United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

October 3, 2011

VIA ELECTRONIC TRANSMISSION

Donald Berwick, M.D., M.P.P
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Berwick:

As authors and sponsors of the Physician Payments Sunshine Act (Sunshine Act), which was included in the Patient Protection and Affordable Care Act, we write today to express our severe disappointment in the Centers for Medicare and Medicaid Services (CMS) for failing to meet the October 1, 2011, deadline to draft the regulations mandated by the health care reform law.

While many interactions between the pharmaceutical and medical device industries and medical professionals are beneficial to medical science and lead to innovation, the Sunshine Act was developed after numerous investigations and hearings revealed that large sums of money were going to physicians for sometimes questionable purposes. Some of these payments were the subject of a federal criminal inquiry which resulted in $400 million in fines and legal costs paid by the major orthopedic medical device manufacturers. Ultimately, Congress passed the Sunshine Act in response to growing concerns over industry payments to physicians and their potential negative effects on patient care and efforts to restrain healthcare costs.

Under the provisions of this law, manufacturers are required to report to the Secretary of the Department of Health and Human Services (HHS) all payments to physicians, including consulting fees, honoraria, travel, and entertainment, for public disclosure by the Secretary. The Secretary is then instructed to include the identity of the manufacturer, the physician, and the drug or device associated with the payment on the internet. An additional provision requires manufacturers and group purchasing organizations (GPOs) to report all ownership or investment interests held by physicians or members of their family, also for public reporting by the Secretary. It is our understanding that the Secretary has delegated implementation of this provision to CMS.

Manufacturers and GPOs are required to start complying with the law by collecting data beginning January 1, 2012, and must begin reporting this information to the government on March 31, 2013. Beginning on September 30, 2013, the details of these payments must be made available to the public. Violations of the disclosure requirements can result in civil monetary penalties ranging from $1,000 to $100,000.

In order to ensure that manufacturers had adequate time to comply, the law required that the Secretary establish procedures not later than October 1, 2011, describing how manufactures are to submit information and how the information will be made available to the public. In addition, in establishing these procedures the Secretary was required to "consult with the Inspector General, affected industry, consumers, consumer advocates and other interested parties to ensure that the information made available to the public is presented in the appropriate context."

The deadline for establishing procedures has passed and there has not been, to our knowledge, adequate consultation with either industry representatives or consumer advocates. Therefore, we are concerned that CMS's failure to implement the statutory provisions on time with clear guidance, standards and definitions will create confusion among both manufacturers and consumers, potentially placing taxpayer dollars at risk.

Although many of the large pharmaceutical and medical device manufacturers, universities, and even the National Institutes of Health (NIH) have already begun to implement disclosure policies voluntarily, we are concerned that smaller companies are waiting for clarity and direction from CMS and will find the lack of timely guidance burdensome and costly. Prompt federal guidance is urgently needed to ensure a smooth path toward increasing disclosure, eliminating conflicts, and ultimately providing patients with the tools they need to make informed health choices.

In a conference call with our staff on Friday, September 23, 2011, your agency assured us that you have sent the proposed rule over to the Office of Management and Budget (OMB) for review. So that we may better monitor this progress, please answer the following questions in writing no later than October 14, 2011:

(1) What is your timetable for implementing the Sunshine Act?
(2) When did you originally send the proposed rule to the Office of Management and Budget (OMB)? Please include any dates that follow-up was conducted and for what reason.
(3) Why have you failed to meet the statutory deadline?
(4) What is the anticipated release date of the preliminary regulations? How long will the regulations be open for comment as required by the statute? What is your timeline for issuing final regulations?

In addition to your written response, please have the appropriate CMS officials contact our staff no later than October 7 to schedule an in-depth briefing on these issues and an open discussion on a path forward that allows both a timely implementation and a robust comment period.

Should you have any questions regarding this letter, please contact Erika Smith of the Senate Judiciary Committee staff at (202) 224-5225 or Jack Mitchell of the Senate Special Committee on Aging staff at (202) 224-5364. Thank you for your immediate attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

Herb Kohl
Chairman
Senate Special Committee on Aging