February 17, 2012

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

Re: CMS-5060-P Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Acting Administrator Tavenner:

The American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE), the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), and the American Association for the Study of Liver Diseases (AASLD) appreciate the opportunity to provide comments on the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests proposed rule published on December 19, 2011 in the *Federal Register*. Our societies support the underlying goal of transparency, however we are concerned that CMS misinterpreted the intent of Congress regarding the inclusion of indirect payments and transfers of value. As a result, the proposed rule, if implemented, would have detrimental effects to continuing medical education (CME) accredited activities and would create unnecessary regulatory burdens on physicians and organizations.

Our societies offer comment on the follow aspects of the proposed rule:

- Indirect Payments and Other Transfers of Value
    - Exclusion of Reporting of Payments and Other Transfers of Value Made through a Third Party
    - Distinction between participation in CME-accredited activities and other activities
- Form and Nature of Payment
    - Food and Beverage
- Report Submission, Review and Correction
    - Reporting of and Review by Third-Party Entities or Individuals
    - 45-Day Review Period
- Public Availability of Reported Information
    - Public Web Site Disclosure

Indirect Payments and Other Transfers of Value

Exclusion of Reporting of Payments and Other Transfers of Value Made through a Third Party
When Congress passed Sec. 6002 of the Affordable Care Act (ACA), it did so with the intent of not requiring reporting on indirect transfers of value, except for instances when manufacturers would report on indirect payments and transfers of value to a third party at the request of the physician or designated on behalf of the physicians. Earlier versions of the Sunshine Act (H.R. 5605 and S. 2029), which would ultimately become Sec. 6002 in the ACA, would have required that manufacturers report payments or transfers of value provided directly, indirectly, or through third parties. This language was not included in Sec. 6002 of the ACA. As noted above, the subsection in the ACA was included in order to capture instances when reporting on indirect payments and transfers of value would be required, which would occur at the request of the physician or on behalf of the physician. The intent of the ACA was to provide guidance in this particular situation and did not intend to expand reporting of all indirect payments or transfers of value.

It appears the CMS is relying on the ACA's definition of a reportable payment or other transfer of value, which is defined as a transfer of anything of value, except when the transfer of value is made indirectly to a covered recipient through a third party and the applicable manufacturer is unaware of the identity of the covered recipient. As stated above, we believe that CMS' inference that manufacturers must report indirect payments or transfers of value when "aware" of a covered recipient's identity is inconsistent with congressional intent.

We urge CMS to modify its proposed standard so that indirect payments or transfers of value made to a covered recipient through a third party are not reportable if the payment or transfer is not made at the request of a covered recipient or designated on behalf of a covered recipient. If CMS does not agree that this was the intent of Congress, we encourage CMS to provide, at a minimum, an exemption for certified CME activities by an accredited CME provider.

Distinction between participation in CME-accredited activities and other activities

As accredited providers of CME, our organizations are required by the Accreditation Council for Continuing Medical Education (ACCME) to keep a clear separation between developing educational content (including faculty selection) and pursuing and securing commercial support. One of the hallmarks of accredited CME activities is that they are based on evidence-based needs for improvement in physician practice, and not the financial interests of any commercial supporter. The CME provider must control all aspects of the activity, including how all commercial support is spent. For example, faculty honoraria payments must be made in accordance with the CME provider's policy (i.e., not the commercial supporter).

CME providers are highly regulated, particularly by the ACCME's Standards for Commercial Support, which specifically states the following:

- A CME provider must ensure that the following decisions were made free of the control of a commercial interest… Selection of all persons and organizations that will be in a position to control the content of the CME.
- The (CME) provider must make all decisions regarding the disposition and disbursement of commercial support.
- The (CME) provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- 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.

As a result of these guidelines, CME providers are the recipients of funding from commercial entities and faculty only have a financial relationship with the CME provider. If CME providers are asked to provide to manufacturers the names of specific faculty members whose honoraria was supported by that company, they would be stating that there is a financial relationship that, in reality, does not exist.

There is a significant difference between education that is developed by commercial entities for which physicians are paid directly, and education that is funded through a CME provider. CME is highly regulated, must demonstrate that it is developed based on the needs of the audience, and creates a clear firewall between faculty and industry supporters. Faculty members typically identify their involvement with CME activities as a service to their society or hospital, and their financial relationship is only with the ACCME-accredited organization for the purposes of the CME activity. To portray a relationship directly between the physician and manufacturer for these activities would be inaccurate and misrepresentative and could undermine the independence of certified CME activities. The inaccurate impression of a relationship would likely reduce the interest of physicians, who are experts in their fields, from participating and teaching in CME programs, which will lead to fewer hours of CME activities.

We urge CMS to distinguish CME from other activities by excluding, as a reportable event, indirect payments or transfers of value made through a certified CME provider for CME activities. Direct payment from a manufacturer to a physician for a CME speaking engagement would not occur due to strict CME guidelines. Therefore, it is inappropriate and misleading to

not distinguish between participation by a covered recipient in CME accredited activities and other activities.

Form and Nature of Payment

Food and Beverage
The proposed rule provides additional context for some of the categories for nature of payment, including food and beverage. While the examples provided under this section are useful, we believe that CMS should provide explicit guidance for other common scenarios. We believe that because of the threat of imposition of civil monetary penalties on applicable manufacturers, explicit guidance is necessary to prevent over reporting by applicable manufacturers. However, we reiterate our position that indirect payments or transfers of value made to a covered recipient through a third party should not be reportable if the payment or transfer is not made at the request of a covered recipient or designated on behalf of a covered recipient. Should CMS accept this recommended modification, further guidance on food and beverage, as suggested below, would be unnecessary.

We are pleased that CMS is proposing that applicable manufacturers would not need to report any offerings of "buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings."

It is unclear from the proposed rule whether CMS is excluding the reporting of buffet meals at conferences or other similar events, or just the offering of food, snacks and beverages at booths at conferences or other similar events. We believe that under both scenarios, it would be difficult for applicable manufacturers to definitively establish the identities of individuals who accept these offerings. If CMS is to broadly require reporting of the offering of food, snacks and beverages at conferences and other similar events, the added burden on specialty societies and other organizations to track the names of individuals who accepted the offering of food, snacks and beverages would be considerable. Furthermore, consistent with our previous comments, physicians who avail themselves of food, snacks and beverages made available through the financial support of applicable manufacturers would likely be unaware that such consumption could trigger a reportable transaction. **We therefore ask that CMS clarify in the final rule that the offering of food, snacks and beverages at conferences or other similar events, including booths, be excluded from reporting.**

Report Submission, Review, and Correction

Reporting of and Review by Third-Party Entities or Individuals
It is proposed that applicable manufacturers will be required to report the name of the entity or individual who receives a payment at the request of or designated on behalf of a covered recipient. However, the proposed rule states that CMS does not believe it is feasible to provide a review period for these entities or individuals before the data is made publicly available on the CMS Web site. CMS contends that review by the covered recipient is sufficient. If CMS chooses to use its administrative discretion to require reporting of third-party entities or individuals, we

believe that CMS must give third-party entities an opportunity to review data before it is made publicly available.

There are many professional societies and trade associations that share the same or similar acronyms. There are also societies that are identical in specialty and similar in name (e.g., American Gastroenterological Association and American College of Gastroenterology). It is not difficult to see how easily reporting errors could occur.

Furthermore, we believe that by giving third-party entities the opportunity to review information, perceived reporting discrepancies between applicable manufacturers and covered recipients could be minimized. As stated previously, we do not agree with CMS' proposal to require reporting on all indirect transfers of payment or other transfers of value. However, if CMS finalizes that all indirect payments must be reported, it is conceivable that covered recipients will not have advance knowledge of all reportable indirect payments. For example, a manufacturer could provide a grant to a specialty society for a symposium, which covers the honorarium for the physician presenter. Under the proposed rule, if the manufacturer was "aware" of the presenter's identity, then it would be required to report the amount of the honorarium received indirectly by the covered recipient, as well as report the society through which the honorarium was paid. In such cases, it is possible that the physician would not be aware that the honorarium for the presentation is being covered by a grant from an applicable manufacturer. Instead, the physician may assume it is being covered by the sponsoring society. By allowing third-party entities to review information prior to publication, it should help to resolve perceived reporting discrepancies.

It is indicated in the proposed rule that CMS is considering having covered recipients and physician owners and investors sign into a secure Web site, during the review period, to view information reported about them. We see no reason why third-party entities and individuals could not have the same secure access to pre-published information and data. We suggest that CMS could operationalize such review by allowing professional societies and other organizations that represent covered recipients (e.g., through membership) to register with CMS. Registration would indicate that the society or organization desires to review information during the review period. Upon receipt and verification of registration, organizations would be given a passcode to access the information. If CMS declines to accept our recommendation for third-party review, we respectfully ask that CMS provide in the final rule an explanation as to why it would not be feasible to provide this level of review to third-party entities and individuals.

45-Day Review Period

The ACA states that an applicable manufacturer, group purchasing organization (GPO), or covered recipient must have an opportunity to review and submit corrections to information submitted by an applicable manufacturer or GPO "for a period *of not less* than 45 days prior to such information being made available to the public." CMS proposes that the 45-day review period will be the primary opportunity to correct errors or contest data. Once the review period has passed, CMS is proposing that data could not be amended by any party for the remainder of that calendar year. **We believe that a physician's ability to challenge the accuracy of reports should not be limited to a 45-day window each year. Rather, CMS should work in an**

expeditious manner to correct misinformation that is identified outside review period, rather than waiting until the end of the calendar year to make corrections.

We believe that reporting error and the need for pre- and post-publication correction will be reduced significantly if manufacturers and GPOs are required to provide covered recipients, as well as third-party entities, with a "pre-submission review" of their reportable information. **Therefore, we recommend that CMS modify its proposal to require applicable manufacturers and GPOs to offer covered recipients and third-party entities pre-review of their information.** We further recommend that CMS require that manufacturers offer this pre-review quarterly, or, at a minimum, at six months and again at the end of the calendar year.

Public Availability of Reported Information

Public Web Site Disclosure

Our organizations agree with CMS' proposal that the public Web site should clearly state that disclosure of a payment or other transfer of value does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. **We also believe that the disclosure should indicate that the accuracy of the information has not been verified by CMS.** Furthermore, given the potential for inaccurate reporting and misinterpretation of information by the public, **we strongly recommend that the disclaimer must be presented as a "click through" page to which visitors must indicate that they have read the disclaimer before proceeding.**

Conclusion

While our organizations can appreciate the challenges that have accompanied the drafting of this proposed rule and enormous resources that will be required for implementation, we are troubled by the apparent disconnect between the intent of the legislation and the proposed regulations, and, as a result, the unintended consequences of implementation as proposed, including the costly burden on physicians and our organizations, as well as the potential for the credibility and reputation of physicians to be unnecessarily harmed. We understand the goal of increased transparency. Because it is unknown whether the law will be effective in achieving its intended goal of discouraging inappropriate relationships between physicians and industry, we ask that CMS consider carefully the recommendations of our organizations, as well as the comments submitted by the American Medical Association with multi-society support. We believe that our recommendations are reasonable, consistent with congressional intent, and will help reduce otherwise unnecessary regulatory burdens on physicians and organizations.

The AGA, ASGE, NASPGHAN, and AASLD appreciate the opportunity to provide comments on the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests proposed rule. If we may provide any additional information, please contact Elizabeth Wolf, director of regulatory affairs, AGA, at 240-482-3223 or ewolf@gastro.org; Camille Bonta, consultant to ASGE and NASPGHAN, at 202-320-3658 or cbonta@summithealthconsulting.com; or Sherrie H. Cathcart, executive director, AASLD, at 703-299-9766 or scathcart@aasld.org.

Sincerely,

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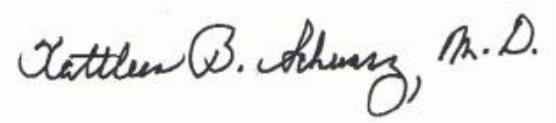

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