



February 13, 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

Re: File code CMS-5060-P; RIN 0938-AR33. Proposed Rule: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Federal Register Vol. 76, No. 243, Dec. 19, 2011, pages 78742-78773; FR Doc No: 2011-32244.

Dear Acting Administrator Tavenner:

On behalf of the American Society of Transplant Surgeons (ASTS), we are pleased to have this opportunity to respond to the proposed rules (the "Proposed Rules") implementing Section 1128G of the Social Security Act (the "Sunshine Act"). ASTS is comprised of over 1900 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

ASTS is extremely concerned that the Proposed Rules will significantly interfere with its financial relationships with industry in a manner that undercuts ASTS' effectiveness in achieving its educational, charitable, and other missions. Unless the Final Rules address a number of the ambiguities in the Proposed Rules regarding the application of the reporting requirements to payments made by industry to ASTS and other professional associations, we believe that applicable manufacturers will be exceedingly cautious in providing critical financial support to professional associations such as ASTS. Without industry support, ASTS and other medical specialty societies dedicated to education and clinical advances will be forced to reduce educational and research programs and other professional development activities. In addition, unless the Proposed Rules are clarified and their application to medical specialty societies narrowed significantly, we believe that we will begin to experience significant difficulty in recruiting and sustaining high quality faculty for our programs, since teaching faculty are likely to be concerned that their acceptance of travel expenses, stipends, or honorarium may be reportable under the proposed rules, adversely impacting their professional reputations. For these reasons, we strongly urge CMS to ensure that the Final Rules are drafted narrowly and clearly, in

a manner that ensures and encourages continued industry support for professional medical societies such as ASTS.

We are also concerned that the Proposed Regulations will result in the widespread dissemination of potentially erroneous information about our individual members' relationships with industry, adversely impacting their professional standing and their effectiveness as leaders in the field.

ASTS is particularly concerned about CMS's proposal to adopt a set of special rules for the reporting of research payments, under which applicable manufacturers would be required to report the full amount of any payment made pursuant to a written research agreement and research protocol not only under the name of the institution that actually receives the payment (both teaching and non-teaching institutions) but also under the name(s) of the physician principal investigator(s) (PIs) conducting the research trial. CMS's proposal is inconsistent with the statute, which does not require reporting of PIs or payments to non teaching hospitals. Rather, we believe that payments teaching hospitals should be reported only as to the teaching hospital, and should not be attributed to the PI. Payments to non-teaching hospitals should not be reported unless the payment is made at the request of or designated on behalf of a covered recipient (e.g. a physician running an investigator-sponsored research study with the backing of a hospital), in which case the third party reporting rules would apply, and the payment would be reported. Payments directly to individual PIs for investigator-sponsored research would be reported only as to the PIs receiving the payment. In any event, we believe that payments reportable in conjunction with research should be separately listed and designated as research payments, to ensure that the public is not misled into believing that these payments were made for food, travel, or other personal benefits.

With regard to both the potential impact of the Proposed Regulations on medical specialty societies and with regard to their impact on individual physicians, we concur with and incorporate by reference the comments on the Proposed Rules submitted on behalf of the American Medical Association (AMA) and the American College of Surgeons (ACS). The comments set forth below are intended to supplement the views set forth in the ACS and the AMA comments.

I. ASTS' Relationships with Industry

The ASTS is a nonprofit organization dedicated to fostering and advancing the practice and science of transplantation for the benefit of patients and the community. The core of the ASTS mission is to define and promote lifelong training and education in the rapidly evolving field of transplantation. The large majority of ASTS members are board-certified surgeons with advanced training in transplantation and a record of peer-reviewed publications. Due to this focused expertise, the opportunity for practice-based learning that will promote competence, performance and patient outcomes is limited outside of specialty societies such as ASTS. ASTS maintains a well-established record of providing valuable learning interventions through its annual State of the Art Winter Symposium (held in conjunction with NATCO, the Organization for Transplant Professionals), the American Transplant Congress (held in conjunction with the American Society of Transplantation), the Surgical Fellows Symposium and the Leadership Development Program. Each of these events is CME credit certified, targets a specific audience,

provides multidisciplinary education and designed to address performance-based learning gaps with a commitment to quality performance improvement and patient care.

The majority of small professional societies that serve narrowly defined subspecialties depend on commercial support to advance their mission; ASTS is no exception. Industry support of ASTS is received in four forms: Grants, Independent Medical Education (IMED), Marketing Opportunities and Unrestricted Funds. The use of grants and IMED funds are restricted via a letter of agreement. The funds are held separately and released quarterly by our controller when ASTS demonstrates it has spent the funds according to the LOA. Unspent funds must be returned to the grantor. Accreditation Council for Continuing Medical Education (ACCME) has strict requirements to separate commercial influence from IMED and ASTS was reaccredited by ACCME with commendation under their guidelines, which demonstrates that ASTS has strong policies and procedures in place to prohibit commercial influence over its educational events. Marketing opportunities are available in limited arenas, are also governed by a written agreement and compliant with ACCME regulations. Unrestricted funds are provided to support the mission and activities of the ASTS. Less than 5% of ASTS' revenue is received in the form of unrestricted funds.

II. Application of Sunshine Act Requirements to Industry Support Received by ASTS and other Professional Associations

We strongly urge CMS to revise the provisions of the Proposed Rules with regard to their application to payments made to professional associations and others who are not “covered recipients.” Congress specifically considered and rejected the idea of requiring manufacturers to report payments made “indirectly” to covered recipients through third parties¹; however, the preamble to the Proposed Rule suggests that CMS is prepared to treat payments made to third parties as if the payments were made directly to covered recipients. More specifically, the Sunshine Act specifically defines the term “payment or other transfer of value” to exclude:

a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(Emphasis added). In addition, the Sunshine Act specifically makes the disclosure requirements applicable to payments made to third parties only to the extent that such payments are made “at the request of or designated on behalf of a covered recipient [i.e., a physician or teaching hospital]” (the “Request Requirement”) Thus the Sunshine Act language deliberately restricts the scope of the reporting requirements imposed on covered manufacturers in two ways: by extending these requirements only to payments made to a third party at the request of or designated on behalf of a covered recipient, and by requiring manufacturers to report indirect payments only when the manufacturer is aware of the identity of the covered recipient. Since the Sunshine Act explicitly includes both of these restrictions on reporting of indirect payments, both requirements should be met in order for a payment to a third party to be reportable: the manufacturer should be aware of the identity of the covered recipient and the payment should be made at the request or designated on behalf of the covered recipient.

A. The “Awareness” Requirement

While the preamble to the Proposed Rules acknowledges that the Sunshine Act excludes payments to third parties if a manufacturer is “unaware” of recipient’s identity, it goes on to suggest that manufacturers have an ongoing obligation to make themselves aware of the identity of covered recipients after the payment is made, indicating that the manufacturer will be deemed to be aware of information that is or becomes “publicly available.” This language could be read to suggest that a manufacturer may be required to report funds contributed to the general support of a professional association, if the association provides stipends, travel expenses or other reimbursement to individual physicians who participate in association programs and activities.

We believe that this result would be inconsistent with Congress’ intent in removing payments to professional associations from the scope of the reporting requirement when it drafted the final Sunshine Act. We strongly urge CMS to take a more narrow view of the circumstances under which a manufacturer will be deemed to be “aware” of the identity of covered recipients. Reporting should only be required if the manufacturer knows the specific identity (not just the fact that a particular physician is a member of a committee or group) of a covered recipient at the time the payment is made and does not participate in the subsequent identification or designation of the covered recipient

B. The Requirement that Payments be made “at the request or designated on behalf of” a covered recipient

The regulations should specifically address the circumstances under which third party payments should be considered to be made “at the request of” or “designated on behalf of” a covered physician recipient. Contrary to the position suggested in the preamble to the Proposed Regulations, a payment made to a third party should be considered to be made “at the request of” or “designated on behalf of” a covered recipient only in extremely limited circumstances and only with the concurrence of the third party. For example, we do not believe that a manufacturer’s provision of coffee and donuts to a department of a hospital should be attributed to all of the hospital’s physicians without the concurrence of the hospital. Rather, a payment should be considered to be made at the request of or designated on behalf of a covered recipient if but only if the manufacturer provides a copy of the information proposed to be reported to both the covered recipient and the entity to which the payment is made and they both concur that the information is complete and accurate.

C. Safe Harbors

Because of the potential impact of the Sunshine Act on the critical educational and other functions of ASTS and other professional societies, we urge CMS to provide a “safe harbor” for industry contributions to support the activities of professional associations. In addition, we strongly urge CMS to adopt a “safe harbor” for industry support of CME-certified programs sponsored by third parties such as ASTS. We believe that, in light of the safeguards instituted by Accreditation Council for Continuing Medical Education (ACCME) with regard to industry support of CME-certified programs, manufacturers should be authorized to support these programs without having to be concerned about whether their payments are reportable to CMS. The ACCME requirements with regard to industry support are clear and stringent (See

Attachment A), and compliance with these requirements by manufacturers and program sponsors should be deemed sufficient to ensure that purposes of the Sunshine Act are met.

This is especially true since the Sunshine Act specifically includes only “direct compensation for serving as faculty or as a speaker for a medical education program.” The statute does not specifically describe other expenditure categories to include only “direct” payments. We believe that this language was likely added specifically to ensure that manufacturer sponsorship of educational programs is not impacted by the Sunshine Act, and, for this reason, it would be particularly troublesome for CMS to require manufacturers to report payments made to support, or otherwise participate in, programs that are accredited by the ACCME.

In order to assist CMS in incorporating the ideas set forth above into regulatory language, we are providing model language for a new regulatory provision specifically addressing indirect payments and incorporating the other changes discussed above. See Attachment B.

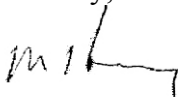
III. Other Issues

Finally, we would like to comment on a number of additional issues:

- We concur with the AMA regarding the need for applicable industry to submit their reports to physicians prior to submitting them to CMS.
- We strongly object to the approach to disputed information set forth in the proposed rule, and believe that only information about which there is agreement should be posted.
- We believe that third parties to whom payments are made at the request of, or pursuant to a designation made by, a covered recipient should have the right to review the information prior to the manufacturer’s submission of a report and should be entitled to access to the information during the statutory 45-day review period.
- We believe that the exemption for educational materials that benefit patients should be extended to educational materials for physicians.

We appreciate the opportunity to submit these comments, and would be delighted to work with CMS to craft the final regulations implementing the Sunshine Act. Please contact ASTS Executive Director, Kim Gifford, via email, kim.gifford@asts.org, or phone, 703 414-7870 if we can be of further assistance.

Sincerely,



Mitchell L. Henry, MD
President

Attachment A

Accreditation Council for Continuing Medical Education (ACCME) Accreditation Requirements

Standards for Commercial Support: Standards to Ensure Independence in CME Activities

Standard 1: Independence

Standard 1.1: A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

Standard 1.2: A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

Standard 2: Resolution of Personal Conflicts of Interest

Standard 2.1: The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Standard 2.2: An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

Standard 2.3: The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

Standard 3: Appropriate Use of Commercial Support

Standard 3.1: The provider must make all decisions regarding the disposition and disbursement of commercial support.

Standard 3.2: A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

Standard 3.3: All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Standard 3.4: The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

Standard 3.5: The written agreement must specify the commercial interest that is the source of commercial support.

Standard 3.6: Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Standard 3.7: The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

Standard 3.8: The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

Standard 3.9: No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

Standard 3.10: If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Standard 3.11: Social events or meals at CME activities cannot compete with or take precedence over the educational events.

Standard 3.12: The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Standard 3.13: The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

Standard 4: Appropriate Management of Associated Commercial Promotion

Standard 4.1: Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

Standard 4.2: Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity. For computer based,

advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.' For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

Standard 4.3: Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

Standard 4.4: Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

Standard 5: Content and Format without Commercial Bias

Standard 5.1: The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

Standard 5.2: Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

Standard 6: Disclosures Relevant to Potential Commercial Bias

Standard 6.1: An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

Standard 6.2: For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Standard 6.3: The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

Standard 6.4: 'Disclosure' must never include the use of a trade name or a product-group message.

Standard 6.5: A provider must disclose the above information to learners prior to the beginning of the educational activity.

Attachment B

Proposed Regulatory Language

§403.904(f) Exclusions from reporting. The following types of payments or other transfers of value are excluded from the reporting requirements specified in this section:

- (1) Transfers of value made indirectly to a covered recipient through a third party, unless the manufacturer is aware of the identity of the covered recipient and the transfer of value is made at the request of or is designated on behalf of a covered recipient.
 - (a) For the purposes of this subsection, an applicable manufacturer will be considered to be aware of the identity of a covered recipient if the applicable manufacturer knows (as defined in §403.902) the specific identity of the covered recipient at the time the payment is made and does not subsequently participate in selection or identification of the covered recipient(s).
 - (b) For the purposes of this subsection, a payment shall be deemed to be at the request of or designated on behalf of a covered recipient only if the covered recipient and the entity to which the payment is made are each provided with a copy of the information to be reported by the manufacturer pursuant to §403.908 and only if both the covered recipient and the entity to which the payment is made each provide written notification to the manufacturer that they agree with the information to be submitted.
 - (c) The following transfers of value made indirectly to a covered recipient through a third party shall be deemed to be excluded from reporting:
 - i. A transfer of value made to a professional medical society, so long as the specific covered recipient(s) is not identified or otherwise designated.
 - ii. The payment is made to support, exhibit at, or otherwise participate in an educational program accredited by ACCME and is made in accordance with the industry support guidelines established by ACCME.

§403.902(Additional Definition) Professional Medical Society shall mean a voluntary association of physicians and other specialists engaged in medical and public health research and practice that is exempt from federal income tax under the provisions of Section 501 (c) of the Internal Revenue Code and whose governing board does not include voting representation by any applicable manufacturer.

ⁱ Both the House and the Senate bills from which the Sunshine Act was derived would have explicitly required reporting of both direct and indirect payments made by manufacturers to covered recipients:

Reporting of Payments or Other Transfer of Value- On January 1, 2009, and the first day of each fiscal year quarter beginning thereafter, each manufacturer of a covered drug, device, or medical supply who provides a payment or other transfer of value, directly, *indirectly, or through an agent, subsidiary, or other third party, to a physician; to an entity that a physician is employed by, has tenure with, or has a significant ownership interest in; or to a covered organization in which a physician has a significant professional membership interest*, shall submit to the Secretary, in such electronic form as the Secretary shall require, the following...

(Emphasis added.) H.R. 5605; S. 2029. The final Sunshine Act struck all of the language extending the reporting requirements to indirect payments; to payments made to physicians' employers, entities that provide physicians tenure, and physician-owned entities; and to professional associations.