

**Sixth Annual Summit On
Disclosure, Transparency and Aggregate Spend**
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Mini Summit IV: Sunshine for Medical Device Manufacturers

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Overview

- AdvaMed and Advocacy for the Medical Device Industry
- Specific Sunshine Issues for Medical Device Companies
 - Physician Ownership Issues
 - Indirect Physician Payments – e.g., Fellowship Grants
 - Demonstration and Evaluation Equipment (and other un-returned equipment)
 - Bundled Product Sales/Discounts with Minimum Purchase Requirements
 - Legal Settlements
- Ongoing Efforts
 - Reprints
 - Benchmarking
 - Public Outreach
 - Global harmonization

AdvaMed and Advocacy for the Medical Device Industry

- Sunshine as a top advocacy priority
- Goals:
 - Offer a device-specific voice
 - Extoll the value of industry collaboration
 - Creating a level playing field

Physician Ownership

- **Physician owned manufacturers and distributors**
 - History of PODs and Sunshine
 - Impact of the special fraud alert and OIG report
 - Sunshine reporting issues
 - Potential effects and pitfalls of the Sunshine report on manufacturer relationships with PODs
- **Indirect physician payments**
 - To physician owned companies
 - Fellowship grants

Indirect Payments to Physicians

- What are Indirect Payments under Sunshine?
- Key issues for Medical Device Companies:
 - Purchases from physician owned companies
 - Fellowship grants

Demonstration and Evaluation Equipment

- What rules apply?
- Key issues for Medical Device Companies:
 - When is a demo/eval not a demo/eval?
 - How to treat demos/evals past 90 days?
 - Penalty provisions in demo/eval contracts
 - How to value?

Bundled Sales Arrangements

- What are Bundled Sales Arrangements?
- Key issues for Medical Device Companies:
 - Failure to meet minimum purchase requirements
 - How to value?

Legal Settlements

- How do the Final Regulations address legal settlements?
 - FAQ
- Key issues for Medical Device Companies:
 - Does the FAQ apply to most situations?
 - Royalty resolutions
 - Malpractice liability indemnifications

Ongoing Efforts

- Reprints status
- Benchmarking
 - Availability of tools for small companies.
- Specialty society outreach and education efforts
- Promotion of the value of industry collaboration
- Global harmonization issues
 - EFPIA Code for devices?

Questions?

