

United States Senate

WASHINGTON, DC 20510

April 4, 2012

The Honorable Marilyn Tavenner
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244

Dear Acting Administrator Tavenner,

As the authors of the Physician Payments Sunshine Act (“Sunshine Act”), we remain committed to ensuring transparency and accountability through the accurate reporting of financial transactions between health care providers and the drug, device, and group purchasing industries. While these financial relationships are important for developing new therapies and technologies, it is equally as important that these ties are disclosed to the public so that potential conflicts of interest can be managed and do not affect optimal, evidence-based care for patients or increase costs to consumers and the health care system.

Our goal is to promote the implementation of the law as expeditiously as possible. We are disappointed that regulations implementing the Sunshine Act were not complete by the statutory deadline of October 1, 2011. We request that the final rule on implementation be released no later than June of this year so that partial data collection for 2012 can commence. We also strongly urge the Centers for Medicare and Medicaid Services (CMS) to work closely with stakeholders to finalize these rules so that they comprise a feasible approach to providing the valuable data that patients deserve.

Our comments focus on these essential elements of the law: transparency must be thorough, data must be accurate, and data must have context in order for it to be useful.

CLEAR DEFINITIONS AND GUIDELINES

We encourage CMS to be clear on guidelines and context so that the data posted online is meaningful and understandable. While CMS provided some definitions in the proposed rule, a number of questions remain unanswered. The purpose of the Sunshine Act is to make information readily available and accessible to consumers. We urge CMS to narrowly define precise payment categories so that all stakeholders are operating under the same assumptions. In addition, CMS should consider removing the proposed “other” payment category so that it does not obscure the true nature of some payments.

We have heard several concerns from stakeholders regarding the way CMS proposed to require reporting on indirect research payments. We strongly urge CMS to work with various stakeholders so that reporting is complete, but that unintended consequences are avoided. Specifically, we urge CMS to more clearly define instances when indirect research payments and

indirect research payments to third parties are reportable and how and with what context these payments will be reported on the public website.

ACCURATE DATA/ERRORS

The transparency provided by the Sunshine Act is best served by accurate data. While CMS has proposed updating reporting errors once a calendar year, we urge CMS to update the website with correct information once CMS is made aware of inaccuracies in the reported data. We believe that since accurate data is the goal of the legislation, CMS should include mechanisms by which the agency can update errors on a quarterly basis. Prolonged inaccurate data does not help inform the public on provider-industry relationships and could cause confusion among patients, physicians, and manufacturers.

Additionally, we agree with CMS, that CMS should not become the default dispute arbiter between applicable manufacturers and covered recipients; but we agree that CMS must develop mechanisms by which disputes can be reported as smoothly as possible. CMS should also consider requiring that applicable manufacturers share the data manufacturers plan to report with covered recipients before reporting the data to CMS. We believe this information sharing will reduce the number of inaccurate payments and disputes reported.

PHYSICIAN OWNED DISTRIBUTORS ("PODs")

We were pleased that CMS has included PODs in the definition of applicable group purchasing organizations. As we stated in our June 9, 2011, letter with Senators Baucus, Hatch, and Corker, "The POD model at its basic level is exactly the type of entities envisioned by the Sunshine Act."

THE PUBLIC INTERFACE AND CONTEXT OF DATA

The website, as the public point of interaction with the disclosed data, is essential to the Sunshine Act and must be designed in a user friendly manner so that data can be searched, sorted, and aggregated without duplication. The disclosed data should be in an easy-to-use format and with terms and product and manufacturer names recognizable to patients. For example, if an applicable manufacturer is a subsidiary of a recognizable, larger brand name company, we encourage the use of the recognized brand name for reporting so that patients can more readily recognize the source of the transfer of value. We encourage you to work with stakeholders to best determine how to release the public data on the website.

The website should also define the terms of transfers of value and provide context so that the public best understands what these payments are for and in what capacity. Research transfers are often vitally important to the development of new therapies and technologies, but without context, a patient could find a large sum of money attached to his/her physician and not know for what that funding was provided.

PHYSICIAN OUTREACH

CMS should increase its outreach to physicians and other covered recipients about Sunshine Act implementation. A survey of 500 compliance officers and physicians in the March 1, 2012, issue of "Inside CMS" reported that 47 percent had not heard of the Sunshine Act. As CMS finalizes its rules, CMS must engage the provider community to ensure proper implementation.

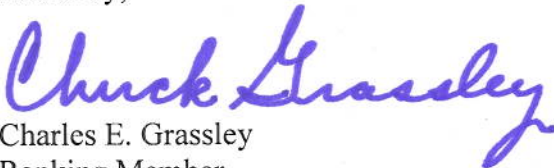
IMPLEMENTATION QUESTIONS

In addition to these comments, we respectfully request answers to the following questions relating to the implementation of the Sunshine Act.

1. Can CMS commit to completing a final rule by this summer so that data collection can begin in 2012?
2. Since CMS missed the initial required Congressional deadline, has CMS increased the resources or personnel assigned to the implementation of the Sunshine Act, including a dedicated information technology lead?
3. Will CMS commit to issuing an RFP to begin designing the website?
4. Does CMS have a dedicated working group assigned to implementation of the Sunshine Act, and what technical expertise and program areas are represented?
5. Does CMS have a public education and outreach plan to raise awareness of the new law with the provider community and with health care consumers?
6. Has CMS allocated dedicated implementation funds for the Physicians Payment Sunshine Act?

We look forward to working together ensure a fully implemented Sunshine Act so that companies can collect and release partial 2012 data. We respectfully request that you respond to our offices by no later than close of business on April 18, 2012. Additionally, we request a staff briefing from CMS on the progress of implementation. Please contact Sarah Levin in Senator Kohl's office (sarah_levin@aging.senate.gov, 202-224-5364), or Erika Smith in Senator Grassley's office (Erika_smith@judiciary-rep.senate.gov, 202-224-5225) with any questions.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on the Judiciary



Herb Kohl
Chairman
Senate Special Committee on Aging