On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act of 2009 into law. Section 6002 of the law, commonly known at the Physician Payment Sunshine Provision, contains provisions designed to increase transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies.

The Sunshine Provision requires drug and device manufacturers reimbursed through Medicare, Medicaid, or State Children’s Health Insurance Programs (SCHIP) to report to the Secretary of Health and Human Services (HHS) all payments to physicians and teaching hospitals on an annual basis. The first report is due on March 31, 2013. The bill also requires reporting of physician ownership interests in private companies including the dollar amount invested, the current value, and any payment or transfer of value to the owner, including dividends or other payments.

Information in these reports will include the name, business address, National Provider Identifier (for physicians), amount of payment or other transfer of value, date(s) on which payment was provided to the covered recipient, a description of the form of payment or other transfer of value (e.g. cash, in-kind items or services, stock, and stock options), and the nature of the payment or other transfer of value (e.g. consulting fees, honoraria, gifts, education, research funding or grants, and charitable contributions). The Act also grants the Secretary of HHS discretion to define other reportable forms of payment or other transfer of value.

The Secretary of HHS will make all of the information in these reports, except for the National Provider Identifiers, available to the public through the internet. Any physician named in the report will have 45 days to review and make corrections to the information submitted, prior to the report being made available to the public.

The Sunshine Provision provides for delayed publication for payments made pursuant to product research or development agreements and clinical investigations. Disclosure of these types of payments may be delayed until the date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration (FDA) or up to four calendar years after the date the payment or other transfer of value was made.

Payments or transfers of $10 or less are excluded from the reporting requirements unless the aggregate annual payment or transfer exceeds $100. Other excluded information includes product samples provided for patient use (provided the samples will not be resold), patient educational materials, loan of a covered device for a short-term trial period (not to exceed 90 days), replacement products provided under a warranty, discounts and rebates, and ownership or investment interest in a publically traded mutual fund.

Manufacturers that fail to comply with the reporting requirements are subject to penalties ranging from $1,000 to $10,000 for each unreported payment (not to exceed $150,000), and $10,000 to $100,000 for each knowing failure to report a payment (not to exceed $1,000,000).