



February 16, 2012

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS -5060-P: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Ms. Tavenner:

On behalf of the National Physicians Alliance, I ask CMS to consider the following comments regarding proposed rules CMS-5060-P: Medicare, Medicaid, Children's Health Insurance Program; Transparency Reports and Reporting of Physician Ownership or Investment Interests.

The National Physicians Alliance (NPA) is a nonpartisan, nonprofit 501(c) (3) research and educational organization that promotes health and fosters the engagement of physicians within communities across the country in an effort to achieve high quality, affordable health care for all. NPA supports the proposed rules published in the Federal Register, vol. 76, no 243, pages 78742 – 78773, as they would lead the way to implementation of Section 6002 of the Patient Protection and Affordable Care Act of 2010 (PPACA). This section of the PPACA requires drug, device, biological, or medical supply manufacturers to report certain payments and transfers of value to covered recipients, entities, individuals and teaching hospitals, and also requires the reported information to be available on a public website.

The NPA strongly supports public disclosure of payments and gifts to covered entities from manufacturers described in the PPACA and urges CMS to finalize rules that promote greater transparency regarding such payments. We have received dozens of general comments from our members asserting the need for such disclosure. Examples include:

- *I am a physician in academia who has worked in the pharmaceutical industry. I strongly support disclosing payments and gifts from the pharmaceutical and device industry as well as any other industry that can profit from physician decisions. Our patients come first and transparency helps with our integrity.*
- *It's very important for the integrity of the medical establishment to require drug companies and manufacturers of medical devices to disclose payments made to doctors for speaking, research, travel, entertainment and consulting.*

- *It is only fair that patients and the public be able to assess their physicians' industry connections and make informed decisions as to whether or not these connections impact their care. Making this information public is a necessary step to return integrity to medicine.*
- *Full transparency – please require disclosure of all these payments.*

While NPA believes the proposed rules offer a good start in providing greater transparency and urges CMS to adopt rules as soon as possible so data collection can commence, we believe a few issues need further work or clarification before the rules are finalized.

Definitions Regarding Nature of Payment: NPA urges CMS to provide clearer definitions for each “nature of payment” category listed in the PPACA. The proposed rules allow manufacturers to use dictionary definitions. This is problematic because dictionaries often provide multiple definitions for one term or word. The result could be potentially significant inconsistency in reporting, which would confuse consumers and others seeking to use the reports. NPA appreciates the proposed rules requiring each payment made by manufacturers to be reported as only one “nature of payment” category and urges CMS to require that disclosure of lump sum payments/transfers of value be reported in detail, with different aspects of such payments broken down and reported separately within a specific “nature of payment” category.

Exclusions/Educational Materials: NPA understands that educational materials which directly benefit patients or are intended for patient use are excluded from disclosure requirements in statute. NPA recommends CMS limit such exempted material to those that are purely educational and that in contrast, all marketing or advertising materials provided by manufacturers for patient use be included in the reporting requirements. Further, NPA believes that any educational materials provided to covered recipients (prescribers, teaching hospitals and other entities) to educate the covered recipients themselves, but which are not actually given to patients (e.g., medical textbooks) should absolutely be included as part of the reporting requirements. Such materials can have significant financial value and should not be exempt.

Research: NPA supports requiring the disclosure of research payments made to teaching hospitals or other third parties in cases where the manufacturer knows who will serve as the principal investigator for research. Because large research payments may be awarded or given to teaching hospitals or other third parties under the guise of a principle investigator, without information on other physician researchers who may also receive a portion of the research payment, NPA recommends CMS strengthen reporting requirements regarding these payments to include: 1) the amount of the total research payment, 2) the amount that will be passed along to the PI, and 3) the amounts paid to other physicians participating in the research who may be paid directly by the teaching hospital or other third party or indirectly through other research contracts.

NPA also urges CMS to require manufacturers to submit corrections to their annual reports in any event where the manufacturer has learned the identity of a physician who received a payment as a result of a research payment made to a teaching hospital or other third party. NPA recommends that CMS require manufacturers to collect information on all physicians who receive funding as result of research payments and that such information should be submitted with the same level of detail that would have been required had they learned of the payment prior to submission of the original report.

Report Certification: NPA also supports the proposal to require that each report and correction submitted by a manufacturer/applicable group purchasing organization include certification by the chief executive, financial or compliance officer that the report is true, correct and complete to the best of his or her knowledge and belief.

Public Availability: NPA believes the final regulation should include more information regarding how payment information will be presented on the public website. We believe the information should be simple to access, easy to understand, and straightforward to use. We urge CMS to provide opportunity for public discussion/comment on the proposed website design, perhaps through a public forum where the proposed site could be viewed, considered and refined.

Compliance: NPA recommends that CMS provide greater detail on specific enforcement mechanisms that will be put into place to ensure manufacturers and others required to report information comply with the law and the final rules. NPA urges CMS to provide additional information regarding which agencies will be responsible for making sure manufacturers comply with the final rules, including who is responsible for investigating the lack of reporting and inaccurate or incomplete reporting as well as steps to be taken to identify the failure to report.

The National Physicians Alliance appreciates CMS's thoughtful consideration of these comments. Feel free to contact me at 202-420-7896 with any questions or if you would like more information about the National Physicians Alliance. We are very supportive of this initiative and want to see it succeed in its purpose.

Sincerely,

A handwritten signature in black ink that reads "Jean Silver-Isenstadt". The signature is written in a cursive, flowing style.

Jean Silver-Isenstadt, MD, PhD
Executive Director