

THE "SUNSHINE" ACT: RELEVANCE TO DENTAL PRACTICE AND RESEARCH

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"Sunlight is said to be the best disinfectant." - Justice Brandeis.



Why the Sunshine Act?

- 1. Lack of definitive resource for patients regarding physician-industry relationships;
- 2. Physicians had limited insight into potential conflicts of thought leaders, article writers, and speakers
- 3. The inability of research institutions to effectively monitor potential conflicts of employee researchers
- 4. Only few states have disclosure/transparency laws
- 5. Companies required to comply with different (sometimes contradicting) state law requirements
- 6. Most state laws do not address medical device companies
- 7. In most states where law exists, information is not public
- 8. Anticipated overall effect of the various potential conflicts on healthcare cost

Weapon of Mass Instruction

"The Sunshine Law protects the rights of citizens"



- The sunshine law is expected to enhance transparency into the relationship between industry and healthcare providers in a form publicly accessible to patients and the population at large
 - Does not prohibit/restrict industry-physician interaction, including payments/TOVs
- Requires TRACKING and REPORTING!**

OUTLINE

- Timeline evolution of the Physician Payments Sunshine Act (PPSA)
- Reporting requirements (clinicians and Researchers)
- Potential impact on Dental Practice and Research
- Suggested Steps to manage own public profile vis-à-vis physician-industry relationship and PPSA

Timeline Evolution of the Sunshine Act I

Antecedent:

- **1993-2011**: Six jurisdictions passed some form of the Sunshine Act
 - Vermont; D.C.; Massachusetts; Maine; Minnesota; West Virginia.
 - **Maine repealed its law in 2011**
- **2003-04**: Survey of physicians across 6 specialties shows 94% of respondents admitting to some degree of physician-industry relationship:
 - Gifts; industry provided food in workplace; drug samples (50%)
 - Reimbursement costs for professional meetings/CEs (33%)
 - Consulting, lecturing, enrolling patients in clinical trials (24%)

Timeline Evolution of the Sunshine Act II:

- 2007: The Physician Payments Sunshine Act (PPSA) of 2007 (senators Charles Grassley and Herb Kohl)
 - To “shed light” on financial relationships between industry and physicians (researchers) in order to discourage COI capable of compromising clinical integrity and interfering with patient care
 - increased cost in healthcare (*Failed to be pass*)
- 2009: The Institute of Medicine (IOM) Conflict of Interest (COI) Report
 - Identified risks posed by financial conflicts:
 - Withholding reports of negative (research) results erosion of trust, harm to patients
 - (e.g. *Systemic review of trial of BMP as adjunct to spine surgery, 2011*). Authors:
 - Underestimated adverse effects
 - Failed to disclose financial relationships with sponsors
 - Non-disclosure of lucrative consulting arrangements

PPSA: REPORTABLES

- Payments and TOVs:
 - Of \$10 or more
 - If < \$10 and if aggregate (sum) over a year is >\$100
 - Direct and Indirect payments/TOVs
 - Made via 3rd parties at request/on behalf of physician
 - Provided to physician owner/investor
- Ownership and investment interests
 - In GPOs and Manufacturers: \$ amount of investment; value; terms of ownership/investment
 - Does not include interest in publicly traded securities/mutual funds

THE PPSA AS A COMPONENT OF THE PATIENTS PROTECTION AND AFFORDABLE CARE ACT, 2010

- March 2010: POTUS signed into the law the Patients Protection and Affordable Care Act (ACA), incorporating the PPSA.
 - Public disclosure of payments to physicians from the industry
 - Report of certain ownership and investment interests held by physicians and immediate family members from manufacturers and Group Purchasing Organizations (GPOs)

PPSA: DETAILS FOR REPORTABLES

- | | |
|--|---|
| <ul style="list-style-type: none"> • Name • Business Address • Amount of Payment • Date(s) of Payment • Mode/form of Payment • Nature of Payment | <ul style="list-style-type: none"> ■ Name ■ Specialty ■ Address ■ NPI ■ Professional license # |
|--|---|

PPSA: WHO MUST REPORT?

- The PPSA requires “applicable manufacturers” to disclose “payments or other transfers of value (TOV)” to “covered recipient” as a physician or a teaching hospital.
 - “Applicable Manufacturer”: Manufacturers (including certain wholesalers/ distributors) of drugs, devices, biological materials/medical supplies (*participate in any fed. Healthcare prog*)
 - Group Purchasing Organizations (GPO) and manufacturers also must report ownership and investment interests held by physicians and/or family members.
 - “Physician”: MD; DDS; OD; Podiatrist; Optometrist; Chiropractor; Fellows
 - *Physicians are not required to Self-Report!*

Payments/TOVs to Residents and Allied Health Professionals are not reportable

PPSA: REPORTABLES II

- Payment categories
 - Consulting fee;
 - Faculty/speaker fee for accredited/non-accredited CEs
 - Honoraria
 - Entertainments/Gifts
 - Food and Beverages
 - Travel/Lodging (specifying destination)
 - Education/Research
 - Charitable contribution
 - Royalty/License
 - Ownership/investment interests (current/prospective)

Report is to Center for Medicare and Medicaid (CMS)

* PENALTIES FOR NON-COMPLIANCE

- *Non-willful: \$1000 - \$10,000*
- *Willful ("knowingly" failing to report): \$10,000 - 100,000 with a max of 1million (annually)*
- **for each payment/TOV not reported!*

DENTISTS and PPSA

- Anticipate inquiries from manufacturer/GPO related to reporting
 - TOVs and other types of payments inquiries toward the required reporting of Sunshine Act transfers of value, including certain payments, entertainment costs, gifts, meals and travel costs
- Some dental related companies offer advance notification regarding reportable TOVs to you with an opportunity to decline transfer. If Dentists agrees to TOV company will request information listed:
 - NPI number, dental license number, dental specialty, etc.
- Be aware that final rule creates an exemption for compensation for speakers at ADA, accredited CE program provided event is:
 - ADA CERP event during which the dentist is speaking;
 - Manufacturer does not pay the dentist (recipient) speaker directly;
 - Manufacturer played not part in selecting the dentist speaker for the CE program.

Caution!!! Beware of IRS!

REPORTING RESEARCH-RELATED PAYMENTS

- **Research related payments are to be reported separately:**
 - Usually, to be submitted the year payment occurs
 - Delayed Publication by CMS may be requested where sensitive (e.g. proprietary items) are involved so as to avoid premature disclosures
- **Final rule:** For a range of pre-clinical and FDA phase research, publication of reported research payments related to new products are delayed for four years or until FDA approval date, whichever comes first.
 - However, payments for research on new applications of existing products may not be subject to delayed publication.

DENTAL ORGANIZATION ROLE: ADA?

Dentistry's relationship with industry is essential for maintaining scientific progress in dentistry

- Properly managed partnership needed
- Develop and institute policies in the dental community to ensure that support from industry has no influence on:
 - Clinical documents (practice guidelines, etc);
 - Contents of CE courses
- Overall goal is to ensure full transparency and the highest ethical standards
- Proposed Guide Areas:
 - Advertising; charitable donations; clinical document development; CEs; grants and foundation support; sponsorships

"With strict and carefully constructed relationships that prevent bias or commercial interest, why should industry not share some responsibility for education that requires funding and life-long learning for the (dental) professional?"

IMPLEMENTATION TIMELINE FOR PPSA

- **Aug. 1, 2013:** Manufacturers begin collating information about payments, transfers of value, and ownership interests.
- **Feb. 18, 2014 – Mar. 31, 2014:** (*Phase 1 Data Submission*) ** Manufacturers & GPOs submit aggregate 2013 payment data to CMS. Submission to be completed by March 31, 2014.
- **May 2014 + 30 days or more:** (*Phase 2 Data Submission*) ** Manufacturers and GPOs submit detailed 2013 data (for the period August – December 2013)
- **August 2014** (May, in subsequent years): Physicians and Teaching Hospitals access their data online for accuracy/corrections:
 - 45 days for reviews and initiation of disputes
 - 15 days to resolve any disputes
- **September 30, 2014:** 2013 data published on CMS public website (June 30 in subsequent years)

The 2-phase approach applies on 2014. subsequent reports will cover entire calendar years

JUSTIFYING VOLUNTARY AND AVOIDABLE PHYSICIAN-INDUSTRY RELATIONSHIP: Myths

1. "I was just there to Teach"
2. "Nobody told me what to say"
3. "I always disclose my conflicts of interest"
4. "The money won't influence me because I know what they're trying to do"
5. "I don't ever remember who bought me dinner"
6. "I need to network with industry leaders"
7. "My department can't get along without industry money"
8. "Being on an industry advisory committee lets me see what's going on in the inside"
9. "Companies need my advise and that's why they pay me"
10. "Since I consult for many different companies, conflict of interest is a moot point"
11. "A company can't influence me to change my prescribing"

3 STEPS YOU NEED TO TAKE TODAY!

STEP 1
Complete CMS
e-Verification
Process Today

STEP 2
Register with
CMS Open
Payment System

STEP 3
Review and
dispute Data by
Sept 8

Step 1: CMS requires a two-phase registration process:

Phase 1, now open, physicians/dentists complete CMS' e-verification process via the [CMS Enterprise Portal \(EIDM\)](#). Access [detailed instructions](#) at *AMA Wire*®.

Step 2: On gaining access to EIDM, physicians/dentists register in [CMS' Open Payments System via EIDM](#). Access [detailed instructions](#) at *AMA Wire*.

Step 3. Request individual report, review and flag disputes. Physicians/Dentists must initiate disputes by Sept.8 in order to have potentially erroneous entries flagged in the initial public release. **CMS does not resolve disputes**, but errors can be reported to manufacturers through the Open Payments System /Open Payments contacts.

SELECTED REFERENCES

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2. Brennan TA, Rothman DJ, Blank L et al., Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA* 2006; 295:429-433 .
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4. Brandeis LD. Other People's Money: And How the Bankers Use It. Washington, DC: national Home Library Foundation; 1933: 63.

Final Question!

Is Physician-Industry Relationship Dispensable?

No

- Some have advocated absolutely no financial ties with industries
- Scarcity of public funding for research and publications, high cost of education makes this above position untenable.

Indeed, industry, in addition to its role in developing new drugs and devices, has an "obligation and expectation" to provide funding for the education of practitioners as part of its social contract with patients, clinicians, and the society.

"What is needed is strict and carefully constructed relationship to prevent bias or commercial interest"

GOOD AFTERNOON!

And

Thank You All for Listening