

2009 Update:

# THE PHYSICIAN PAYMENTS SUNSHINE ACT

# Push for federal disclosure legislation

- ◆ Only a handful of states currently have disclosure requirements, but the number is growing.
- ◆ Companies have to comply with a growing number of state laws and regulations.
- ◆ Of existing requirements, most don't cover medical device companies, few make information public.

- ◆ Patients have no definitive resource for information on physician-industry relationships.
- ◆ Medical professionals have limited ways to learn about potential conflicts of thought leaders, article writers, speakers.
- ◆ Research institutions have demonstrated inability to monitor potential conflicts of their employees.

# New legislation

- ◆ What must be reported:
  - ◆ Name
  - ◆ Business address
  - ◆ Value of payment
  - ◆ Dates of payment
  - ◆ Form of payment
  - ◆ Nature of payment
  - ◆ Product connected to payment, if any

# New legislation

- ◆ What must be reported:
  - ◆ Payments over \$100 annually
  - ◆ Differs from prior \$500 threshold
  - ◆ Physician ownership in nonpublic companies

# New legislation

- ◆ Penalties for noncompliance:
  - ◆ \$1,000 to \$10,000, with annual cap of \$100,000
  - ◆ **Knowing noncompliance:**
    - ◆ \$10,000 to \$100,000, with \$1,000,000 annual cap.

# Preemption

- ◆ “the provisions of this section shall preempt any law or regulation... that requires an applicable manufacturer to disclose or report information regarding a payment or other transfer of value provided by the applicable manufacturer to a covered recipient.”
- ◆ This law “shall not preempt any law... that requires the disclosure or reporting of information not required to be disclosed or reported under this section.”

# What is next

- ◆ Currently accepting comments
- ◆ Input, questions always welcome: (202) 224-4515