

March 18, 2014

Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Sunshine Act (Open Payments Program) Implementation and Physician Registration and Dispute Process**

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to convey the AMA's strong concern with the Centers for Medicare & Medicaid Services' (CMS) decision to delay and reduce the timeframe provided for physicians to register with the agency's Physician Payments Sunshine Act system (referred to by the agency as the Open Payments Program). This has unreasonably shortened the period of time in which physicians will be able to register with the Open Payments Program system, and will adversely impact their ability to challenge false and inaccurate reports.

Background

Physicians are facing an unprecedented number of challenges—quality reporting, meaningful use, ICD-10, payment and delivery reform, and a host of changes resulting from the Affordable Care Act. Taken together, these costly changes are likely to lead to significant practice disruptions and administrative burdens over the next few years. This is why the AMA was pleased when agency officials repeatedly indicated that physicians could begin to access the Open Payments Program system on January 1<sup>st</sup>, thereby ensuring any problems with registration would be resolved before physicians began accessing and, if necessary, disputing their individual reports. Although CMS indicated through most of 2013 that physicians, manufacturers, and group purchasing organizations (GPOs) would be permitted to register with the Open Payments Program system on January 1<sup>st</sup> of this year, this deadline passed without notice or comment by the agency.

In February, CMS announced that manufacturers and GPOs would be permitted to register, but are not yet able to submit their reports. This is in direct conflict with the regulation and raises very serious concerns that CMS will not have adequate time to prepare accurate, individualized consolidated reports for physicians. CMS is building a new system that reportedly has not been beta tested, and the amount of data that will be submitted by manufacturers and GPO is substantial. The AMA is also concerned that there will be inconsistencies in reporting across manufacturers and GPOs that will further undermine the accuracy and consistency of the reports.

In light of the foregoing, there is a compelling need to ensure that physicians have an adequate amount of time to register with the Open Payments Program system, to review their consolidated reports, to dispute errors, and obtain corrections. Unfortunately, CMS declined to mandate that manufacturers and GPOs provide physicians the option to review their disclosures and to correct errors before the data are submitted to CMS. As a result, it will be very difficult to determine whether errors are a result of faulty manufacturer and GPO reporting or CMS. The decision to deny physicians the ability to dispute and ensure accurate information, is submitted to the federal government is at odds with statutory language that requires CMS to ensure accurate and fair reporting.

CMS has an obligation to implement a process that produces accurate reports and cannot deprive physicians of their ability to protect themselves from the deleterious impact to employment, grants, professional standing, and associations that will result from false and misleading reports. More concerning still, the agency acknowledged in the final rule published on February 8, 2013, that transparency reports could bring to light potential liability associated with payments or other transfers of value, or ownership or investment interests under the Federal Anti-Kickback statute or the False Claims Act. This is alarming where there is a high probability of inaccurate or misleading reporting, resulting from deficiencies in manufacturer and GPO reporting or the limitations and shortcomings of the database and analytics CMS deploys to consolidate individualized physician reports. CMS cannot deny physicians the right to protect their professional standing and reputation by failing to provide adequate notice and time to register, limiting availability of reports, arbitrarily limiting the time physicians have to flag disputes, and denying physicians a right to publicly provide comment on all transfers through the existing platform.

We strongly urge CMS to compel manufacturers to begin registering and submitting their data by March 31, 2014, as already provided in the regulation. Further, we urge CMS to immediately permit physicians to begin registration in the Open Payments Program. **Finally, if CMS is unable to do the foregoing, CMS must take steps to adjust the public reporting date until the agency can ensure that physician due process rights are protected, and the agency has in place a process and system that will produce accurate reports.** If you have any questions, please do not hesitate to contact Jason Scull, Assistant Director of Federal Affairs, at 202-789-4580 or [jason.scull@ama-assn.org](mailto:jason.scull@ama-assn.org).

Sincerely,

James L. Madara, MD