



January 28, 2009

Grassley, Kohl Introduce Physician Payments Disclosure Law

New Provisions Expand Disclosure Requirements

On Thursday, January 22, 2009, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) introduced the Physician Payments Sunshine Act of 2009 (S.301). The Senators introduced a similar bill in September 2007 (S.2029) and offered a substantially revised version of S.2029 in May 2008. The revised version of S.2029 was widely endorsed by industry; however, it was never formally introduced.

The new legislation, which was referred to the Senate Finance Committee, contains many provisions that are similar to prior legislation introduced by Sens. Grassley and Kohl, including:

- Reports will be first due on March 31, 2011, and then annually on the 90th day of each calendar year thereafter.
- Delayed reporting for payments made pursuant to product development agreements and clinical investigations.
- Broad definition of a clinical investigation that covers any experiment involving one or more human subjects in which a drug or device is administered, dispensed or used.
- Much of the information with respect to the descriptions of payments is similar.
- Many of the definitions are similar.
- Preempts state reporting laws (although there is some variation in the preemption provision in S.301, as discussed below)

However, there are several significant differences between S.301 and the revised version of S.2029, including:

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- S.301 preempts state laws relating to the disclosure or reporting of information regarding payments or transfers of value provided to covered recipients by manufacturers. (Note: The revised version of S.2029 preempts state laws that require reporting “for purposes of including such information in any state-sponsored database or other repository of information.”) In addition, S.301 provides that it does not preempt state laws that require disclosure or reporting of information not required to be reported under the bill.
- S.301 lowers the minimum annual aggregate amount provided to a particular covered recipient that triggers reporting of payments to that particular covered recipient from \$500 to \$100 (this is a change from the revised version of S.2029).
- S.301 does not contain the de minimus \$25 threshold for a payment to qualify as a payment or other transfer of value (this is a change from the revised version of S.2029).
- S.301 provides for increased specificity of information to be reported with respect to the covered recipient of the transfer of value, requiring reporting of the business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and Medicare billing number of the covered recipient.
- S.301 provides three additional categories to describe the nature of a transfer of value: current or prospective ownership or investment interest; compensation for serving as faculty or as a speaker for a CME program; and grants.
- S.301 requires reporting of the name of the covered drug, device, biological, or medical supply, if the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply.
- S.301 requires manufacturers to report the aggregate amount of all payments or other transfers of value provided by the applicable manufacturer to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the preceding year.
- In general, penalties for failure to report any required information range from \$1,000 to \$10,000 for each transfer of value not reported. The total amount of the penalty for failure to report shall not exceed \$150,000 with respect to each annual submission. (Note: Penalties in the revised S.2029 range from \$1,000 to \$5,000, with an annual cap of \$50,000.)
- Penalties for knowingly failing to report any required information range from \$10,000 to \$100,000 for each transfer of value not reported. The total amount of the penalty for knowingly failing to report shall not exceed \$1,000,000 with respect to each annual submission. (Note: Penalties in the revised S.2029 range from \$5,000 to \$50,000, with an annual cap of \$250,000.)



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- As opposed to the revised S.2029, S.301 does not provide manufacturers, group purchasing organizations, or covered recipients the opportunity to review information that will be posted on a public website prior to the information being released. The bill provides covered recipients, however, the opportunity to submit corrections to the information made publicly available, with respect to the covered recipient.
- Not addressed in the revised version of S.2029, S.301 requires the Secretary of Health and Human Services to annually submit to Congress a report of all information submitted for the previous year, aggregated for each manufacturer and group purchasing organization. In addition, the Secretary will annually submit to each state a report that includes a summary of the information submitted during the preceding year with respect to covered recipients in the state.

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If you have questions about the new legislation, or state pharmaceutical and medical device disclosure laws, please do not hesitate to contact any of the following:

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.



Summary of Physician Payments Sunshine Act of 2009 (S.301)

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| <p>Information to be Reported</p> | <p>Requires “<i>applicable manufacturers</i>” to report payments or other transfers of value to a “<i>covered recipient</i>” (or to an entity or individual on behalf of a covered recipient) in electronic format for the preceding calendar year.</p> |
| <p>“Applicable Manufacturer”</p> | <p>Means the ‘<i>manufacturer of a covered drug, device, biological or medical supply</i>’ i.e., any entity engaged in the production, preparation, propagation, compounding, conversion, processing, marketing or distribution of a covered drug, device, biological, or medical supply (or any subsidiary of or entity affiliated with such an entity).</p> <p>A “<i>covered drug, device, biological or medical supply</i>” means any for which payment is available under Medicare, Medicaid, or State Children’s Health Insurance Program (or a waiver of such a plan).</p> |
| <p>“Covered Recipient”</p> | <p>Means a physician, a physician medical practice, or a physician group practice.</p> |
| <p>Types of Payments to be Reported</p> | <p>The report must include a description of the nature of the payment or transfer of value indicated as one or more of the following (includes three new items): consulting fees; compensation for services other than consulting; honoraria; gift; entertainment; food; travel; education; research; charitable contributions; royalty or license; current or prospective ownership or investment interest; compensation for serving as faculty or as a speaker for a CME program; grant; or any other payment or transfer of value as defined by the Secretary.</p> |
| <p>Content of Reports</p> | <p>The following data must be included in the annual reports (adds new information requirements):</p> <ul style="list-style-type: none"> • name, business address, specialty, and Medicaid billing number of the covered recipient • value of payment or transfer of value • dates provided to covered recipient • description of the form of payment, i.e., cash or cash equivalent; in-kind items or services; stock or stock options, or any other ownership interest, dividend, profit, or other return on investment • any other form of payment or transfer of value as defined by the Secretary |



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| | <ul style="list-style-type: none"> • the name of the covered drug, device, biological, or medical supply for any payment related to marketing, education, or research related to the same • any other of categories of information as the Secretary determines appropriate |
| <p>Aggregate Reporting</p> | <p>The report must include the <u>aggregate amount</u> of all payments or other transfers of value to a covered recipient (and to entities and individuals at the request of a covered recipient) for the preceding calendar year.</p> |
| <p>Exclusions from Reporting</p> | <p>The following exclusions apply to an applicable manufacturer required to report (note that the revised bill removes all references to reporting by applicable distributors and applicable GPOs):</p> <ul style="list-style-type: none"> • Any payment or other transfer of value where the aggregate amount to the covered recipient does not exceed \$100 during the calendar year (without counting any excluded payments or transfers of value toward the aggregate). • The \$25 de minimus for reporting was removed. • Educational materials that directly benefit patients or are intended for patient use • Transfer to a covered recipient when a covered recipient is a patient • The “qualitative value of any training/education” exclusion was removed. • Samples that are not intended to be sold and are intended for patient use • Discounts (including rebates) • Loan of a covered device for a short term trial period (not to exceed 90 days) to permit evaluation • Items or services under a contractual warranty where the terms of the warranty are set forth in the purchase or lease agreement • In-kind items used for the provision of charity care • Any dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund |



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| <p>Clinical Trial Payments</p> | <p>Reporting of payments or other transfers of value made in connection with a clinical investigation is delayed until the reporting period after the earlier of (1) the date of the approval or clearance of the covered drug, device, biological, or medical supply is approved by FDA; or (2) two calendar years after the payment is made.</p> <p><i>“Clinical investigation”</i> means “any experiment involving 1 or more human subjects in which a drug or device is administered, dispensed, or used.”</p> |
| <p>Payments on Behalf of a Covered Recipient</p> | <p>For payments or transfers of value made to an entity or individual at the request of or designated on behalf of a covered recipient, manufacturers must disclose the payment under the name of the covered recipient.</p> |
| <p>Physician Ownership Interest</p> | <p>Applicable manufacturers and group purchasing organizations must report information about the ownership or investment interest of a physician or a physician’s immediate family members in the manufacturer or GPO for the preceding calendar year, including: the dollar amount invested; the value and terms of any interest; and any payment or transfer of value to a physician with ownership interest, e.g., consulting fees, gifts, honoraria with the same level of detail for reporting as required above.</p> <p>Not required to report a physician’s interest in a publicly traded security or mutual fund.</p> <p><i>“Applicable group purchase organization”</i> means a GPO (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply.</p> |
| <p>Report Due Dates</p> | <p>March 31, 2011 and annually on the 90th day of each calendar year for every report thereafter.</p> <p>Date applies to both Transparency Reports and Physician Ownership Interest Reports.</p> |
| <p>Penalties for Noncompliance</p> | <p>Provides for CMPs, but the ranges and caps are increased:</p> <p>CMP of \$1,000 - \$10,000 for failing to report any required transfer of value or ownership or investment interest. With respect to each annual submission, the total amount of the penalty for failure to report shall not exceed \$150,000.</p> <p>CMP of \$10,000 - \$100,000 for “<u>knowingly</u>” (as defined in the False Claims Act) failing to report any required transfer of value or ownership or investment interest. With respect to each annual submission, the total amount of the penalty for knowingly failing to report shall not exceed \$1,000,000.</p> |



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| <p>Public Availability of Reported Information</p> | <p>Allows for the same timing for making reports public (September 30, 2011, and by June 30 of each following year), but provides some additions to the information to be presented, including: name of the applicable manufacturer or applicable group purchasing organization; the specialty of the covered recipient; and the name of the covered drug, device, biological, or medical supply, as applicable.</p> <p>In addition to being easily aggregated, information on the website must be easily downloaded. Other requirements with respect to website characteristics are similar.</p> <p>The bill does <u>not</u> provide manufacturers, group purchasing organizations, or covered recipients the opportunity to review information that will be posted on the website prior to the information being released. The bill provides covered recipients, however, the opportunity to submit corrections to the information made publicly available, with respect to the covered recipient.</p> |
| <p>Annual Report to Congress and States</p> | <p>By April 1 of each year starting with 2011, the Secretary will submit to Congress a report of all information submitted for the previous year, aggregated for each manufacturer and group purchasing organization. The report will also include any enforcement action taken relating to the reporting requirements during the preceding year.</p> <p>In addition, by April 1 of each year starting with 2011, the Secretary shall annually submit to each state a report that includes a summary of the information submitted during the preceding year with respect to covered recipients in the state.</p> |
| <p>Preemption of State Laws</p> | <p>Provides a date for preemption, January 1, 2010, and removes the phrase “for purposes of including such information in any state-sponsored database or other repository of information” that had been included in previously introduced legislation.</p> <p>In addition, the bill provides that it does not “preempt any law or regulation of a State or of a political subdivision of a State that requires disclosure or reporting of information not required to be disclosed or reported under this section.”</p> |