HHS | Hart Health Strategies

Sunshine Act: Final Regulation and Short Summary for Physicians

Beginning August 30, 2013, most drug, device, and biological manufacturers must collect and then report annually to the Secretary of Health and Human Services (HHS) all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) to certain non-employee physicians and teaching hospitals. In addition to reporting on payments, most manufacturers, as well as certain group purchasing organizations (GPOs), must report ownership and investment interests held by physicians (or the immediate family members of physicians) in such entities.

Public Availability. HHS will then make most of the reported information publicly available. To ensure accuracy, applicable manufacturers, applicable GPOs, physicians, teaching hospitals, and physician owners and investors will have one 45 day period to review and correct the information before HHS posts it on a publicly available website. To expedite the review process, HHS encourages all physicians to register with HHS prior to the review period. By registering, HHS will be able to provide the information to be publicly reported expeditiously to the physician for review. HHS also has a 15 day period following the 45 day period by which to allow for any dispute resolution between the reporting manufacturer and the physician or teaching hospital. If, after that 15 day period, there is no resolution to the dispute, then the information submitted by the manufacturer will be captured on the public website, with an additional notation regarding ongoing dispute. The information on the public website will be available by September 30, 2014 and must be easy to aggregate, download and search.

Treatment of Requests for Transfers of Value. In situations when a physician or covered recipient requests that a payment or other transfer of value be transferred by the manufacturer to another individual or entity instead of being provided directly to himself/herself, HHS requires that these payments be reported under the name of the physician and that the manufacturer further note that it was transferred to an "individual" (name unspecified, given that such individual will not be able to review and confirm the accuracy of the information before it is made publicly available).

Research Payments. Applicable manufacturers are required to report numerous types of payments to physicians and teaching hospitals. These are outlined in the statute and include categories, such as consulting fees, food and beverages, and research payments. The proposed rule provides special consideration to research payments since collaboration between physicians and teaching hospitals, and manufacturers is essential to the development of new products. Research payments often include payment for all research activities, including patient tests and supplies, and the administration of the study, so the final rule outlines procedures to ensure that the nature of these relationships is understood, but there is also sufficient information on the extent of the research relationship. In addition to including information on the nature of these relationships, the statute also protects applicable manufacturers' competitive interests by allowing HHS to delay publication of certain research payments until the earlier of: (1) Food and Drug Administration (FDA) approval of the product that is the subject of the research; or (2) four years after the payment date.

Continuing Medical Education. While HHS did not provide a blanket exclusion for all payments to physicians serving as speakers at an accredited or certified continuing education program, HHS did provide a reporting exemption, provided that the following conditions are met: (1) the program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; (2) the applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and (3) the applicable manufacturer does not directly pay the covered recipient speaker.

Penalties for Failure to Report. The statute provides that violators of the reporting requirements (i.e., manufacturers) will be subject to civil monetary penalties (CMPs), capped at $150,000 for failure to report, and $1,000,000 for knowing failure to report.

State Law Preemption. That statute also preempts any State or local laws requiring reporting of payments or other transfers of value made by applicable manufacturers to covered recipients. No State or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under this statute, unless such information is being collected by a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight.

Timeline

- December 19, 2011 – Proposed rule released
- February 1, 2013 – Final rule released
- February 8, 2013 – Final rule published in the Federal Register
- On or about April 2, 2013 – Final rule goes into effect
- August 1, 2013 – Applicable manufacturers and applicable GPOs begin collecting data required
- March 31, 2014 – First data reporting requirement for applicable manufacturers and applicable GPOs to cover the time period from August 1, 2013 through December 31, 2013
- September 30, 2014 – CMS report to States regarding the first data reporting requirement for those States
- September 30, 2014 -- Information will be available on a public website
- April 1, 2015 – Report due to Congress regarding the first data reporting requirement