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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Physician Payments Sunshine Act-comments on proposed changes

On July 3, 2014 the Centers for Medicare and Medicaid Services (CMS) released for comment proposed changes to the Physician Payments Sunshine Act. Thank you for providing the opportunity to comment on the proposed changes. I am a financial executive with experience in the medical device industry and recently coordinated the reporting for a medical device company under the Physician Payments Sunshine Act. **The comments in this letter are my personal opinions, not those of any organization.**

Since the initial reporting deadline was June 30, 2014, **CMS should wait and determine the overall effect of the regulations and the burden placed on the industry in reporting the information before considering any changes to the regulations.** The first cycle of reporting, verifying and posting the information on a CMS web site is not yet complete and it is premature to consider any changes to the regulations, particularly if the changes may increase the burden on the industry to report information. Clarification may be required in other instances.

Two of the proposed changes may increase the burden on industry and require significant changes in their systems for gathering and reporting information. The two changes are 1) requiring the reporting of the **market name** for **all** covered and non-covered drugs, biologicals, devices and medical supplies associated with a payment or other transfer of value and 2) removing the exclusion for compensation provided to physicians for speaking at accredited education programs.

Requiring the reporting of the **market name** for **all** covered and non-covered drugs, biologicals, devices and medical supplies associated with a payment or other transfer of value may be an onerous requirement. Many companies do not currently gather and record payments and transfers of value in a fashion that permits easy, or any, identification of the specific product by market name. Companies have families of products with each product having a separate market name and also have product systems with components of the system having a different market

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name. A payment or transfer of value could relate to a variety of products, a family of products or a product system. In one situation where a payment or transfer of value is made there could be discussion of a multitude of products with different market names. For example, in an educational or training meeting with a physician in which lunch is purchased for $11 for the physician, several product market names could be discussed. **Many current information and financial systems do not include a process for gathering specific product market names when a payment or transfer of value is made and any identification of specific product market names may be burdensome. In addition, a physician must later verify the payment or transfer of value and may not remember the specific product market names discussed, generally months before the verification is required.**

Removing the exclusion for compensation provided to physicians for speaking at accredited education programs is also problematic. Currently a payment or transfer of value to a physician for speaking at a continuing medical education program is excluded from reporting if (1) the program meets the accreditation requirements and standards for continuing education of one of five listed organizations*; (2) the manufacturer does not select the covered recipient speaker or provide the third party, such as a continuing education vendor, with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program; and (3) the manufacturer does not pay the speaker directly. I understand the proposal by CMS is to replace the existing exemption with the concept (emphasis added) of when an applicable manufacturer or applicable GPO provides **funding (suggest definition of this word)** to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients **(suggest adding ",as part of a written agreement,") to be considered** as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting. Since someone from the organization must certify to the report when it is made to CMS, this concept is not adequate. First **funding** of a program can be done in several ways...for example a donation of an amount as a sponsor, funding of a meal or social event for the participants (that is not paid to the program vendor) or by registering a number of individuals to attend the event. **The word funding needs to be defined so the reporting entity knows for which event payments should be evaluated.** For example, if a company recommends a certain speaker and then has employees register, pay a fee and attend the event...does this constitute funding?

In addition, contacts between a company and an accredited education program vendor mostly occur by the operations staff of the reporting company. Suggestions for speakers **to be considered** (as included above) can be made verbally or outside of a written agreement and these suggestions may not be documented and the certifier may not be aware of the suggestions for speakers to be considered. Accordingly, **I suggest that reporting be limited to those instances where a written agreement exists** and suggestions for speakers to be considered that are covered recipients are identified in the agreement. Gathering of information and reporting cannot be based on conversations that may have occured.

My understanding of the language that is proposed is to require (emphasis added) "the reporting of the following distinct forms of **payment**: stock, stock option and any other ownership interests". **Inclusion of the word payment eliminates the need to report any type of ownership outside the reporting period and any ownership that is not a payment, which I agree with.** For example, if a physician makes an investment in a company at fair market value of the company at the time the issuance of stock is not a payment and does not need to be reported, since it is not a **payment**. In addition it is my reading that any ownership interest existing during the period but the transaction to acquire the ownership interest occurs outside the period, this ownership does not require reporting since it is not a **payment** during the reporting period, which I agree with.

In some instances, companies are privately owned and not publicly traded. Therefore, the value of their stock and stock options may not be readily available at a point in time and the value may change, sometimes quickly, as positive or negative events occur for the company. Existing regulations require a value to be placed on the investment or option in order to report. **The new regulations should clarify whether the value of the payment should be based on the value of the service provided by the physician or the estimated value of the investment at the time of payment, if any.** Another option may be to not require a reporting of value which indicates to the consumer that a physician has an ownership interest, when the value of the investment or option is not available from a public market or other source.

The regulations do not exempt the reporting of some forms of transfer of value that are clearly not needed to be reported. For example if the CEO of an orthopedic company is married to a dentist and the CEO buys his wife a present for a special occasion, does that gift need to be reported? I would argue that it is clearly not the intent of the regulations but where is the line to be drawn on what transfers of value that are made for personal reasons are to be reported? **In my view any reporting should be limited to transfers of value or payments from a company to a physician in the same medical practice or specialty in which the company markets products, not any physician.** This will not result in a complete elimination of reporting requirements since if the company was in the orthopedic business and the wife is an orthopedic surgeon the gift for a special occasion would be required to be reported, which might have some justification to report.

Clearly these **proposed changes are too granular and would place additional burdens on many companies**, specifically the information technology and finance departments of the companies. Generally the information technology and finance departments design and implement the systems for payments and reporting. It frequently takes a significant amount of time to change the information gathering and reporting systems and to educate the users on what and how information is to be reported in the system.

Based on the above comments, **I suggest that CMS not implement any meaningful changes to the reporting requirements that would place additional burdens on companies until the impact of the existing regulations run through a complete cycle and the overall impacts of the**

existing regulations are evaluated. Once the full cycle is complete and the public has a full overview of the regulations impact, request comments on all aspects of the reporting requirements from the public.

Sincerely,

Robert J. Dickson

*The five organizations include: (1) the Accreditation Council for Continuing Medical Education; (2) the American Academy of Family Physicians; (the American Dental Association's Continuing Education Recognition Program; (4) the American Medical Association; and (5) the American Osteopathic Association.