

Statement of U.S. Senator Chuck Grassley
Roundtable Discussion of the Senate Special Committee on Aging
“Let the Sunshine in: Implementing the Physician Payments Sunshine Act”
Wednesday, September 12, 2012

Thank you, Mr. Chairman, for holding this important roundtable today. I also want to thank you for your continued leadership on this issue.

In 2007, I began conducting extensive oversight and seeking disclosure of industry financial ties with groups including taxpayer funded research, physicians, medical schools, medical journals, continuing medical education companies, and patient advocacy non-profit organizations.

We exposed numerous cases where there were vast disparities between drug company payments received and reported by leading medical researchers. Two examples of disparities included:

- At Stanford University, the chairman of psychiatry received an NIH grant to study a drug, while partially owning as much as \$6 million in stock in a company that was seeking FDA approval of that drug. After exposure, the NIH removed the individual from the grant.
- At Harvard University, three professors failed to report almost a million dollars each in outside income while heading up several NIH grants. In response to my oversight, Harvard revised the conflict of interest policies and conducted an internal investigation of these professors.

These problems led to the Physician Payments Sunshine Act. The Sunshine Act establishes a nationwide standard requiring drug, device and biologic makers to report payments to doctors to the Department of Health and Human Services.

It requires information about those payments to be posted online in a user friendly way for public consumption. It also establishes penalties as high as \$1 million for knowingly failing to report the information.

As we all know, the legislation was ultimately included as Section 6002 of the Patient Protection and Affordable Care Act.

The Centers for Medicare and Medicaid Services (CMS) was eventually tasked with carrying out the Sunshine Act. The agency had until October 1, 2011, to issue regulations.

When CMS failed to meet that deadline, Senator Kohl and I wrote to CMS about why it failed to meet the deadline. We asked for a timetable for issuing the preliminary regulations and implementing the Sunshine Act.

CMS's response was incomplete and uninformative. There was no explanation for the delay and no indication of when to expect completion.

At the time of the response, the U.S. government just settled with a medical device maker for \$2.4 million over allegations of kickbacks to doctors to use the company's products. The payments to doctors are the kind that might be prevented through disclosure as soon as the Sunshine Act is in place.

Senator Kohl and I then scheduled a hearing to force the agency to publicly explain why the rule was taking so long. Not surprisingly, on the eve of the hearing CMS finally issued the proposed rule.

For the most part I was very pleased with CMS's proposed rule. CMS stuck to the goals and integrity of the Sunshine Act -- providing clarification where it was needed.

However, many questions remain on the technical aspects of the rule and how the data will be presented.

I have said from the very beginning, if the information provided to the public is not concise, easily readable and understandable, then we have all failed the American taxpayer.

It has now been nearly nine months since the proposed rule was issued and CMS cannot tell us when they plan on issuing the final rule.

The longer we wait, the more taxpayers miss out on the benefits of public disclosure.

CMS is simply dragging its feet on implementing the Sunshine Act. But why? It doesn't make sense.

Rarely do you find all stakeholders, including consumer groups, industry, professional medical organizations, and provider organizations, MedPAC, the Institutes of Medicine, and Congress all on the same side of an issue. In fact, industry and consumer groups sent a joint letter to CMS on October 25, 2011, urging full implementation of the Sunshine Act. Yet, still there is delay.

Our efforts to engage with CMS on the implementation of the Sunshine Act have been met with resistance and silence. Why is CMS so unwilling to being open and transparent with the implementation process?

I am never one to put a lot of stock into rumors, but one that keeps popping up is that CMS has completed the final rule and sent it over to OMB – but OMB will not issue the final regulation until after the election. That doesn't make sense, but that is what people are saying.

CMS needs to clarify if there is any truth to this rumor. Is the rule at OMB? Is it being held until after the election? If so, why?

We need to find out what the hold-up is, deal with it, and get the job done.

The American people deserve the full disclosure and transparency this law promises and industry needs certainty about what the specifics of the rules so that compliance can begin. The time for delays is over.

Today's roundtable is geared toward gaining a better understanding from CMS officials on why they have failed to implement the Sunshine Act, their anticipated release of the regulations, and the consequences facing industry due to the lack of guidance from CMS.

Due to the structure of the law, companies must establish an internal data collection system and educate all employees on the new requirements.

However, companies do not have the luxury of going to Best Buy and purchasing the latest data collection system off-the-shelf. Companies build the systems.

They must train and educate their employees on the proper use of the system in order to properly capture the necessary data.

Many companies have already begun piloting these systems to ensure they are capturing all the relevant information. However, with a lack of recognized practices from CMS on how to move forward, companies cannot prepare to meet the letter of the law.

Lastly, I want to thank our participants in today's roundtable. Collectively, these participants represent the government agency in charge of carrying out the intent of the law, the industry the law is intended to regulate, the consumer group representing the patients the law is intending to help, and various experts in the field.

It is my sincere hope that CMS is prepared to be open and honest about where it is in the process and why it has failed to implement the law in a timely manner.

Letting the sun shine in and making information public is basic to accountability. The sooner we can properly implement this law, the sooner we can establish greater accountability for patients and consumers, especially with medical research.