

Dealing with Transparency – How Drug and Device Companies are Operationalizing Disclosure of Education Grants

Grant Transparency and Medical Device Companies

Vickie McCormick
Chief Compliance Officer



ST. JUDE MEDICAL

MORE CONTROL. LESS RISK.

Disclosure Issues Facing Device Companies

- Responses to 2/26/08 Grassley Letter
 - Disclosing Now
 - Stryker (per DPA)
 - Future Disclosure in Process
 - Medtronic (05/01/2008)
 - Appears limited to Foundation grants
 - Boston Scientific
 - In process to comply with Sunshine
 - Merck
 - Pfizer (2008)
 - Amgen
 - AstraZeneca (Aug, 2008)
 - Bristol-Myers Squibb (Q1 2009)
 - J&J (Q1 2009)
 - Evaluating
 - Abbott
 - Supports Disclosure (Sunshine Legislation)
 - Baxter
 - St. Jude Medical
 - Reservations/No
 - Schering Plough
 - Wyeth (Also evaluating)

Disclosure Issues Facing Device Companies

- Same/similar as for pharmaceutical companies
- Multiple divisions and grant procedures for larger diverse companies
 - Different and incompatible systems
- Data accuracy and completeness
 - Inconsistent data collection practices
 - Difficulty in identifying matching organizations and distinguish between different organizations with similar names
 - Collecting all necessary and appropriate information
- CME provider relationships
 - Effect of ACCME clarification on industry providing program topic/faculty ideas and suggestions
- Prior notification to and acceptance by recipients
 - Issue for orthopedic company disclosure of consulting payments and benefits in kind
 - Condition of accepting grant
- What and how much to publish
 - Criteria for evaluating grant requests
 - Making it useful to public
 - Effect on demand

DPA and CIA Lessons Learned

- Difficulty of quickly compiling information
 - \$25K increments for consulting agreement disclosures under ortho company DPAs
 - Grant information may be easier to compile than consulting/research payments and benefits
 - Start figuring out now how to compile information from multiple sources
- Grants are typically “contractual arrangements” under CIAs
 - Compliance with requirements for contractual arrangements including signed agreements
- Identifying the recipient
 - Multiple requests from same organization with different names
 - Using tax identification numbers
 - CME Provider receiving check vs. sponsoring medical organization
 - Related organizations
- Centralizing Grant Function
 - Limit sources of information
 - Improve consistency and accuracy of information
 - Consistent criteria for evaluating grant requests

Impact of the Physician Payments Sunshine Act

- Scope appears to not include most educational grants
 - Limited to items of value given to physicians and organizations at physicians' direction
 - Most educational grants given to organizations (CME providers) and institutions (academic medical centers), not physicians or physician groups
 - What about a physician group affiliated CME provider?
 - Scholarships?
 - Although physicians-in-training benefit from the scholarship, they are typically paid to academic institution or program sponsor