May 10, 2012

The Centers for Medicare & Medicaid Services ("CMS") announced on May 3, 2012 that it will delay until at least January 1, 2013 commencement of data collection obligations for life sciences and other companies subject to the "sunshine" provisions in Section 6002 of the Patient Protection and Affordable Care Act ("PPACA"). These sunshine provisions require "applicable manufacturers"[1] and "applicable group purchasing organizations"[2] (collectively "Reporting Entities") to track and report annually to CMS certain payments and transfers of value to physicians and teaching hospitals as well as physician ownership and investment interests. As we discussed in a **January 2012 *Cooley Alert***, not only will the sunshine provisions require pharmaceutical and medical device manufacturers with commercialized products and many GPOs to track and make public most of their financial arrangements with physicians, but they will also potentially lead to increased scrutiny of such arrangements.

Given that CMS will not require data collection in 2012, the sunshine provisions' March 31, 2013 deadline for Reporting Entities to register and report 2012 payments and transfers of value will likely be revised. Likewise, with no data collection required in 2012, it appears that CMS will not have 2012 data to make public online by September 30, 2013, as the sunshine provisions required.

Later this year, CMS intends to issue a final rule implementing the sunshine provisions. The final rule is expected to establish the start date for the data collection requirement and the deadlines for Reporting Entities' registration and reporting, and to update procedures and specifications implementing the sunshine provisions.

For details on the sunshine provisions, their applicability to Reporting Entities, and CMS' December 2011 proposed rule, including its requests for comment, please see our **January 2012 *Cooley Alert*** and contact one of the attorneys listed above.

Notes

1 In its December 19, 2011 proposed rule implementing the sunshine provisions, CMS defines an "applicable manufacturer" as an entity that is:

> (1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
>
> (2) Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

76 Fed. Reg. 78742, 78767 (Dec. 19, 2011).

2 The proposed rule defines an "applicable GPO" as an entity that:

> (1) Operates in the United States, or in a territory, possession or commonwealth of the United States; and
>
> (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

76 Fed. Reg. 78742, 78767. (Dec. 19, 2011). CMS adds:

> We propose that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Rather, it is our intent to capture entities (including physician-owned entities) that purchase covered drugs, devices, biologicals, or medical supplies for resale or distribution to others.

76 Fed. Reg. 78742, 78752. (Dec. 19, 2011).