compensation (honoraria, consulting fees, etc.) for a defined period before and after the activity from a commercial supporter that has an interest in the educational subject matter could similarly promote independence. Decisions to require that physicians involved in CME as faculty members or in other roles change the terms of their relationships with industry must, of course, be made fairly and consistently across individual cases.

That said, it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely. In some situations financial relationships with industry can be ethically justifiable. When not accepting support from a commercial source or not permitting participation by individuals who have financial interests in the educational subject matter would significantly undermine medicine's capacity to ensure that physicians have access to appropriate, high-quality CME, it can be acceptable to permit such support or participation. In these situations, vigorous efforts must be made to mitigate the potential influence of financial relationships.

Mitigating Potential Influence

While there should be a presumption that physicians who organize, design, develop content, or teach in CME should not have concurrent financial ties to industry related to their CME responsibilities, it is important to recognize that not all relationships with industry are equally problematic. A relationship that is only indirectly related to an educational activity, modest in scope, or distant in time is not likely to adversely affect—or be perceived to affect—the activity in question. For example, having once conducted sponsored research or accepted a modest honorarium for speaking on behalf of a company would not necessarily create such clear potential for bias as to preclude an individual with the appropriate expertise from developing content or serving as a faculty member for a given CME activity.[41]

Financial relationships that are direct or substantial, however, have significant potential to undermine confidence in educational activities, even if they do not actually compromise those activities. Examples of a direct or substantial financial interest include ownership or equity interest in a company that has an interest in the educational subject matter of a CME activity or royalties or ongoing compensated relationships (e.g., consulting arrangements or service on scientific advisory bodies or speakers bureaus).[4] Relationships that involve fiduciary responsibilities on behalf of the funder (such as service on a corporate board of directors) or decision-making authority in financial matters can be similarly problematic.[42] In such situations, ethically strong practice requires that steps be taken to mitigate the possible influence of financial relationships on educational activities.

PRINCIPLES FOR SUSTAINING TRUST

The goal of mitigation is to promote–and enhance confidence in–the integrity of continuing professional education. Commitment to transparency, independence, and accountability enables physicians to achieve that goal, whatever role they may play in CME. Moreover, being transparent about financial relationships that have the potential to influence CME and forthcoming about what

steps have been taken to minimize possible influence supports physician-learners in exercising critical judgment individually as "consumers" of CME.

Transparency

As the ACCME Standards for Commercial Support℠ recognize, transparency—i.e., disclosing the existence of a financial relationship—is a necessary first step in mitigating the potential of financial relationships to create bias (or the appearance of bias),[7] but it is not sufficient and may even have perverse effects. Disclosure places the burden on learners themselves to determine how skeptical they should be about possible bias in an educational activity.[43] To the extent that disclosure fosters the impression that the presenter is particularly honest and trustworthy, it can encourage false confidence in the activity. To the extent that the presenter believes disclosing a financial relationship is adequate to mitigate its potential influence, he or she may be less circumspect in ensuring content is free of such influence.

While transparency is essential, disclosing financial relationships is necessary but not sufficient to mitigate the potential for influence in CME.

Independence

Taking concrete steps to ensure that CME is independent and objective is equally important. Creating a "firewall" between funders and decisions about educational goals, content, faculty, pedagogical methods and materials, and other substantive dimensions of CME activities can help protect the independence of professional education. Both ACCME and the Inspector General of the Department of Health and Human Services have recommended clearly separating decisions about funding from substantive decisions about CME activities,[7,19] and many organizations are developing models, such as "blind trusts," to do so.[e.g.,44,45] Support of individual CME activities by multiple, competing funders may also help diffuse the potential influence of any one funder. Carrying out educational needs assessments prior to seeking or accepting commercial support or identifying faculty can similarly enhance the independence of the planning process and resulting CME programming. Likewise, having prospective peer review of a presentation (review of slides or other forms of communication in advance of the presentation by an objective and independent expert who has the power to require changes prior to the public showing) can help ensure that the presentation is free of commercial bias.

Accountability

Physician-learners, patients, the public, and the medical community as a whole should be able to be confident that physicians who organize, design, develop content, or teach in CME will uphold principles of transparency and independence. The expectation that physicians involved in CME will hold themselves accountable to address the potential that financial relationships with industry have to influence professional education is a cornerstone of self-regulation. That responsibility can be greatly enhanced by the efforts of accrediting and certifying bodies, but it cannot be supplanted by them. In particular, physician leaders in CME should be able and willing to discuss how the principles of transparency and independence have been applied in the educational activities with which they are involved or over which they have decision-making authority.

Exceptional Cases

At times it may be impossible to avoid a financial interest or extraordinarily difficult or even impossible to mitigate its potential impact on an educational activity. For the most part, accepting

support from a company or permitting participation by an individual when there is an irreducible financial interest would not be ethically acceptable. However, in certain circumstances, it may be justifiable.

Such circumstances include instances when accessible, high-quality CME cannot reasonably be carried out without support from sources that have a direct financial interest in physicians' clinical recommendations, such as activities that require cadavers or high-cost, sophisticated equipment to train physicians in new procedures or the use of new technologies. Similarly, in the earliest stage of adoption of a new medical device, technique, or technology the only individuals truly qualified to train physicians in its use are often those who developed the innovation. These individuals may have the most substantial and direct interests at stake, whether through employment, royalties, equity interests or other direct financial interests in the adoption and dissemination of the new technology. Physicians who organize CME should be transparent about what considerations led them to decide to permit an individual with a problematic financial interest to participate in a particular CME activity to ensure that such decisions are justifiable and persuasive to the professional community at large.

Putting Principles into Practice – The Exercise of Judgment

Inevitably, putting principles of transparency, independence, and accountability into practice calls for the exercise of judgment. It requires knowledge of the particular circumstances and thoughtful deliberation. Yet this is no different from the kinds of judgments physicians routinely make in the context of caring for patients and applying other portions of the *Code of Medical Ethics* to their daily practice.

One approach is to reflect on what "consumers" of CME (which arguably includes patients and the broader professional community, as well as individual physician-learners) would want to know to exercise their skills of critical judgment; that is, to make well-considered judgments for themselves about the objectivity and quality of a CME activity, its faculty, and its educational content. Such factors might include not only the existence of a financial interest(s), but equally the source of that interest, the type of interest (such as honoraria, consulting fees, equity, stock options, royalties), and the magnitude of the interest, e.g., dollar amount to the nearest $1,000, as currently required by the North American Spine Society.[46]

Similarly, consumers of CME could reasonably want to know how the potential influence of a financial interest has been addressed to protect the independence of the activity; or consumers may want to know on what grounds an individual who has a direct, substantial, and unavoidable financial interest has been permitted to participate in a CME activity. In the latter case, for example, reasonable decision-making criteria might include that the dissemination of the device, technique or technology will be of significant benefit to patients and to the public and the professional community; that the individual is uniquely qualified as an expert in the relevant body of knowledge or skills; that the individual discloses the source, nature, and magnitude of the specific financial interest at stake; that there is demonstrated, compelling need for the specific CME activity; that all feasible steps are taken to mitigate influence; and that this expert's participation in dissemination will, eventually, enable those without such financial interests to take on the educational role. An individual might be considered "uniquely qualified" when he or she is the only expert (or one of a few) who has significant knowledge about or experience in treating a rare disease or was involved in the early development or testing of a new treatment, device, or technology. A "compelling need" for a particular educational activity may be present when a new therapy becomes available to treat a disease present in the local community for which the new treatment represents a substantial improvement.

The need to rely on "conflicted expertise" can be affected by local conditions—CME in small or rural communities, for example, may not always have ready access to experts who are free of problematic ties to industry. In any event, when a substantial body of peer-reviewed evidence has evolved in a given subject area, or when a cohort of individuals without direct, substantial interests has become experienced in using a new medication, device, or technology and is available to teach, using a "uniquely qualified" expert becomes less justifiable.

As the professional community gains experience, it is to be expected that consensus will coalesce around core interpretations. As Harvard Medical School notes in its conflict of interest policy:

> These classifications are not intended to serve as a rigid or comprehensive code of conduct or to define "black letter" rules with respect to conflict of interest. It is expected that the guidelines will be applied in accordance with the spirit of the mission of Harvard Medical School in education, research and patient care. By this process, it is expected that a common institutional experience in the application of these guidelines will gradually evolve.[47]

We expect that a similar shared understanding of how principles of transparency, independence, and accountability should apply to financial relationships with industry in continuing medical education will evolve for the medical profession.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

> In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.
>
> Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.
>
> CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.
>
> In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that that vigorous efforts will be made to maintain the independence and integrity of educational activities.
>
> Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with

all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

(a) be transparent about financial relationships that could potentially influence educational activities.

(b) provide the information physician-learners need to make critical judgments about an educational activity, including:

(i) the source(s) and nature of commercial support for the activity; and/or

(ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and

(iii) what steps have been taken to mitigate the potential influence of financial relationships.

(c) protect the independence of educational activities by:

(i) ensuring independent, prospective assessment of educational needs and priorities;

(ii) adhering to a transparent process for prospectively determining when industry support is needed;

(iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;

(iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;

(v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and

(vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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February 17, 2012

Marilyn B. Tavenner
Acting Administrator
Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Acting Administrator Tavenner:

On behalf of the undersigned organizations, we appreciate the opportunity to provide comments in response to the proposed regulation published on December 19, 2011, *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests (CMS-5060-P)* (Proposed Rule). We are pleased that the majority of the Proposed Rule comports with the Affordable Care Act (ACA) statutory provisions and congressional intent; however, we are concerned that Centers for Medicare and Medicaid Service (CMS) has exceeded its statutory authority with regard to at least one significant provision and misconstrued Congress' overall intent and statutory requirements in other areas. While we support the underlying goal of enhancing transparency, we believe the proposed rule, if implemented without significant modifications, will result in the publication of misleading information and impose costly and burdensome paperwork requirements on physicians while shedding very little light on actual physician-industry interactions.

Background

The ACA mandates that beginning in 2012, manufacturers of specified drugs, medical devices, and biologicals participating in U.S. federal health care programs must begin tracking any transfers of value or payments of $10 or more (as indexed by Consumer Price Index) to physicians and teaching hospitals.[1] These reports must be submitted to the Secretary of Health and Human Services on an annual basis. The majority of the information contained in the reports will be available on a public, searchable website in 2013. In

[1] The statute and regulations exclude transfers of value less than $10, unless the aggregate amount transferred to a physician by a manufacturer exceeds $100. As a result, manufacturers must track all transfers (as physicians must as well to in order to challenge any inaccurate manufacturer reporting) in order to report transfers of value that are less than $10, but cumulatively exceed $100.

addition, the ACA mandates that manufacturers and group purchasing organizations (GPOs) must report ownership interests held by physicians and their close family members.

Implementation

We strongly support the proposal to delay reporting until a final rule has been issued by CMS to ensure that physicians have adequate notice of final transparency report requirements and to provide CMS and manufacturers/GPOs an adequate opportunity to establish a reporting process that is consistent with the statute and congressional intent. The proposed rule has generated many questions and there remains a great deal of confusion. We urge CMS to provide physicians and physician organizations adequate time to provide training and information about the final program prior to implementation.

CMS Is Required to Publish Accurate Transparency Reports

CMS has stated in the proposed rule that it does not believe that the federal government should "be actively involved in arbitrating disputes between" physicians and manufacturers/GPOs. CMS proposes (1) that manufacturers/GPOs voluntarily employ a pre-submission review/dispute process for physicians; and (2) a post-CMS submission process where physicians are provided aggregate reports by the agency, but must contact manufacturers/GPOs to resolve disputes. CMS indicates that to the extent disputes remain outstanding between a physician and manufacturer/GPO, the disputed information would be flagged by CMS in the public Web site and the agency would consider using the physician's disputed aggregated total. **At a minimum, we support the use of the aggregated total specified by the physician.**

Despite the foregoing, we are concerned that the proposed process does not provide an adequate means for physicians to challenge reports. False, misleading, and inaccurate information could be publicly posted on a government website while denying physicians basic due process rights to challenge such information. **It was reasonably expected that an objective arbiter and a standard, expedited process would be utilized to address disagreements concerning the contents of transparency reports**. We urge CMS to establish an independent process for resolving disputes between manufacturers/GPO and physicians about reports. This dispute resolution process could be conducted by CMS itself or by a separate entity. For example, CMS relies on accredited Independent Review Organizations (IRO), Independent Review Entities (IRE), and Qualified Independent Contractors (QIC) as part of the Medicare appeals procedures. These independent entities are contracted by Medicare to re-determine previous, lower level, decisions.

Even where an independent arbiter is utilized, if a physician continues to dispute a manufacturer's report, CMS should flag the disputed information on the public Web site and provide a comment section that allows a physician to include a rebuttal in narrative form. In addition, CMS should utilize the aggregated total specified by the physician. The consequences of a dispute between a manufacturer/GPO and a physician do not have the same impact on the standing and reputation of each party. A few disputes between a manufacturer and a handful of physicians are unlikely to ruin a

manufacturer/GPO's standing or even subject the manufacturer/GPO to civil money penalties (CMP). In contrast, physicians may have their careers and professional reputations damaged as a result of one disputed report, and physicians may incur significant expenses to resolve a dispute with a manufacturer/GPO.

The proposed rule outlines a process where the government would purport to bear no responsibility for ensuring the accuracy of publicly posted transparency reports (and that it is merely a conduit of reporting provided by manufacturers). Yet, as outlined in the proposed rule, there is little to no consequence for a manufacturer/GPO when they inaccurately report on transfers of value or ownership, whereas the consequences to an individual physician are potentially significant. In fact, manufacturers/GPOs have a strong incentive to report rapidly (as opposed to accurately) because failure to timely submit a complete report will be evident to the agency (and subject the manufacturer/GPO to CMPs). While CMS proposes to include an evaluation of the nature and amount of information reported in error and the degree of diligence exercised in correcting information reported in error when imposing a CMP, we are concerned that what a manufacturer/GPO and CMS may consider minor (when weighed against the totality of information reported) could actually have significant consequences for individual physicians. Furthermore, while it is straight-forward to determine whether a manufacturer missed a deadline, a dispute about the accuracy is likely to generate fewer sanctions for the manufacturer/GPO.

CMS has proposed that manufacturers/GPOs establish a voluntary process that allows physicians to review their applicable manufacturer/GPOs report prior to submission to CMS. The technology exists that would impose a minimal burden on manufacturers/GPOs to provide real-time as well as regular cumulative reports to physicians in multiple formats (e.g., mail, electronically, or web-based). **In order to meet the agency's obligation to ensure accurate reporting, manufacturers/GPOs should be required to establish a standardized process and procedures that provide ongoing notifications to physicians of all transfers of value/ownership interests with an opportunity to correct reports as well as a cumulative report before the manufacturer/GPO transmits a report to CMS.** If CMS bears the sole responsibility for providing such reports to physicians within a 45-day period, there will be an increased probability that false and misleading reports will be made public. We also support the secure Web site portal proposed by CMS, but we believe it is insufficient to ensure that reports are accurate and do not contain erroneous information that could be damaging to individual physicians.

The ACA provides physicians with a statutory right to challenge all reports even after publication. In the proposed rule, however, we believe this right would be diluted. **We oppose limiting a physician's ability to challenge the accuracy of reports to the "current" and prior reporting year within a compressed 45-day window each year.** There is no statutory support for this provision and it is inconsistent with the Congress' intent to ensure such reports are accurate. The ACA provides that before a report is made public, physicians are to have 45 days to review and submit corrections, ***at a minimum.*** This does not apply to corrections after the reports are made public.

Congress intended that disputes would not delay publication, but never provided that all disputes were to be compressed into a 45-day once a year period. Given the prescriptive nature of the statutory scheme, this would deny physicians substantive and procedural due process rights. In light of the current state of technology, CMS and manufacturers/GPOs have the capability to allow for real-time updates and modification of reports. Instead of compressing the challenge period into a short period of time that could require significant allocation of staff resources during this condensed period, it is reasonable to require manufacturers and CMS to allow modification and correction of reports on an ongoing basis as part of their normal workflow. **In sum, the statute does not establish a maximum 45-day window in which to challenge the accuracy of transparency reports and we do not support CMS imposing such an arbitrary limitation on the due process rights of physicians.**

We strongly urge CMS to re-structure the process the agency has outlined. The proposed rule opens the door to the real possibility that a large number of physicians could become the victims of false, inaccurate, or misleading reporting and suffer significant damages including investigation by government and private entities, potential disciplinary actions, public censure, ridicule, and destruction of professional reputation and livelihood. During congressional hearings, investigations, and legislative negotiations, the unambiguous intent of Congress was to provide a mechanism to ensure that the actual interactions between physicians and manufacturers were transparent. It was never contemplated that the information in the transparency reports would be false, misleading, or materially inaccurate.

<u>Congress Did Not Authorize CMS to Expand Reporting to Indirect Transfers (Not Otherwise Specified in Statute)</u>

When Congress passed ACA's Sec. 6002, it expressed an unambiguous intent to strike prior legislative language that would have required reporting on indirect transfers of value except when manufacturers make a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a physician as specified in Section 6002(a)(1)(B). Earlier versions of what eventually became ACA Sec. 6002, H.R. 5605, *Physician Payments Sunshine Act of 2008*, and S. 2029, *Physician Payments Sunshine Act of 2007,* would have explicitly required that manufacturers report a payment or other transfers of value made, "directly, indirectly, or through an agent, subsidiary, or other third party." This language was not included in the ACA version of the Physician Payments Sunshine Act.

Sec. 6002 of the ACA provides for reporting on direct transfers except as outlined in Sec. 6002(a)(1)(B). This latter subsection was added in the ACA version of the Physician Payments Sunshine Act in order to capture when reporting on indirect payments and transfers would be required. As stated above, this would be where manufacturers are transferring payment or value to a third party at the request of the physician or designated on behalf of the physician. When Congress conferred the agency with the authority to add additional reportable categories, it did not confer the agency with the authority to expand reporting to indirect payments or transfers except in this carefully prescribed area.

Despite the foregoing, CMS's interpretation of "payment or other transfer of value," Sec. 6002(e)(10)(A), includes instances where the manufacturer learns of the identity of a physician before, during, or after the manufacturer makes a payment or transfers value to a third party or when made through an "agent." CMS proposes to require reporting where a manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of a physician. This interpretation is inconsistent with congressional intent, is unworkable, and could undermine the independence of certified CME and other activities where manufacturers make grants, but are barred from any control over how funds are used. This is amplified by the agency's overbroad proposal to make attribution of value even where there is little to no evidence that the physician receives any payment or value.

CMS proposes to expand the universe of detailed information manufacturers would demand to have about physicians where the manufacturer is reasonably expected to learn that a physician received a benefit from a transfer to a third party. This would add to the complexity of the reporting requirement since the third parties would have to report in detail back to all manufacturers the value attributed to each physician in their organization/company/conference after the indirect transfer is made.

For example, certified Continuing Medical Education (CME) activity faculty would have to be listed as receiving a payment from industry despite the fact that manufacturers are explicitly prohibited from having any control over the content, speakers, or attendees. While industry does not name the faculty, they could learn the identity of the faculty since this information is typically public. Many conferences that physicians attend in order to earn certified CME credit (either certified by the American Academy of Family Physicians, the American Osteopathic Association or the AMA) also publish a list of the participants so the manufacturer could "know" or "should know" who potentially received an indirect transfer of value after the transfer is made to the third party. However, the manufacturer cannot accurately report how to make proper attribution of value unless the CME provider or conference host provides a detailed attribution for all faculty and CME/conference attendees. The consequence of such an approach would be the transfer of an exhaustive amount of information to manufacturers about individual physicians participating in independent, certified CME. Congress never intended that transparency reports would become a gold mine of physician information for manufacturers.

All of the foregoing concerns were raised with congressional staff, and Congress elected to strike reporting on indirect transfers or transfers through an "an agent, subsidiary, or other third party." **At a minimum, CMS should replace the proposed standard with a regulation that provides that in all instances where a manufacturer would not necessarily know the identities of the specific recipients (who eventually receive a benefit) and the transfer is not made at the request of a covered recipient or designated on behalf of covered recipient, an indirect transfer is not reportable.** Further, we strongly oppose the effort to expand this provision to the agents of manufacturers since CMS fails to define the term agent and, more importantly, Congress specifically considered including agents, but rejected this approach as discussed fully above.

The Proposed Rule's overbroad interpretation of the statutory language is inconsistent with the Administration's stated goal of reducing regulatory burdens on physicians. As discussed more fully below, CMS has significantly understated the paperwork burden this imposes on all physicians since the wide swath of indirect reporting dictates that physicians track any activity that could conceivably have any indirect transfers of value (even where there isn't any transfer of value since most physicians will not know until they receive notice from a manufacturer or CMS whether or not they received anything of value from a manufacturer indirectly).

Congress Excluded Certified Continuing Medical Education (CME) from Reporting

We believe that CMS has exceeded its statutory authority to the extent it requires reporting on certified CME since Congress excluded certified CME from transparency reporting requirements. Though Congress contemplated including CME in transparency reports, it ultimately rejected this option. The American Medical Association (AMA) requires that accredited CME providers that certify CME activities for *AMA PRA Category 1 Credit*™ comply with the Standards for Commercial Support which include the Standards to Ensure the Independence of CME (SCS), promulgated by the Accreditation Council for Continuing Medical Education (ACCME), as well as the AMA's *Code of Medical Ethics.* In addition, all certified CME includes course content approved by the previously named certifying bodies.

Because certified CME is independent and manufacturers have no control or input into the content, the speakers, or the attendees, it is not covered by ACA Sec. 6002. The law includes a broad category of educational activities that are subject to reporting. These include promotional activities that are defined by the Food and Drug Administration (FDA) as education developed by or on behalf of a commercial entity and under the substantive influence of that entity to provide information on the therapeutic use of a product or service. Congress explicitly deleted reference to CME when the final version of the Physician Payments Sunshine Act was signed into law as part of the ACA.

We urge CMS to exclude from reporting certified CME as this is a reasonable interpretation of both congressional intent and the legislative history of this provision. As discussed above, earlier versions of the Physicians Payments Sunshine Act, S. 2029 and H.R. 5605, required reporting on a far larger universe of transfers/payments including all indirect transfers/payments and for "participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar." Once Congress deleted CME and limited the universe of indirect transfers/payments that are reportable, it made clear its intent that certified and accredited CME were not to be included as part of the transparency reports.

CMS Is Required to Ensure Accurate Attribution and Not Estimates

The ACA mandates that manufacturers are required to specify and report the portion of the transfer of value/payment made directly to a physician or an indirect transfer made at their

request or designated on the physician's behalf. CMS's proposal to estimate or impute attribution even where there is no direct transfer or a qualifying indirect transfer is beyond its statutory authority, violates basic principles of due process, and is inconsistent with congressional intent. Congress did not direct CMS to develop reports that provide an approximation of the value transferred by manufacturers to physicians nor did Congress intend that transfers of value made by manufacturers to an organization or entity that employ physicians would be attributed to a physician without regard to whether they received the transfer, requested the transfer, or it was designated on their behalf. CMS has proposed that where an organization receives a payment or transfer of value, it will be apportioned among the physicians in the organization or institution. This, of course, could result in grossly misleading reporting. Physicians employed by a large organization or institution could have funding and transfers imputed to their report that they cannot reject, they do not receive directly (or even indirectly but in the most attenuated sense), and for which they have no knowledge so they are unable to effectively challenge it. We also strongly oppose CMS's proposal to attribute to a physician transfers of value or payment that are made to other individuals where the physician personally did not request the transfer, it was not designated on their behalf, and they did not receive it. **CMS is required to direct manufacturers to document and report only those payments and transfers made directly to physicians or those specified indirect transfers/payments requested by the physician or designated on their behalf.**

Furthermore, we oppose efforts to attribute the total manufacturer payment/transfer of value for research when in many cases only a very small percentage could reasonably be attributed to a physician even were CMS to segregate these amounts into a separate reportable column on the public website as suggested in the Proposed Rule.

Notice

All individuals and entities that are the subject of public reporting have a basic due process right to notice of any report that implicates them as well as a right to correct false, misleading, and inaccurate reports. Where a payment or transfer of value is made at the request of a physician or designated as being made on behalf of the physician, the physician should receive notice as well as the entity/individual receiving the payment/transfer of value. Manufacturers will have the name and contact information for individuals/entities that receive the payment/transfer of value. Transmitting this information to CMS so that the agency is able to provide an aggregate report and an opportunity to review/correct the reporting is not anymore burdensome than doing so for physicians.

Personal Relationship Exemption & Reporting on Family Ownership Interest

CMS has proposed a personal relationship exemption where there are transfers of value/payment between individuals who have a personal relationship. We strongly support this proposal and recommend that CMS structure these exemptions for personal relationships to parallel those applicable to federal employees and those developed under the Lobbying Disclosure Act as amended.

CMS has also proposed that a physician's family member ownership interests should be reported in aggregate without identification of individual family members. We support this approach when manufacturers/GPOs transmit the reports to CMS. There are serious privacy concerns when detailed information about family relationships and ownership interests are introduced into the public arena (including the government) for no other reason than an individual is a family member of a physician. We urge CMS to mandate that manufacturers/GPOs report this information to the family member and the physician. There is no other way that a physician (or the family member) is able to dispute the report when it is false, misleading, or otherwise inaccurate.

Website Publication of Additional Helpful Information

We urge CMS to modify the language that it proposes to include as explanatory and background information generally concerning the transparency reports. The general public is inclined to conclude that these interactions constitute conflicts of interest or inappropriate relationships. CMS appears to take the view that the publication of these interactions will have the opposite impact since CMS proposes that it merely post on the Web site that the information in the database does not indicate that the payments/transfers of value are legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing." The transparency reports and requirements do not establish ethical guidelines. We urge CMS to state unequivocally that the transparency reports and the Web site do not establish ethical guidelines that govern physician and industry interactions. We would urge CMS to include links to sites that do provide ethical guidelines for physician and industry interactions.

Exclusion of Educational Materials that Benefit Patients

We strongly support the exclusion from reporting educational materials that directly benefit patients. We urge CMS to adopt such an exclusion as well as offer clear guidance providing that this exclusion would also apply to items that are not necessarily given to patients, but includes educational materials that increase a physician's medical knowledge.

Information Collection Requirement Burden on Physicians is Significant

CMS has provided a very limited estimate and analysis of the burden associated with the information collection requirements for physicians of the Proposed Rule. While we strongly believe this estimate would be alleviated by requiring manufacturers/GPOs to provide ongoing updates and cumulative reports to physicians in their preferred mode, the current Proposed Rule would require all physicians to maintain ongoing records of every activity that they engage in so that they are able to ensure accurate reporting. This is not an overstatement given the large universe of indirect reporting requirements contained in the Proposed Rule. We believe that CMS has greatly underestimated the amount of time physicians would need to review cumulative reports and to challenge them before they were posted given the resources that physicians would likely need to dispute inaccurate, false, and misleading reports. The 45-day review time proposed in the rule is far too short and would dictate that all physicians maintain detailed reports of all professional activities. Realistically, we would

anticipate that the paperwork requirements of documenting all of a physician's activities could easily exceed 80 hours a year.

We disagree that this would impact only a subset of the universe of physicians. All physicians would have to document their activities since they cannot know in advance when an indirect transfer/payment becomes a reportable event. The foregoing is contrary to congressional intent that physicians would not bear this paperwork burden. CMS would need to revise this assessment and the underlying assumptions to the extent the Proposed Rule remains unchanged. The overall paperwork burden for physicians would be substantially diminished if manufacturers/GPOs were required to provide ongoing notification and a cumulative report before submitting a report to CMS, proper attribution was required, and only those indirect transfers/payments specified in statute were included.

We appreciate the opportunity to provide our comments and look forward to working with you to ensure that the transparency reports contain meaningful and accurate information.

Sincerely,

American Medical Association
Aerospace Medical Association
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Mohs Surgery
American College of Osteopathic Family Physicians
American College of Osteopathic
American College of Osteopathic Surgeons
American College of Phlebology
American College Radiology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Medical Group Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association

American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Pediatric Nephrology
American Society for Radiation Oncology
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Hematology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Thoracic Society
American Urogynecologic Socity
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Heart Rhythm Society
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Gynecologic Oncology
The Endocrine Society
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Alaska State Medical Association
Arkansas Medical Society
California Medical Association
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association

Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
West Virginia State Medical Association
Wyoming Medical Society

February 16, 2012

Marilyn Tavenner, Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Acting Administrator Tavenner,

The undersigned represent the national organizations involved in Continuing Medical Education (CME) in the United States, including Accreditation of CME Providers, granting of CME Credit for CME activities, and fulfillment of the responsibility of the Profession of Medicine to self-regulate in the arena of Continuing Medical Education. We are pleased to comment on the proposed rule "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests", 42 CFR Parts 402 and 403 [CMS-5060-P] RIN 0938-AR33.

The CME community in the United States is supportive of the Physician Payments Sunshine Act (PPSA), as adopted by Congress as Section 6002 of the Patient Protection and Affordable Care Act of 2010. Indeed, during the crafting of the PPSA we had the opportunity to describe to legislative staff the complexities of relationships in Accredited and Certified CME offered by CME Providers in the US, in contrast to promotional educational programs offered to physicians directly by pharmaceutical and device manufacturers. For example, we were able to provide information on definitions and nuances of relationships, such as the distinction between grants to providers of certified CME, who in turn select faculty, in contrast to direct payments to physicians by companies for purposes related to drug development, marketing and promotion.

Language of the PPSA as adopted appropriately addressed a few specific issues, which appear in the proposed rule to need clarification and modification, to avoid unintended consequences. These issues include:

1. Distinguishing between Accredited and Certified CME offered by CME providers, and promotional education offered by pharmaceutical and medical device manufacturers;
2. Recognizing the roles and relationships that faculty in Accredited and Certified CME programs have with CME Providers and not with companies which may provide grants to CME Providers; and
3. Recognizing that attendees at or participants in Accredited and Certified CME programs have no relationships with companies which may provide grants to CME Providers.

We will address our comments to the two sections of the proposed rule, including <u>first</u>:

- Page 78748, Column 1, bullet 13, Direct compensation for serving as faculty or as a speaker for a medical education program, and
  Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program;
  - In the federal register, it states "We propose that this category be interpreted broadly to encompass all instances where applicable manufacturers pay physicians to serve as speakers, not just those situations involving 'medical education programs.'" It goes on to state "We realize that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. We are considering, and welcome comments on, whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category."

And <u>second</u>:

- Page 78750, Column 2, h. Exclusions, bullet 13, Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient, and
  Page 78751, Column 2, (5) Indirect Payments Through a Third Party;
  - In the federal register it states "However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an

applicable manufacturer or operating in the US, must be reported, if the applicable manufacturer is aware of the covered recipient's identity."

First, let us provide some applicable background. For example, the Federal Register references accredited CME, but does not reference extant firewalls in place in the Professional Self-regulation of relationships between CME Providers and industry.

Accredited and Certified CME:

"**Accredited CME**" refers to those activities in Continuing Medical Education that have been deemed to meet the requirements and standards of a CME accrediting body (ex., the Accreditation Council for Continuing Medical Education (ACCME); the America Osteopathic Association, the American Academy of Family Physicians). **"Certified CME"** refers to those activities in Continuing Medical Education that carry CME credit offered by one of the three grantors of CME credit in the US: the American Academy of Family Physicians (since 1948), the American Medical Association (since 1968), and the American Osteopathic Association (since 1972).

Professional Self-regulatory Firewalls in Accredited and Certified CME:

All organizations involved in Accredited and Certified CME in the US have adopted and operate under the strict firewalls which are promulgated, monitored and enforced through the "Standards for Commercial Support (SCS): Standards to Ensure the independence of CME Activities" of the Accreditation Council for Continuing Medical Education (ACCME), to which the entire profession of medicine adheres. The SCS (most recently revised in 2004) set standards for relationships between Accredited and Certified CME Providers and the companies which may provide grants to CME Providers. Faculty of certified Continuing Medical Education (CME) programs are selected, directed, reviewed, evaluated and paid by the Accredited CME providers, and have no relationship with the manufacturers. Indeed, not only is this a requirement of SCS, but also of the "Code on Interactions with Health Professionals" of the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

Faculty who have no relationships with companies supporting certified CME programs will not be pleased to be put in a position of being assumed and reported to have a relationship with a manufacturer, by virtue of their accepting an invitation to present at the CME program. Indeed, many if not most speakers who have no relationships with manufacturers will refuse to serve as faculty, in order to avoid being assumed and reported to have such relationships.

In the context of Accredited and Certified CME, direct payments to physicians (either in the role of faculty or attendees) by companies are prohibited, cannot occur, and therefore would be irrelevant when it comes to disclosure under the PPSA. Manufacturers will not be in a position to comply with this provision of the Act, as they have no relationships with CME faculty, either directly or indirectly.

Required Disclosure of Relationships Between Physicians and Industry:

When a faculty member at a CME program has a relationship with a manufacturer, pre-dating and outside of the CME program, such as serving on a corporate speakers' bureau, stock ownership, or other relationship, those relationships must be disclosed as part of the CME activity. Such relationships are reportable under PPACA Section 6002 and must be disclosed under transparency reports. However, in the context of Accredited and Certified CME, a speaker's participation in the CME activity does not qualify as a reportable activity under Sec. 6002, as the manufacturers cannot have any role in speaker selection for the Accredited and certified CME activity. Furthermore, manufacturers cannot, and do not, under all rules governing faculty of CME programs, provide *"direct compensation for serving as faculty or as a speaker for a continuing medical education program."*

Company Relationships with Speakers in Promotional Education:

In the proposed rule, there may be confusion of the roles and relationships of faculty in Accredited and Certified CME programs as contrasted with the roles of speakers in promotional education offered directly by pharmaceutical and medical device companies, as reflected on page 78748 of the proposed rule, column one, bullet thirteen, where one of the categories listed for reporting is "Direct compensation for serving as faculty or as a speaker for a medical education

program", and which are instead overseen by the Food and Drug Administration (FDA). This is the critical distinction we successfully made with congressional staff during the period of crafting the PPSA.

We agree with disclosure of relationships between manufacturers and speakers at a promotional educational program sponsored by the manufacturers, as these relationships should be transparent and are appropriately included under other categories, such as consulting fees, compensation for services other than consulting, or honoraria. However, these speakers should not described as "faculty or speakers in a CME program" since promotional educational programs, offered directly by manufacturers, are not Accredited and Certified CME programs.

Absence of Relationships of Participants in Accredited and Certified CME Programs:

There could be unintended consequences inherent in the communication of the names of physician participants to funding companies. CMSS Member Organizations are concerned that publishing the names of participants who attend independent CME events funded by commercial support, and identifying those participants as having a relationship with the funding company, may discourage physicians from attending. Moreover, communication of such a list of names could be used by funding companies for marketing purposes, which would seem to defeat the ultimate intent of these bills, to control expenditures in the Medicare and Medicaid programs.

Summary:

Direct compensation by an applicable manufacturer to a physician serving as a speaker in a promotional educational program should be reportable. Payments made by a CME Provider to faculty of Accredited and Certified CME activities are not reportable under Sec. 6002 of the PPACA. Grants from applicable manufacturers to CME Providers are governed by the ACCME Standards for Commercial Support, which prohibit direct payments from manufacturers to faculty, and prohibit manufacturers from having any influence on the CME program, including selection of faculty.

The proposed rule needs to be clarified and modified to avoid unintended consequences in two areas that relate to Accredited and Certified CME:

1. Page 78750, column 1, (4) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

   The final rule needs to distinguish between direct compensation for serving as a speaker in a promotional educational program offered by an applicable manufacturer, which should be reportable under the Act; in contrast to faculty serving as speakers in Accredited and Certified CME programs, in which the faculty are selected and paid by the CME Provider and have no relationship with any applicable manufacturer which might be supporting the CME activity through an educational grant to the CME Provider.

2. Page 78751, Column 2, (5) Indirect Payments Through a Third Party

   The final rule needs to clarify that grants from applicable manufacturers to CME Providers for Accredited and Certified CME activities do not constitute an indirect transfer of value, either to faculty independently selected and paid by the CME Provider, or to participants in the Accredited and Certified CME activity, nor are there in such cases payments made at the request of or on behalf of the faculty.

Thank you for the opportunity to comment on the proposed rule to implement the Physician Payments Sunshine Act, of which we are supportive. Should you have any questions, or should our comments require clarification, please do not hesitate to contact us.

Signers:

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