

Federal Physician Payment Sunshine Bills – The Current State of Play

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by any measure

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Federal Sunshine Law – Senate Version (HR 3590)

- Drugs, devices, biologics or medical supplies for which payment is available under Medicare or a state plan (or waiver program)
- **Key Point:** Covered recipients include only physicians or teaching hospitals
- Only covers payments of \$10 or more unless aggregate amount exceeds \$100 in a calendar year (amt. will be adjusted annually consistent with CPI for urban consumers)

Federal Sunshine Law – Senate Version

- Timeline
 - October 1, 2011 – Secretary to devise procedures for submission of information by manufacturers and GPOs and to make such information publicly available
 - January 1, 2012 – preemption of state law disclosure requirements which overlap with federal law
 - March 31, 2013 – First annual electronic disclosures to be made by industry
 - April 1, 2013 – First annual report to Congress due
 - September 30, 2013 – first public disclosures to be made on searchable, understandable internet website; first report to states is due
 - June 30, 2014 – next report to states is due (to become annual at this time)

Senate Version – Covered Payments

- **Which Payments Need to Be Disclosed?**
 - consulting fees
 - services other than consulting
 - honoraria
 - gift
 - entertainment
 - food
 - travel (including destinations)
 - education

Senate Version – Covered Payments

- **Which payments need to be disclosed?**
 - research
 - charitable contributions
 - royalty/license payments
 - current or prospective ownership/investment interest
 - direct compensation for faculty/speaker role at educational program
 - grants
 - any other type of payment/transfer (TBD)

Federal Sunshine Law – Scope of Senate Version

- **What payments/items do not need to be disclosed?**
 - product samples
 - patient educational materials
 - devices for evaluation purposes only
 - items/services provided under warranty
 - items/services when the covered recipient is a patient
 - discounts
 - in-kind items for charity care
 - indirect payments where manufacturer is unaware of identity of recipient (e.g., survey companies, others)

Federal Sunshine Law – Scope of Senate Version

- **What payments/items do not need to be disclosed?**
 - dividend/profit from publicly traded security and mutual fund
 - payments for health care under self-insured plan
 - payments to licensed non-medical professionals if for non-medical professional services only
 - payments to physicians solely for services in connection with a civil, criminal or administrative proceeding

Senate Version – Required Disclosures

- **Disclosures must include the following:**
 - recipient name
 - business address
 - if physician, NPI and specialty of the physician
 - amount of payment or other transfer of value
 - dates of payment/value transfer

Senate Version – Required Disclosures

- **Disclosures must include the following:**
 - description of type of payment
 - cash or equivalent
 - in kind items or services
 - stock, option or other interest/ROI
 - any other form of payment/value (TBD)
 - payment to third party at request of the covered recipient
 - description of the nature of payment
 - if for marketing, education, research on specific drug, device, biological or supply, provide the name of the relevant article
 - anything else the Secretary deems relevant

Senate Version – Disclosure of Other Interests

- Disclosure of Ownership/Investment Interest by Physicians or Immediate Family Members (outside of publicly traded securities and mutual funds)
 - dollar amount invested
 - value and terms of interest
 - any payments requiring disclosure (as outlined in previous slide)

Senate Version – R&D Agreements and Clinical Trials

- **What falls under the research/R&D delayed reporting exception?**
 - research on potential new medical technology
 - research on new application of existing technology
 - development of a new drug, device, biological or supply
 - clinical investigation regarding a new drug, device, biological or supply

Senate Version – R&D Agreements and Clinical Trials

- **How long is the reporting delay?**
 - next disclosure date following the earlier of:
 - date of approval/clearance of the article by the FDA, or
 - four calendar years after the date the payment or other transfer was made
- **Benefits of the delay?**
 - renders the information confidential and not subject to FOIA disclosure until the date of public release pursuant to the Sunshine Act
 - may render moot any state provisions requiring disclosure of clinical trial payments

Senate Version – Public Disclosures

- disclosure will be on an accessible internet webpage
- includes a searchable database for payments, ownership or investment interests, penalties or other enforcement actions, clinical research payments (maintained separately)

Senate Version – Public Disclosures

- incorporates a review/correction procedure for errors made (manufacturers, GPOs, and covered recipients have 45 days to review prior to information becoming public)
- provides background information on industry relationships with physicians

Senate Version – Penalties

- Failure to Report
 - CMP of \$1,000 - \$10,000 for each payment or ownership/investment interest not disclosed
 - annual limit of \$150,000 for failure to report where no showing of a knowing failure to report
- Knowing Failure to Report
 - CMP of \$10,000 - \$100,000 for each payment or ownership/investment interest not disclosed
 - annual limit of \$1,000,000 for knowing failure to report
- Assessment of Penalties will be available on public website
 - public can search which entities were required to pay penalties
 - other enforcement activity also to be reported

House Version (HR 3962)

- covers much broader range of “covered recipients”
 - physicians, group practices, other prescribers, pharmacy/pharmacist, health plan or health insurer, PBM, hospital, medical school, CME sponsor, patient advocacy group, organization of health care professionals, GPO, or biomedical researcher
- earlier reporting/disclosure dates (2011 vs. 2013)
- includes reporting of drug samples (though this information would not be disclosed to the public)
- doesn't include charitable contributions

House Version (HR 3962)

- shorter delay in reporting for product development agreements or clinical investigations
 - keyed off of date of approval/clearance
 - keyed off of registration of trial on public site
 - two calendar years
- doesn't include payments of less than \$5, no aggregate limit
- modified penalty provisions for knowing failure to report (0.1% of total annual revenues) if greater than \$1 million

Preemption

Preemption will apply only as to payments made to “health care providers” or “covered recipients” however those terms are defined

- **Example: state can't say it wants 10 more types of data for payments to physicians, BUT if nurse practitioners with prescribing privileges are not “covered recipients” then a state law could require industry to report payments to those individuals – and in differing amounts/formats than the federal law**
- **Example: if Senate version is adopted, would leave MA to gather data separately on payments made to institutional providers other than academic medical centers**

Preemption

- Will not preempt the “plus” components imposed by various states
 - compliance program requirements
 - prohibitions on certain activities
 - leaves room for continued disparity across states
 - training/implementing policies geared toward most stringent standards

Federal Sunshine Laws – Areas of Ongoing Debate

- Areas of debate/dispute throughout process
 - Threshold dollar amounts to trigger reporting and aggregating payments
 - Inclusion or exclusion of clinical trial dollars
 - Scope of coverage (what types of payments to what types of people)

Federal Sunshine Laws – Potential Fallout

- Conflict of interest issues even further heightened at AMCs and other institutions and an increase in related press coverage
- Impact on various types of litigation (e.g., malpractice, securities, criminal investigations)
- Impact on whistleblower actions

Federal Sunshine Laws – Potential Fallout

- Impact on willingness of individuals to participate in industry-sponsored research or other legitimate activities
- Impact on ability to complete post-marketing studies or comparative efficacy studies which health care reform bills seek to require
- Impact on patient care