

**U.S. SUNSHINE STATUTORY & REGULATORY PROVISIONS**

In September 2007, Senators Charles Grassley and Herb Kohl introduced the Physician Payments Sunshine Act of 2007 (S. 2029) in an effort to “provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.” In January 2009, Senators Grassley and Kohl reintroduced the Physician Payments Sunshine Act (S. 301). The proposed act was incorporated into the Patient Protection and Affordable Care Act (ACA) (H.R. 3590), which was signed into law on March 23, 2010. On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule, “Transparency Reports and Reporting of Physician Ownership or Investment Interests,” which will implement Section 6002 of the ACA. The proposed rule was published in the December 19, 2011 edition of the *Federal Register*. View a copy of the proposed rule at <http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf>.

The effective date for applicable manufacturers and applicable group purchasing organizations to begin collecting the required information is delayed until CMS issues its final rule. The comment period deadline is February 17, 2012. The effective date for the reporting requirement by statute remains March 31, 2013. Below are the details of the statutory provisions and the proposed implementing rules. CMS has sought comment on nearly 60 issues relating to its proposed definitions, interpretations, and processes, which are set forth by category at the end of the chart.

**Sec. 6002. Transparency Reports and Reporting of Physician Ownership or Investment Interests**

Provision Section of Social Security Act [U.S. Code citation]		REQUIREMENT
1.	<b>Effective Date of Reporting Requirement</b> § 1128G(a)(1)(A) [42 U.S.C. § 1320a-7g(a)(1)(A)]	Beginning <b>March 31, 2013</b> and on the 90th day of each calendar year thereafter (i.e., March 31), any <b>applicable manufacturer</b> that provides a <b>payment or other transfer of value</b> to a <b>covered recipient</b> (or to an entity or individual at the request of or designated on behalf of a <b>covered recipient</b> ) shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information regarding any <b>payments or transfers of value</b> for the preceding calendar year.
2.	<b>Procedures for Submission</b> § 1128G(c)(1)(A)-(B) [42 U.S.C. § 1320a-7g(c)(1)(A)-(B)]	No later than <b>October 1, 2011</b> , the Secretary [of HHS] will establish procedures for <b>applicable manufacturers</b> and <b>applicable group purchasing organizations</b> to submit required information to the Secretary [of HHS] and to make such information available to the public. These procedures shall provide, as appropriate, for the definition of terms not otherwise defined in the statute.
3.	<b>Information that Must Be Reported Regarding Payments of Value</b> § 1128G(a)(1)(A)(i)-(viii) [42 U.S.C. § 1320a-7g(a)(1)(A)(i)-(viii)]	An <b>applicable manufacturer</b> must report the following information with respect to the preceding calendar year of any <b>payment or other transfer of value</b> to a <b>covered recipient</b> : <ol style="list-style-type: none"> <li>1. The name of the <b>covered recipient</b>;</li> <li>2. The business address of the <b>covered recipient</b> (and if the covered recipient is a physician, the specialty and National Provider Identifier of the covered recipient);</li> <li>3. The amount of the <b>payment or other transfer of value</b>;</li> <li>4. The dates on which the <b>payment or other transfer of value</b> was provided to the <b>covered recipient</b>;</li> <li>5. A description of the form of the <b>payment or other transfer of value</b>, indicated as: <ul style="list-style-type: none"> <li>• Cash or cash equivalent</li> <li>• In kind items or services</li> <li>• Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment</li> <li>• Any other form of <b>payment or other transfer of value</b>, and</li> </ul> </li> <li>6. A description of the nature of the <b>payment or other transfer of value</b>, indicated as: <ul style="list-style-type: none"> <li>• Consulting fees</li> </ul> </li> </ol>

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		<ul style="list-style-type: none"> <li>• Compensation for services other than consulting</li> <li>• Honoraria</li> <li>• Gift</li> <li>• Entertainment</li> <li>• Food</li> <li>• Travel</li> <li>• Education</li> <li>• Research</li> <li>• Charitable contribution</li> <li>• Royalty or license</li> <li>• Current or prospective ownership or investment interest</li> <li>• Compensation for serving as a faculty or as a speaker for a CME program</li> <li>• Grant</li> <li>• Any other nature of the payment or transfer of value</li> </ul>
4.	<p><b>Additional Information to Be Submitted If Payment Is Related to Marketing, Education, or Research Specific to a Covered Drug</b></p> <p>§ 1128G(a)(1)(A)(vii) [42 U.S.C. § 1320a-7g(a)(1)(A)(vii)]</p>	<p>If the <b>payment or other transfer of value</b> is related to marketing, education, or research specific to a <b>covered drug, device, biological, or medical supply</b>, the <b>applicable manufacturer</b> also must provide the name of that <b>covered drug, device, biological, or medical supply</b>.</p>
5.	<p><b>Additional Categories of Information Specified by the Secretary</b></p> <p>§ 1128G(a)(1)(A)(viii) [42 U.S.C. § 1320a-7g(a)(1)(A)(viii)]</p>	<p>An <b>applicable manufacturer</b> also must report any other categories of information regarding the <b>payment or other transfer of value</b> the Secretary [of HHS] determines appropriate.</p>
6.	<p><b>Payment or Other Transfers of Value to an Entity or Individual at the Request of a Covered Recipient</b></p> <p>§ 1128G(a)(1)(B) [42 U.S.C. § 1320a-7g(a)(1)(B)]</p>	<p>If an <b>applicable manufacturer</b> provides a <b>payment or other transfers of value</b> to an individual or entity at the request of or designated by a <b>covered recipient</b>, the <b>applicable manufacturer</b> must disclose that <b>payment or other transfer of value</b> under the name of the <b>covered recipient</b>.</p>
7.	<p><b>Physician Ownership in Applicable</b></p>	<p>In addition to the requirements summarized above in rows #1 through #5, beginning <b>March 31, 2013</b> and on the 90th day of each calendar year thereafter (i.e., March 31), any <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b> shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information</p>

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	<b>Manufacturer</b> § 1128G(a)(2) [42 U.S.C. § 1320a-7g(a)(2)]	regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security or mutual fund) held by a <b>physician</b> (or an immediate family member of such physician) in the <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b> during the preceding year.
8.	<b>Information that must be Reported Regarding Ownership or Investment Interest</b> § 1128G(a)(2) [42 U.S.C. § 1320a-7g(a)(2)]	An <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b> must report the following information with respect to the preceding calendar year of any ownership or investment interest held by a <b>physician</b> in the <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b> : <ol style="list-style-type: none"> <li>1. The dollar amount invested by each <b>physician</b>.</li> <li>2. The value and terms of each ownership or investment interest.</li> <li>3. Any <b>payment or other transfer of value</b> provided to a <b>physician</b> holding such ownership or investment interest (or to an entity or individual at the request of or designated on behalf of the physician), including the information required under proposed new section 1128G(a)(1)(A)(i)-(viii) .</li> <li>4. Any other information regarding the ownership or investment interest the Secretary [of HHS] determines appropriate.</li> </ol>
9.	<b>Penalties: Failure to Report</b> § 1128G(b)(1) [42 U.S.C. § 1320a-7g(b)(1)]	Failure to submit the information required above may result in a CMP of not less than <b>\$1,000</b> but not more than <b>\$10,000</b> for each payment or other transfer of value or ownership or investment interest not reported. The total amount of CMPs imposed with respect to each annual submission shall not exceed <b>\$150,000</b> .
10.	<b>Penalties: Knowing Failure to Report</b> § 1128G(b)(2) [42 U.S.C. § 1320a-7g(b)(2)]	A knowing failure to submit the information required above may result in a CMP of not less than <b>\$10,000</b> but not more than <b>\$100,000</b> for each payment or other transfer of value or ownership or investment interest not reported. The total amount of CMPs imposed for knowing failures to report with respect to each annual submission shall not exceed <b>\$1,000,000</b> .
11.	<b>Public Availability of Information</b> § 1128G(c)(1)(C) [42 U.S.C. § 1320a-7g(c)(1)(C)]	No later than <b>September 30, 2013</b> , and on <b>June 30</b> of each calendar year thereafter, the information required to be submitted will be made available to the public through an Internet website that: <ol style="list-style-type: none"> <li>1. Is searchable and in a format that is clear and understandable;</li> <li>2. Contains information that is presented by: <ul style="list-style-type: none"> <li>• the name of the <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b>,</li> <li>• the name of the <b>covered recipient</b>,</li> <li>• the business address of the <b>covered recipient</b>,</li> <li>• the specialty of the <b>covered recipient</b>,</li> <li>• the value of the <b>payment or other transfer of value</b></li> <li>• the date on which the <b>payment or other transfer of value</b> was made to the <b>covered recipient</b>,</li> <li>• the form of <b>payment or other transfer of value</b>,</li> <li>• the nature of the <b>payment or other transfer of value</b>, and</li> <li>• the name of the <b>covered drug, device, biological, or medical supply</b>.</li> </ul> </li> <li>3. Can be easily aggregated and downloaded;</li> <li>4. Describes any enforcement action taken, including CMPs;</li> </ol>

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		<p>5. Contains background information on industry-physician relationships;</p> <p>6. Contains any other information the Secretary determines would be helpful to the average consumer;</p> <p>7. Does not contain the National Provider Identifier of the <b>covered recipient</b>; and</p> <p>8. Provides the <b>applicable manufacturer</b>, <b>applicable group purchasing organization</b>, or <b>covered recipient</b> an opportunity to review and submit corrections to the information listed for a period of not less than 45 days prior to such information being made available to the public.</p> <p>For information related to payments made for product development agreements and clinical investigations such information must be listed separately on the website and must designate such information as funding for clinical research.</p>
12.	<p><b>Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations</b> § 1128G(c)(1)(E) [42 U.S.C. § 1320a-7g(c)(1)(E)]</p>	<p>In the case of information submitted with respect to a <b>payment or other transfer of value</b> made pursuant to a product research or development agreement for services furnished in connection with the development of a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply or in connection with a <b>clinical investigation</b> regarding a new drug, device, biological, or medical supply, such information shall be made available to the public on the first publication date after the earlier of the following:</p> <ul style="list-style-type: none"> <li>• The date of the approval or clearance of the <b>covered drug, device, biological, or medical supply</b> by the FDA; or</li> <li>• Four calendar years after the date such <b>payment or other transfer of value</b> was made.</li> </ul>
13.	<p><b>Annual Reports</b> § 1128G(d)(1)-(2) [42 U.S.C. § 1320a-7g(d)(1)-(2)]</p>	<p>No later than <b>April 1, 2013</b> (and on <b>April 1</b> each year thereafter), the Secretary must submit a report to Congress that includes the information submitted for the preceding year aggregated for each <b>applicable manufacturer</b> or <b>applicable group purchasing organization</b> and a description of any enforcement actions taken.</p> <p>No later than <b>September 30, 2013</b> (and on <b>June 30</b> each year thereafter), the Secretary must submit a report to the States that summarizes the information submitted for the preceding year with respect to <b>covered recipients</b> in the State.</p>
14.	<p><b>Relationship with State Law</b> § 1128G(d)(3) [42 U.S.C. § 1320a-7g(d)(3)]</p>	<p>Effective <b>January 1, 2012</b>, these transparency provisions will preempt any law or regulation of a state that requires an <b>applicable manufacturer</b> to disclose or report the type of information reported hereunder for <b>payments or other transfers of value</b> provided by the <b>applicable manufacturer</b> to a <b>covered recipient</b>.</p> <p><b>EXCEPTION:</b> These transparency provisions do not preempt any law or regulation of a state that requires the disclosure or reporting of information</p> <ul style="list-style-type: none"> <li>• that is not required to be disclosed by these transparency provisions;</li> <li>• that is expressly excluded under section 1128G(e)(10)(B) [see Row #15 below on exclusions];</li> <li>• by any person or entity other than an <b>applicable manufacturer</b> or <b>covered recipient</b>; or</li> <li>• to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.</li> </ul> <p>The state preemption provisions are not to be construed to limit the discovery or admissibility of information in a criminal, civil, or administrative proceeding.</p>
15.	<p><b>Exclusions</b> § 1128G(e)(10)(B) [42 U.S.C. § 1320a-</p>	<p>An <b>applicable manufacturer</b> shall not be required to submit information with respect to the following:</p>

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7g(e)(10)(B))	<ul style="list-style-type: none"> <li>• A transfer of anything the value of which is less than \$10, unless the aggregate amount to a <b>covered recipient</b> during a calendar year exceeds \$100. For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index.</li> <li>• Product samples that are not intended to be sold and are intended for patient use.</li> <li>• Educational materials that directly benefit patients or are intended for patient use.</li> <li>• The loan of a <b>covered device</b> for a short-term trial period, not to exceed 90 days, to permit evaluation of the <b>covered device</b> by the <b>covered recipient</b>.</li> <li>• Items or services provided under a contractual warranty, including the replacement of a <b>covered device</b>, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.</li> <li>• A transfer of anything of value to a <b>covered recipient</b> when the <b>covered recipient</b> is a patient and not acting in the professional capacity of a <b>covered recipient</b>.</li> <li>• Discounts (including rebates).</li> <li>• In-kind items used for the provision of charity care.</li> <li>• A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.</li> <li>• In the case of an <b>applicable manufacturer</b> that offers a self-insured plan, payments for the provision of health care to employees under the plan.</li> <li>• In the case of a <b>covered recipient</b> who is a licensed nonmedical professional, a transfer of anything of value to the <b>covered recipient</b> if the transfer is payment solely for the non-medical professional services of such licensed nonmedical professional.</li> <li>• In the case of a <b>covered recipient</b> who is a physician, a transfer of anything of value to the <b>covered recipient</b> if the transfer is payment solely for the services of the <b>covered recipient</b> with respect to a civil or criminal action or an administrative proceeding.</li> </ul>	
16.	<b>Definition - Applicable Group Purchasing Organization</b> § 1128G(e)(1) [42 U.S.C. § 1320a-7g(e)(1)]	A group purchasing organization that purchases, arranges for, or negotiates the purchase of a <b>covered drug, device, biological or medical supply</b> which is operating in the United States, or in a territory, possession, or commonwealth of the United States.
17.	<b>Definition - Applicable Manufacturer</b> § 1128G(e)(2) [42 U.S.C. § 1320a-7g(e)(2)]	A manufacturer of a <b>covered drug, device, biological or medical supply</b> which is operating in the United States, or in a territory, possession, or commonwealth of the United States.
18.	<b>Definition - Clinical Investigation</b> § 1128G(e)(3) [42 U.S.C. § 1320a-7g(e)(3)]	Any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed or used.

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19.	<b>Definition - Covered Drug, Device, Biological, or Medical Supply</b> § 1128G(e)(4) and (5) [42 U.S.C. § 1320a-7g(e)(4) and (5)]	Any drug, biological product, device, or medical supply for which payment is available under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [CHIP] (or a waiver of such a plan).
20.	<b>Definition - Covered Recipient</b> § 1128G(e)(6) [42 U.S.C. § 1320a-7g(e)(6)]	<ul style="list-style-type: none"> <li>• A physician (but does not include a physician employed by an <b><u>applicable manufacturer</u></b>). The term "Physician" is defined by reference to Section 1861(r) of the Social Security Act and includes a doctor of medicine or osteopathy, a doctor of podiatric medicine, a doctor of optometry and a chiropractor.</li> <li>• A teaching hospital</li> </ul>
21.	<b>Definition - Payment or Other Transfer of Value</b> § 1128G(e)(10) [42 U.S.C. § 1320a-7g(e)(10)]	<p>A transfer of anything of value, but does not include a transfer of anything of value that is made indirectly to a <b><u>covered recipient</u></b> through a third party in connection with an activity or service in the case where the <b><u>applicable manufacturer</u></b> is unaware of the identity of the <b><u>covered recipient</u></b>.</p> <p>Reporting is not required for the Exclusions provided in section 1128G(e)(10)(B).</p>

On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule, "Transparency Reports and Reporting of Physician Ownership or Investment Interests," to implement Section 6002 of the Patient Protection and Affordable Care Act (ACA). **To ensure consideration, CMS must receive comments no later than 5 p.m. ET on February 17, 2012.**

**CMS Proposed Regulations for U.S. Sunshine**

	Citation	REQUIREMENT
1.	<p><b>Effective Date of Reporting Requirement</b> 42 C.F.R. § 403.908 (a)-(b) 76 Fed. Reg. 78769</p>	<p>Beginning <b>March 31, 2013</b> and on the 90th day of each calendar year thereafter (i.e., March 31), any <b>applicable manufacturer</b> that provides a <b>payment or other transfer of value</b> to a <b>covered recipient</b> (or to an entity or individual at the request of or designated on behalf of a <b>covered recipient</b>) shall submit to CMS, as comma separated value (CSV) files, information regarding any <b>payments or transfers of value</b> for the preceding calendar year.</p>
2.	<p><b>Procedures for Electronic Submission of Reports</b> 42 C.F.R. § 403.908 (c)-(f) 76 Fed. Reg. 78769</p>	<ol style="list-style-type: none"> <li><b>Registration:</b> Any applicable manufacturer or applicable group purchasing organization that is required to report under this provision must <b>register</b> with CMS <b>before March 31, 2013</b>. During registration, applicable manufacturers and applicable group purchasing organizations must <b>name a point of contact</b> with appropriate contact information.</li> <li><b>Consolidated Reporting:</b> If an applicable manufacturer and an entity (or entities) under common ownership choose to file a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers.</li> <li><b>Errors and Omissions:</b> If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS <b>immediately upon discovery</b> of the error or omission.</li> <li><b>Attestation:</b> Each report, including any subsequent corrections to a filed report, must include a <b>certification</b> by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is <b>true, correct, and complete</b> to the <b>best of his or her knowledge and belief</b>.</li> </ol>
3.	<p><b>Information that Must Be Reported Regarding Payments of Value</b> 42 C.F.R. § 403.904 (b) 76 Fed. Reg. 78768</p>	<p>An <b>applicable manufacturer</b> must report the following information with respect to the preceding calendar year of any payment or other transfer of value to a covered recipient:</p> <ol style="list-style-type: none"> <li>The <b>name of the covered recipient</b>;</li> <li>If the payment or other transfer of value was provided to another individual or entity at the request of (or designated on behalf of) any covered recipient, the <b>payment or transfer of value</b> must be <b>disclosed in the name of that covered recipient</b>;</li> <li>The <b>business address of the covered recipient</b>, including street address, suite or office number (if applicable), city, state, and ZIP code;</li> <li>If the covered recipient is a physician, the specialty and <b>National Provider Identifier</b> (if applicable) <b>of the covered recipient</b>;</li> <li>The <b>amount of the payment</b> or other transfer of value;</li> <li>The <b>dates on which the payment or other transfer of value was provided</b> to the covered recipient;</li> <li>A <b>description of the form of the payment</b> or other transfer of value, indicated as: <ul style="list-style-type: none"> <li>Cash or cash equivalent</li> <li>In kind items or services</li> <li>Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment.</li> </ul> </li> </ol>

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		<p>8. <b><u>A description of the nature of the payment</u></b> or other transfer of value, indicated as:</p> <ul style="list-style-type: none"> <li>• Consulting fees</li> <li>• Compensation for services other than consulting</li> <li>• Honoraria</li> <li>• Gift</li> <li>• Entertainment</li> <li>• Food and beverage</li> <li>• Travel and lodging</li> <li>• Education</li> <li>• Research</li> <li>• Charitable contribution</li> <li>• Royalty or license</li> <li>• Current or prospective ownership or investment interest</li> <li>• Compensation for serving as a faculty or as a speaker for a medical education program</li> <li>• Grant</li> <li>• Other</li> </ul> <p>9. Indication of <b><u>whether the payment or other transfer of value is subject to delayed publication</u></b> as outlined below in section #14. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.</p> <p>10. Indication of <b><u>whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest</u></b> (as defined within § 403.902) in the applicable manufacturer.</p>
4.	<p><b>Additional Information to Be Submitted If Payment Is Related to Marketing, Education, or Research Specific to a Covered Drug, Device, Biological, or Medical Supply</b> 42 C.F.R. § 403.904 (b) (8) 76 Fed. Reg. 78768</p>	<p><b><u>If the payment</u></b> or other transfer of value is <b><u>related to marketing, education, or research</u></b> specific to a covered drug, device, biological, or medical supply, the applicable manufacturer must also provide the <b><u>name under which the covered drug, device, biological, or medical supply is marketed</u></b>. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name.</p> <p>Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value.</p>
5.	<p><b>Special Rules for Research Payments</b> 42 C.F.R. § 403.904 (e) 76 Fed. Reg. 78768-78769</p>	<p>Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research.</p> <p>1. <b><u>Direct research</u></b>: Payments or other transfers of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity).</p> <ul style="list-style-type: none"> <li>• Direct research payments must be reported individually under the name(s) and NPI(s) (if applicable) of the covered recipient. The total must indicate the amount the covered recipient received.</li> <li>• Direct research payments made to a teaching hospital must be reported under the name of the teaching hospital.</li> </ul>

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	<p>2. <b>Indirect research:</b> Payments or other transfers of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).</p> <ul style="list-style-type: none"> <li>• Indirect research payments must be reported individually under the name(s) and NPI(s) (if applicable) of the physician covered recipient principal investigator(s). The total amount paid to the clinic, hospital or other institution conducting the research, must be reported for each principal investigator.</li> <li>• Indirect research payments made to a teaching hospital must be reported under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s).</li> </ul> <p>3. <b>Physician Payments:</b> For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.</p> <p>4. <b>Requirements:</b> All payments or other transfers of value designated as research (direct or indirect) must be subject to a written agreement and research protocol.</p>
6.	<p><b>Payment or Other Transfers of Value to an Entity or Individual at the Request of a Covered Recipient</b> 42 C.F.R. § 403.904 (b) (10) 76 Fed. Reg. 78768</p> <p>If an applicable manufacturer provides a payment or other transfer of value to an individual or entity at the request of (or designated on behalf of) a covered recipient, the applicable manufacturer must <b>disclose that payment or other transfer of value</b> under the name of the covered recipient. The name of the other individual or entity that receives the payment or other transfer of value must also be disclosed.</p>
7.	<p><b>Physician Ownership and Investment Interest</b> 42 C.F.R. § 403.906 (a) 76 Fed. Reg. 78769</p> <p>In addition to the requirements summarized above in rows #1 through #6, beginning <b>March 31, 2013</b> and on the 90th day of each calendar year thereafter (i.e., March 31st), any applicable manufacturer or applicable group purchasing organization <b>must report</b> to CMS on an annual basis <b>all ownership or investment interests in the applicable manufacturer or applicable group purchasing organization</b> that were held by a physician or an immediate family member of a physician during the preceding year.</p>
8.	<p><b>Information that Must be Reported Regarding Ownership or Investment Interest</b> 42 C.F.R. § 403.906 (b) 76 Fed. Reg. 78769</p> <p>An applicable manufacturer or applicable group purchasing organization must report the following information with respect to the preceding calendar year of any <b>ownership or investment interest held by a physician in the applicable manufacturer or applicable group purchasing organization:</b></p> <ol style="list-style-type: none"> <li>1. The <b>name of the physician</b> (and whether the ownership or investment interest is held by an immediate family member of the physician);</li> <li>2. The <b>business address of the physician</b>, including street address, suite or office number (if applicable), city, state, and ZIP code;</li> <li>3. The <b>physician owner’s specialty and National Provider Identifier</b> (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician’s specialty and NPI must be reported;</li> <li>4. The <b>dollar amount invested by each physician or immediate family member;</b></li> <li>5. The <b>value and terms of each ownership or investment</b> interest.</li> <li>6. Any <b>payment or other transfer of value provided to a physician holding such ownership or investment interest</b> (or to an entity or individual at the request of or designated on behalf of the physician), including the information required under proposed 42 C.F.R. § 403.904 (b).</li> </ol>

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9.	<b>Penalties: Failure to Report</b> 42 C.F.R. § 403.912 (a) 76 Fed. Reg. 78771	Failure to accurately and completely submit the information required above may in a timely manner may result in a <b><u>CMP of not less than \$1,000 but not more than \$10,000 for each payment</u></b> or other transfer of value or ownership <b><u>or investment interest not reported.</u></b> The <b><u>total amount of CMPs</u></b> imposed with respect to each annual submission <b><u>shall not exceed \$150,000.</u></b>
10.	<b>Penalties: Knowing Failure to Report</b> 42 C.F.R. § 403.912 (b) 76 Fed. Reg. 78771	A <b><u>knowing</u></b> failure to accurately and completely submit the information required above may in a timely manner may result in a <b><u>CMP of not less than \$10,000 but not more than \$100,000 for each payment</u></b> or other transfer of value <b><u>or ownership or investment interest not reported.</u></b> The <b><u>total amount of CMPs</u></b> imposed for knowing failures to report with respect to each annual submission <b><u>shall not exceed \$1,000,000.</u></b>
11.	<b>Records Retention</b> 42 C.F.R. § 403.912 (b) 76 Fed. Reg. 78771	Applicable manufacturers and applicable group purchasing organizations must <b><u>maintain all books, contracts, records, documents, and other evidence</u></b> sufficient to enable the audit, evaluation, and inspection of the organization's compliance with the requirement to accurately and completely submit information in a timely manner <b><u>for a period of at least five years from the date the payment</u></b> or other transfer of value, or ownership or investment interest is published publicly on the website.
12.	<b>45-Day Review Period to Allow for Error Correction</b> 42 C.F.R. § 403.908 (g) 76 Fed. Reg. 78770	Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an <b><u>opportunity to review</u></b> and submit corrections to the information submitted for a <b><u>period of not less than 45 days before CMS makes the information available to the public.</u></b> In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public. <ol style="list-style-type: none"> <li>1. <b><u>Notification:</u></b> CMS will notify the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.</li> <li>2. <b><u>Data Verification:</u></b> An applicable manufacturer, applicable group purchasing organization, covered recipient, and a physician owner or investor may log into a secure website where each applicable manufacturer, applicable group purchasing organization, covered recipient, and physician owner is able to view the information reported specific to it.</li> <li>3. <b><u>Certification:</u></b> If the reviewer agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.</li> <li>4. <b><u>Data Disputes:</u></b> If the covered recipient or physician disputes the reported data, the covered recipient or physician owner or investor must directly contact the applicable manufacturer or applicable group purchasing organization to attempt to resolve any dispute. At the discretion of the parties involved, one entity must notify CMS that a specific payment or other transfer of value, or ownership or investment interest is disputed and the outcome of the dispute at the end of the 45-day review period. If the dispute is not resolved by the end of the 45-day review period, CMS publicly reports both the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, as well as the covered recipient's or physician owner's version of the payment or other transfer of value, or ownership or investment interest data.</li> </ol>
13.	<b>Public Availability of Information</b>	No later than <b><u>September 30, 2013</u></b> , and on June 30 of each calendar year thereafter, the information required to be submitted will be <b><u>made available to the public through</u></b>

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<p>§ 1128G(c)(1)(C) [42 U.S.C. § 1320a–7g(c)(1)(C)] 76 Fed. Reg. 78755–78756</p>	<p><b>an Internet website</b> that:</p> <ol style="list-style-type: none"> <li>1. Is <b>searchable</b> and in a format that is clear and understandable;</li> <li>2. Contains the following information for reporting received related to payments or other transfers of value to covered recipients:               <ul style="list-style-type: none"> <li>• the <b><u>name of the applicable manufacturer or applicable group purchasing organization</u></b>,</li> <li>• the <b><u>name of the covered recipient</u></b>,</li> <li>• the <b><u>business street address</u></b> of the covered recipient,</li> <li>• the <b><u>specialty</u></b> of the covered recipient (physician only),</li> <li>• the <b><u>value of the payment</u></b> or other transfer of value,</li> <li>• the <b><u>date</u></b> on which the payment or other transfer of value was made to the covered recipient,</li> <li>• the <b><u>form of payment</u></b> or other transfer of value,</li> <li>• the <b><u>nature of the payment</u></b> or other transfer of value,</li> <li>• the <b><u>name of the covered drug, device, biological, or medical supply</u></b>, and</li> <li>• the <b><u>name of the entity that received the payment or other transfer of value</u></b>, if not provided to the covered recipient directly.</li> </ul> </li> <li>3. Contains the following information for reporting received <b><u>related to physician ownership and investment interest</u></b>:               <ul style="list-style-type: none"> <li>• the <b><u>name of the applicable manufacturer or applicable group purchasing organization</u></b>,</li> <li>• the <b><u>name of the physician owner</u></b>,</li> <li>• the <b><u>business street address</u></b> of the physician owner,</li> <li>• the <b><u>specialty</u></b> of the physician owner,</li> <li>• the data to <b><u>designate whether the ownership or investment interest is held by the physician or an immediate family member</u></b> of the physician,</li> <li>• the <b><u>dollar amount invested</u></b>,</li> <li>• the <b><u>value</u></b> an terms of each ownership or investment interest, and</li> <li>• the data related to any payment or other transfer of value provided to the physician owner, including:                   <ul style="list-style-type: none"> <li>▪ the <b><u>amount of payment</u></b> or other transfer of value,</li> <li>▪ the <b><u>date of payment</u></b> or other transfer of value,</li> <li>▪ the <b><u>form of payment</u></b> or other transfer of value,</li> <li>▪ the <b><u>nature of the payment</u></b> or other transfer of value, and</li> <li>▪ the <b><u>name of the covered drug, device, biological, or medical supply</u></b>.</li> </ul> </li> </ul> </li> <li>4. Can be <b><u>easily aggregated and downloaded</u></b>;</li> <li>5. <b><u>Describes any enforcement action</u></b> taken, including CMPs;</li> <li>6. <b><u>Contains background information</u></b> on industry-physician relationships;</li> <li>7. <b><u>Does not contain the National Provider Identifier</u></b> of the covered recipient;</li> <li>8. <b><u>Contains publication of information on payments</u></b> or other transfers of value that were granted delayed reporting; and</li> <li>9. Clearly <b><u>states that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate</u></b> nor does it necessarily indicate a conflict of interest or any wrongdoing.</li> </ol>	
<p>14.</p>	<p><b>Delayed Publication for Payments Made</b></p>	<p>In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, <b><u>payments may be delayed from publication</u></b></p>

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<p><b>Under Product Research or Development Agreements and Clinical Investigations</b>                      42 C.F.R. § 403.910                      76 Fed. Reg. 78770-78771</p>	<p><b><u>on the website.</u></b> Publication of a payment or other transfer of value is delayed when made in connection with either research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply as well clinical investigations regarding a new drug, device, biological, or medical supply. The research or development agreement must include a written agreement and research protocol between the applicable manufacturer and covered recipient.</p> <p><b><u>Payments must be reported to CMS on the first reporting date following the year in which they occur,</u></b> but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:</p> <ul style="list-style-type: none"> <li>• <b><u>The date of the approval, licensure or clearance</u></b> of the covered drug, device, biological, or medical supply by the FDA; or</li> <li>• <b><u>Four calendar years after the date the payment or other transfer of value</u></b> was made.</li> </ul> <p>It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.</p> <p>An applicable manufacturer must continue to indicate annually in its report that FDA approval of the new drug, device, biological or medical supply, with which the payment is associated, is pending.</p> <p>Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.</p> <p>If, after four years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.</p>
<p>15. <b>Annual Reports</b>                      § 1128G(d)(1)-(2)                      [42 U.S.C. § 1320a-7g(d)(1)-(2)]                      76 Fed. Reg. 78758</p>	<p>No later than <b><u>April 1, 2013</u></b> (and on April 1 each year thereafter), the <b><u>Secretary must submit a report to Congress</u></b> that includes the information submitted for the preceding year aggregated for each applicable manufacturer or applicable group purchasing organization and a description of any enforcement actions taken.</p> <p>No later than <b><u>September 30, 2013</u></b> (and on June 30 each year thereafter), the <b><u>Secretary must submit a report to the states</u></b> that summarizes the information submitted for the preceding year <b><u>with respect to covered recipients in the state.</u></b></p> <p>These reports will not include any payments or other transfers of value that were not published under the delayed publication requirements in section 1128G(c)(1)(E) of the Act.</p>
<p>16. <b>Preemption of State Laws</b>                      42 C.F.R. § 403.914                      76 Fed. Reg. 78771</p>	<p>In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, <b><u>this subpart preempts any statute or regulation of a state or political subdivision of a state that requires an applicable manufacturer to disclose or report,</u></b> in any format, <b><u>the type of information regarding the payment or other transfer of value required to be reported under this provision.</u></b> Note that a state law may require information other than that required under this provision, including items listed below as exclusions.</p> <p><b><u>Exception:</u></b> These provisions <b><u>do not preempt any law or regulation</u></b> of a state that <b><u>requires the disclosure or reporting of information collected for public health purposes.</u></b> Information required to be reported to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes. Such information must still be reported to appropriate federal, state, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.</p>

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<p>17.</p> <p><b>Exclusions from reporting</b></p> <p>42 C.F.R. § 403.904 (f)</p> <p>76 Fed. Reg. 78769</p>	<p>An applicable manufacturer <b><u>shall not be required</u></b> to submit information with respect to the following:</p> <ul style="list-style-type: none"> <li>• Transfers of value <b><u>made indirectly to a covered recipient through a third party</u></b> in cases when the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in §403.902) the identity of the covered recipient.</li> <li>• A transfer of anything the value of which is <b><u>less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 during the calendar year.</u></b> For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.</li> <li>• <b><u>Product samples</u></b> that are not intended to be sold and are intended for patient use.</li> <li>• <b><u>Educational materials</u></b> that directly benefit patients or are intended for patient use.</li> <li>• The <b><u>loan of a covered device for a short-term trial period</u></b>, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.</li> <li>• <b><u>Items or services provided under a contractual warranty</u></b>, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.</li> <li>• <b><u>A transfer of anything of value to a covered recipient when the covered recipient is a patient</u></b> and not acting in the professional capacity of a covered recipient.</li> <li>• <b><u>Discounts</u></b> (including rebates).</li> <li>• <b><u>In-kind items used for</u></b> the provision of <b><u>charity care</u></b>.</li> <li>• <b><u>A dividend or other profit distribution</u></b> from, or ownership or investment interest in, a publicly traded security or mutual fund.</li> <li>• In the case of an applicable manufacturer who offers a self-insured plan, <b><u>payments for the provision of health care to employees under the plan.</u></b></li> <li>• In the case of a covered recipient who is a licensed non-medical professional, <b><u>a transfer of anything of value to the covered recipient if the transfer is payment solely for the nonmedical professional services of the licensed non-medical professional.</u></b></li> <li>• In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.</li> </ul>	
<p>18.</p> <p><b>Definition - Applicable Group Purchasing Organization</b></p> <p>42 C.F.R. § 403.902</p> <p>76 Fed. Reg. 78767</p>	<p>An entity that</p> <ol style="list-style-type: none"> <li>1. <b><u>Operates in the United States</u></b>, or in a territory, possession or commonwealth of the United States; and</li> <li>2. Purchases, arranges for or negotiates <b><u>the purchase of a covered drug, device, biological, or medical supply</u></b> for a group of individuals or entities, and <b><u>not solely for use by the entity itself.</u></b></li> </ol>	
<p>19.</p> <p><b>Definition - Applicable Manufacturer</b></p> <p>42 C.F.R. § 403.902</p> <p>76 Fed. Reg. 78767</p>	<p>An entity that is</p> <ol style="list-style-type: none"> <li>1. Engaged in the <b><u>production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply</u></b> for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or</li> </ol>	

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		2. Under <b>common ownership</b> with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply for sale and distribution in the United States, or in a territory, possession, or commonwealth of the United States.
20.	<b>Definition – Charity Care</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	<b>Services provided</b> by a covered recipient specifically for a <b>patient who cannot pay</b> , where the <b>covered recipient neither receives, nor expects to receive, payment</b> because of the patient's inability to pay.
21.	<b>Definition – Charitable Contribution</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	Any <b>payment</b> or <b>transfer of value</b> made to an <b>organization with tax-exempt status</b> under the Internal Revenue Code of 1986.
22.	<b>Definition – Clinical Investigation</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	Any <b>experiment involving one (1) or more human subjects</b> , or <b>materials derived from human subjects</b> , in which a <b>drug or device is administered, dispensed or used</b> .
23.	<b>Definition – Common Ownership</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	Entities that are <b>owned, in whole or in part, by the same individual, individuals, entity, or entities</b> , directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.
24.	<b>Definition – Covered Device</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	Any device for which <b>payment is available under Title XVIII [Medicare] or</b> under a State plan under <b>Title XIX [Medicaid] or XXI [SCHIP]</b> (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). This definition is limited to those devices (including medical supplies) that, by law, <b>require premarket approval by or premarket notification to the Food and Drug Administration</b> .
25.	<b>Definition – Covered Drug, Device, Biological, or Medical Supply</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	Any drug, device, biological, or medical supply for which <b>payment is available under Title XVIII [Medicare] or</b> under a State plan under <b>Title XIX [Medicaid] or XXI [SCHIP]</b> (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, <b>require premarket approval by or premarket notification to the Food and Drug Administration</b> .
26.	<b>Definition – Covered Recipient</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767	<ul style="list-style-type: none"> <li>A <b>physician</b> (but does not include a physician employed by an applicable manufacturer).</li> </ul> <p>The term "Physician" is defined by reference to Section 1861(r) of the Social Security Act and includes a <b>doctor of medicine or osteopathy, dentists, podiatrists, optometrists and licensed chiropractors</b>.</p> <ul style="list-style-type: none"> <li>A <b>teaching hospital</b></li> </ul>

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	The term “Teaching Hospital” is defined as <b><u>any institution that received a payment under Social Security Act Section 1886(d)(5)(B) (IME), 1886(h) (GME), or 1886(s) (psychiatric hospitals IME)</u></b> during the last calendar year for which such information is available.
27.	<p><b>Definition – Employee</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767</p> <p>An individual who is considered to be <b><u>“employed by”</u></b> or <b><u>an “employee”</u></b> of an entity if the individual would be considered to be an employee of the entity <b><u>under the usual common law rules applicable in determining the employer-employee relationship</u></b> (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).</p>
28.	<p><b>Definition – Immediate Family Member</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767</p> <ul style="list-style-type: none"> <li>• Spouse</li> <li>• Natural or adoptive parent, child, or sibling.</li> <li>• Stepparent, stepchild, stepbrother, or stepsister.</li> <li>• Father-, mother-, daughter-, son-, brother-, or sister-in-law.</li> <li>• Grandparent or grandchild.</li> <li>• Spouse of a grandparent or grandchild.</li> </ul>
29.	<p><b>Definition – Know, Knowing, or Knowingly</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78767-78768</p> <p>A person, with respect to information, who</p> <ul style="list-style-type: none"> <li>• Has <b><u>actual knowledge</u></b> of the information;</li> <li>• <b><u>Acts in deliberate ignorance</u></b> of the truth or falsity of the information; or</li> <li>• <b><u>Acts in reckless disregard</u></b> of the truth or falsity of the information.</li> </ul> <p><b><u>Requires no proof of a specific intent to defraud.</u></b></p>
30.	<p><b>Definition – Ownership or Investment Interest</b> 42 C.F.R. § 403.902 76 Fed. Reg. 78768</p> <ol style="list-style-type: none"> <li>1. Includes, but is not limited to— <ul style="list-style-type: none"> <li>• <b><u>Stock, stock option(s)</u></b> (other than those received as compensation, until they are exercised);</li> <li>• <b><u>Partnership share(s)</u></b>;</li> <li>• <b><u>Limited liability company membership(s)</u></b>;</li> <li>• Loans, bonds, or other financial instruments that are secured with an entity’s property or revenue or a portion of that property or revenue.</li> </ul> </li> <li>2. May be <b><u>direct or indirect and through debt, equity or other means</u></b>; and</li> <li>3. <b><u>Must not include an ownership or investment interest in a publicly traded security or mutual fund</u></b>, as described in section 1877(c) of the Act, nor any of the following: <ul style="list-style-type: none"> <li>• An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician’s (or immediate family member’s) employment with that applicable manufacturer or applicable group purchasing organization.</li> <li>• Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.</li> <li>• An unsecured loan subordinated to a credit facility.</li> </ul> </li> </ol>

**PROPOSED REGULATIONS - CMS REQUESTED COMMENT ISSUES**

On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule, “Transparency Reports and Reporting of Physician Ownership or Investment Interests,” to implement Section 6002 of the Patient Protection and Affordable Care Act (ACA).

CMS is soliciting substantial comments from the public on definitions, exclusions, and processes related to applicable manufacturer reporting of payments or transfers of value provided to physicians or teaching hospitals (covered recipients), as well as applicable manufacturer and applicable group purchasing organization (GPO) reporting of certain physician ownership or investment interests. **To ensure consideration, CMS must receive comments no later than 5 p.m. ET on February 17, 2012.**

<b>CMS Requests for Comments</b>		
<b>GPOs</b>		<b>Proposed Rule Page Number(s)</b>
1.	<p>Proposed definition of “applicable GPOs”</p> <p style="padding-left: 40px;">An entity that (1) operates in the United States, or in a territory, possession or commonwealth of the United States, and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.</p> <p>The definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Intention to capture entities (including physician-owned entities) that purchase covered drugs, devices, biologicals, or medical supplies for resale or distribution to others.</p>	76 Fed. Reg. 78752
2.	Estimate that on average, an applicable GPO would dedicate 10 percent of an FTE employee to reporting under this section for year 1, followed by 7.5 percent for year 2 and annually thereafter.	76 Fed. Reg. 78760
3.	Interpret the statute to encompass in the definition of GPOs entities that purchase covered drugs, devices, biological, and medical supplies for resale or distribution to groups of individuals or entities. This would include physician owned distributors (PODs) of covered drugs, devices, biological, and medical supplies.	76 Fed. Reg. 78765
<b>Information That Must Be Submitted</b>		<b>Proposed Rule Page Number(s)</b>
4.	Feasibility of submitting the required information for part of CY 2012 by March 31, 2013.	76 Fed. Reg. 78743
5.	Report applicable manufacturer payments or other transfers of value to covered recipients and applicable manufacturers and applicable GPOs ownership and investment interests of physicians, and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors separately to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished.	76 Fed. Reg. 78743
6.	Consider mandating that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified, but do not have an NPI. What other unique identifiers could be used, including whether these unique identifiers are readily obtainable by applicable manufacturers.	76 Fed. Reg. 78746

<b>CMS Requests for Comments</b>		
<b>Information That Must Be Submitted</b>		<b>Proposed Rule Page Number(s)</b>
7.	Applicable manufacturers report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. Review by the covered recipient is sufficient.	76 Fed. Reg. 78746
8.	Applicable manufacturers use their discretion over whether to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item. Either approach would comply with the regulations. Consider requiring manufacturers to report multiple payments in a single consistent manner.	76 Fed. Reg. 78747
9.	Applicable manufacturer should report a related covered drug, device, biological, or medical supply (if there is one) using the name under which the product is marketed. In the event that a covered drug, device, biological or medical supply does not yet have a market name, the applicable manufacturer should report the scientific name. Additionally, applicable manufacturers should report only one covered drug, device, biological, or medical supply as related to a payment or other transfer of value, even though there arguably may be multiple products related to the payment. As an alternative, allow applicable manufacturers to report multiple covered drugs, devices, biologicals, or medical supplies as related to a single payment or other transfer of value.	76 Fed. Reg. 78747
10.	Require reporting payments under a single form of payment and nature of payment.	76 Fed. Reg. 78747
11.	Do not add any forms of payment beyond those outlined in the statute. What is provided in the statute is sufficient to describe payments and other transfers of value.	76 Fed. Reg. 78748
12.	Allow applicable manufacturers to submit with their data a document describing the assumptions used when categorizing the natures of payments. Submission of the assumptions document will not be mandatory, but could become mandatory in the future.	76 Fed. Reg. 78748
13.	Consider adopting different “per covered recipient costs” for solo physician offices and multi-physician offices, but only if different approaches are more equitable but not overly burdensome.	76 Fed. Reg. 78748
14.	Adopt proposed method for reporting research payment, or alternative method if it is less burdensome.	76 Fed. Reg. 78749
15.	For both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient. Report on the public website the payment amount separately and not aggregate it into the total for physician covered recipients. For teaching hospitals, it is appropriate to aggregate this into the teaching hospital’s total payment amount.	76 Fed. Reg. 78749
16.	Proposed reporting requirements for research payments and transfers of value may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research activities (e.g., post-marketing research or other research or studies not conducted pursuant to a written contract between the applicable manufacturer and the organization conducting the research, and studies without a research protocol).	76 Fed. Reg. 78749
17.	Add another nature of payment category to describe situations when a covered recipient provides speaking services that are outside of medical education programs; however we believe that fewer categories for nature of payment is preferable. Consider limiting this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category.	76 Fed. Reg. 78750
18.	Consider mandating report of the relationship and/or the name of the immediate family member holding the ownership and investment interest.	76 Fed. Reg. 78752

<b>CMS Requests for Comments</b>		
<b>Information That Must Be Submitted</b>		<b>Proposed Rule Page Number(s)</b>
19.	Appropriateness of the CSV format for data submission, and suggestions for alternative formats.	76 Fed. Reg. 78754
<b>Collection and Submission of Information</b>		<b>Proposed Rule Page Number(s)</b>
20.	Appropriateness of data elements that must be submitted.	76 Fed. Reg. 78754
21.	Consider requiring that applicable manufacturers report another unique identifier, such as state license number, for physicians who are identified but do not have an NPI.	76 Fed. Reg. 78765
22.	Amount of time applicable manufacturers and applicable GPOs will need following publication of the final rule in order to begin complying with the data collection requirements of section 1128G of the Act. Considering a 90-day preparation period.	76 Fed. Reg. 78743
23.	Alternative approach of allowing a payment or other transfer of value for an activity that is associated with multiple segregable categories to be reported as a single lump sum, rather than separately by each segregable category.	76 Fed. Reg. 78747
24.	Plan to work with applicable manufacturers and applicable GPOs to create the best data submission system for all parties involved. Consider whether an alternative data submission system is preferable.	76 Fed. Reg. 78753
25.	Following FDA approval, licensure or clearance, applicable manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. Failure to indicate to CMS in a timely fashion that a payment or other transfer of value should no longer be granted a delay in publication, due to FDA approval, licensure or clearance, may be subject to penalties under section 1128G(b) of the Act. If a report includes a date of payment four years prior to the current year, then the payment or other transfer of value would be automatically published, regardless of whether the applicable manufacturer indicates that the payment should be delayed.	76 Fed. Reg. 78756
26.	Applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. Applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least five years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website.	76 Fed. Reg. 78758
27.	Estimate that approximately 1,150 applicable manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers), and approximately 420 applicable GPOs would submit reports, based on the number of manufacturers reporting in States with similar transparency provisions, as well as the number of manufacturers registered with FDA.	76 Fed. Reg. 78759
28.	Costs of five-year record retention are negligible for electronic recordkeeping. Estimates also include the time of employees, such as sales representatives, who have direct relationships with covered recipients and physician owners or investors. These employees would have to record the details of each relationship with the covered recipient, or physician owner or investor for reporting purposes. This overall estimate is based primarily on the judgmental estimates of persons we have consulted that are expert in the overall cost of existing reporting systems.	76 Fed. Reg. 78759

<b>CMS Requests for Comments</b>		
<b>Collection and Submission of Information</b>		<b>Proposed Rule Page Number(s)</b>
29.	Smaller firms with only a few products and only a few financial relationships might well already have systems in place that essentially meet the proposed requirements or that could do so with minimal effort.	76 Fed. Reg. 78759-78760
30.	Neither the statute, nor this proposed rule, contains a recordkeeping requirement for physicians or teaching hospitals. Therefore, there is no estimate of the burden for keeping records.	76 Fed. Reg. 78760
31.	Estimated Annual Information Collection estimates are, by necessity, uncertain, and need a better basis for final estimates.	76 Fed. Reg. 78762
32.	For purposes of the RFA, estimate that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard.	76 Fed. Reg. 78763
33.	A few large companies are already reporting similar information on a national level in order to comply with Corporate Integrity Agreements (CIAs) with HHS OIG. These companies may not have to invest as much to comply with the requirements in section 1128G of the Act, so the burden of these requirements may be lower for these companies. However, given the differing requirements for each State and CIA, and broad scope of section 1128G of the Act, it is not possible to approximate the lessened burden for entities already reporting.	76 Fed. Reg. 78764
34.	Assume that future outlay costs may be similar to those costs experienced in year two. Envision that the number of financial relationships required to be reported will remain similar, so the cost of reporting the information will not change significantly.	76 Fed. Reg. 78766
<b>Definitions</b>		<b>Proposed Rule Page Number(s)</b>
35.	Clarify that any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered drug, device, biological, or medical supply is considered an applicable manufacturer, even though it may also manufacturer products that do not fall within that category. All payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported as required under section 1128G of the Act regardless of whether the particular payment or other transfer of value is associated with a covered drug, device, biological, or medical supply. Additionally, clarify that the proposed definition includes entities that hold FDA approval, licensure, or clearance for a covered drug, device, biological, or medical supply, even if they contract out the actual physical manufacturing of the product to another entity. Interpret these entities as being engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply.	76 Fed. Reg. 78744
36.	Limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. This would be subject to the same requirements as the proposed definition described previously, but would only apply to interests of 5 percent or more. Proposed definition of "common ownership," including, whether a more specific definition is needed and, if a minimum percentage threshold is adopted, whether 5 percent is appropriate.	76 Fed. Reg. 78744
37.	Limit the definitions of covered drugs and biologicals to those that require a prescription to be dispensed.	76 Fed. Reg. 78745

<b>CMS Requests for Comments</b>		
<b>Definitions</b>		<b>Proposed Rule Page Number(s)</b>
38.	Limit definitions of covered device or medical supply to those devices (including medical supplies) that, by law, require premarket approval by or notification to FDA. This limitation may be appropriate for applicable manufacturers, because manufacturers that solely produce these exempt products have not been shown to have extensive relationships with covered recipients. This limitation might be appropriate because these financial relationships (to the extent they exist) are less likely to influence patient care. Concern that this would be overly limiting for the definition of applicable GPOs, which also incorporates the phrase “covered drug, device, biological, or medical supply.”	76 Fed. Reg. 78745
39.	Define “teaching hospital” by linking it to Medicare graduate medical education (GME).	76 Fed. Reg. 78745
40.	Consider whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that “directly benefit patients.”	76 Fed. Reg. 78751
41.	Limit the covered drug, device, biological, and medical supply definitions to only those drugs and biologicals that, by law, require a prescription to be dispensed and to only those devices (including medical supplies) that require premarket approval by or notification to FDA.	76 Fed. Reg. 78752
42.	Consider “medical technology” broadly as any drug, device, biological, or medical supply. Define “medical technology” narrowly as a subset of drugs, devices, biologicals, and medical supplies.	76 Fed. Reg. 78757
43.	Consider the possibility of assigning different meanings to “research” and “development.”	76 Fed. Reg. 78757
44.	Delayed publication should apply to payments to covered recipients for services in connection with research on, or development of new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biologicals, or medical supplies. Limit delayed publication for payments in connection with clinical investigations for new drugs, devices, biologicals, or medical supplies, and not new applications of existing drugs, devices, biologicals, or medical supplies.	76 Fed. Reg. 78757
<b>Review of Information Before Publication; Disputes Regarding Information Reported</b>		<b>Proposed Rule Page Number(s)</b>
45.	Consider a way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS, thus lessening potential changes during the statutory review and correction period, and thereby strengthening the accuracy of the data.	76 Fed. Reg. 78753
46.	Recommend that applicable manufacturers and applicable GPOs provide for a pre-submission review.	76 Fed. Reg. 78753
47.	Allow covered recipients and physician owners or investors to register with CMS to ensure they receive communication about the processes for review. Notify physicians and hospitals through CMS’ list serves and posting the information publicly. Consider posting either on the CMS website or on the <i>Federal Register</i> . Provide annual notifications to announce the covered recipient and physician owner and investor review and correction period, and include the specific instructions for performing this review. Consider that covered recipients and physician owners and investors would sign in to a secure website to see the information reported about them.	76 Fed. Reg. 78754–78755

<b>CMS Requests for Comments</b>		
<b>Review of Information Before Publication; Disputes Regarding Information Reported</b>		<b>Proposed Rule Page Number(s)</b>
48.	If an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradicting information that cannot be resolved by the parties involved, propose that the data would be identified as contradictory and both the original submission from the applicable manufacturer or applicable GPO, and the modified information provided by the covered recipient, or physician owner or investor would appear in the final publicly available website. Consider that in these cases, the individual payment would be flagged as contested, but the contradictory data, as corrected by the covered recipient or physician owner or investor, would be used for aggregated totals for the physician, as necessary. Consider aggregating the original information, as submitted by the applicable manufacturer and applicable GPO.	76 Fed. Reg. 78755
49.	Adopt procedures outlined for data submission and the 45-day review period, and consider the best way to contact covered recipients and physician owners or investors to ensure they receive notification of the review period.	76 Fed. Reg. 78755
50.	Each physician and teaching hospital would be only allowed to review the information attributed to them by all applicable manufacturers and applicable GPOs. Estimate that on average, physicians would need one hour to review the information reported. Estimate it would take a representative from a teaching hospital 10 hours to review the submitted data.	76 Fed. Reg. 78761
51.	Require a 45-day review period during which applicable manufacturers and GPOs, covered recipients, and physician owners or investors can review the data before it is made available to the public, perhaps via a two-step process, in which the information when first released as provisional date, and then "final" data is released after a second opportunity for correction. Consider mail or e-mail options for purposes of data review.	76 Fed. Reg. 78765
<b>Registration with CMS; HHS Website</b>		<b>Proposed Rule Page Number(s)</b>
52.	With respect to teaching hospitals, publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct or indirect GME) on the CMS website once per year. List of teaching hospital covered recipients should include the name and address of each teaching hospital.	76 Fed. Reg. 78746
53.	Open the registration process at the beginning of the calendar year, giving applicable manufacturers and applicable GPOs time to register and submit their data. The first opportunity for registration and the data submission would be January 1, 2013.	76 Fed. Reg. 78753
54.	Alternatively, consider requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they have information to report. If an applicable manufacturer or applicable GPO had no payments or transfers of value and/or ownership or investment interests to report, the chief executive officer, chief financial officer or chief compliance officer would be required to submit an attestation that, to the best of his or her knowledge and belief, there were no reportable payments or transfers and value and/or ownership or investment interests during the previous calendar year.	76 Fed. Reg. 78753- 78754
55.	Consider how to structure for ultimate usability the publicly available website that will include data reported by applicable manufacturers and applicable GPOs.	76 Fed. Reg. 78755
56.	Website should clearly state that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing.	76 Fed. Reg. 78757

<b>CMS Requests for Comments</b>		
	<b>CMP Factors</b>	<b>Proposed Rule Page Number(s)</b>
57.	<p>In determining the amount of the CMP, factors to be considered include, but are not limited to, the following:</p> <ul style="list-style-type: none"> <li>• The length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.</li> <li>• Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report.</li> <li>• Level of culpability.</li> <li>• Nature and amount of information reported in error.</li> <li>• Degree of diligence exercised in correcting information reported in error.</li> </ul>	76 Fed. Reg. 78757– 78758