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COVINGTON & BURLING LLP

E-ALERT | Food & Drug

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SUNSHINE ACT DATA COLLECTION TO BEGIN AUGUST 1

Medical device manufacturers are just days away from being required to track and report financial arrangements with health care providers, as required by the Physician Payment Sunshine Act (the "Sunshine Act"). Beginning August 1, 2013, most device manufacturers will be required to annually collect data regarding payments and transfers of value provided to physicians and teaching hospitals. Data collected between August 1 and December 31 must be reported to the Centers for Medicare & Medicaid Services (CMS) in March of 2014. CMS will subsequently publish the information on a publicly available website.

In general, device manufacturers are subject to the reporting requirements if they manufacture at least one device: (1) that requires premarket approval by or notification to the Food and Drug Administration; and (2) for which reimbursement is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). Under this standard, companies that manufacture only investigational products may be required to report if their products are covered by one or more of these programs.

Despite the impending August 1 compliance date, much uncertainty still remains regarding the scope of payments and transfers of value that must be reported and the methodology for valuing those payments and transfers of value. For device manufacturers, who may have less experience reporting at the state level than drug manufacturers, the reporting requirements pose unique challenges. Noteworthy issues for device manufacturers include:

- Reporting royalties or license fees paid to physician inventors
- Valuing long-term loans of medical devices provided to customers to evaluate the device prior to purchase
- Collecting data from third parties who make indirect payments to physicians and teaching hospitals (e.g., CME providers and vendors)
- Reporting expenses made in connection with clinical trials that are not set forth in the clinical trial agreement or research protocol (e.g., costs associated with investigator meetings)
- Designating research payments as subject to delayed publication
- Disclosing ownership and investment interests in private companies held by physicians and their immediate family members
- Preparing an assumptions document to accompany disclosure reports

Companies are encouraged to review their policies, procedures, and systems for complying with the Sunshine Act to ensure that they collect the necessary data regarding payments and transfers of value beginning August 1.

If you have any questions concerning your company's reporting obligations or processes for implementing the requirements, please contact the following members of our Food and Drug Practice Group:

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