

E-ALERT | Health Care

May 7, 2012

CMS DELAYS PHYSICIAN PAYMENTS SUNSHINE ACT DATA COLLECTION REQUIREMENT

On May 3, 2012, the Centers for Medicare & Medicaid Services (CMS) posted on its official blog a statement delaying enforcement of the requirement that applicable manufacturers of drugs, devices, biologicals, or medical supplies for which coverage is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) collect information about certain payments or other transfers of value to physicians and teaching hospitals.¹ The collection requirement, along with an accompanying requirement to report such data to CMS annually, are contained in Section 6002 of the Affordable Care Act (ACA) (Pub. L. 111-148, as amended by Pub. L. 111-152).²

Section 6002 further requires the Department of Health and Human Services to establish reporting procedures by October 1, 2011, and manufacturers to begin collecting data on January 1, 2012. As set forth in the statute, the first report, which must include information about payments and transfers of value made to covered recipients in calendar year 2012, is due on March 31, 2013.

In a proposed rule implementing Section 6002, published on December 19, 2011, CMS stated that it would not require manufacturers to begin collecting the required information until 90 days after the publication of the final rule. Under this approach, manufacturers would have been required to collect data for only part of 2012 (the exact portion would have been dependent on the timing of the final rule); data collected for 2012 would have been reported to CMS by the statutory date of March 31, 2013.

In the blog post of May 3, CMS announced that, due to the high volume of comments on the proposed rule and the operational and implementation issues raised, the rule will not be finalized until "later this year."³ As a result, CMS will not require data collection to begin before January 1, 2013. CMS reiterated this position in a May 4 letter to Senators Charles Grassley and Herb Kohl, the authors of the Physician Payments Sunshine Act.⁴ In the letter, CMS stated that "CMS is committed to publishing a final rule this year" but added that CMS does not believe it is feasible to address all of the remaining issues on a schedule that would allow manufacturers to begin collecting data in 2012. The agency also explained that "data accuracy is a primary concern" in finalizing the rule, and that "CMS is also committed to working with stakeholders throughout the implementation process." CMS did not indicate, in either its blog post or its letter to Senators Grassley and Kohl, when the first report would be due.

¹ Section 6002 also requires applicable manufacturers and GPOs to report certain information regarding the ownership or investment interests held by physicians or their immediate family members in such entities.

² Covington's client alert on the enactment of Section 6002 is available [here](#), and our client alerts on CMS's proposed rule implementing Section 6002 are available [here](#), [here](#), and [here](#).

³ CMS's blog post is available [here](#).

⁴ CMS's letter to Senators Grassley and Kohl is available [here](#). The letter was issued in response to an April 4 letter from the senators to Marilyn Tavenner, Acting Administrator of CMS, which urged the publication of a final rule no later than June 2012 and emphasized the importance of timely implementation.

In response, Senators Grassley and Kohl issued a statement expressing their disappointment with CMS's decision. 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 accomplishing these goals [of providing information about financial relationships with physicians]."⁵ Similarly, Senator Kohl said, "I do look forward to working with CMS to finalize the rules so that data collection can begin in January 2013."

Please contact one of the attorneys listed below if you have questions regarding implementation of the disclosure requirements.

Erika Lietzan	202.662.5165	elietzan@cov.com
Anna Kraus	202.662.5320	akraus@cov.com
Stefanie Doeblner	202.662.5271	sdoebler@cov.com
Amalia Fenton	202.662.5445	afenton@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2012 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.

⁵ The statement is available [here](#).