

Value of Industry-Provider Collaborations

Collaboration and interactions between medical technology companies and health care providers is essential to advancing new, safe and effective medical technologies that benefit patients. AdvaMedDx recognizes that this goal must be balanced against the obligation of health care professionals to make independent decisions regarding the health care of their patients. AdvaMed and its member medical technology companies are committed to transparency with patients about the ethical collaboration and interactions between their providers and industry. For this reason, AdvaMed supported the Physician Payments Sunshine Law.

AdvaMedDx member companies who have certified to the AdvaMed Code of Ethics on Interactions with Health Care Professionals support ethical collaborations. It is by driving ethical collaborations that we help protect patients. To see the companies that have certified to the Code, please visit:

www.advamed.org/CodeCertification



For more information about the value of interacting with a company that has certified to the AdvaMed Code of Ethics

This brochure is intended to provide a brief educational summary of Sunshine Law's key transparency provisions. Please visit AdvaMedDx.org to see the entire text of the law.

HOW CAN TEACHING HOSPITALS WORK TOGETHER WITH MEDICAL TECHNOLOGY COMPANIES TO PROMOTE ETHICAL COLLABORATION?

AdvaMedDx and its members support the transparency goal of the Sunshine Law to ensure that physicians and teaching hospitals make independent decisions regarding the health care of their patients. Teaching hospitals can work together with medical technology companies to facilitate this goal by promoting ethical interactions with industry and educating their health care professionals and patients about the requirements of Sunshine. Important points about Sunshine include:

- The importance of industry support of teaching hospitals and collaboration with health care professionals to advance research, education, improved patient care and other charitable goals.
- The need for educating patients and other stakeholders on the benefits of industry support of teaching hospitals and collaboration with health care professionals, the ethical context of such support and collaboration, and how such support and collaboration may result in interactions that include bona fide payments and transfers of value.
- The payment reporting requirements for all covered medical technology companies under the Sunshine Law and the penalties associated with non-compliance.
- The specific information that is required to be reported and will be made publicly available by HHS under Sunshine.
- The importance of working collaboratively with manufacturers to promote the accurate capture, tracking, auditing and monitoring, documentation and reporting of data and ensure maximum compliance with the Sunshine Law.



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THE PHYSICIAN PAYMENTS SUNSHINE LAW

a teaching hospital guide to industry transparency reporting requirements



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What is the Physician Payments Sunshine Law?

Signed into law in 2010, it requires medical technology manufacturers operating in the U.S. to comply with specific transparency requirements.

It's important to note that the Sunshine Law does not restrict industry-physician collaboration or interactions, or prohibit payments or transfers of value. *Rather, it requires tracking and reporting of payments and transfers of value that result from these interactions.*

Why was the Sunshine Law enacted?

The main purpose of the law is to provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies.

What is the timing on the Sunshine Law requirements?

In a proposed rule published in December 2011, the U.S. Department of Health and Human Services (HHS) indicated that companies will be required under the Sunshine Law to begin tracking payments and transfers of value on a date in 2012 to be determined by HHS after the proposed rule becomes final. Manufacturers must report this 2012 data by March 31, 2013. The government must post that data on a public searchable government-maintained website not later than September 2013.

Which recipients of payments or transfers of value will be reported?

The Sunshine Law requires that payments and transfers of value made by life science manufacturers to *Physicians* and *Teaching Hospitals* be reported.

How are "teaching hospitals" defined?

In the proposed rule, HHS defines "teaching hospitals" as institutions which receive Medicare graduate medical education funds under certain provisions of the Social Security Act. In addition, HHS has proposed that it will publish a list of teaching hospitals that fall within this definition on a public website once per year.

What "payments or transfers of value" must be reported?

Any single item worth \$10 or more
- and -
items worth less than \$10 when the aggregate transferred over a year exceeds \$100 given to a Physician or Teaching Hospital.

This includes reporting certain ownership or investment interests in companies, as well as the following examples:

- Consulting Fees
- Royalty Payments
- Research & Clinical Trial-related Expenses
- Training & Education Expenses
- Licensing Fees
- Honoraria
- Grants & Charitable Donations
- Meeting Support
- Educational Items
- Expenses such as Travel, Lodging, & Meals
- Payment made to another entity "at the request of" or "on behalf of" a Physician or Teaching Hospital

Details that must be captured & reported:

- Name and Address of the Covered Recipient
- Form of Payment (Cash or Other Transfer of Value)
- Dollar Value and Date of the Transfer/Payment
- Nature of Payment (e.g., Charitable Donation, Grant)
- Product Associated with Interaction
- Category (from government list)
- Other Identifying Information (Contact Type, Specialty, National Provider ID)

Are medical technology companies tracking the data to ensure compliance with the Sunshine Law?

Yes. Companies are now enhancing their existing tracking systems to ensure the accurate capture of required payment data beginning in 2012.

Can teaching hospitals review the data and make corrections, if necessary?

The Sunshine Law provides the opportunity for physicians and teaching hospitals receiving payments or other transfers of value to review and make corrections to publicly submitted data. In addition, some medical technology companies are developing internal procedures which will enable physicians and teaching hospitals to review company-specific payment data prior to public disclosure.

What are the penalties for non-compliance?

Depending on the circumstances, non-compliance with the Sunshine Law's reporting requirements could subject a medical technology company to financial penalties ranging from: (a) \$1,000 to \$10,000 for each payment or transfer of value not reported; and (b) \$10,000 to \$100,000 for "knowingly" failing to report a payment or transfer of value.

In addition, reporting incomplete or inaccurate information has the potential to mislead patients and other stakeholders and damage the reputation of medical technology companies, physicians and teaching hospitals.

How will the data be reported? What will be done with the reported information?

The data will be reported annually by companies. By 2013, HHS will make the submitted data available through a public website that is searchable and understandable. The Secretary of HHS will also be required to submit a report to Congress on an annual basis.