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February 17, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services
Attention: CMS-5060-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare, Medicaid, CHIP; Transparency Reports and Reporting of Physician Ownership or Investment Interests, Proposed Rule

Dear Ms. Tavenner:

The American College of Gastroenterology (ACG or College) appreciates this opportunity to comment on the proposed rule, *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests*, published in the *Federal Register* on December 19, 2011.[1] We are pleased to offer our perspective on the implementation of the new reporting requirements enacted in section 6002 of the Patient Protection and Affordable Care Act (ACA) as these requirements will affect our physician membership and organization.[1]

The College is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, ACG currently numbers over 12,000 physicians among its membership of health care providers of gastroenterology specialty care. The College focuses its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, promoting evidence-based medicine and optimizing quality care. This includes providing continuing medical education to clinicians at regional courses and the College's annual meetings. The College is a certified continuing medical education (CME) provider by the Accreditation Council for Continuing Medical Education (ACCME). The College also publishes the *American Journal of Gastroenterology*, which includes the latest science and peer-reviewed medical literature in the field of clinical gastroenterology. Our services also include providing medical education to clinicians through other scientific publications, meetings, and other programs.

[1] CMS, Medicare, Medicaid, CHIP; Transparency Reports and Reporting of Physician Ownership or Investment Interests, Proposed Rule, 76 Fed. Reg. 78742, et seq. (Dec. 19, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf.

[2] Social Security Act § 1128G, as added by the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148 as amended by Pub. L. No. 111-152.

Annual Scientific Meeting and Postgraduate Course
October 19 – 24, 2012, The Venetian, Las Vegas, Nevada
www.acgmeetings.gi.org

Under the new section 1128G of the Social Security Act (Act), most drug, device and medical supplies manufacturers will have to file annual disclosure reports to the Secretary of Health and Human Services (HHS) that detail their financial relationships with physicians and teaching hospitals. As a professional medical society of physicians, the new transparency reporting requirements will certainly impact our membership but could impact the College as well. The College supports the general goal of the statute -- to dissuade inappropriate conflicts of interest. Indeed, the College has adopted its own conflict of interest policies that govern permitted activities and appropriate disclosure for its leaders, Committee members and staff as well as organizational contacts with industry. With respect to crafting the new disclosure the rules under Section 1128G, it is important that implementation of the rules does not go beyond the intention of the statute in a way that is harmful to beneficial relationships that exist between physicians, professional societies and manufacturers of drugs, devices, biologicals, or medical supplies. As CMS noted in the preamble to the proposed rule, "disclosure alone is not sufficient to differentiate beneficial, legitimate financial relationships from those that create conflict of interests . . . [and] moreover, financial ties alone do not signify an inappropriate relationship."[3]

In this comment letter, we focus on three related issues: physician ties to manufacturers, the indirect payments through a third party exception, and the educational materials exception. We address each of these issues in detail below.

I. Physician Ties to Manufacturers

The College has concerns over potential unintended consequences related to inferred relationships between manufacturers and physicians that may result from the proposed regulation as it is currently drafted. In particular, the College is concerned that the proposed regulation could inaccurately infer the existence of substantive relationships between manufacturers and the physicians who present at an educational course or medical society meeting that is financially supported by the manufacturer. As discussed below, one might read the proposed rule as requiring an applicable manufacturer to trace how payments made to a third party, such as a professional society, were ultimately used by that professional society to develop meetings or events at which physicians attended or participated. This would be the case even when no relationship between the physician and manufacturer exists.

The field of medicine takes very seriously the issue of conflicts of interest, including the perception of a conflict, because of the great impact that it can have on patients and practitioners. The critical nature of this issue carries through the practice of medicine, clinical research, and continuing education. Patient care through unfettered and objective decision-making is the hallmark of medicine and something the College and its membership strive to preserve. Physicians and professional societies have in place safeguards to disclose any conflict of interest when one exists and policies to prevent any inappropriate conflicts from occurring in the first place. These policies protect patients and the integrity of the field and practice of medicine. The College believes it is also important to have these policies in place to protect practitioners and providers of care from inaccurate or undue portrayals of conflict. Once out in the public domain, there is no recanting a perceived conflict of interest or inappropriate ties to industry, even where no such conflict of interest or inappropriate ties exist.

Many continuing educational courses would not exist (or be affordable) but for industry and pharmaceutical manufacturers' support. That is why the ACCME Standards allow industry support so long as the strict standards are met and guidance is followed. Medical professional societies routinely pay modest honoraria and travel expenses in order to get the most qualified experts to present and speak at

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[3] 76 Fed. Reg. at 78743.

their educational courses and meetings. This provides an opportunity for members to learn from the most respected physicians in an area of medicine; for example, in the case of ACG, clinical gastroenterology.

While a physician might attend or even present at an event such as a meeting or CME course, the manufacturer has no control over the event, including program content, speaker selection or physician attendance. Moreover, the physician in such situations has no control over which manufacturer has provided support for the meeting or course. The ACCME Standards, which ACG follows, help to ensure that industry support in no way eclipses the independence and objective nature of these events. While a scenario where a physician chooses to independently consult for a pharmaceutical company or attend speaking engagements on behalf of the manufacturer should certainly fall under the new transparency reporting requirements, a physician speaking for a CME course or society meeting represents a completely different scenario. Unfortunately, as currently drafted, the proposed rule does not adequately distinguish between these two scenarios. The College believes further distinction must be made so that the public websites that will publish the transparency reports will not infer inaccurately that certain relationships exist between manufacturers and physicians when they in fact do not.

II. Indirect Payments Through a Third Party

Under section 1128G(a)(1) of the Act, the manufacturer disclosure requirements apply to certain "payment or other transfers of value" made "to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient)."[4] The statute defines the term "covered recipient" as including a physician (as defined in the Social Security Act) or a teaching hospital.[5] The statute also provides exceptions where "payment or other transfers of value" would not be reportable and thus, not considered a "payment or transfer of value" for purposes of the statute. In particular, the statute states that the term "payment or other transfer of value"

> does not include 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.[6] (Emphasis added).

In the proposed rule, CMS addressed this statutory exclusion for payments or transfers of value to a covered recipient through a third party, explaining that the exception "hinges on whether an applicable manufacturer is 'unaware' of the identity of the covered recipient."[7] CMS proposed that, similar to the fraud and abuse standard, "awareness" will be found if "the applicable manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient."[8] CMS sought to explain this standard further by providing the example of where an applicable manufacturer, through a third party, provides a payment to department chairs at a specific hospital. This, CMS said, would be an example of where the payment would need to be reported "because even though the applicable manufacturer did not name the recipients, their identities are publicly available."[9]

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[4] Social Security Act, § 1128G(a)(1)(A).

[5] Social Security Act, § 1128G(e)(6)(A).

[6] Social Security Act, § 1128G(e)(10)(A).

[7] 76 Fed. Reg. at 78751.

[8] *Id*.

[9] *Id*.

Further Clarification Requested with Respect to Third Party Payments

While the department chairs example provided in the proposed rule may seem straightforward, we believe CMS' explanation creates uncertainty regarding the impact of the disclosure requirements on professional societies. For example, many applicable manufacturers provide grants or other financial contributions to professional societies, which societies use to provide CME courses, events, or meetings for their members. The question arises whether such financial contributions would be a reportable payment or transfer of value simply because the grant or sponsorship of the course, event, or meeting would benefit physicians and the manufacturer could attempt to identify the physicians who attended or participated.

The ACCME *Standards for Commercial Support: Standards to Ensure Independence of CME Activities* allows industry to support CME and provides guidance on how to safeguard the critical independence of such CME activities and events.[10] Specifically, the ACCME Standards state that commercial contributions must not include a stipulation of how, or for whom, this money will be spent.[11] Under the ACCME Standards, the CME provider must ensure that the following are made free of the control of a commercial interest: identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content of CME, selection of educational methods and evaluation of the activity. These standards include speakers receiving honoraria who have elected to speak at the event *at the invitation of the society*.

Thus, while an applicable manufacturer may theoretically have the ability to trace their financial contribution to a CME event to a specific speaker or attendee, the manufacturer has no control over the program agenda, speaker's selection or presentation, nor control over the physicians who attend the event. The College believes that it would be contrary to the spirit and intent of the statute to require such a manufacturer to either report these payments or face significant penalty for not reporting them. In other words, manufacturers in such a situation should not be viewed as acting in "deliberate ignorance or reckless disregard" for failing to identify and report the identity of covered recipients (i.e., physicians) who attend a CME event that the manufacturer has financially contributed to or sponsored. Even if a manufacturer may be able to identify the physicians attending or speaking at an event or meeting, such identification would be almost meaningless because there is no relationship between the manufacturer and physician for the particular payment or transfer of value at issue. Furthermore, to the extent that such a reporting requirement would depend upon manufacturers obtaining data from nonprofit educational organizations like us, it would create an unnecessary administrative burden with no corresponding benefit.

As a professional society dedicated to increasing knowledge in the field, supporting our membership and promoting continuing medical education through a variety of venues and resources, our relationships with manufacturers who are at the cutting edge of innovative technology and improving therapies helps us to further advance knowledge and continuing medical education activities, which allow our clinicians to provide the best care possible to their patients. Our programs, meetings and materials are designed to benefit a wide range of clinicians and treatment options, including *not treating patients with drugs or pharmaceuticals when the medical literature supports other treatment options*. While ACG may receive funding or grants from manufacturers for educational programs, events, or meetings, the College maintains complete control and autonomy over how, and to whom, those funds are spent.

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[10] ACCME *Standards for Commercial Support: Standards to Ensure Independence of CME Activities*, *available at* http://cme.med.miami.edu/documents/scs.pdf.

[11] *Id*.

Thus, ACG respectfully requests that CMS clarify the third parties language to assure professional societies that such payments made to them by applicable manufacturers are not intended to be swept into the payments or transfers of value that need to be reported under the new transparency requirements. While this conclusion can be inferred from the proposed rule, we believe it would be helpful for CMS to state it expressly in the final regulation to avoid any confusion.

III. Educational Materials Exception

In addition to the exception in the statute for indirect transfers of payment made through a third party, there are also twelve other types of payments or other transfers of value that are excluded from the reporting requirements. One of the excluded types of payment or excluded transfer of value is: "educational materials that directly benefit patients or are intended for patient use."[12] In the proposed rule, CMS stated that the Agency is

> considering whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that 'directly benefit patients.'[13]

We believe this is an important exception and should be interpreted as broadly as possible. In particular, the College requests that CMS clarify that speaking engagements at a professional society meeting or CME event, or the complimentary CME available to faculty fall under the "education materials" exemption. Such speaking engagements "directly benefit patients" because they increase the medical knowledge that physicians use to care for their patients. Including CME and professional society speaking engagements under the "educational materials" exception is appropriate because physicians are invited to speak by the professional society, and not by any manufacturer who may or may not have contributed financially to the event or meeting. As part of this clarification, the exception could be renamed the "Educational Materials and Services Exception. The College urges CMS to specifically list this category in the final regulation or include "sponsorship to a medical professional society meeting or continuing education course" in the examples of this "educational materials" exemption.

Again, the College appreciates this opportunity to provide these comments. If we can be of any assistance or if you have any questions, please do not hesitate to contact Brad Conway, Vice President of Public Policy, at bconway@gi.org or 301.263.9000.

Sincerely,

Lawrence R. Schiller, MD, FACG
President
American College of Gastroenterology

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[12] Social Security Act, § 1128G(e)(10)(B)(iii).

[13] 76 Fed. Reg. at 78751.