



June 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Agency Information Collection Activities: Submission for OMB Review; Comment Request [Document Identifier: CMS-10495]

Dear Administrator Tavenner:

The American College of Physicians (ACP) appreciates the opportunity to provide comments on the above referenced U.S. Department of Health & Human Services (HHS) Agency Information Collection Activities: Submission for OMB Review. The College, while supportive of the transparency provided under the Open Payments program regarding industry-physician relationships, has significant concerns regarding the dispute resolution process included in this submission. **The College strongly urges CMS to modify their indicated processes to prevent what appears to be the ability of an applicable industry representative to unilaterally dismiss a dispute from a reported data element regarding a covered physician or teaching hospital.**

The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 137,000 internal medicine physicians (internists), related subspecialists, and medical students committed to advancing the science and practice of medicine. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College's understanding from the Open Payments program final rule (CMS-5060-F, February 8, 2013) is that covered physicians and teaching hospitals would have an opportunity to review industry reported data prior to public display, and request correction of any apparent inaccuracies. CMS is obligated to provide a mechanism to facilitate communication between the reporting industry entity and the covered physicians/teaching hospitals for the purpose of addressing and ideally resolving any noted discrepancies. Discrepancies that cannot be mutually resolved will then be publically displayed as reported by the industry entity, but flagged as disputed. It was our further understanding from the final

rule that this dispute flag would remain until the issue was resolved in a mutually acceptable manner by both parties. This was perceived by the College as a reasonable approach.

A review of the recently submitted information to the Office of Management and Budget (OMB) appears to reflect a significant change in the Open Payments program from the final rule. Before outlining this apparent change, we must note that the brief time period (30 days) to review this complex material, and the format in which it was released—a series of miscellaneous documents enclosed in a zip file with minimal explanatory language—has made understanding of the proposed dispute processes very difficult.

It is our current understanding that under the recently submitted OMB review procedures, the industry entity would have the right to unilaterally decide to dismiss an indicated dispute. This understanding comes primarily from the document *Open Payments System: Review and Dispute Email Notifications, Centers for Medicare & Medicaid Services, April 2014*, where on page 2 the agency proposes to provide the following notification to manufacturers after a physician or teaching hospital has initiated a dispute:

“You [the manufacturer or GPO] may resolve the dispute by submitting and attesting to the corrected data. After reviewing the disputed information, if you determine that no change is required to the data, **you may dismiss the dispute** (emphasis added) or request that physician or teaching hospital who initiated the dispute to withdraw it.”

The College believes that this apparent new right of the industry entity to dismiss the dispute unilaterally is in direct violation of the final rule. It further places covered physicians and teaching hospitals in the position of having financial information about them publically reported without indication of possible inaccuracy, which has the potential for significant adverse effects to their professional reputation and related activities.

The College urges CMS to revert back to the procedures outlined in the final rule, which maintains an indication of a disputed reported data element until the dispute is resolved in a mutually acceptable manner by both parties.

Please contact Neil Kirschner, PhD at 202 261-4535 or nkirschner@acponline.org if you have any questions regarding this comment letter.

Respectfully,

A handwritten signature in black ink, appearing to read "David A. Fleming" with a stylized flourish at the end.

David A. Fleming, MD, MA, FACP
President, American College of Physicians