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October 10, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
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:

The American Medical Association (AMA) appreciated the opportunity to participate, along with the Centers for Medicare & Medicaid Services (CMS), in the September 12, 2012 Roundtable on the Physician Payments Sunshine Act (Sunshine Act) hosted by the U.S. Senate's Special Committee on Aging. In light of the issues raised, we are submitting follow-up comments to you on Sunshine Act implementation. Although the Roundtable participants represented disparate stakeholder interests, there appeared to be consensus on a number of key issues, including the need to ensure an adequate period of time for implementation prior to triggering the reporting requirement, limiting the scope of the reporting requirement to transfers explicitly specified by statute, and ensuring that legitimate, legal, and ethical transfers of value and other interactions between industry and physicians are not framed as suspect, inappropriate, or fraudulent. **All stakeholders agreed, including the U.S. Senators who introduced the Sunshine Act, that the purpose of the law is to promote transparency, not to chill, or curb, otherwise appropriate interactions that advance the art and science of medicine.**

As we have stated previously in discussions with CMS and in our formal written comments on the proposed rule, we support the underlying goal of enhancing transparency. However, 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. Below we have amplified on 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.

Implementation of the Final Regulation

The AMA supports transparency and to that end, we have worked with Congress on the Sunshine Act. As we noted during the Senate Roundtable, there were modifications made to the Sunshine Act that reflected a considered decision to avoid a "boil the ocean" approach to transparency reporting as this would create more questions than answers, increase disputes, and impose a substantial administrative burden.

Several key points that we made during the congressional debate and at the Senate Roundtable bear repeating here as CMS makes important decisions with regard to implementation of the Sunshine Act. It is critically important that the final rule and resulting mode of implementation do not create the impression that the transparency reporting requirements establish ethical standards or reflect program integrity or fraud and abuse laws.

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. **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 has 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.**[1] 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.

[1] In 2011, the AMA's House of Delegates, a deliberative body comprised of representatives from state medical associations and medical specialty societies, adopted an 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.

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.

The Sunshine Act does not set ethical standards for the medical profession nor does it codify fraud and abuse or program integrity laws. We urge CMS to take steps to make the foregoing clear. **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.

For the above reasons, we urge you to reconsider tasking the Center for Program Integrity with implementation of the final Sunshine Act regulation because it will cause significant confusion about the purpose of the transparency reports and create a strong perception that anything contained in a transparency report presumptively raises ethical, fraud, abuse, and program integrity concerns. The sponsors of the Sunshine Act made clear during the Senate Roundtable that this was not their intent since the majority of the interactions are appropriate. Yet, CPI's implementation could create the perception that the reports raise program integrity concerns. Combating this perception could be exceedingly difficult and will unduly chill appropriate, legal, and ethical physician-industry interactions that promote innovation and advances in clinical knowledge. While we appreciate that CPI has experience with the imposition of civil money penalties (which manufacturers potentially would be subject to if they fail to comply), **we recommend bifurcation of the responsibility whereby another component of the agency is responsible for the data collection, reporting, and appeals while CPI is referred**

compliance matters including enforcement. Further, we have additional concerns that some transparency reports—we anticipate a small number—could be used as evidence by CPI in its program integrity role and, yet, CPI would control the corrections and other elements of what would become evidence. This creates a strong perception of, if not an actual, conflict of interest where a component of an agency molds and generates the evidence that then is used by the very same component of the agency to establish violations of agency policies or fraud and abuse/program integrity laws. The foregoing is mitigated through checks and balances and is not an uncommon practice and policy within the U.S. Department of Health and Human Services.

Areas of Concern with the Proposed Rule

The following areas provide a summary of the AMA's additional concerns and recommended changes to the proposed rule.

CMS is Required to Publish Accurate Transparency Reports

CMS has proposed a process that would deny physicians substantive and procedural due process rights. The proposed process 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.

Limiting physician response to a 45-day window is inconsistent with Congress' intent to ensure such reports are accurate and is inconsistent with the fact that there is no similar constraint on requesting correction once a report has been made public. In light of the current state of technology, industry has the capability to allow for real-time updates and modification of reports. All of the foregoing was born out during the Senate Roundtable by the comments offered by the Sunshine Act sponsors as well as the industry participants that included representatives of pharmaceutical and medical device companies.

We strongly urge CMS to restructure the process that the agency has outlined and require industry to provide physicians with ongoing access to reports, provide physicians an opportunity to include commentary to any public disclosures of transfers, 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) Such as Certified CME

Although the statute limits reporting to direct payments/transfers of value to physicians (with certain carefully specified exceptions), CMS has proposed expanding the category of transfers subject to reporting to a broad class of indirect transfers. The statute requires that manufacturers report indirect payments and transfers of value made to third parties at the request of the physician or as designated by the physicians, thereby closing a potential loophole to avoid reporting that had characterized original Senate and House bills (S. 2029, "Physician Payments Sunshine Act of 2007" and H.R. 5605, "Physician Payments Sunshine Act of 2008"). By opening the door to a far broader number of indirect transfers that are of questionable relevance, the proposed regulation would obscure significant interactions between industry and physicians and impose a significant paperwork burden.

Equally concerning, CMS has proposed reporting standards that will include indirect transfers that occur through certified CME[2]—this interpretation is not supported by statutory language. 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. Furthermore, there was broad agreement among the Senate Roundtable participants that requiring reporting on indirect transfers including certified CME would pose a significant administrative challenge and were not the type of transfers that most concern patients.

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

Whereas the Affordable Care Act (ACA) provides for reporting of actual payments/transfers of value to a covered physician, CMS has proposed attributing a payment/transfer on the basis of a physician's employment, affiliation, or association with an entity or person that received a direct payment/transfer even if the physician him or herself did not receive any payment/transfer, direct or indirect. Attribution even where there is no direct transfer or qualifying indirect transfer is beyond CMS' statutory authority, violates basic principles of due process, and is inconsistent with congressional intent.

Congress did not intend that transfers of value made by manufacturers to an organization or entity that employ physicians be apportioned among physicians affiliated with the organization without regard to whether individual physicians received the transfer, requested

[2] Certified CME is defined as: 1. nonpromotional learning activities certified for credit prior to the activity by an organization authorized by the credit system owner, or, 2. nonpromotional learning activities for which the credit system owner directly awards credit.

the transfer, or designated a third party to receive it on their behalf. To do so could result in grossly misleading reporting. Physicians employed by a large organization or institution could have payments/transfers imputed to them that they had no knowledge of, no opportunity to decline, did not receive directly (or even indirectly), and are unable to challenge effectively. 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. We strongly oppose CMS' proposal for reporting of payments/transfers attributed to individual physicians solely on the basis of their affiliation with organizations or institutions that received payments/transfers of value.

We appreciate the opportunity to provide our views to CMS staff, and we look forward to working with you and other stakeholders to promote the goal of transparency in a meaningful manner. If you have any questions, please contact Carol Vargo, Assistant Director, Federal Affairs at 202-789-7492 or carol.vargo@ama-assn.org.

Sincerely,

James L. Madara, MD

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.

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

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.

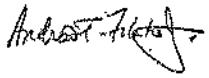
2. Page 78751, Column 2, (5) Indirect Payments Through a Third Party

   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:

Murray Kopelow, MD, MS(Comm), FRCPC
ACCME Chief Executive and Secretary
Accreditation Council for Continuing Medical Education (ACCME)



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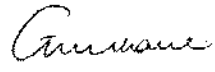

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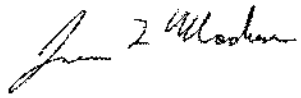

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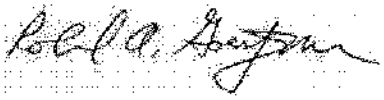

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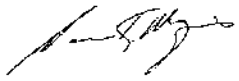

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