

The Physician Sunshine Act

Strengthening Industry-Physician Interactions Through Transparency

What is the Physician Payments Sunshine Act?

This law requires medical technology manufacturers that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals.

The Sunshine Act was signed into law in 2010 and Final rule published in the US Federal Register on February 8, 2013 (*Reference: 42 CFR 402 and 403*).

What is an "Applicable Manufacturer"?

Medical technology manufacturers operating in the U.S. that manufacture medical products covered under Medicare or Medicaid programs must register with the Center for Medicare and Medicaid Services (CMS) and report payments and transfers of value. Extremity Medical is an applicable manufacturer as defined under the Sunshine Act.

Who is a "Covered Recipient"?

The Sunshine Act requires that payments and transfers of value made by medical technology manufacturers to **Physicians** and **Teaching Hospitals** be reported.

Under the Sunshine Law, "Physicians" include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors.



What "Payments or Transfers of Value" must be reported?

Any single transfer of value exceeding \$10 or \$100 aggregate per calendar year for each "covered recipient". Examples of reportable payment types include:

- Consulting Fees
- Speaking Fees
- Expenses such as Travel, Lodging and Meals
- Grants and Charitable Donations
- Payments made to a third-party "at the request of" or "on behalf of" a Physician

What details must be reported?

- · Name and address of covered recipient
- Recipient identifying information (e.g., recipient specialty, NPI number, state licensure number)
- Form of payment
- Dollar value and date of transfer/payment
- Nature of payment (e.g., Consulting Fee, Grant)
- Product(s) associated with interactions

What is the reporting period?

The first report will be filed by March 31, 2014 and will include transfers of value for the time period of August 1, 2013 through December 31, 2013.

Regulations indicate that the reported information will be made available to the public on the CMS website beginning September 2014.

Can Physicians review data and make corrections?

The Sunshine Act provides an opportunity for Physicians to review and make corrections to manufacturer-reported spends. Physicians will be notified by CMS and given 45 days to dispute a report. Dispute resolution must be made between the Manufacturer and Physician and resolution presented to CMS within 15 days after the 45 day review period.

What are the penalties for non-compliance?

Non-compliance with the Sunshine Act'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 could mislead the public and damage the reputations of medical technology companies, Physicians and Teaching Hospitals.

Extremity Medical Compliance

Extremity Medical conducts its affairs in compliance with all applicable laws and regulations and in accordance with Extremity Medical's high ethical standards. Extremity Medical remains current with evolving laws and regulations and continuously augments our practices for the benefit of our company and our surgeon partners.

Strict compliance to the laws and regulations, industry guidance and to Extremity Medical policies governing interactions between manufacturers and physicians is in our mutual best interest.

Contact

Please contact Extremity Medical with any questions related to reporting under the Sunshine Act or Extremity Medical's Compliance Program.

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