

## Physician Payments Sunshine Act

\*The underlined portions represent differences between the two bills

<p style="text-align: center;"><b>H.R. 5605</b></p> <p><b>Sponsors:</b> Reps. Peter DeFazio (D-OR) and Pete Stark (D-CA)  <b>Introduced:</b> March 13, 2008  <b>Status of Legislation:</b> Referred to the House Committee on Energy and Commerce and the House Committee on Ways and Means</p>	<p style="text-align: center;"><b>S. 2029</b></p> <p><b>Sponsors:</b> Sens. Charles Grassley (R-IA) and Herbert Kohl (D-WI)  <b>Introduced:</b> September 6, 2007  <b>Status of Legislation:</b> Referred to the Senate Committee on Finance</p>
<p>Reporting of Payments or other Transfers of Value (transfer): On <u>January 1, 2009</u>, and the first day of each fiscal year quarter beginning thereafter. An annual summary report is due by December 31 of each year.</p>	<p>Reporting of Payments or other Transfers of Value: On <u>January 1, 2008</u>, and the first day of each fiscal year quarter beginning thereafter. An annual summary report is due by December 31 of each year.</p>
<p>Each manufacturer of a covered drug, device or medical supply who provides payment or other transfer, 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, has a <u>significant</u> ownership interest in, <u>or to a covered organization in which a physician has a significant professional membership interest</u>, must submit a form to the Secretary.</p>	<p>Each manufacturer of a covered drug, device or medical supply who provides payment or other transfer, 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, must submit a form to the Secretary.</p>
<p>The form to the Secretary must include</p> <ul style="list-style-type: none"> <li>• The name of the physician, if payment or transfer was provided to an entity that the physician is employed by, has tenure with, or has a <u>significant</u> ownership interest in, the name of the entity, <u>and if the payment or transfer was provided to an organization so specified in which the physician has a significant professional membership interest, the name of the organization.</u></li> <li>• The address of the physician's office, the primary business or headquarters address for any entity</li> <li>• The value of the payment or transfer</li> <li>• The date on which the payment or transfer was provided</li> </ul>	<p>The form to the Secretary must include</p> <ul style="list-style-type: none"> <li>• The name of the physician, and if payment or transfer was provided to an entity that the physician is employed by, has tenure with, or has an ownership interest in, the name of the entity</li> <li>• The address of the physician's office, the primary business or headquarters address for any entity</li> <li>• <u>The facility with which the physician is affiliated</u></li> <li>• The value of the payment or transfer</li> <li>• The date on which the payment or transfer was provided</li> <li>• Description of the nature of payments or transfers <ul style="list-style-type: none"> <li>○ Compensation</li> <li>○ Food, entertainment, gifts</li> </ul> </li> </ul>

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<ul style="list-style-type: none"> <li>• Description of the nature of payments or transfers             <ul style="list-style-type: none"> <li>○ Compensation</li> <li>○ Food, entertainment, gifts</li> <li>○ Trips or travel</li> <li>○ A product or item provided for under market value</li> <li>○ Participation in a medication conference, CME or other educational or informational program, <u>or funded research (i.e. lab-based or health services research) that is not a clinical trial</u>; provision of materials related to the conference, program, or <u>research</u>; remuneration for promoting or participating in such a conference, program, or <u>research</u>.</li> <li>○ Product rebates or discounts</li> <li>○ Consulting fees or honoraria</li> <li>○ <u>Dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (excluding publically traded security and mutual fund)</u></li> <li>○ Any other economic benefit, as defined by the Secretary.</li> </ul> </li> <li>• <u>The purpose of the expenditure according to categories specified by the secretary, such as consulting, education, royalty and research</u></li> </ul>	<ul style="list-style-type: none"> <li>○ Trips or travel</li> <li>○ A product or item provided for under market value</li> <li>○ Participation in a medication conference, CME or other educational or informational program; provision of materials related to the conference or program; remuneration for promoting or participating in such a conference or program.</li> <li>○ Product rebates or discounts</li> <li>○ Consulting fees or honoraria</li> <li>○ Any other economic benefit, as defined by the Secretary.</li> </ul> <ul style="list-style-type: none"> <li>• <u>The medical issue or condition addressed, if any, that was the basis for the payment or transfer</u></li> </ul>
<p>Annual Summary Report – Each manufacturer that is required to submit information must do by December 31 of that year, in the form requested by the Secretary. <u>The report must include the aggregate amount of all transfers of anything of value that is less than \$25, including any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate or services.</u></p>	<p>Annual Summary Report – Each manufacturer that is required to submit information must do by December 31 of that year, in the form requested by the Secretary.</p>
<p><u>Clinical Trials – Notwithstanding the</u></p>	<p>(The Senate version includes no</p>

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<p><u>above, a payment or other transfer made for the general funding of a clinical trial (an applicable clinical trial for which clinical trial information is required to be submitted under section 402(j)(2)(C) of the Public Health Service Act) shall be disclosed in the first quarterly report after the date clinical trial information for such trial is required to be posted under section 402(j)(2)(D) of the Public Health Service Act.</u></p>	<p>comparable language)</p>
<p>Any manufacturer that <u>knowingly</u> fails to submit the information required above will be subject to a civil money penalty between \$10,000 and \$100,000 for each failure.</p>	<p>Any manufacturer that fails to submit the information required above will be subject to a civil money penalty between \$10,000 and \$100,000 for each failure.</p>
<p>All information submitted to the Secretary must be made available to the public by <u>June 1, 2009</u></p>	<p>All information submitted to the Secretary must be made available to the public by <u>June 1, 2008</u></p>
<p>No later than April 1 of each year beginning in <u>2010</u>, a report must be submitted to Congress with all information submitted to the Secretary, and any enforcement actions being carried out.</p>	<p>No later than April 1 of each year beginning in <u>2009</u>, a report must be submitted to Congress with all information submitted to the Secretary, and any enforcement actions being carried out.</p>
<p>Definitions:</p> <ul style="list-style-type: none"> <li>• Covered drug, device or medical supply – any drug, biological product, device or medical supply for which payment is available under Medicare, Medicaid or SCHIP</li> <li>• <u>Covered organization – an organization that is involved in health care financing, organization or delivery</u></li> <li>• Manufacturer of a covered drug, device or medical supply – any entity with annual gross revenues over <u>\$1,000,000</u> that is engaged in the production, preparation, compounding, conversion or processing of a covered drug, device or medical supply.</li> <li>• Payments or other transfer – in general means anything of value that exceeds \$25, including any compensation, gift, honorarium, speaking or consulting fee, travel,</li> </ul>	<p>Definitions:</p> <ul style="list-style-type: none"> <li>• Covered drug, device or medical supply – any drug, biological product, device or medical supply for which payment is available under Medicare, Medicaid or SCHIP</li> <li>• Manufacturer of a covered drug, device or medical supply – any entity with annual gross revenues over <u>\$100,000,000</u> that is engaged in the production, preparation, compounding, conversion or processing of a covered drug, device or medical supply <u>or the packaging, repackaging, labeling, relabeling or distribution of a covered drug, device or medical supply.</u></li> <li>• Payments or other transfer – in general means anything of value that exceeds \$25, including any compensation, gift, honorarium, speaking or consulting fee, travel,</li> </ul>

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<p>discount, cash rebate, services, <u>dividend, profit distribution, stock or stock option grant, or any ownership or investment held by a physician in a manufacturer (excluding publically traded security or mutual fund)</u></p> <ul style="list-style-type: none"> <li>○ Exclusions – product samples intended for patients, payment or other transfer made for the general funding of a clinical trial, <u>other than an applicable clinical trial for which clinical trial information is required to be submitted</u>, a transfer of anything of value while the physician is a patient, <u>compensation paid by a manufacturer to a physician who is solely employed by them.</u></li> <li>○ Physician – the meaning given that term in section 1861(r)</li> <li>○ <u>Significant professional membership interest – a physician is voluntarily a paying member or receives professional certification through a covered organization.</u></li> </ul>	<p>discount, cash rebate or services</p> <ul style="list-style-type: none"> <li>○ Exclusions – product samples intended for patients, payment or other transfer made for the general funding of a clinical trial, a transfer of anything of value while the physician is a patient</li> <li>○ Physician – the meaning given that term in section 1861(r)</li> </ul>
<p><u>Limitation on Tax Deductions for advertising by certain manufacturers of drugs, devices or medical supplies – No deduction should be allowed under this chapter for any taxable year for any expenditure relation to the advertising, promoting, or marketing (in any medium) of any covered drug, device, or medical supply manufactured by the taxpayer if, during the taxable year, a penalty is imposed on the taxpayer under section 1128G(d) of the Social Security Act (relating to quarterly transparency reports from manufacturers of covered drugs, devices or medical supplies under</u></p>	<p>(The Senate version includes no comparable language)</p>

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<p><u>Medicare, Medicaid or SCHIP</u></p>	
<p><u>Definitions and Special Rules</u></p> <ul style="list-style-type: none"> <li>• <u>Covered drug, device or medical supply – has the meaning given such a term by section 1128G(g) of the Social Security Act</u></li> <li>• <u>Aggregation Rules – all members of the same controlled group of corporations (within the meaning of section 52(a)) and all persons under common control (within the meaning of section 52(b)) shall be treated as 1 person</u></li> </ul>	<p>(The Senate version includes no comparable language)</p>
<p><u>Conforming Amendment – The table of sections for such part IX is amended by adding after the item relating to section 280H the following: “Sec 280I. Limitation on tax deductions for advertising by certain manufacturers of drugs, devices, or medical supplies.”</u></p>	<p>(The Senate version includes no comparable language)</p>
<p><u>Effective date for Limitation on Tax Deductions for Advertising – The amendments made by this section shall apply to taxable years beginning ending after the date of the enactment of this act.</u></p>	<p>(The Senate version includes no comparable language)</p>