

Practical Approaches to Implementing an Aggregate Spend Program

Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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ROPES
& GRAY

Eve Brunts
Ropes & Gray
617.951.7911
eve.brunts@ropesgray.com

Overview of Federal Sunshine Law

Manufacturers of a drug, device, biological or medical supply that is covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient

Overview of Federal Sunshine Law: Applicability

- Manufacturer
 - Scope of Activity
 - Any entity engaged in the production, preparation, propagation, compounding, or conversion of a covered product **or**
 - Any entity under common ownership with manufacturing entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product
 - Location of Operations
 - Entity must operate in the United States, or in a territory, possession or commonwealth of the United States

Overview of Federal Sunshine Law: Applicability

- Covered Product
 - Manufacturer must manufacture (or support) drug, device, biologic or medical supply
 - No definition of any terms
 - Compare to state laws that incorporate FDA definitions for regulated products
 - Potential uncertainty
 - Are there any products considered medical supplies that are not also medical devices?
 - Product must be reimbursable under Medicare, Medicaid or Children's Health Insurance Program
 - No distinction on separate reimbursement versus reimbursement as part of global payment for service, procedure or stay

Overview of Federal Sunshine Law: Applicability

- **Manufacturer of Covered Product**
 - Entity supporting manufacturing entity
 - Multiple companies or multiple operating divisions
 - Foreign manufacturers
 - Any covered products distributed in U.S.?
 - Foreign laws permit disclosure of interaction?
 - Co-marketing arrangements
 - Independent contractor distributors
 - Title to product retained?
 - Contract manufacturer/component manufacturer

Overview of Federal Sunshine Law: Applicability

- Covered Recipients
 - Physician
 - Physician defined consistent with Medicare statute to include physician, osteopath, dental surgeon, podiatrist, optometrist and chiropractor
 - Excludes manufacturer employee
 - Teaching Hospital
 - How identify teaching hospital? Not defined in statute
 - What transfers tracked when teaching hospital is component of larger entity (such as university)?
 - Track payments to teaching hospital only **or** to hospital and individual employees and agents as well?
 - Requests for CMS Database of Physicians and Teaching Hospitals Outstanding

Overview of Federal Sunshine Law: Reporting Requirements

- Covered Recipients
 - Manufacturers must report certain payments or other transfers of value made **directly or indirectly** to:
 - Covered recipient (*i.e.*, physician or teaching hospital)
 - Physician not defined to include office staff (as most state laws do) so when attribute transfer of value to physician practice or staff as transfer to physician?
 - Entity or individual at the request of or designated on behalf of a covered recipient
 - **Exclusion** for **indirect** transfers of value **if** identity of recipient not known

Overview of Federal Sunshine Law: Reporting Requirements

- Covered Recipients
 - Payments to Third Parties
 - Principle:
 - Identity known? When known - time of selection or time of payment?
 - Pass through of payment?
 - Income tax treatment?
 - Specific Issue:
 - Physician employer
 - Clinical site (with affiliated physician investigator)
 - Contract research organization
 - Grant to academic institution or professional society

Overview of Federal Sunshine Law: Reporting Requirements

- Transfers of Value
 - Reportable payments or transfers of value include anything of value **unless** specifically excluded
 - Exclusions generally relate to amount, type or purpose of transfer
- Excluded Transfers of Value
 - Amount of Transfer
 - Any transfer less than \$10 unless annual aggregate value transferred in calendar year exceeds \$100
 - Manufacturer still needs to track in case aggregate threshold met

Overview of Federal Sunshine Law: Reporting Requirements

- Excluded Transfers of Value
 - Common Business Practices
 - Discounts (including rebates)
 - Loan of a covered device for 90 days or less to permit evaluation
 - Items or services provided under contractual warranty if terms set forth in purchase or lease agreement
 - Patient/Charitable Activities
 - Product samples not intended to be sold and intended for patient use
 - Educational materials that directly benefit patients or are intended for patient use
 - In-kind items used for the provision of charity care

Overview of Federal Sunshine Law: Reporting Requirements

- Excluded Transfers of Value
 - Transfers Not Related to Business Relationship
 - Transfer of value to covered recipient as patient
 - Payment for non-medical professional services of licensed non-medical professional
 - Payment for services related to civil or criminal action or administrative proceeding
 - Payment by self-insured employer for health care to employees
 - Dividend/profit distribution from publicly traded security and mutual fund

Overview of Federal Sunshine Law: Reporting Requirements

- Information Reported
 - Name
 - Business address
 - Specialty and National Provider Number (if physician)
 - Amount of transfer of value
 - Date value provided to recipient
 - Form of value
 - Cash or cash equivalent
 - In-kind items or services
 - Ownership interest or return on investment

Overview of Federal Sunshine Law: Reporting Requirements

- Information Reported

- Nature of value

- Consulting fees
 - Compensation for services (other than consulting)
 - Honoraria
 - Gift
 - Entertainment
 - Food
 - Travel (including destinations)
 - Education
 - Research
 - Charitable contribution
 - Grant
 - Royalty or license
 - Current or prospective investment interest
 - Direct compensation for serving as faculty or speaker at medical education program

Overview of Federal Sunshine Law: Reporting Requirements

- Information Reported
 - Covered product *if* transfer of value related to marketing, education or research specific to particular product
 - Identifying the “related product” for medical device companies?
 - Any other information as specified by CMS

Overview of Federal Sunshine Law: Reporting Requirements

- Research and Development Activities
 - Required information reported for transfers of value related to services provided for research and development activities but delay in public disclosure on website
 - Delay relates to research and development activities, including clinical investigations, of new product or new use of existing product
 - Sponsored clinical trials v. investigator-initiated trials
 - Delay until first public website update after the earlier of new product or new use approval/clearance or four years after payment date
 - Information maintained by government as confidential during delay period

Overview of Federal Sunshine Law: Interpreting Reporting Requirements

- Allocating to Multiple Recipients
 - Trade show
- Direct and Indirect Costs
 - Speaker program
 - Product training
- Specific Costs
 - Loaners/Demos
 - Reprints
 - Educational Materials and Activities
 - Research Materials (research grant *versus* sponsored research)
 - Data (e.g., for research)
 - Stock Options
- Payment Date

Overview of Federal Sunshine Law: State Pre-emption

- Preemption of state law (or portion of state law) that requires disclosure “in any format” of information required to be reported under federal law
- No preemption of state law (or portion of state law) that requires disclosure of information:
 - Other than by “applicable manufacturer” to “covered recipient”
 - Other than information reported under federal law (except no reporting transfers of value less than \$10)

Federal Sunshine Law: Compliance in the Face of Uncertainty

- Reasonable Interpretations Made and Documented
 - State law approaches if no federal guidance
 - IRS treatment if no federal guidance
 - Industry benchmarking
 - Policies, procedures and internal records
- Capture More rather than Less Information
 - Broader collection now and selective reporting later
 - Recipients
 - Transfers of value without exclusions
 - Information necessary to characterize transfer of value
 - Allows flexibility if/when guidance issued
 - Assists with coordination of federal and state reporting responsibilities
- Revise Business Practices to Minimize Reporting Obligations and/or Enhance Information Flow from Third Parties