



AMERICAN ACADEMY OF  
FAMILY PHYSICIANS  
STRONG MEDICINE FOR AMERICA

February 8, 2012

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

Re: Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Ms. Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 100,300 family physicians and medical students nationwide, I write in response to the [proposed Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests](#) as published on December 19, 2011 in the *Federal Register*.

Overview

The AAFP supports and values transparency as it can help the public and policymakers understand the dynamic relationships between health care professionals and the medical industry. As such, we support Section 6002 of the *Affordable Care Act* which this proposed rule aims to implement. However the proposed reporting requirements create significant complexities, such that CMS estimates it will cost healthcare companies and health care providers \$224 million in the first year, and over \$163 million annually thereafter to comply. Therefore the AAFP offers the following recommendations to improve the final regulation.

Need to Ensure Accuracy

The AAFP [policy](#) on transparency explicitly states that any reported information needs to be easily verified for accuracy. The proposed rule fails to address adequately the need for robust safeguards so that CMS posts only accurate information online. Erroneous and potentially negligent reporting practices could be misleading and have severe implications for a physician's credibility with patients. The AAFP therefore encourages CMS to reexamine the agency's role and responsibilities to prevent the dissemination of inaccurate or disputed data.

We urge CMS to establish a uniform, national, and mandatory data verification and arbitration process. This should involve an ongoing pre-review ability so physicians can easily identify and quickly resolve conflicts before inaccurate information becomes publicly available. We do not support any proposals that attempt to sidestep inevitable disputes by merely publishing both the applicable entity's reported value and the

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physician's self-reported amount. In addition, CMS should structure the review and arbitration process such that physicians do not incur legal fees to defend themselves from erroneous manufacturer reporting.

The AAFP appreciates that the proposed rule recognizes the need for the agency to identify “a streamlined and automated process for reporting disputes and changes to ensure that the review and correct process is as smooth as possible” and eagerly awaits further details. The AAFP also encourages CMS to work with physician organizations on this process in order to achieve these goals.

### Indirect payments

Section 6002 of the law specifically states that reportable transfers of value do, “not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.” The AAFP is therefore very concerned that CMS commentary in the proposed rule discusses indirect transfers of value. Since the AAFP was involved in legislative negotiations that ultimately resulted in the *Affordable Care Act*, we are aware that previous versions of the underlying bill included language that considered indirect payments a reportable event. However, since the statute was intentionally finalized to specify that indirect transfers of value are not reportable events, the AAFP believes that CMS does not have the authority to expand beyond the scope of the law and propose policies that require in any circumstance that an indirect transfer of value be reported.

Physicians must stay up to date on the latest medical research and medications so they can provide the most appropriate care to their patients. Each year, this research results in new treatment breakthroughs, medications, diagnostic procedures, and clinical guidelines. Communication between physicians, device manufacturers, and pharmaceutical companies is critical if physicians are to remain current with the latest research. Physicians stay informed through continuing medical education, professional meetings, research journals, and meetings with pharmaceutical and other medical company representatives. The AAFP is committed to supporting physicians' continuing professional development and lifelong learning, including participation in certified or accredited Continuing Medical Education (CME). Some of these programs are supported by industry through a rigorous grant review process.

In the context of Accredited and Certified CME, direct payments to physicians (either in the role of faculty or attendees) by companies are prohibited and therefore would be irrelevant when it comes to disclosure under Section 6002. Manufacturers will not be in a position to comply, as they have no relationships with CME faculty, either directly or indirectly.

The AAFP strictly adheres to the “Standards for Commercial Support (SCS): Standards to Ensure the Independence of CME Activities” of the Accreditation Council for Continuing Medical Education (ACCME). The SCS (most recently revised in 2004) outlines standards for relationships between Accredited and Certified CME Providers and the companies that may provide grants to CME providers. Faculty of certified and accredited CME programs are selected, directed, reviewed, evaluated and paid by the Accredited CME providers, and have no relationship with the manufacturers. Indeed, this is a requirement of both SCS and the “Code on Interactions with Health Professionals” of the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

As the nation's leading CME provider organization for one of the nation's largest physician member specialty societies, as well as one of the three national credit systems for physicians, the AAFP strongly supports having safeguards in place to ensure CME independence, validity and relevance. The AAFP has instituted guidelines and policies to provide for physicians, whether learners or faculty, the assurance to clearly identify CME programs that are ethically sound, evidence-based, scientifically objective, clinically relevant, and educationally effective. The AAFP has consistently implemented a variety of strategies and mechanisms

to manage relationships between CME and industry, in order to identify, disclose, and mitigate real or potential conflicts of interest. The AAFP closely monitors its adherence to the ACCME 2004 SCS, and compliance with SCS is a requirement for our credit certification. In addition, the AAFP adheres to other pertinent standards, laws, regulations, ethical codes, guidelines and considerations that enhance our ability to ensure the identification, disclosure, and resolution of real or perceived conflicts of interest.

However, CME faculty and attendees have relationships with the actual CME provider, such as the AAFP, not the supporting company. Since the AAFP already follows the ACCME SCS, we strongly urge CMS to clarify in the final rule that all certified and accredited CME activities are excluded from reporting.

The AAFP and the AAFP Foundation both aim to advance the value of family medicine by promoting humanitarian, educational, and scientific initiatives that improve the health of all. Some of these efforts are supported by the medical industry. If funds from the medical industry are contributed to the AAFP or the AAFP Foundation they are considered reportable under Section 6002, these important efforts could be hampered because physician interest would likely decrease. For example, efforts that could be less appealing to members might be:

- The AAFP Vaccine Science Fellowship - funding supports focus group research designed to identify barriers to immunizations.
- The Office Champions Tobacco Cessation Project - funding covers clinical time spent on chart reviews, evaluations, staff training, writing clinical content for practice manuals, or leading training sessions. Participants' practices complete a W-9 form and provide their Employer identification number.
- Americans In Motion—Healthy Interventions (AIM-HI) – grant funds are used to pay family physicians to present at AAFP conventions and conferences on the subject of fitness. The AAFP (not the funding entity) decides which physician is selected to present.

In the final rule, the AAFP urges CMS to specify that only direct transfers of value to physicians are reportable events. This would establish a clear distinction between reportable and non-reportable transfers of value. Specifying that only direct transfers of value are reportable would also significantly simplify compliance with Section 6002 requirements.

### Meetings and Conventions

The AAFP appreciates that CMS streamlines reporting requirements by proposing that applicable manufacturers do not need to report any offering of meals, snacks, or coffee at medical industry conferences, booths or events where CME certified or accredited educational materials are offered. As noted in the proposed regulation, it would be administratively burdensome and difficult for applicable manufacturers to definitively identify participants.

Regarding “speaker fees,” paid by manufacturers to speakers at promotional educational programs, the AAFP agrees with the CMS proposal that these are reportable events under Section 6002. However, CMS should clarify in the final rule that speaker fees for accredited and certified CME programs should not be considered reportable events since these are indirect payments and covered under ACCME SCS.

### The Medical Practice

The majority of AAFP members are busy practicing medicine and do not frequently consult, travel, or have a direct ownership interest on behalf of any specific medical product or prescription drug; thus, the impact of Section 6002 reporting requirements should be minimal on the typical family physician. The AAFP appreciates the illustrative examples provided by CMS in the proposed rule regarding situations when an applicable entity’s representative visits the medical practice. In the spirit of streamlining reporting

requirements and serving both educational and outreach purposes, the AAFP requests that CMS expound further and offer supplementary examples of both reportable and non-reportable events that can occur when a representative meets with the medical practice.

The AAFP strongly objects to the CMS proposal that, in instances where group meals are being provided in a group setting (for example, buffet style food in a physician's office), applicable manufacturers report the cost per covered recipient receiving the meal even if the covered recipient does not actually partake of the meal. This will result in inaccurate and misleading reporting. The AAFP urges CMS to specify that Section 6002 reporting requirements only apply to physicians that personally decide to accept such transfers of value from applicable entities.

The AAFP remains extremely concerned with the proposed 45-day review period. For such a new and complicated program, that time-frame is simply too brief for a practicing physician to access, review, and then potentially appeal a detailed financial document. The AAFP appreciates that CMS recognizes this is problematic since the proposed rule discusses that "it may be difficult for CMS to contact covered recipients and physician owners or investors, since they do not actively participate in the data submission process with CMS prior to their review, so we propose to notify covered recipients and physician owners or investors in a few ways." The AAFP finds it unreasonable to suggest that practices must habitually find and check various CMS websites or electronic newsletters for updates on their transparency reports. Placing this unnecessary responsibility onto the practice will consume a tremendous amount of valuable time and resources that should be spent on patient care. Instead, the AAFP urges CMS to work with physician organizations to strengthen and lengthen the review process.

### Teaching Hospitals

The *Affordable Care Act* specifically requires applicable entities to report on transfers of value made to "teaching hospitals" defined as those entities that receive Medicare Graduate Medical Education or Indirect Medical Education payments. Although this definition may omit a few entities with teaching programs, we find this approach to be a reasonable proposal.

### Research

Since the proposed rule creates risk in showing a financial relationship with an applicable entity, the AAFP is concerned that these reporting requirements could deter physicians' willingness to conduct medical research. It is the AAFP's position that shedding light on the nature and extent of financial relationships between physicians and applicable entities in no way should interfere or disrupt clinical research.

Physicians conducting clinical medical research have direct financial relationships with their academic institutions. These institutions may receive support from applicable entities, but the AAFP encourages CMS to specify in the final rule that Section 6002 reporting requirements do not apply to clinical research when funds are indirectly made to the researcher.

In addition to specifying that indirect transfers of value are not reportable events, the AAFP also urges CMS to specify in the final rule that approved clinical research subject to "human subjects IRB review" is excluded from these reporting requirements since most clinical research already requires that financial ties to manufacturers be disclosed.

### Consumer Website

The proposed rule indicates that CMS will provide educational information for the general public on a website. The AAFP strongly urges that the content of this information be promulgated as a proposal with the

opportunity for public comment to be sure that the information is useful and unbiased. CMS must avoid casting an unfavorable or incomplete light on the appropriate collaboration that exists among physicians, teaching hospitals, and industry manufacturers. We appreciate CMS's recognition that disclosures alone are not sufficient to differentiate legitimate and beneficial financial relationships from those that create conflict of interests or are otherwise improper.

Conclusion

The AAFP strongly urges your consideration of these recommendations for improving the proposed rule and avoiding unintended consequences that will undermine commercially supported CME in particular. Several months after the final rule becomes effective, we suggest that CMS reassess Section 6002 reporting requirements and improve the program by removing any identified inefficiencies. We make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or [rbennett@aafp.org](mailto:rbennett@aafp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Roland A. Goertz". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Roland A. Goertz, MD, MBA, FAAFP  
Board Chair