Published on *The National Law Review* https://natlawreview.com

Stakeholders Call for Final Sunshine Act Rule

Article By:

Brian P. Dunphy

On January 14, 2013, a group of stakeholders, including the AARP and the AFL-CIO, urged the Obama Administration to issue the long-awaited final rule (the "Final Rule") implementing the Physician Payments Sunshine Act (the "Sunshine Act"). Many organizations have directed similar requests to the Administration in recent weeks. The Sunshine Act requires manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program ("Manufacturers") to annually report payments or transfers of value given to physicians and teaching hospitals. Manufacturers and group purchasing organizations ("GPO") must also annually report physician ownership or investment interests. The Sunshine Act, passed as part of the Affordable Care Act, required Manufacturers and GPOs to begin collecting payment information on January 1, 2012 and to submit the information to the Department of Health and Human Services ("HHS") by March 31, 2013. Despite these statutory deadlines, the Centers for Medicare & Medicaid Services ("CMS") has yet to publish the Final Rule.

Manufacturers have been monitoring a circuitous regulatory process in preparing to comply with the Sunshine Act's requirements. In December 2011, CMS issued a proposed rule, shortly before the data collection requirement was set to take effect on January 1, 2012 (Tom Crane, Karen Lovitch, and I discussed the proposed rule in an article published in BNA's Health Care Fraud Report). CMS also postponed data collection until after promulgation of the Final Rule. On May 3, 2012, CMS againpostponed the start of data collection until January 1, 2013 and said that "CMS intends to release the final rule later this year." CMS sent the Final Rule to the Office of Management and Budget ("OMB") for review on November 27, 2012.

Predicting the timing of publication is difficult. Executive Order 12866, "Regulatory Planning and Review," requires OMB's Office of Information and Regulatory Affairs to waive review or notify the agency in writing of the results of its review within 90 days after the agency submits the required information (which would be late February 2013 based upon CMS's transmittal of the rule to OMB on November 27, 2012). However, HHS's Regulatory Agenda, published in the Federal Register on January 8, 2013, lists "12/00/14" as the deadline for final action.

With the January 1, 2013 deadline to begin collecting data having passed without publication of the Final Rule, Manufacturers are anxiously awaiting final guidance. Manufacturers have invested substantial resources to prepare for compliance with the Sunshine Act. In the absence of the Final Rule, however, Manufacturers remain in the dark about many operational and implementation details, and they cannot fully implement processes to comply with the Sunshine Act's

data collection and reporting requirements.

National Law Review, Volume III, Number 18