

Shedding Light on the Sunshine Act

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Jean C. Hemphill
hemphill@ballardspahr.com
215.864.8539

Mary J. Mullany
mullany@ballardspahr.com
215.864.8631

Program Agenda

- Sunshine Act and Final Rule Overview
- Definitions
- What's Required and What's Not
- Process from Data Collection to Publication by CMS
- Enforcement Issues
- What to Do Now

Physician Payment Sunshine Act

- Section 6002 of the Affordable Care Act
- **Purposes of the Sunshine Act:**
 - Through the transparency of public disclosure, decrease potential conflicts of interest and improper influence on research, education and clinical decision-making resulting from payments and/or investment relationships between physicians and/or teaching hospitals and covered drug, device and other product manufacturers or GPOs
 - Preserve clinical integrity and patient care
 - Potentially decrease healthcare costs

Sunshine Act Final Rule

- Published in Federal Register: February 8, 2013
- Effective Date: April 9, 2013
- First Data Collection Date: August 1, 2013
- First Reports Due By: March 31, 2014
- First Publication Date By: September 30, 2014
- Subsequent Year Publications By: June 30
- CMS OPENPAYMENTS site:
<http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>

Sunshine Act Annual Reports

- **Report 1 – Payments to Covered Recipients**
 - Applicable manufacturers of drugs, devices, biologicals or medical supplies covered under Title XVII of the Social Security Act (Medicare) or a State plan under Title XIX of the Act (Medicaid) or Title XXI of the Act (CHIP) report certain payments or other transfers of value to physicians and teaching hospitals
- **Report 2 – Physician Ownership/Investment Interests**
 - Applicable manufacturers and applicable group purchasing organizations report information about the ownership or investment interests held by physicians or immediate family members in such entities

Sunshine Act Definitions

- **Covered Entities** – Applicable Manufacturers and Applicable GPOs
- **Covered Recipients** – Physicians and Teaching Hospitals
- **Covered Product** – a drug, device, biological or medical supply (1) for which payment is “available” under Medicare, Medicaid or CHIP, **AND** (2) for which a prescription is required to dispense or, if a device or medical supply, that requires premarket approval by or notification to the FDA

Sunshine Act Definitions (cont.)

- **Applicable Manufacturer** is an entity that is:
 - engaged in production, preparation, propagation, compounding or conversion of a Covered Product operating in the U.S.
 - under common ownership with such an entity, and provides assistance to such entity with respect to such activities
- Applicable Manufacturers considerations
 - Operating in the U.S.
 - Distributors and Wholesalers
 - Contract Manufacturers
 - Joint ventures/co-promoters

Sunshine Act Definitions (cont.)

- Exemptions from Applicable Manufacturer definition
 - Hospitals, hospital-based pharmacies and laboratories that produce or manufacture materials/products solely for own use
 - Compounding pharmacy that:
 - Maintains establishment in compliance with local laws;
 - Regularly engages in dispensing prescription drugs or devices based on prescriptions from licensed practitioners; and
 - Does not produce, prepare, propagate, compound or convert drugs or devices for sale other than in the regular course of its retail business to individual patients.

Sunshine Act Definitions (cont.)

- If Applicable Manufacturer gives something of value to a third party and is unaware of the identity of a subsequent Covered Recipient payee, the Applicable Manufacturer does not need to report
 - Most commented upon section of the proposed rule
 - CMS does not want the exception to swallow the rule
 - Knowledge standard similar to False Claims Act definition
 - Includes knowledge of an agent of the Applicable Manufacturer

Sunshine Act Definitions (cont.)

- **Covered Recipients** – (1) physicians, other than a bona fide employee of the Applicable Manufacturer, and (2) teaching hospitals
 - Physician as defined in Section 1861(r) of the Act (medicine, osteopathy, dentists, podiatrists, optometrists and chiropractors legally authorized to practice by a State)
 - Teaching Hospital – any institution receiving payments directly or indirectly under graduate medical education, including psych hospitals
- **Applicable GPO** is a group purchasing organization operating in the U.S. that purchases, arranges for or negotiates the purchase of a Covered Product

Payments

- Payments are direct or indirect payment or any transfer of value either (1) to a Covered Recipient or (2) to an entity or individual at the request of or designated on behalf of a Covered Recipient
 - Discernable economic value on the open market
- Once a Covered Entity is subject to reporting, it must report all payments to Covered Recipients, even if it is not related to a Covered Product
 - Exception – if less than 10% of total gross revenues from Covered Products during prior fiscal year, only need to report payments associated with Covered Products

Form of Payments

- Form of Payments
 - cash and cash equivalents
 - in-kind or services
 - stock or other ownership interest
 - dividends, profit or other return on investment
 - other form of payment

Nature of Payments

- Consulting Fees
 - Written agreement
- Compensation for services other than consulting
 - One of the catch-all categories
- Honoraria
- Gifts
 - Don't use as default if other category is more exact
- Charitable contributions
 - Only use for true charitable contributions

Nature of Payments (cont.)

- Entertainment
- Food and beverage
- Travel and lodging
- Royalty or license fees
- Grants
- Space rental or facility fees
- Current or prospective ownership or investment interests in Applicable Manufacturer

Nature of Payments Education

- Education - multiple categories within education, including exemption
 - Reportable
 - serving as faculty or speaker at unaccredited education sessions or other classes, activities, programs or events that involve imparting or acquiring particular knowledge or skill
 - serving as faculty or speaker at accredited CME that does not fit within exemption
 - other payments to attendees of education programs, such as meals, travel

Nature of Payments (cont.)

- Exempt - direct compensation for faculty or speaker fees at accredited CME, if all of the following are met:
 - meets requirements of ACCME, AOA, AMA, AAFP or ADA CERP;
 - Applicable Manufacturer does not select speakers or provide agency with list of recommended speakers to be considered; and
 - Applicable Manufacturer does not pay speaker directly.

Nature of Payments – Research

- Research Payments
 - Scope of Research
 - Includes pre-clinical and FDA Phase I to IV research, investigator-initiated study or investigation and product development
 - Subject of a written agreement **or** a research protocol
 - Can be through a CRO or other intermediary with chain of agreements
 - Any payment should be reported if fits as “research” but research-related payments that don’t fit here should be reported in another category
 - Include payments to PI who is a physician even if not treating patients

Nature of Payments – Research (cont.)

- Reporting Research Payments
 - Reported in a different CMS-provided template with information different from other payments
 - Do not split into direct or indirect payments, instead report entire payment, including the entity paid and the PI(s)
 - The payee is named even if not a Covered Recipient

Nature of Payments – Research (cont.)

- Reporting items:
 - Applicable Manufacturers name
 - Name of research institution and business address
 - Name of PI (and all information like other Covered Recipients)
 - Total payment
 - Name of study
 - Related Covered Product(s), including NDC
 - Context of research (optional)
 - Clinicaltrials.gov identifier (optional)
 - Whether a public disclosure delay should be granted pending publication or results (Yes/No)

Nature of Payments – Research (cont.)

- Special guidance for Pre-Clinical Research
 - Relates to lab and animal studies prior to human studies.
 - Only need to report name of research institution, PI and total payment (no study details)
- Payments aggregated – patient care, including diagnostics, exams, lab, treatment and managing study, provision of Covered Product and other in-kind items, medical writing and publication
- Reported separately – study steering committee service, data monitoring and travel and lodging and meals (in that other category unless specified in agreement)
- Research payments will be listed separately by CMS for teaching hospitals and physicians

Nature of Payments – Research (cont.)

- Delayed Reporting for Certain Research Payments
 - Section 1128G(c)(1)(E) of the Act provides for delayed publication of payments made pursuant to certain research activities/clinical investigations in advance of publication of research results
 - Research activities for *new* Covered Products will fit within the delay exception, but *new applications* for existing Covered Products will only be granted if the research does not meet the “clinical investigation” definition
 - Clinical investigation – Phase I to IV for drugs/biologics and clearance trials for devices/medical supplies

Nature of Payments – Research (cont.)

- Reporting is later of receipt of (1) FDA approval, clearance or licensure or (2) 4 calendar years after the date of payment
 - Reported even if product is not approved, licensed or cleared by FDA
- Covered Entities may (but are not required to) identify select research payments as eligible for delayed reporting
 - If not identified, CMS will publish in next annual cycle
- Need to report every year until FDA action is achieved and/or 4 year period passes – the information will then be reported in next cycle

Payments Excluded from Reporting

1. Existing Personal Relationships
2. Value less than \$10, until aggregate of \$100/year/recipient
 - Small value items at conferences exempted from aggregation and reporting rules
 - Will increase with CPI on a CY basis beginning for CY 2014
3. Education Materials intended for Patient Use or for Patient Benefit
 - Includes written and electronic materials and other items, such as wall models and anatomic models for office use (items that device and medical supply manufacturers frequently provide)

Payments Excluded from Reporting (cont.)

4. Discounts and Rebates

5. In-Kind Items for Provision of Charity Care

- Applicable Manufacturer and Covered Recipient can agree in writing that in-kind donations are to be used only for charity care
- Does not apply to donations to fund charity care or to in-kind items that can be used for all patients, regardless of ability to pay

6. Product Samples

- Includes coupons and vouchers
- No need to track how actually used
- Does include demonstration materials (*e.g.*, syringes)

Payments Excluded from Reporting (cont.)

7. Short Term Loans

- Includes devices and medical supplies provided for demonstration purposes, both marketed and under development
- 90-day limit on such placement, otherwise becomes reportable

8. Contractual Warranty

- Includes maintenance contracts, replacements in event of product recalls and traditional contractual warranties, including extensions and services outside warranty period

Payments Excluded from Reporting (cont.)

9. Covered Recipient as Patient

- Includes participation in research study

10. Provision of Healthcare

- Includes healthcare to covered recipients and immediate family members under self-insured plans or outside of such plans (health fair or on-site clinic are examples used)

11. Nonmedical Professional

- If transfer of value affects only the nonmedical professional and is for rendering professional services (not personal benefit)

12. Civil or Criminal Actions or Administrative Proceedings

Sunshine Act – Report 1

- Payments under Section 1128G(a)(1)(A)
- Elements Contained in Report
 - Name (middle initial and suffix (may be in NPES))
 - Business Address - full street address
 - for teaching hospitals, CMS-identified address
 - for physician or group, primary business address
 - Physician's NPI and State license number
 - Specialty (use the NPES provider taxonomy categories of specialties; only need to report one per physician)

Sunshine Act – Report 1 (cont.)

- Date of Payment
 - can aggregate on date of first payment or list each on separate line (*i.e.*, consulting agreement)
 - report only payments for that year; don't shift payments into another year
 - be consistent in reporting, *i.e.*, for flights use flight date or date of purchase of ticket
- Amount of Payment
- Context of Payment (optional)

Sunshine Act – Report 1 (cont.)

- Covered Product if the payment is related to “marketing, education or research” of a particular Covered Product
 - Cannot just leave blank if N/A or multiple, or mix of non-covered and Covered Products – be as descriptive as possible within such possibilities
 - Marketed name if available, including National Drug Code (NDC) identifier; name registered on clinicaltrials.gov if not
 - For devices, supplies, can list therapeutic area or product category
 - Multiple Covered Products, up to 5 can be reported

Sunshine Act – Report 1 (cont.)

- Form and Nature of Payment
- Name of entity receiving payment if not direct
- Whether Covered Recipient is a physician owner or investor (Yes/No)
- Research Payment-related information
- Assumptions Document
 - Voluntary
 - Not made public or given to Covered Recipients by CMS
 - Potential FOIA and Enforcement Agency requests

Sunshine Act – Report 2

- Physician Ownership and Investment Interests – Payments under Section 1128G(a)(2)
 - Applies to Applicable Manufacturers and Applicable GPOs
 - Applies to all physicians, even physicians employed by Applicable Manufacturers
- Ownership or Investment Interests
 - Definition similar to that used in physician self-referral law
 - Direct or indirect interest in equity, debt or other means (includes secured notes, derivatives, all types of entity equity)

Sunshine Act – Report 2 (cont.)

- Ownership/Investment Interests (cont.)
 - Does not include
 - Publicly traded securities or mutual funds
 - Retirement plan interests
 - Stock options and convertible securities intended as compensation until they are exercised
 - Unsecured loan subordinated to a credit facility
 - Stock options may need to be reported as indirect transfer of value in Report 1 (not applicable to GPOs) or as an indirect value under this Report 2

Sunshine Act – Report 2 (cont.)

Report Line Items:

1. Name, address, NPI, at least one State professional license number and specialty
2. Dollar amount invested
3. Value and terms of the ownership or investment interest
4. Date
5. Whether held directly or by immediate family member of physician

Sunshine Act – Report 2 (cont.)

6. Any payments or transfers of value in CY, plus indicate physician is an owner/investor
7. Form and nature of payment
8. Name of Covered Products, including NDC, if available
9. Name of entity paid if not to physician directly
10. Statement of context and assumptions (optional)

Sunshine Act – Report Submission

- Registration with CMS
 - Covered Entities
 - Covered Recipients
- File Format
- Attestation Process
 - Timeliness, accuracy and completeness of information
 - Data not “submitted” until certification filed
 - Need to certify updates or amendments
- Notice of Errors/Omissions

Sunshine Act – Report Submission (cont.)

- Review Period prior to public disclosure
 - 45-day review period
 - Only Covered Recipients will be given review access via secure website
- Dispute Resolution
 - 15-day period after end of review period
 - CMS as facilitator, not mediator
 - If dispute not resolved, Covered Entity data will be published with “disputed” notation

Sunshine Act – Penalties

- Authorizes imposition of CMPs for failure to report required, accurate and complete information on a timely basis.
 - Inadvertent/Unknowing Failure to Report: At least \$1,000 and no more than \$10,000 for each payment not reported as required; maximum annual penalty of \$150,000.
 - Knowing Failure to Report: At least \$10,000 and no more than \$100,000 for each payment not reported as required; maximum annual penalty of \$1,000,000.
- Maximum penalty of \$1,150,000 for each Covered Entity

Sunshine Act – Penalties (cont.)

- Factors CMS to consider when setting penalties:
 - Length of delay in filing; length of Covered Entity knowledge of payment; amount of payment; level of culpability; nature and amount of mis-reported data; degree of diligence
- No penalties will apply to corrected reports during the review/correction process, but will apply afterwards
- HHS OIG also has ability to assess penalties
- Books/records retention at least 5 years after date of publication to allow for audit (can mean up to 9 years b/c of delayed reporting)

Sunshine Act – Other Issues

- Annual Report by CMS
 - Congress
 - States
- Preemption of State Law
 - Preempts transparency laws
 - Preemption starts with Effective Date of Rule
 - Does not preempt other State laws collecting similar data for other purposes
- Audits by CMS

Sunshine Act – What to Do Now?

- Do you have Covered Products?
 - Contribution to gross revenue
 - Are there any wholesalers/distributors, contract manufacturers or joint venture or co-promotion partners you need to evaluate and contact?
- Gain familiarity with dedicated web portal
OPENPAYMENTS
- Consolidated Reporting
 - Is it relevant to your business?

Sunshine Act – What to Do Now? (cont.)

- **Develop Data Collection and Submission Process**
 - Assess data availability in your current systems
 - When available, compare to CMS data, particularly with respect to physicians
 - Identify principal contacts for CMS and team leaders
 - Determine whether to provide data on a pre-submission basis to Covered Recipients
- **Determine when/how to communicate with Covered Recipients**

Sunshine Act – What to Do Now? (cont.)

- Evaluate ongoing research activities
 - Data collection
 - Any research qualify for delayed reporting?
- Develop internal procedures for identifying those payments that need to be reported, and those that can be excluded
- Attestation Certificates
 - Who will sign?

Sunshine Act – What to Do Now? (cont.)

- Covered Recipients
 - Education about process and opportunity to review data
 - Independent data collection to streamline review process
 - Determine whether you want to request pre-submission review from Applicable Manufacturers and Applicable GPOs
 - Group practice considerations



Questions?

Ballard Spahr, LLP Health Care Practice

Jean C. Hemphill
Practice Group Leader
(215) 864-8539
hemphill@ballardspahr.com

Mary J. Mullany
Practice Group Member
(215) 864-8631
mullany@ballardspahr.com

Our Health Care Reform Dashboard provides online resources for developments under the Affordable Care Act
<http://www.healthcarereformdashboard.com>