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

Submitted electronically at www.regulations.gov

Re: Docket Number CMS-5060-P, Notice of Proposed Rulemaking concerning *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests*, published in the December 19, 2011 Federal Register (76 FR 78742).

Dear Ms. Tavenner:

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to comment on the Notice of Proposed Rulemaking entitled *Transparency Reports and Reporting of Physician Ownership or Investment Interests*, issued by the Centers for Medicare and Medicaid Services (CMS).

The AAMC is a not-for-profit association representing all 136 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 62 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

The AAMC supports CMS' efforts to implement this important provision of the Affordable Care Act (ACA). An effective and principled partnership between academic medical centers and the industries that manufacture the products used to improve health is vital to encourage and facilitate biomedical research and to ensure advances in the prevention, diagnosis, and treatment of disease to benefit patients and populations. A critical component of these principled relationships is the transparency of the interactions. Ultimately, creating a national database of

this information can help increase understanding of the scope and nature of these interactions and maintain public trust.

Fundamentally, to achieve the goals of transparency the information provided by CMS on a publicly available database must be **accurate**, must represent **consistent application and understanding of definitions** by CMS, manufacturers, physicians, and teaching hospitals, and must include **sufficient context** for the information to be meaningful. Below we specify areas of the proposed rule that meet these criteria and that we believe are consistent with Congressional intent, and those provisions that we believe need revision or clarification to accomplish the statute's goals.

I. Definitions

Teaching Hospital

In the proposed rule, CMS defines a *teaching hospital* as any institution that received direct graduate medical education (DGME), indirect medical education (IME) payments, or psychiatric hospital teaching payments through the Medicare program during the most recent year for which data is available. The term teaching hospital has not previously been defined by Congress or by CMS through regulations. **The AAMC believes that the proposed definition is straightforward and appropriate for the purpose of identifying hospitals that are covered by the obligations of the proposed rule.**

Further, the AAMC supports the proposal to publish a list of teaching hospitals on the CMS website once per year to identify the institutional covered recipients for purposes of this rule. Once the appropriate entities are identified, the information CMS proposes to publish (each teaching hospital's name and address) will provide sufficient clarity for both teaching hospitals and manufacturers to identify which hospitals are covered entities under this regulation. For purposes of communicating with the teaching hospital, both by manufacturers and by CMS, we recommend that CMS list a single institutional contact or office, as designated by the institution, for each listed teaching hospital.

Applicable Manufacturer

The definition of *applicable manufacturer* is broad and generally captures the universe of entities from which reports of payments to physicians or teaching hospitals would be of value. We are concerned, however, that in some cases the broad definition of *applicable manufacturer* may inadvertently capture academic medical centers or teaching hospitals. We do not know how often this situation may occur, but recommend that CMS revise the proposed regulation to ensure that the definition of applicable manufacturer would not apply to academic medical centers or teaching hospitals when the result would be counter to the intent of the ACA.

In one example, an AAMC member institution produces a radiopharmaceutical agent for use in clinical diagnostic care and internal research purposes. The institution was required under FDA regulations to file an Abbreviated New Drug Application (ANDA) to continue producing the agent. In this particular situation, as a result of the FDA regulatory requirement, the institution now holds “Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply,” and might thus be considered an *applicable manufacturer* under the proposed regulation.

One solution is to clarify that an “applicable manufacturer” does not include an academic medical center or teaching hospital that manufactures or produces a drug, device, biological or medical supply for diagnostic, training, or research use, even if the use of that product may be reimbursable. CMS could also clarify that the “sale or distribution” of a covered drug, biological or medical supply product does not include an academic medical center or teaching hospital manufacturing and supplying a covered drug, biological or medical supply to its own or an another teaching hospital for diagnostic, training, or research activities.

It would not promote the goals of Section 6002 of the ACA if academic medical centers and teaching hospitals became “applicable manufacturers” for purposes of the regulations solely as a result of complying with the requirements of another regulatory requirement. Because an applicable manufacturer must report *all* transfers of value to covered recipients, not just those transfers of value linked to a covered product, the designation of an academic medical center as an applicable manufacturer would require the institution to report all payments or transfers of value *to all other teaching hospitals and non-employed physicians*. The data that would result and the systems needed to collect this information would lead to public reports of little value and absurd results.¹ AAMC does not believe that this was Congress’s intent, or is CMS’s intent in this proposed rule.

II. Unintended Consequences of Reporting Certain Indirect Payments

Statutory Support for Excluding Reporting of Indirect Payments

Several of our concerns relate to the potential difficulties and unintended consequences of reporting *indirect transfers* from an applicable manufacturer to a covered recipient. Congress recognized these concerns and addressed them by narrowing the scope of the reporting obligations included in the ACA from the language of the “Physician Payments Sunshine Act.”

¹ Further, because the proposed rule excludes from the definition of covered recipient any employee of an applicable manufacturer, if an academic medical center became an applicable manufacturer, no employed physicians of that entity would be covered recipients. Implicit in this definition is the assumption that a covered recipient is not contemplated to be an applicable manufacturer.

Both the House and Senate bills² introduced in the 110th Congress contemplated that manufacturers would report payments or other transfers of value provided “directly, indirectly, or through an agent, subsidiary, or other third party, to a physician, or to an entity that a physician is employed by, has tenure with, or has an ownership interest in.” The final language of Section 6002 of the ACA removed all reference to indirect transfers or transfers made through agents of the manufacturer or third party, and only requires reporting of “a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient.” The proposed regulation appears to be contrary to Congressional intent and again introduces the possibility of inaccurate or misleading information being included in the CMS database.

Section 403.904(a) of the proposed rule mirrors the language from the ACA, but adds the phrase “or a third party (on behalf of an applicable manufacturer)” to the end of the general rule.³ It is the addition of this phrase that broadens the potential payments that would be reported. **We suggest that the final rule echo the language of the ACA alone and that CMS revise the rule to ensure reporting of only those payments that are made directly to a covered recipient or are intended for specific covered recipients but are routed through a third party at the direction of the manufacturer.**

As further explained below, we have specific concerns with the effect of reporting indirect payments in the context of accredited CME programs, research grants provided to institutions, and donations or grants for which the ultimate recipient of the funds is not known nor could be reasonably assumed by the manufacturer.

Reporting of Indirect Payments for Accredited Continuing Medical Education (CME) Programs

AAMC has significant concerns about the reporting of indirect payments in the context of accredited CME programs. The clearest listed category of payments that must be included in the transparency reports is “Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program.” In the preamble to the proposed rule CMS asks “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.” The question suggests an incomplete understanding of the accreditation process for CME and the difference between an industry-sponsored speaking engagement organized by a commercial entity (whether for scientific or marketing purposes) and an accredited CME event.

² Physician Payments Sunshine Act of 2008, H.R. 5605, 110th Cong. (2008); Physician Payments Sunshine Act of 2007, S. 2029, 110th Cong. (2007).

³ Section 403.904(a) requires reporting of: “Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer).”

The category title as written provides evidence of Congress' intent to exclude from reporting those situations in which a commercial funder of an accredited CME program is wholly excluded from the process of designing the content of the program, and contacting and hiring speakers.

We urge CMS to retain the plain meaning of this category and to clarify, through the rule and associated guidance, that compensation to physicians who serve as faculty members for accredited CME providers should not constitute reportable indirect payments from applicable manufacturers who provide unrestricted grants to support the accredited CME program.

The standards for CME provider accreditation are specifically designed to prevent commercial interests from influencing both content and faculty for the programs. When an accredited CME provider receives funds to present an educational program, the standards of the Accreditation Council for Continuing Medical Education (ACCME) require that all key decisions in the development of the program be made "free of the control of a commercial interest."⁴

Commercial entities may provide unrestricted grants to an accredited provider to support medical education, with the full knowledge and understanding that the commercial entity will have no control over the identity of the speaker. Reporting such engagements as indirect payments from applicable manufacturers to the faculty physicians would result in information that would be inaccurate, misleading, and could serve to weaken public trust in the medical education of our healthcare workforce by suggesting a financial relationship between industry sponsors and faculty members that does not exist. Institutions that encourage their faculty to participate in accredited CME events often do so precisely because the link to commercial sponsors is broken by a accredited CME provider

We agree that when a manufacturer *directly contacts and compensates a physician* for serving as a faculty member or speaker, this interaction should be included in a publicly available database intended to provide transparency into relationships between physicians and industry. We support this transparency measure as well as real-time disclosures to ensure that the audiences of these events are made aware of the funding source for the speaker.

We are concerned, however, that the rule will be interpreted by manufacturers as requiring them to ascertain the identity of speakers chosen by accredited CME providers and report an unrestricted grant as a payment to a physician through a third party. Without a change to the rule, it is likely that when a physician is paid to serve as a faculty member for an accredited CME event supported by an unrestricted grant from a manufacturer, that compensation will be reported erroneously as an indirect payment to the physician from the manufacturer. In the proposed rule,

⁴ The standard in its entirety reads: "A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity." (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>)

no report of payment or transfer of value is required for indirect payments *when the applicable manufacturer is unaware of the identity of the covered recipient*. Although the commercial sponsor of an accredited CME program has no control over or input into the content or speakers presenting the material and is thus unaware of who will be asked to speak at the event, the identity of the speakers is readily available once the program has been finalized and is publicly announced. Applicable manufacturers may become aware of the identity of the speaker after the announcement or after the program, and may also be concerned that failure to seek out the names of the faculty would constitute “deliberate ignorance” or “reckless disregard” of their identities, under the definition of *know* in §403.903 of the proposed rule.

The reporting of an unrestricted grant to an accredited CME provider as an indirect payment made by a manufacturer to a physician speaker would mislead the public by suggesting that ACCME standards had been violated, the manufacturer had selected the speaker, and the educational content was potentially driven by the manufacturer. **In order to ensure that the information in the public database represents accurate and reliable information, unrestricted grants to accredited CME providers should be specifically excluded from the reporting requirements of the regulations.**

Reporting of Payments for Research

The importance of knowing the identity of research sponsors and any financial interests that could be perceived to affect the research results has led to robust systems such as disclosure requirements in publications for industry-sponsored research and internal financial and ethical reviews at institutions. It is equally important that information about industry-sponsored research reflect the process and structure of formal research agreements between industry sponsors and academic institutions. We are concerned that the proposal to attribute the full amount of the payment both to the institution that receives and manages the payment *and* to the principal investigators who conduct the research is misleading and mischaracterizes the relationship between the manufacturer and the physicians conducting the research.

When an industry sponsor provides funds to an institution for research, the payment is made in accordance with a budget and agreement negotiated by the sponsor and the institution. While some portion of the funds may be used to support the salary of the principal investigators who are committing an often pre-determined percentage of their time to the research, such payments cover many costs other than the investigators’ time and services, including, for example, equipment, diagnostic procedures, support and research staff time, and facility overhead costs.

Research-related payments made to institutions should be reported as payments to those entities, not as payments to individual physicians. We support CMS’ proposal not to include the value of research-related payments in the aggregated totals of payments made to individual physicians, but believe that this question of aggregation should not arise if the amount of the

payment made to an institution is attributed only to that institution. Even with the addition of an explanatory statement indicating that the physician is a principal investigator on the research, linking the full payment amount to the principal investigators suggests that research sponsors' payments are made directly to investigators and that the funds received by those investigators for research are controlled directly by the investigator. These assumptions do not reflect how industry-sponsored research is managed and funded. Additionally, in the case of multiple principal investigators, attributing the full amount of a payment to an institution *and* to each investigator could result in a database where the amount of a single payment provided by a manufacturer appears to be several times higher than the actual amount.

In consideration of the concerns outlined above, we recommend that CMS (1) include payments for research in a separate section of the database, (2) attribute the full amount of the payment only to the institution that receives and manages the payment, not to the principal investigators, and (3) publish information about research-related grants or payments in a context that clarifies the flow of funds and role of various covered recipients. For example, "a payment in the amount of \$xxx made to [name] institution for research conducted by the following principal investigators." Contextual statements drafted by a standing advisory board or convened stakeholder committee could provide general information about how such research agreements may cover portions of principal investigators' salaries.

Reporting Indirect Payments to Unidentified Recipients

The public database should provide information that is both accurate and meaningful. To achieve these goals, a payment reporting system should accurately capture not only the amount of the payment, but also the mechanism by which the payment is directed to a specific individual. The above examples of accredited-CME programs and principal investigators on research grants best illustrate the potential for publishing information that could cloud, rather than illuminate, the nature of the relationship between the reporting manufacturer and a physician or teaching hospital.

As institutional policies and systems are developed to administer the relationships between academic institutions and physicians, other similarly effective firewalls could be implemented to shield certain additional activities from perceived commercial influence. **Therefore, we suggest that the regulation state as a general rule that when the identity of a covered recipient is unknown at the time of payment or transfer of value, and the applicable manufacturer has no control of who will receive the transfer, the payment or transfer of value is not reportable as an indirect transfer to the covered recipient who eventually receives the payment.** If the payment was made to a third party at the request of or designated on behalf of a covered recipient, the payment would still be reportable under the proposed regulations.

III. 45-Day Review Period and Resolution of Disputes

After CMS has collected all submissions from manufacturers for the previous calendar year, covered recipients will be notified at the beginning of a 45-day review period, during which each covered recipient has an opportunity to see the reports of payments that have been made about that covered recipient, review the reports for errors, contact the manufacturer who made the report about the disputed report, resolve any dispute with the manufacturer, and report back to CMS whether or not a resolution has been reached. There is no requirement that this window be only 45 days; the ACA only requires that the period be “not less than 45 days.” We understand the statutory time constraints, but also recognize that CMS has the ability to provide more than 45 days for review. Under the statute, applicable manufacturers must submit annual reports to CMS by March 31 of the subsequent calendar year. After 2013, the review period must begin no later than May 16. To ensure the accuracy of the published information and facilitate the resolution of disputes, CMS has an obligation to provide access to the submitted reports as early and for as long as possible. **We urge CMS to provide the reported information to covered recipients as soon as possible after the March 31 manufacturer submission deadline in order to extend the review period to more than 45 days.**

Notification to Covered Recipients

Especially in the early years of implementation of this rule, the timely notification of covered recipients that the review period has begun is essential. Given the significant amount of work to be accomplished within this brief timeframe, we recommend that CMS use several methods to notify teaching hospitals and physicians. **We support the proposals to notify covered recipients of the commencement of the review period through the Federal Register and on the CMS website, and recommend that CMS also establish a notification system through which individuals and institutions can enter an email address through a website to get an email notification at the time that the date of the review period is known.**

We note that much of the burden of the 45-Day review period could be allayed by a system that provides earlier evaluation of the reported payments, prior to the review period. **We encourage CMS to work with manufacturers to develop a system through which covered recipients are able to review payments being reported throughout the annual reporting cycle.** Such a process could decrease the number of disputes and the likelihood that a dispute would be unresolved at the conclusion of the review period.

Review of Reported Information

The proposal to create a secure website through which covered recipients can review information specific to them is a good one. We recommend that CMS issue FAQs and instructions on the use of the website well in advance of the first review period, as there will be significant use of the

site as soon as the review period begins. **In addition, AAMC strongly recommends that for individual covered recipients, CMS allow physicians to designate an institutional proxy who is allowed to see and compile the information for employees or faculty.** Institutions where individual physicians teach, do research, or see patients have internal reporting requirements and processes for reviewing potential conflicts of interest. Other federal regulatory requirements, including the recent final rule on individual financial conflicts of interest in research funded by the Public Health Service,⁵ include requirements that certain relationships are publicly accessible, and some institutions include information about their faculty's financial relationships with industry on their own websites. The final publication of the CMS database should not be the first time that institutions are able to see the information that is reported, especially since CMS has proposed that no additional corrections can be made until the subsequent year's review and correction period.

Dispute Resolution

In the preamble to the proposed rule CMS states that it “should not be actively involved in arbitrating disputes ... regarding the receipt, classification, or amount of any payment or other transfer of value,” and proposes that covered recipients contact applicable manufacturers to try to resolve any dispute. Further, the proposal would result in the publication of two numbers (one provided by the manufacturer and one by the covered recipient) for any disputed transfers of value that have not been resolved by the conclusion of the review period. **We urge CMS to consider establishing a dispute resolution process that better addresses circumstances where an applicable manufacturer and a covered recipient cannot reach an agreement before the end of the 45-day review period.** We recommend that CMS provide more assistance in both these processes to ensure that published reports are accurate, and information about the nature of any unresolved dispute is readily available to the public.

The structure of the reporting system as laid out in the ACA and the proposed rule provides no incentives for manufacturers to resolve disputed payments unless the manufacturer has underreported a payment. If a covered recipient believes that a reported payment is too high, there is a potential for reputational harm, contradictions with other disclosures the covered recipient has made, or institutional processes triggered by a payment of a certain threshold. The penalties that manufacturers face for underreporting,⁶ however, could result in active dispute resolution processes only occurring when covered recipients suggest payments are missing or too low. The establishment of an independent third party who could settle unresolved disputes would be helpful in accomplishing the goal of the ACA to have accurate, meaningful reports

⁵ Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, Final Rule. 76 Fed. Reg. 0925-AA54 (August 25, 2011) (codified at 42 C.F.R Part 50 and 45 C.F.R Part 94).

⁶ Section 403.912(c) requires that the amount of civil monetary penalties will be determined, in part, by the “amount of the payment the applicable manufacturer or applicable group purchasing organization *failed to report*.”

publicly available. **A system in which the costs for the independent review would be borne by the manufacturer or by the party with the inaccurate amount in the dispute would increase incentives to resolve any disputes in a timely manner prior to the end of the review period.** AAMC would be happy to work with CMS to develop the framework for this type a system.

Reporting Disputed Payments

Section 6002 of the Affordable Care Act (ACA) requires that the information submitted by applicable manufacturers and made available through a website is “searchable and is in a format that is clear and understandable” and is “able to be easily aggregated and downloaded.” The proposal to publish both numbers in the event of an unresolved dispute about the value of a payment or transfer of value would thwart both of these requirements. First, the publication of two values could result in substantial confusion and an assumption that a disputed payment necessarily represents a suspect payment or relationship. Second, the publication of two values could lead to useless information in the aggregate, especially if there are multiple disputed payments or transfers of value to a single covered recipient. The number of disputed records may be high for two reasons: (1) the 45 day review period is insufficient time for covered recipients to both identify potential concerns and come to resolutions with each relevant applicable manufacturer, and (2) the proposed regulations provide neither a mechanism nor incentives for resolving disputes prior to public availability of the information. As described above, these concerns underscore the importance of incentivizing and facilitating the timely resolution of disputes so that a disputed payment reported in the database is a relatively rare occurrence.

In the event that the database is finalized as proposed and that all unresolved disputes are published with both disputed amounts, we suggest that the database include a free-text notation field to allow covered recipients to provide information about the nature of the dispute or the reasons it was not resolved during the review period. This approach is similar to that taken by the National Practitioner Data Bank when a physician wants to provide an explanation of a reportable payment. For purposes of aggregation of payments to a single covered recipient, it makes sense to include the covered recipient’s reported value, with an indication that one or more of the reported numbers is disputed by a manufacturer.

IV. Context and Education for the Public Database

We were pleased to see CMS’ intention not only to adopt wholeheartedly the statutory requirements that the public website contain background information on industry-physician relationships and present the information in the appropriate overall context, but also to clearly state on the website that “disclosure of a payment or other transfer of value on the Web site does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest

or any wrongdoing.” We question the use of the word “legitimate” in this context, as it suggests that CMS is disclaiming the accuracy of the reported payments. **The AAMC supports the inclusion of a similar statement, and we strongly recommend that CMS engage stakeholders to draft additional general and category-specific text to accompany the information provided in the database to ensure the clarity and context of the information.**

Without sufficient context, transparency measures may obfuscate the meaning of the information being provided. The broad nature of the proposed reporting requirements means that this database will have substantial information on a number of different types of payments and interactions between manufacturers and teaching hospitals and physicians. Category-specific context is critical to ensure that the information is meaningful. As important as explaining the types of payments that are in each category is the need for an explanation of what types of payments or relationships would not be covered by that category.

V. Estimated Burden on Teaching Hospitals

The Agency is required to estimate the burden that a regulation will impose on affected entities. However, we believe that the CMS estimate is inaccurate because it does not take into consideration the burden on teaching hospitals and physicians. While we recognize that neither the statute nor the proposed rule contains a recordkeeping requirement for physicians or teaching hospitals, we believe that it is important for CMS to acknowledge the significant regulatory and financial impact associated with the collection, review and correction process that teaching hospitals and physicians will incur. As detailed in our comments on the 45 Day review-period, institutions are already becoming concerned about the resources that will be needed to review all reported payments and address any disputes. The fact that all covered recipients will be attempting to resolve the disputes during the same timeframe only exacerbates the potential problems. Given the extensive impact of the regulation on covered recipients, we believe that the estimated burden for teaching hospitals of an average of 10 hours per year in the first year and 7.5 hours in subsequent years vastly underestimates the resources that will be spent by teaching hospitals in responding to the regulatory requirements.

VI. Additional Comments

Implementation Period

It is appropriate that the collection of information for the transparency reports should be delayed until after publication of the final rule to ensure that manufacturers and teaching hospitals and physicians are clear about the scope, categorization, and details of the reporting requirement. **AAMC supports the proposal to delay implementation of the requirements of the regulations until at least 90 days after publication of the final rule.**

Assumptions Documents

CMS has proposed that in order to ensure consistency in the reporting and selection of categories, applicable manufacturers may submit a document describing the assumptions used when categorizing the natures of payments to explain the reasoning behind their category selection. Although this is not a mandatory requirement and the information will not be posted on the public website, CMS proposes that it will help clarify how applicable manufacturers classify payments or other transfers of value and whether significant differences among applicable manufacturers exist. **We suggest that when a payment or transfer of value to a covered recipient is disputed, that manufacturers can opt in advance to make the assumptions document available to covered recipients to explain and potentially facilitate the resolution of disputes.**

Technical Correction

In the proposed §403.904(e), in the definition of “direct research,” the Notice refers to transfers of value provided to a “covered entity.” We believe that this term should be “covered recipient” as “covered entity” is neither defined nor used elsewhere in the proposed regulations.

At a time when physicians and teaching hospitals are committing substantial human and financial resources to providing information and context about their relationships and partnerships with industry, it is particularly important to ensure that the information collected and reported by CMS is accurate and meaningful. AAMC is willing to provide any additional support and input that would be helpful to the Department in realizing these goals. Please do not hesitate to contact me or Heather Pierce, Senior Director for Science Policy and Regulatory Counsel, at hpierce@aamc.org or (202) 478-9926 with any questions.

Sincerely,



Ann Bonham, Ph.D.
Chief Scientific Officer

cc: Heather Pierce, AAMC