

August 8, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Delays in the Open Payments Review and Dispute Process

Dear Administrator Tavenner,

The Association of American Medical Colleges (AAMC) is concerned that the validity and usefulness of the Open Payments website is threatened by recent delays and complications in the Open Payments process for reviewing and initiating disputes related to reports of payments and transfers of value from manufacturers to physicians and teaching hospitals. The AAMC, a not-for-profit association, represents all 141 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions, the AAMC represents 128,000 faculty members, 83,000 medical students, 110,000 resident physicians, and thousands of graduate and post-doctoral trainees in the biomedical sciences.

The “Sunshine” provisions in Section 6002 of the Affordable Care Act reflect Congress’ intent that pharmaceutical, device or other manufactures of covered products annually report to the Centers for Medicare and Medicaid Services (CMS) payments or transfers of value made to physicians and teaching hospitals. CMS is required to make that information available to the public after physicians and teaching hospitals have had an opportunity to review the reported information and dispute any listed payments that appear to be incorrect. The final rule (78 Fed. Reg. 9458) further specifies that if an initiated dispute “is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer’s or applicable group purchasing organization’s version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.” Thus, any record not marked as “disputed” may be presumed by the public to be either accurate as originally submitted or resolved after communication between the parties (i.e., the manufacturer and the covered recipient).

The announcement on Friday, July 11th that the Open Payments registration and opportunity to review reported payments would open on July 14th and close August 27th gave teaching hospitals, physicians, and institutions that employ physicians little notice for this critical process. The first days of registration were marked by technical problems and difficulties getting into the Open Payments site, and institutions have struggled to provide physicians with the support they need to get through the many required steps before they can access reported payments. *The Open Payments system has been inaccessible since Monday, August 4th, with no indication from CMS as to when it will be available again.* During this brief 45-day period for reviewing reports and initiating disputes, to have no access to the system for an extended period of time calls into question not only the validity of the reports already reviewed by the individual physician and teaching hospital representatives, but the usefulness of the database when it is released. Frustration and discouragement with a difficult to navigate and then inoperable system has caused

physicians and teaching hospitals to disengage from the process, assuming that they will be unable to provide any feedback on the accuracy of the reports.

To better validate the accuracy of information on the Open Payments website, the time period for reviewing and disputing reported payments must be extended. Given the extensive delays and technical problems with the Open Payments website, it is not sufficient simply to extend the deadline for the review and dispute process by the number of days that the Open Payments site was unavailable.

Assuming that the Open Payments website is fully operational by August 11th, 2014, **the AAMC requests that CMS extend the review and dispute process deadline by at least two weeks, to September 10th, 2014 or later.** We recognize that CMS has committed to making the Open Payments database public by September 30, 2014. However, if this information is made public before physicians and teaching hospitals have adequate opportunity to review the information that has been reported about them and notify companies about errors in payment amounts, this will decrease, not increase transparency.

We further propose that if the agency is unable to process the disputes resolved after extended review period and before September 30th, CMS consider releasing the information, indicating each disputed payment, while the resolution process continues. In the final rule, CMS announced its intention to update the website “at least once annually with corrected information” (78 Fed. Reg. 9527). Confidence in the reliability of this process and the resulting database would be greatly enhanced if CMS agreed to update the information with corrections to any resolved disputes before the end of calendar year 2014.

As we stated in a letter to the agency on June 2, 2014 regarding the critical review and dispute process:

“The key to transparency is ensuring that the information in question is accurate and presented in a meaningful and useful context. The dispute initiation and resolution process within Open Payments is the only check on the accuracy of the reported information. Although the rule itself includes penalties for failure to report accurate information, the consequences of having inaccurate information in the database are potentially much greater for physicians and teaching hospitals. Erroneous or misleading records about payments made by manufacturers can have serious repercussions to an individual’s reputation and career. A miscategorized payment or one that is reported as larger than the actual amount can place an individual at risk of appearing to have violated institutional policies, professional standards, or other legal or ethical requirements. Congress, individuals and institutions who will be listed in the database, and the American public need to know that the information ultimately presented has been reviewed by those who are the subjects of the reports and that CMS has taken every opportunity to confirm that the database more faithfully represents transparency into the relationships between manufacturers and health care providers.”

The AAMC remains very willing to work with CMS as it moves toward the release of the complete Open Payments Program database. Please contact Heather H. Pierce, J.D., M.P.H. at hpierce@aamc.org with any questions or for further information.

Sincerely,



Ann C. Bonham, Ph.D.
Chief Scientific Officer