AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY

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:

The American Academy of Child and Adolescent Psychiatry (AACAP) appreciates the opportunity to comment in response to the proposed regulations 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).

AACAP is a medical membership association established by child and adolescent psychiatrists in 1953. Now over 8,000 members strong, AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7-12 million American youth under 18 years of age who are affected by emotional, behavioral, developmental and mental disorders. AACAP's members actively research, evaluate, diagnose, and treat psychiatric disorders and pride themselves on giving direction to and responding quickly to new developments in addressing the health care needs of children and their families.

A physician's first obligation is their patients. For 56 years, AACAP has worked to facilitate transparency and disclosure throughout all aspects of our organization. At every level, we work to ensure that all children and adolescents living with mental illnesses receive treatment of the highest caliber. We have been diligent about making the process of assessing conflicts of interest easier and developed a transparency portal on our Web site to share AACAP's recommendations and policies.

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AACAP is pleased that the majority of the Proposed Rule conforms to the Affordable Care Act (ACA) statutory provisions and congressional intent; however, there are concerns that the 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 AACAP strongly supports the underlying goal of enhancing transparency, we believe the proposed rule, if implemented without modifications, could result in the publication of misleading information and impose costly and burdensome paperwork requirements on physicians.

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients (including arbitration) - II.B.4

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 that manufacturers/GPOs voluntarily employ a pre-submission review/dispute process for physicians and having 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, AACAP supports the use of the aggregated total specified by the physician.

AACAP opposes 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. The ACA provides physicians with a statutory right to challenge all reports even after publication. In the proposed rule, however, we believe this right is not clear. The ACA states that before a report is made public, physicians are to have 45 days at a minimum, to review and submit corrections. This does not apply to corrections after the reports are made public. AACAP is concerned that the proposed process does not provide an adequate means for physicians to challenge reports.

Inaccurate information could be publicly posted on a government Web site while denying physicians basic due process rights to challenge such information. 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.

The proposed rule outlines a process where the government would have no responsibility for ensuring the accuracy of publicly posted transparency reports posted by manufactures. 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. Errors can happen, primarily because 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 monetary penalties. 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.

Indirect Payments Though a Third Party - II.A.1.h.(5)
The ACA provides for reporting on direct transfers except where manufacturers are transferring payment or value to a third party at the request of the physician or designated on behalf of the physician. CMS's interpretation of "payment or other transfer of value," 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.

If this part of the rule were to apply, certified 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 as this information is typically public. Because many programs are published the manufacturer could know who the recipients are. But, the manufacturer cannot accurately report how to make proper attribution of value unless the CME provider 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.

Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program - II.A.1.g.(4)
We believe that CMS has exceeded its statutory authority to the extent it requires reporting on certified CME as Congress explicitly excluded certified CME from transparency reporting requirements. Though Congress contemplated including CME in transparency reports, it ultimately rejected this option. AACAP's CME programs follow the Accreditation Council for Continuing Medical Education (ACCME) Guidelines, as well as the our own *Operating Principles for Extramural Support of American Academy of Child and Adolescent Psychiatry (AACAP) Meetings and Related Activities*(attached).

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. 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.

Payments or Other Transfers of Value - II.A.1.d

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 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 could result in grossly misleading reporting. A physician employed by a large organization or institution could have funding and transfers credited to them in the report that they cannot reject, they do not receive directly (even indirectly in the weakest sense), and for which they have no knowledge so they are unable to effectively challenge it. We 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.

Additionally, those entities and individuals that are the recipients of a transfer of value must have the opportunity to review the data prior to it being made public just as the covered recipients are. This would violate the right of due process to these entities and individuals as well who may not be aware of the transfer, of the reporting process, or the impact the published data. Organizations such as not-for-profits are often the beneficiaries of these transfers of value and must be able to confirm the data before information that could be construed as misrepresenting the organizations' mission is placed for public view. The same review criteria for covered physicians should exist for the recipients of transfers. 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.

Research - II.A.1.g.(3)
For both indirect research and direct research for payments to teaching hospitals, funds should be attributed to the institution or teaching hospital, and not the physician-covered recipient serving as the Principal Investigator (PI) because in these situations they often do not receive any of the monies from the manufacturer funding as salary or other support. Attributing the full research payment to the physicians would be misleading and it would be difficult to determine exact amounts received by physician-covered recipients. Having payments to teaching hospitals listed twice, once as direct research to the teaching hospital and once as indirect research to the PI, is unnecessarily complicated and confusing for the public to understand.

Thank you for the opportunity to comment. If you have an questions, please contact Kristin Kroeger Ptakowski, Senior Deputy Executive Director; Director of Government Affairs and Clinical Practice at kkroeger@aacap.org, 202-966-7300, ext. 108.

Sincerely,

Martin J Drell MD

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President