Update on Federal and State Developments: Regulation of Financial Interactions between Health Care Providers and Pharmaceutical and Medical Device Companies

Recent weeks have seen two significant developments with respect to federal and state laws regulating financial interactions between pharmaceutical and medical device companies and health care providers: (1) the Centers for Medicare and Medicaid Services ("CMS") submitted a draft of the final regulations implementing the so-called Federal Sunshine Law (42 U.S.C. § 1320a-7h) for the government clearance process that is a mandatory prerequisite for promulgation; and (2) the Massachusetts Department of Public Health ("DPH") approved final regulations (105 C.M.R. § 970.000) implementing statutory revisions to the Massachusetts Marketing Code of Conduct.

Federal Sunshine Law. On November 27, 2012, CMS submitted to the Office of Management and Budget ("OMB") draft final regulations implementing the Federal Sunshine Law (which law requires the tracking and disclosure of certain financial interactions between pharmaceutical and medical device manufacturers and physicians and teaching hospitals). OMB must, absent an extension, complete its review within 90 days and either: (1) clear the regulations (with or without changes) for promulgation; or (2) return the regulations to CMS for further consideration along with a written explanation of its rationale for doing so. If the regulations are returned, CMS must prepare a revised draft of the final regulations and then submit the draft to OMB to review again. Absent an extension to the review period or the return of the regulations, final regulations would be promulgated by February 25, 2013. Pharmaceutical and medical device manufacturers have called for promulgation of the final regulations well in advance of the date when the manufacturers must begin to track financial interactions in order to ensure that their policies, processes and systems can comply with the requirements. The current date manufacturers must begin tracking the interactions is January 1, 2013 (postponed by CMS from the statutory date of January 1, 2012). Although CMS had indicated in the proposed regulations that the agency would provide manufacturers with time after the promulgation of final regulations to ensure compliance, the agency has not yet announced a further postponement.

Massachusetts Marketing Code of Conduct. On November 21, 2012, the Massachusetts Department of Public Health ("DPH") approved final regulations implementing changes to the Massachusetts Marketing Code of Conduct (which regulatory code both restricts and requires the tracking and disclosure of certain financial interactions between pharmaceutical and medical device manufacturers and health care providers). The final regulations replace emergency regulations which implemented a partial repeal of the Massachusetts "gift ban" statute as more fully described here. The final regulations are generally consistent with the emergency regulations and set forth the following conduct and future disclosure obligations.

- Manufacturers may pay the reasonable expenses incurred by health care practitioners when participating in technical training in medical device use *without the need to include the obligation to pay the expenses in a written purchase agreement*.
- Manufacturers may provide "modest meals and refreshments" to health care practitioners *outside* the office or hospital setting if: (1) the food or drink is provided in connection with educating or informing the health care practitioners about a drug or medical device product, disease states or other

scientific information; *and* (2) any such communications occur in a venue and manner conducive to informational communication.
    - DPH ultimately declined to impose a specific dollar cap on modest meals and refreshments, to specify that such meals and refreshments cannot include alcoholic beverages and to define venues outside of the office or hospital setting where modest meals may or may not be provided.
- Manufacturers must also agree to provide quarterly reports on meals and refreshments provided *outside* the office or hospital setting detailing the locations, products discussed, and the associated total and per-participant expenditures.
- Manufacturers must self-report non-compliance.

The emergency regulations would have eliminated the general annual disclosure requirements for financial interactions after calendar year 2012 and the quarterly meals disclosure requirements once the Federal Sunshine Law was implemented. The final regulations instead eliminate disclosure only with respect to information disclosed under the Federal Sunshine Law. As a result, even after implementation of the Federal Sunshine Law, manufacturers will still have to report to DPH those financial interactions that are exempt from reporting under the Federal Sunshine Law or that involve health care providers other than physicians and teaching hospitals.

We continue to monitor these developments. If you have questions with respect to these developments or federal and state laws regulating financial interactions between pharmaceutical and medical device companies and health care providers, please contact your usual Ropes & Gray advisor.