

# Client Alert

FDA & Life Sciences Practice Group

May 11, 2012

## **CMS Announces it Will Not Require Data Collection by Manufacturers under the Physician Payments Sunshine Act Before January 1, 2013**

Margaret Tavenner, Acting Administrator of the Centers for Medicare and Medicaid Services (CMS or the “Agency”), issued a letter to Senator Chuck Grassley on May 3, 2012 formally responding to a letter sent to her by Senator Grassley and Senator Herb Kohl on April 4, 2012 requesting information regarding the Agency’s plans to implement the federal Physician Payments Sunshine Act (the “Sunshine Act”). Among other things, the letter reiterates an announcement that was posted on CMS’s website on May 2, 2012, stating that “data collection [under the Sunshine Act] will not be required before January 1, 2013.”

The Sunshine Act, Section 6002 of the comprehensive Patient Protection and Affordable Care Act enacted in March 2010, requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS any payments or other transfers of value they furnish to physicians and teaching hospitals (deemed “covered recipients”). In addition, the law requires certain manufacturers and group purchasing organizations (GPOs) to report ownership or investment interests in their organizations held by physicians. CMS is required to make publicly available through a searchable website the information that manufacturers and GPOs submit in transparency reports.

CMS issued a proposed rule to implement the Sunshine Act in December 2011. The proposed rule included a 60-day comment period, during which the Agency received more than 300 submissions of comments from stakeholders.

In their April 4 letter, Senators Grassley and Kohl urged CMS to “work closely with stakeholders” and release a final rule implementing the Sunshine Act “no later than June of [2012] so that partial data collection for 2012 can commence.” In their letter, the Senators asked CMS a series of questions about the implementation of the Sunshine Act, including whether the Agency has identified a specific work group to implement the Sunshine Act and whether the Agency will issue a request for proposal to assist with implementation.

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In CMS's May 3 response to the Senators, Administrator Tavenner states that the Agency is "committed to publishing a final rule later this year," and "is drafting the final rule carefully to ensure that the final rule is not only consistent with statutory goals, but is also responsive to stakeholder comments." The letter also reiterates the following announcement that was posted on CMS's website on May 2, 2012:

*CMS is committed to addressing the valuable input received during the comment period, and to ensuring the accuracy of the data collected. In order to provide time for organizations to prepare for data submission and to sufficiently address the important input we received during the rulemaking process, CMS will not require data collection by applicable manufacturers and applicable group purchasing organizations before January 1, 2013.<sup>1</sup>*

In addition, Administrator Tavenner notes in the letter that CMS has identified an internal working group for implementation of the Sunshine Act, composed of both technical and policy staff, which is currently assessing the staffing and resource requirements for full implementation of the Sunshine Act. The letter also indicates that CMS plans to issue a request for proposal this year to further aid with implementation (likely to assist the agency in receiving, aggregating, and publishing data).<sup>2</sup>

Following publication of the letter from CMS, both Senator Grassley and Kohl, who authored the Sunshine Act, expressed disappointment in the Agency's delay in implementation. Senator Grassley stated, "The process has dragged on long past the statutory deadline for implementation. ... Given all of the extra time, CMS will have no further excuses for not accomplishing these goals." Senator Kohl stated, "While I am disappointed by this delay and the timeline, I do look forward to working with CMS to finalize the rules so that data collection can begin in January 2013."<sup>3</sup>

At this time, it appears that CMS is focused on developing a final rule that is consistent with the statutory limits of the Sunshine Act, incorporates stakeholder input, and leads to accurate data being reported to the Agency. To that end, despite increasing Congressional pressure and oversight, it appears that CMS will not require manufacturers and GPOs to begin data collection under the Sunshine Act prior to January 1, 2013.

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*This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.*

<sup>1</sup> Available at <http://blog.cms.gov/2012/05/03/information-on-implementation-of-the-physician-payments-sunshine-act/>.

<sup>2</sup> Acting Administrator Tavenner's May 3 letter to Senator Grassley, as well as Senators Grassley's and Kohl's April 4 letter to Acting Administrator Tavenner, are available on Senator Grassley's website, at [http://www.grassley.senate.gov/news/Article.cfm?customel\\_dataPageID\\_1502=40563](http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=40563).

<sup>3</sup> Press release from Senator Grassley's office on May 4, 2012, available at [http://www.grassley.senate.gov/news/Article.cfm?customel\\_dataPageID\\_1502=40563](http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=40563).