



ENFORCEMENT PANEL: Federal Sunshine Law

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Moderator:

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Federal Sunshine Law Penalties



- ▶ Civil monetary penalties (CMPs) from \$1,000 to \$10,000 for each failure to timely, accurately or completely report a payment or other transfer of value or ownership or investment interest, up to \$150,000 per annual submission
- ▶ CMPs from \$10,000 to \$100,000 for each “knowing failure” to timely, accurately or completely report a payment or other transfer of value or ownership or investment interest, up to \$1 million per annual submission
- ▶ Combined maximum annual penalty of \$1,150,000

- ▶ Factors to be considered when determining the amount of the CMPs include, but are not limited to, the following:
 1. The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest
 2. Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report
 3. Level of culpability
 4. Nature and amount of information reported in error
 5. Degree of diligence exercised in correcting information reported in error

Federal Sunshine Law Assumptions Document



- ▶ Applicable manufacturers and applicable GPOs may submit an assumptions document that explains the reasonable assumptions made and methodologies used to report payments or other transfers of value
- ▶ “We do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution”
 - ▶ Will not be posted on public website or provided to Covered Recipients by CMS
 - ▶ FOIA requests – predisclosure notification
 - ▶ Enforcement authorities – disclosure to DOJ or OIG for audit or investigation

Federal Sunshine Law Audits



- ▶ “HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information”
 - ▶ False certifications

Recent Vermont Reporting Enforcement Activity



- ▶ In September 2013, the Vermont Attorney General (AG) posted information related to 25 recent enforcement activities
 - ▶ First enforcement actions that the Vermont AG has made public since the law was first enacted in 2009
 - ▶ 24 of the 25 posted enforcement actions relate to the failure of the manufacturer to annually report payments and transfers of value provided to health care professionals
 - ▶ Vermont AG entered into an Assurance of Discontinuance with each manufacturer that requires the manufacturer to comply with the statute going forward and to pay the full registration fee due for the year(s) in which the report was not filed
 - ▶ Assurance releases and discharges claims related to the the failure to report under 18 V.S.A. § 4632
 - ▶ Expressly states that gift ban violations under 18 V.S.A. § 4631 are not released

Recent Vermont Reporting Enforcement Activity



- ▶ In September 2013, the Vermont Attorney General (AG) posted information related to 25 recent enforcement activities
 - ▶ 1 enforcement action with Novartis relates to a manufacturer's violation of the law's gift ban requirements for six meals with HCPs between May 2010 and December 2011
 - ▶ Civil penalties of \$36,000
 - ▶ Assurance of Discontinuance
 - ▶ Appears that information regarding gift ban violations was self-disclosed by Novartis to the Vermont AG and that Novartis sought reimbursement from the HCPs for the gift ban violations

Recent Oregon Enforcement Activity



- ▶ In August 2013, two Oregon HCPs entered into settlement agreements with the Oregon Department of Justice (DOJ) for failing to inform their patients of relationships with a medical device manufacturer
 - ▶ Civil action was brought under the Oregon Unlawful Trade Practices Act
 - ▶ The HCPs were compensated by Biotronik, Inc. for participating in a program in which sales representatives were trained and certified to assist other physicians with programming and calibrating the company's products
- ▶ Penalties
 - ▶ \$25,000 fine each
 - ▶ Each must publish on his practice website a hyperlink to the CMS database of payments reported by pharmaceutical and medical device manufacturers under the federal Sunshine Law