



## Client Alert



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### **The Sunshine Act Isn't Shining so Brightly: CMS Misses Deadline for Proposed Regulations for Physicians Payment Sunshine Act**

The Patient Protection and Affordable Care Act (PPACA) mandated the Secretary of the Department of Health and Human Services (HHS) to issue regulations implementing the Physician Payment Sunshine Act (or the Sunshine Act) by October 1, 2011. HHS delegated this task to the Centers for Medicare & Medicaid Services (CMS). When CMS failed to meet the deadline for issuing the regulations, two U.S. legislators who were instrumental in drafting the Sunshine Act—U.S. Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.)—issued a letter to CMS Administrator Donald Berwick, MD, on October 3, 2011, pressing for details as to why CMS missed the statutory deadline and when the agency intends to issue the regulations, which have been highly anticipated by the pharmaceutical and medical device industries.

The Sunshine Act requires certain pharmaceutical, medical device and biologics manufacturers to collect and report data to the government on all payments to physicians, including consulting fees, honoraria, travel and entertainment. The Sunshine Act also requires HHS to publicly disclose the identity of the manufacturer, physician and the drug or device associated with the payment. Manufacturers and group purchasing organizations are also required to report all ownership or investment interests held by physicians or members of their family. PPACA mandates that manufacturers begin collecting data on January 1, 2012, and must begin reporting this information to the government on March 31, 2012.

The letter stresses that “the deadline for establishing procedures has passed” and there has not been “adequate consultation with either industry representatives or consumer advocates.” The Senators expressed their concern 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. According to the letter, “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.”



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AGG previously published a Client Alert on the provisions of the Sunshine Act set forth in PPACA. To view the Alert, please click [here](#).<sup>1</sup> AGG will continue to monitor the situation and will issue a summary of the regulations shortly after they have been released.

To view the letter to CMS Administrator Donald Berwick, MD, please click [here](#).<sup>2</sup>

<sup>1</sup> [http://www.agg.com/media/interior/publications/Kitchens\\_Minsk\\_Burgar\\_Blakely\\_Nguyen-NewReportingRecsForManufacturers&Distributors.pdf](http://www.agg.com/media/interior/publications/Kitchens_Minsk_Burgar_Blakely_Nguyen-NewReportingRecsForManufacturers&Distributors.pdf)

<sup>2</sup> <http://grassley.senate.gov/about/upload/Grassley-Kohl-CMS.pdf>

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