

Proposed Physician Payment Sunshine Provisions

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Agenda

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 - Media Attention
 - Efforts by Senators Grassley and Kohl
 - Industry Response Efforts
- The Proposed Act
 - Senate
 - House
- Preemption of Existing State Laws
- Predictions for the Future

Background: Media Attention

- Starting in May 2007, the New York Times highlights in a series of articles and editorials the issue that payments to physicians by manufacturers can potentially create conflicts of interest, raising public awareness.
- The New York Times, now joined by other media sources, continues to follow the issue today including an article as recently as last week.
- The issue is becoming part of the popular culture.

Background: Legislation Proposed by Grassley and Kohl

- September 6, 2007: Physician Payment Sunshine Act of 2007 (S.2029) introduced by Senators Grassley and Kohl. The legislation would require pharmaceutical and medical device manufacturers to report certain payments made to physicians or their employers.
- Senators Grassley and Kohl conducted investigations that revealed potential conflicts of interest in the relationships between physicians and drug and device manufacturers. The 110th Congress took no action on the bill.
- January 22, 2009: Senators Grassley and Kohl reintroduced the Physician Payment Sunshine Act (S.301).
- The proposed Act has been incorporated into both the Senate health reform bill (America's Healthy Future Act of 2009, S.1796, section 4101) and the House-passed health reform bill (Affordable Health Care for America Act, HR.3962, section 1451).

Background: Industry Response

- Voluntary/Mandatory Reporting Efforts: Despite initial reservations about the move toward transparency, industry trade associations have endorsed the Sunshine Act.
- Many drug and medical device manufacturers are now reporting or are planning to publicly report payments to physicians. For example, Merck and Eli Lilly have just filed their initial reports in the last few weeks.
- While some companies have done this as part of a mandatory obligation under a CIA, including a number of medical device companies, this movement has been largely voluntary.
- A growing number of states have passed their own physician payment disclosure laws (DC, ME, MA, VT, MN, WV). Manufacturers have already collected this type of information to comply with state laws.

Proposed Physician Payment Sunshine Provisions

- On January 22, 2009, Senators Grassley and Kohl reintroduced an amended Physician Payment Sunshine Act (S.301).
 - Notable Revisions:
 - S.301 preempts state law, except to the extent that state law requires reporting of additional information not covered by federal law. S.2029 did not address preemption.
 - S.301 requires annual disclosures; whereas, S.2029 required quarterly.
- The proposed Act has since been rolled into both the House and the Senate health care reform bills.
- The principles overlap in each proposal, but certain distinctions remain.

Proposed Physician Payment Sunshine Provisions

<i>Law</i>	Affordable Health Care for America Act (House Bill)	America's Healthy Future Act of 2009 (Senate Bill)
<i>Scope of Coverage</i>	<p>Pharmaceutical, medical device, biologics, and medical supply manufacturers and distributors (not including wholesale pharmaceutical distributors). <i>(all disclosures)</i></p> <p>Hospitals or other health care entities (not including Medicare Advantage organizations) and group purchasing organizations <i>(reporting of physician ownership interests only)</i></p>	<p>Pharmaceutical, medical device, biologics, and medical supply manufacturers <i>(all disclosures)</i>.</p> <p>Group purchasing organizations <i>(disclosure of ownership interests only)</i></p>
<i>Covered Recipient</i>	<ul style="list-style-type: none"> •Physicians & physician practices; •Prescribers of a covered drug, device, biological, or medical supply; •Pharmacies and pharmacists; •Health insurance issuers, group health plans, or other entities offering a health benefits plans, including employees; •Pharmacy benefit managers, including employees; •Hospitals; •Medical schools; •Sponsors of CME; •Patient advocacy or disease specific groups; •Organizations of health care professionals; •Biomedical researchers, •Group purchasing organizations. <p>Payments or gifts at the request of or on behalf of a covered recipient must be disclosed as if made to recipient directly</p>	<p>Physicians and teaching hospitals.</p> <p>Payments or gifts at the request of or on behalf of a covered recipient must be disclosed as if made directly to the covered recipient</p>

Proposed Physician Payment Sunshine Provisions

<i>Law</i>	Affordable Health Care for America Act (House Bill)	America's Healthy Future Act of 2009 (Senate Bill)
<i>Disclosures</i>	<p>Any payment over \$5, including payments made in connection with:</p> <ul style="list-style-type: none"> •Gifts, food, or entertainment; •Travel; •Honoraria; •Research funding or grants; •Education or conference funding; •Consulting fees, including speaking fees; •Ownership or investment interests, including dividends and other profit distributions; and •Royalties or license fee. <p>Additionally, annually manufacturers, distributors, and group purchasing organizations, must provide information on physician ownership in the entity (including ownership by immediately family) including amount invested, value of the interest, and other payments made to the physician. <u>Hospitals and health care entities</u> will also be asked to provide physician ownership data.</p>	<p>Any payment over \$10 (unless the aggregate annual payments to the recipient exceeds \$100, in which case all payments) including payments made in connection with:</p> <ul style="list-style-type: none"> •Consulting fees and •Compensation for services other than consulting; •Honoraria; •Gifts, entertainment, and food; •Travel; •Education; •Research or grants; •Charitable contribution; •Royalty or license or Ownership interest/ investment; and •Faculty or speaker at medical education program. <p>Additionally, annually manufacturers and <u>applicable group purchasing organizations</u> must provide information on any physician ownership in the entity (including ownership by immediate family).</p>
<i>Exceptions to Required Disclosures</i>	<ul style="list-style-type: none"> •Payments worth less than \$5; •Trial loan of a covered device for 90 days or less; •Items or services provided under a contractual warranty; •In-kind items for charity care; •Mutual fund payments; •Discounts and rebates; •Transfers of value where recipient is a patient and not acting in a professional capacity; • Payments based on direct employment at the manufacturer. •Payments to physician for services to manufacturer's employees, including related to self-insured plans; •Indirect payments for services through another entity for purposes other than marketing where the identity of the recipient is not known. 	<ul style="list-style-type: none"> •Payments or transfers of \$10 or less, unless the aggregate annual payments to the recipient amount exceed \$100; •Loan of a covered device for 90 days or less to permit evaluation; •Items or services provided under a contractual warranty; •In-kind items for charity care; •Mutual fund payments; •Discounts and rebates; •Transfers of value where recipient is a patient; •Patient educational materials; •Payments made to a physician who is also a licensed non-medical professional, if the payments is solely related to non-medical services; •Payments to physician for services to manufacturer's employees; •Payments to a physician for services related legal proceeding.

Proposed Physician Payment Sunshine Provisions

<i>Law</i>	Affordable Health Care for America Act (House Bill)	America's Healthy Future Act of 2009 (Senate Bill)
<i>Special Rules for Clinical Trials and Product Development</i>	<p>Reporting of payments in connection with a clinical investigation may be delayed until the first of: 1) the date the clinical trial is registered with NIH or 2) two years after the date of payment.</p> <p>Reporting of payments in connection with product development may be delayed until the first of: 1) the date of product approval or clearance or 2) two calendar years after the date such payment or other transfer of value was made.</p>	<p>Reporting of payments in connection with clinical investigations or product development agreements may be delayed until the first of: 1) the date of the approval of the product; 2) four calendar years after the date such payment or transfer of value was made.</p>
<i>Special Rules for Drug Samples</i>	<p>Information related to drug samples must be reported, but will not be made available outside of the DHHS.</p>	<p>Information related to drug samples must be reported (through a distinct reporting process), but will not be made available outside of the DHHS.</p>
<i>Disclosed Information</i>	<ul style="list-style-type: none"> •Recipient's name, business address, specialty, and NPI. •Value and date of payment (other than a drug sample); •Name of the related drug, device or supply, if applicable; •Form of payment (cash, in-kind, stock or other ownership interest, other. With respect to a drug sample, the name, number, date, and dosage units of the sample). •Nature of the payment* •Aggregate amount of all payments or other transfers of value provided by the manufacturer or distributor to covered recipients, including payments and transfers of value whether or not individually disclosed. 	<ul style="list-style-type: none"> •Recipient's name, Business address, and NPI (physicians only). •Amount and date of payment; •If the payment relates to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that product; •Form of payment (cash, in-kind, stock or other ownership interest, other); •A description of the nature of the payment (i.e. consulting fees, charitable contribution, etc.). •Any other information that the Secretary deems appropriate.
<i>Effective</i>	<p>Reporting required by March 31, 2011. Information made public by September 30, 2011.</p>	<p>Reporting required by March 31, 2012. Information made public by September 30, 2012.</p>
<i>Confidentiality</i>	<p>Information is confidential until the date that the report is released to the public. Upon release, it will be easily searchable on a website.</p>	<p>Information is confidential until the date that the report is released to the public. It will be easily searchable on a website.</p>

* The House bill lacks clarity on this point. Section (a)(1)(B) does not specifically require manufacturers to report the nature of the payments, but section (c)(1)(B) contemplates that this information will be made public by the Secretary.

Proposed Physician Payment Sunshine Provisions: Reporting Entities

- **House bill**

- Pharmaceutical, medical device, biologics, and medical supply manufacturers and distributors (except wholesale pharmaceutical distributors) must make all disclosures.
- Hospitals or other health care entities (except Medicare Advantage organizations) and group purchasing organizations must report physician ownership only.

- **Senate bill**

- Pharmaceutical, medical device, biologics, and medical supply manufacturers must make all required disclosures.
- Group purchasing organizations must report physician ownership only.

Proposed Physician Payment Sunshine Provisions: Covered Recipients

House bill

- Physicians, other prescribers, hospitals, pharmacists, pharmacies, medical schools, group purchasing organizations, health insurance issuers, biomedical researchers, and certain other health care entities and organizations

- Senate bill

- Physicians and teaching hospitals only

Proposed Physician Payment Sunshine Provisions: Disclosures and Exceptions

- Both bills have broad reporting requirements. For example, both require reporting of gifts, food, travel, grants, consulting fees, and various other types of payments.
- Both bills also provide for a number of exceptions to the reporting requirement, including for *de minimum payments*, discounts, in-kind charity items, and other types of payments.
 - House bill – exception for payments or transfers under \$5
 - Senate bill – exception for payments or transfers of \$10 or less, unless the aggregate annual payments to the recipient amount exceed \$100
- Both bills also require disclosure of physician ownership interests.
 - House bill – certain disclosures by group purchasing organizations, manufacturers, distributors, hospitals and other health care entities
 - Senate bill – certain disclosures by manufacturers and group purchasing organizations

Proposed Physician Payment Sunshine Provisions: Information to be Disclosed

Both the House bill and the Senate bill:

- Recipient's name, business address, and NPI
- Value and date of payment
- Name of the related drug, device or supply, if applicable
 - In Senate bill, only report name of drug if payment relates to marketing, education, or research.
- Form of payment (cash, in-kind, stock or other ownership interest, other)
- Nature of the payment (e.g. consulting fees, charitable contribution, etc.)*

House bill only:

- Aggregate amount of payments provided by the reporting entity to covered recipients, including payments and transfers of value whether or not individually disclosed
- Recipient's specialty
- * Note: the House bill lacks clarity on whether the nature of the payment must be reported.

Proposed Physician Payment Sunshine Provisions: Effective Dates

- **House Bill**
 - Reporting required by March 31, 2011.
 - Information made public by September 30, 2011.
- **Senate Bill**
 - Reporting required by March 31, 2012.
 - Information made public by September 30, 2012.

Proposed Physician Payment Sunshine Provisions: Penalties

- Both bills create CMP liability of \$1,000 to \$10,000 for each payment not reported on time and in accordance with regulations, up to an annual maximum of \$150,000.
- Both bills also create CMP liability of \$10,000 to \$100,000 for each payment knowingly not reported on time and in accordance with regulations.
 - The Senate bill imposes an annual maximum of \$1,000,000.
 - The House bill imposes an annual maximum of \$1,000,000 or if greater, 0.1% of the total annual revenues of the manufacturer.

Proposed Physician Payment Sunshine Provisions: Preemption

- Under both bills, federal law would preempt state law, except to the extent that state law requires reporting of additional information not captured by federal law.
 - Except that the Senate bill would preempt a state law that requires reporting more detailed than the \$10 de minimus/\$100 aggregate reporting requirement, and
 - The House bill would preempt a state law the requires reporting more detailed than a \$5 transfer of value.
- States would also not be prohibited from collecting the same type of information for public health purposes.
- The House bill explicitly permits states to collect information in connection with legal proceedings.
- The House bill also gives the state attorneys general enforcement power where the Secretary declines to bring an action.

What's Next?

- Passage of the Sunshine Act may be dependent upon passage of overall health care reform.
- The remaining differences between House and Senate bills should be able to be resolved, but it is unclear whether the Sunshine Act would pass as a freestanding bill.