

## WSGR ALERT

DECEMBER 2011

# CMS DELAYS IMPLEMENTATION OF THE PHYSICIAN PAYMENT SUNSHINE ACT

Considerably after the statutory deadline of October 1, 2011, the Centers for Medicare and Medicaid Services (CMS) finally has issued proposed regulations aimed at implementing what is known as the "Physician Payment Sunshine Act." The 121-page document, which was published yesterday in the Federal Register, sets forth in considerable detail how CMS proposes to interpret the Sunshine Act and plans to enforce its provisions. As it spells out its views on what and how industry must report in its dealings with healthcare professionals, CMS also solicits industry's input in the form of comments it will consider before releasing a final rule sometime in 2012. We anticipate that the final regulations could be modified significantly based on comments from regulated industry.

***Importantly, until a final rule is issued, applicable manufacturers are not required to start collecting payment information that must be reported in order to comply with the Sunshine Act.***

### About the Sunshine Act

The Physician Payment Sunshine Act is the portion of the healthcare reform law enacted in 2009 that requires United States manufacturers of marketed drugs, devices, biological products, or medical supplies that are reimbursed under governmental programs such as Medicare and Medicaid to report to the Department of Health and Human Services (HHS) most "payments or other transfers of value" to physicians and teaching hospitals that are greater than \$10 in value.

### The Proposed Regulations

The proposed rules go into considerable detail setting forth how CMS intends to implement the Sunshine Act, including clarification of the terms and definitions used in the statute, as well as proposed procedures for the submission, review, and publication of the reported data. For terms undefined by the statute, CMS seeks to provide, where necessary, appropriate definitions and explanations of how it proposes to interpret them.

### Timing

Although the Sunshine Act requires manufacturers to report transactions beginning January 1, 2012, CMS recognizes that final regulations will not be published in time for manufacturers to begin collecting the required information by that date due to the timing of the publication of the proposed regulations. Consequently, CMS will not require manufacturers to collect payment information until final regulations are released. Since CMS will accept comments on the proposed regulations until February 17, 2012, and must then review, analyze, and reflect the comments in its final regulations, it is anybody's guess when implementation will actually begin. For its part, CMS hopes to finalize the regulations sometime during calendar year 2012. Depending on the publication date of the final regulations, CMS is considering requiring the collection of data for part of 2012 to be reported to HHS by the statutory date of March 31, 2013.

In spite of the delayed implementation of the Sunshine Act, we recommend that

manufacturers set up systems now to gather reportable data. In doing so, they should use the proposed regulations as guidance on what will be expected. Although CMS's positions likely will change on some provisions following its review of the public comments, there is much to be gleaned from a review of the proposed regulations in order to understand CMS's thinking on this subject.

Setting forth specific CMS proposals is beyond the scope of this alert, but if you have any questions about the proposed regulations or what it will take to comply with the Sunshine Act, please contact David Hoffmeister, Farah Gerdes, or Jon Nygaard in Wilson Sonsini Goodrich & Rosati's life sciences/FDA and healthcare practice.



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