

February 17, 2012

Submitted electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

**Re: CMS-5060-P: The Pew Charitable Trusts and Medtronic, Inc.'s
Joint Comments on Medicare, Medicaid, Children's Health
Insurance Programs; Transparency Reports and Reporting of
Physician Ownership or Investment Interest**

Dear Acting Administrator Tavenner:

The Pew Charitable Trusts "Pew" and Medtronic, Inc. ("Medtronic") are pleased to jointly comment on the Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") proposed rule ("Proposed Rule") implementing Section 6002 of the Affordable Care Act (the "Sunshine Provisions"), and we look forward to continuing our conversations with CMS regarding the implementation of the Sunshine Provisions. We submit these comments in response to CMS' draft regulations and request for comments.

Both Pew and Medtronic independently have commented on various technical and other aspects of the Proposed Rule through separate submissions. The following comments, however, reflect our shared goals regarding the regulations that we feel are critical to the success in implementing the spirit and intent of the Sunshine Act. We believe it is significant for CMS to know that fundamentally different constituencies endorse the core principles set out in these comments as priorities, and to know our shared concern that any final regulations and eventual display of data about transfers of value conform to these guiding principles.

Our comments center on the following five guiding principles:

1. CMS must act quickly to implement the law.
2. Data must be contextual, informative and not mislead or confuse patients or the public.
3. Data must be accurate.
4. Similar activities must be reported the same across manufacturers using common payment category definitions.
5. Complete reporting from manufacturers and closing of potential loopholes is essential.

I. The Centers for Medicare and Medicaid Services must move quickly to implement the law in 2012.

Although manufacturers should not be responsible for reporting data on transfers of value occurring before CMS finalizes the regulations, Section 1128G of the Social Security Act required data collection to begin on January 1, 2012. We believe it is important that CMS limit further delays in implementation.

We recognize the potential complications that manufacturers may encounter updating their systems and making reports for the first time. We therefore also recommend that CMS move as swiftly as possible to conduct a full review of all comments submitted, dedicate the resources appropriate to fully vet such comments, prioritize within CMS the drafting of final regulations, and create a robust technical infrastructure to handle report receipt and meaningful display of reported transfers on a public website. We urge CMS to carefully study what a reasonable period of time is for manufacturers to have to implement final regulations, with due care to balance both the urgency of reporting data as reflected in the Act and its legislative history and a fair assessment of technical challenges manufacturers may have in conforming their systems to match the final regulations. We urge CMS to undertake all of the above in such a way as to allow for at least partial reporting of 2012 transfers.

II. Context about the payment and transfer of data is critical for consumers of the data.

CMS should ensure that the website provide background context on the rationale for disclosure of financial relationships and that manufacturers have the opportunity to submit contextual information associated with the reported transfer.

As stated by Sen. Grassley when he introduced the Sunshine Act legislation “The goal...is to lay it all out, make the information available for everyone to see, and let people make their own judgments about what the relationships mean or don’t mean” and “Patients want to know that they can fully trust the relationship they have with their doctor”¹. Additionally, Grassley stated ‘...making information public is basic to building people’s confidence in medical research, education, and the practice of medicine.’²

¹ http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=18901

² http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=24413

The Physician Payments Sunshine Act was intended to provide information to patients regarding their physician's relationships with industry, to help them ask targeted questions, and make informed decisions about their health care. To further this goal it is important for patients and other consumers of the data to know why a payment or other transfer of value to a physician or teaching hospital occurred. Displaying only the recipient, date, amount, and payment category without clear definitions or context is potentially misleading for patients. Consumers of the data may need a more complete picture of the circumstances of this information to make reasonable and accurate interpretations about payments and transfers of value.

As background, it is important for the public to understand that collaboration between physicians and manufacturers is necessary to bring a new therapy or innovation from the basic research stage through clinical trials and to FDA approval.

The public website should provide transfer of value information in a way that is easily consumable and informative so that discussions between patients and their health care provider can be substantial and meaningful. We respectfully request that CMS engage patients, physicians, manufacturers and other stakeholders to provide input on the design of a user-friendly public website where payment and transfers of value information will be posted.

III. Accuracy of the publicly posted data and consistent reporting across manufacturers is critical to having meaningful data. CMS must ensure that the regulations provide clear guidance on how to classify every reportable transaction.

It is critical that the data made available to the public be accurate and that similar transfers of value be presented to the public in the same manner across manufacturers. To this end, CMS should ensure the regulations provide clear definitions and guidance for manufacturers. Most concerning are the definitions of the natures of payment and 'at the request of or designated on behalf of'. These are the two most significant areas in which the proposed regulations can reasonably be interpreted differently by manufacturers, as well as consumers. Ambiguity in these interpretations would be problematic for patients, physicians, and manufacturers, and be counter to the goal of the Sunshine Act.

Additionally, so as not to diminish the value of the information provided, the data publicly posted must be as accurate as possible. We encourage CMS to make corrections to the website as soon as is practicable. If an error involves attribution to the wrong recipient, waiting to update the website with the corrections may result in incomplete or inaccurate information to patients and public mischaracterization of a physician's financial relationships.

IV. Complete reporting from manufacturers and closing of potential loopholes.

We support the proposed regulation's requirement to report both the identity of the covered recipient as well as the payee for payments made 'at the request of or designated on behalf of' a covered recipient.

We respectfully request that CMS provide very clear guidance to manufacturers about those situations it considers to meet the criteria of 'at the request of or designated on behalf of' or 'awareness'. Such guidance is necessary to ensure complete reporting from manufacturers and consistent reporting of similar situations and to avoid situations where some manufacturers are disclosing fully and completely and others are establishing structures to avoid complete reporting. Additionally, such guidance should balance the need for transparency about physician-industry relationships with the operational challenges that may result from manufacturers trying to infer a relationship in situations where one cannot reasonably be established.

Sincerely,



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