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# The Physician Payments Sunshine Act Legislation

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# Physician Payments Sunshine Act



- **S. 2029 introduced by Senators Kohl and Grassley, September 2007**
- **HR 5605 introduced by Congressman DeFazio, March 2008**
- **Bills as introduced are very similar but Senate bill has changed since introduction**

# Physician Payments Sunshine Act: Basics



- **Requires manufacturers to submit reports to HHS disclosing a wide range of payments made directly or indirectly to physicians. Threshold is \$25**
- **Requires HHS to post the reports on website that is “easily searchable, downloadable, and understandable.”**
- **Imposes significant penalties for failure to report information.**

# Physician Payments Sunshine Act: A Few Key Issues



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- **Scope of reporting- what payments are reportable**
- **Thresholds**
- **Exemptions**
- **Preemption – Federal standard and 50+ state standards?**

# Physician Payments Sunshine Act: Scope of Requirements



- ***S. 2029: Payments or other transfers of value, provided “directly, indirectly, or through an agent, subsidiary, or other third party, to a physician, or to an entity that a physician is employed by, has tenure with, or has an ownership interest in...”***
- ***Revised Working Draft of Bill: Payments or other transfers of value to a covered recipient or to an entity or individual at the request of or designated on behalf of a covered recipient. Covered recipient defined as a physician or physician medical practice***

# Physician Payments Sunshine Act: Thresholds



- ***S. 2029: \$25***
- ***Revised Working Draft of Bill: \$500*** threshold in a year before payments to a particular physician are reported and then all payments above the nominal \$25 are reported.

# Physician Payments Sunshine Act: Exceptions



- ***S. 2029:***
  - Samples
  - Clinical trial payments
  - Transfers to physician as patient
  - De minimus payments (\$25 or less)

# Physician Payments Sunshine Act: Exceptions



- ***Revised Working Draft of Bill:***

- Samples
- Discounts including rebates
- Educational materials that are intended for patient use or to benefit patient.
- Transfer to physician when physician is patient
- Qualitative value of any training or education related to payment or other transfer of value reported that is indicated on the report to be for education.
- Loan of a covered device for a short term trial period
- Items or services provided under a contractual warranty where the terms of the warranty are set forth in the purchase or lease agreement
- *De Minimus* payments: Anything below \$25 in value (increased each year by CPI)
- In kind items used for the provision of charity care.



# Physician Payments Sunshine Act: Preemption



- **Bills as introduced – no preemption**
- **Revised Working Draft of Bill: Preemption included**

# Draft Preemption Language



"The provisions of this section shall preempt any law or regulation of a State or political subdivision of a state relating to disclosure or reporting of information regarding payments or other transfer of value provided to covered recipients by an applicable manufacturer to the State or to any other governmental entity for purposes of including such information in any State-sponsored database or other repository of information."

# Proposed Preemption Provision: What Does It Cover?



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- Fairly broad set of state laws or regulations relating to reporting and disclosure requirements of drug and device manufacturers
- Applies to reporting or disclosure requirements regarding payments or other transfer of value to physicians
- Payments of all sizes and types

# Proposed Preemption: What Might It Not cover?



- **Requirements to report payments to other health care providers?**
- **Requirements to report all marketing costs?**
- **Bans on gifts or other payments?**
- **Prescriber data laws?**
- **Code compliance laws?**