



September 18, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Tavenner:

As life science trade associations representing thousands of medical device, biotechnology and pharmaceutical companies, we express our longstanding support for the goals of the Physician Payments Sunshine Act (“the Sunshine Act”), section 6002 of the Affordable Care Act of 2010, which will provide transparency in industry collaboration with teaching hospitals, physicians; and report physician ownership and investment interests.

We believe such transparency will help ensure that health care professionals make independent decisions regarding the health care and treatment of patients and the development and improvement of medical technology and medicines. The life science industries are fueled by intense competition, a commitment to scientific research, and the innovative energy of our member companies. Our constant innovation leads to the introduction of new and improved treatments that prevent illness, allow earlier detection of diseases, and improve patient outcomes. As industry representatives, we believe it is important that collaboration with physicians and other health care providers continues and thrives. These interactions help encourage R&D as well as physician education and training, and benefit patients.

However, for implementation of the Sunshine Act to be successful and for the data to be meaningful to patients and the public, the CMS Open Payments program public website must provide clear background information and context regarding such industry relationships. Such background ensures the reported data is helpful in patient decision-making. Further, providing context for reported payments and other transfers of value is critical to ensuring patients do not form mistaken impressions that all payments to physicians are suspect. We have repeatedly encouraged CMS to engage all stakeholders in a public process to develop this important context, consistent with the statutory requirement that CMS consult with affected industry and other stakeholders to ensure that the information made available to the public is presented in the appropriate overall context.

Unfortunately, with only less than two weeks before the public website is to go live, we have not been given an opportunity to review how CMS intends to present this crucial contextual information or to consult with CMS on its content. We are hopeful that this situation can be addressed before the first expected release of Sunshine data September 30. Indeed, the need for context is even more critical where CMS intends to post only a portion of manufacturer-submitted data.

In addition, CMS has announced that it intends to withhold as much as one-third of the data that was submitted by manufacturers and group purchasing organizations to the Open Payments system for the first reporting period. Based on preliminary reviews that many of our member companies have conducted of the removed data, it appears that those companies reported data to CMS in a manner that was consistent with the reporting guidelines and parameters established by CMS. Accordingly, it is not clear why this volume of data is being withheld. We are hopeful that this issue can be resolved expeditiously so that the data that is made available to the public is accurate, useful and complete.

Manufacturers have expended considerable time, energy and resources to provide timely, accurate and complete information to the Open Payments program. We are committed to working with CMS and all stakeholders to ensure the successful implementation of the Sunshine Act.

Regards,



Stephen J. Ubl
President and CEO, AdvaMed



James C. Greenwood
President and CEO, BIO



John J. Castellani
President and CEO, PhRMA