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June 2, 2014 ***Submitted Electronically***

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard
Baltimore, Maryland 21244–1850

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

Dear Administrator Tavenner:

The American Urological Association (AUA), representing more than 90 percent of the practicing urologists in the United States, welcomes the opportunity to submit comments for revision of a currently approved collection titled *Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments.* The long-standing mission of the AUA is to promote the highest standards of clinical urological care through education, research and formulation of health care policy. We appreciate your attention to the concerns of America's urologists.

**Background**

In the final rule on Transparency Reports and Reporting of Physician Ownership or Investment Interests, the Centers for Medicare & Medicaid Services (CMS) agreed that effective and accurate resolution of disputes is essential to the Open Payments program, and believes the agency does have a responsibility to facilitate the capability for correcting data and resolving disputes among parties, but should not be actively engaged in mediating dispute resolutions. In justifying this decision, CMS notes that it is the manufacturers and group purchasing organizations (GPOs) that are responsible for collecting, reporting, and attesting to the accuracy of information.

The final rule allows 45-days for a covered recipient, physician owner or investor to review and either certify or dispute the data published on their behalf by a manufacturer or GPO.

If a covered recipient, physician owner or investor decides to initiate a dispute, he or she will be directed to fill out details on the secure CMS website. The system will automatically flag the transaction and notify the manufacturer or GPO. The manufacturer or GPO will have 15 days to resolve the dispute and submit corrected data.

If the parties reach a resolution, the manufacturer or GPO must submit a correction to CMS within the allotted time frame and re-attest to the new data by the end of the resolution period. CMS will then publish the corrected information. If a dispute cannot be resolved during the 15 day resolution period, CMS will publish the original, attested data, marked as disputed. Although disputes that remain unresolved may still be subsequently resolved, CMS will publish the corrected information after the Open Payments reporting cycle.

**Comments on the Dispute Resolution Process**

The AUA believes that CMS should be actively engaged in mediating dispute resolutions. CMS should be actively involved in arbitrating disputes between manufacturers or GPOs and covered recipients or physician owners regarding receipt, classification, or amount of payments or transfers of value. We believe it is unreasonable to require physicians and their staff to continuously initiate disputes and revive disputes that remain unresolved. Time spent lodging disputes will force physician practices to redirect already scarce time and resources away from providing direct patient care. **As stated in a prior AUA comment letter, to ease the burden of the dispute resolution process, we believe that CMS should accept responsibility for assuring the accuracy of data it publishes in a public website.**

In addition, the AUA is opposed to CMS' plans to move forward with publication of data in dispute. While we recognize the underlying transparency goal of Open Payments reports, we are concerned that publicly posting information that may be false or inaccurate on a federal government website may be misleading and may harm a physician's reputation. Moreover, posting misleading information before it is resolved seems counterintuitive to what a dispute resolution process indicates. **In an effort to reduce the potentially damaging effects of the dispute resolution process, we recommend that CMS withhold publishing data to the Open Payments website if it has been contested, rather than posting the information and flagging it as disputed while waiting for manufacturers or GPOs to correct any inadvertent errors or omissions, or should the affected parties fail to reach a resolution.** This approach also will ensure the dispute resolution process is working as intended.

CMS previously announced the portal for physicians to register and receive notices when data reports are available for review would be launched in January 2014.

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CMS' website currently notes that registration for physicians and teaching hospitals will be conducted in two phases for this first Open Payments reporting year. Starting June 1, physicians and teaching hospitals will be able to register in the CMS' Enterprise Portal. The second phase will start in July. According to the website, at that time, physicians and teaching hospitals will be able to review data that will be made public. CMS also expects final data submissions and attestations to be completed by June 30, in preparation for release to the public by September 30.

We are concerned that the condensed timeline will not provide sufficient time to process registrations. **In light of the repeated delays and general confusion with implementation of key program elements, the AUA recommends that CMS delay publication of information collected under the Open Payments program for six months, to allow adequate time for physician registration and to ensure the database mechanism to process disputes is fully operational.**

The AUA recognizes the importance of providing a reasonable process to resolve disputed data published on the Open Payments website and we appreciate the opportunity to provide comments. If you would like to discuss any aspect of our comments, please contact Lisa Miller-Jones at lmiller@auanet.org or (410) 689-3772. We would be happy to answer your questions.

Sincerely,

David Penson, MD, MPH
Chair, Health Policy Council