

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

Provision Section of Social Security Act [U.S. Code citation]	DESCRIPTION OF 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 90 <sup>th</sup> day of each calendar year thereafter (i.e., March 31 <sup>st</sup> ), 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)]	<p>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>:</p> <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> <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> </li> </ol>

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<p>4. <b>Additional Information to be submitted if payment is related to marketing, education, or research specific to a covered drug</b> § 1128G(a)(1)(A)(vii) [42 U.S.C. § 1320a–7g(a)(1)(A)(vii)]</p>	<p>If the <u>payment or other transfer of value</u> is related to marketing, education, or research specific to a <u>covered drug, device, biological, or medical supply</u>, the <u>applicable manufacturer</u> also must provide the name of that <u>covered drug, device, biological, or medical supply</u>.</p>
<p>5. <b>Additional categories of information specified by the Secretary</b> § 1128G(a)(1)(A)(viii) [42 U.S.C. § 1320a–7g(a)(1)(A)(viii)]</p>	<p>An <u>applicable manufacturer</u> also must report any other categories of information regarding the <u>payment or other transfer of value</u> the Secretary [of HHS] determines appropriate.</p>
<p>6. <b>Payment or other transfers of value to an entity or individual at the request of a covered recipient.</b> § 1128G(a)(1)(B) [42 U.S.C. § 1320a–7g(a)(1)(B)]</p>	<p>If an <u>applicable manufacturer</u> provides a <u>payment or other transfers of value</u> to an individual or entity at the request of or designated by a <u>covered recipient</u>, the <u>applicable manufacturer</u> must disclose that <u>payment or other transfer of value</u> under the name of the <u>covered recipient</u>.</p>
<p>7. <b>Physician Ownership in Applicable Manufacturer</b> § 1128G(a)(2) [42 U.S.C. § 1320a–7g(a)(2)]</p>	<p>In addition to the requirements summarized above in rows #1 through #5, beginning <b>March 31, 2013</b> and on the 90<sup>th</sup> day of each calendar year thereafter (i.e., March 31<sup>st</sup>), any <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u> shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security or mutual fund) held by a <u>physician</u> (or an immediate family member of such physician) in the <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u> during the preceding year.</p>
<p>8. <b>Information that must be Reported Regarding Ownership or Investment Interest</b> § 1128G(a)(2) [42 U.S.C. § 1320a–7g(a)(2)]</p>	<p>An <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u> must report the following information with respect to the preceding calendar year of any ownership or investment interest held by a <u>physician</u> in the <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u>:</p> <ol style="list-style-type: none"> <li>1. The dollar amount invested by each <u>physician</u>.</li> <li>2. The value and terms of each ownership or investment interest.</li> <li>3. Any <u>payment or other transfer of value</u> provided to a <u>physician</u> 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</li> </ol>

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		<p>proposed new section 1128G(a)(1)(A)(i)-(viii) .</p> <p>4. Any other information regarding the ownership or investment interest the Secretary [of HHS] determines appropriate.</p>
9.	<b>Penalties: Failure to Report</b> § 1128G(b)(1) [42 U.S.C. § 1320a-7g(b)(1)]	<p>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.</p> <p>The total amount of CMPs imposed with respect to each annual submission shall not exceed <b>\$150,000</b>.</p>
10.	<b>Penalties: Knowing Failure to Report</b> § 1128G(b)(2) [42 U.S.C. § 1320a-7g(b)(2)]	<p>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.</p> <p>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>.</p>
11.	<b>Public Availability of Information</b> § 1128G(c)(1)(C) [42 U.S.C. § 1320a-7g(c)(1)(C)]	<p>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:</p> <ol style="list-style-type: none"> <li>Is searchable and in a format that is clear and understandable;</li> <li>Contains information that is presented by:               <ul style="list-style-type: none"> <li>the name of the <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u>,</li> <li>the name of the <u>covered recipient</u>,</li> <li>the business address of the <u>covered recipient</u>,</li> <li>the specialty of the <u>covered recipient</u>,</li> <li>the value of the <u>payment or other transfer of value</u></li> <li>the date on which the <u>payment or other transfer of value</u> was made to the <u>covered recipient</u>,</li> <li>the form of <u>payment or other transfer of value</u>,</li> <li>the nature of the <u>payment or other transfer of value</u>, and</li> <li>the name of the <u>covered drug, device, biological, or medical supply</u>.</li> </ul> </li> <li>Can be easily aggregated and downloaded;</li> <li>Describes any enforcement action taken, including CMPs;</li> <li>Contains background information on industry-physician relationships;</li> <li>Contains any other information the Secretary determines would be helpful to the average consumer;</li> <li>Does not contain the National Provider Identifier of the <u>covered recipient</u>; and</li> <li>Provides the <u>applicable manufacturer</u>, <u>applicable group purchasing organization</u>, or <u>covered recipient</u> 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.</li> </ol> <p>For information related to payments made for product development agreements and clinical investigations such information must be listed separately on the website and</p>

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	must designate such information as funding for clinical research.	
12. <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>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. <b>Annual Reports</b> § 1128G(d)(1)-(2) [42 U.S.C. § 1320a-7g(d)(1)-(2)]	<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. <b>Relationship with State Law</b> § 1128G(d)(3) [42 U.S.C. § 1320a-7g(d)(3)]	<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 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. <b>Exclusions</b> § 1128G(e)(10)(B) [42 U.S.C. § 1320a-7g(e)(10)(B)]	<p>An <b>applicable manufacturer</b> shall not be required to submit information with respect to the following:</p> <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,</li> </ul>	

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		<p>to permit evaluation of the <u>covered device</u> by the <u>covered recipient</u>.</p> <ul style="list-style-type: none"> <li>Items or services provided under a contractual warranty, including the replacement of a <u>covered device</u>, 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 <u>covered recipient</u> when the <u>covered recipient</u> is a patient and not acting in the professional capacity of a <u>covered recipient</u>.</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 <u>applicable manufacturer</u> who offers a self-insured plan, payments for the provision of health care to employees under the plan.</li> <li>In the case of a <u>covered recipient</u> who is a licensed non-medical professional, a transfer of anything of value to the <u>covered recipient</u> if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.</li> <li>In the case of a <u>covered recipient</u> who is a physician, a transfer of anything of value to the <u>covered recipient</u> if the transfer is payment solely for the services of the <u>covered recipient</u> 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 <u>covered drug, device, biological or medical supply</u> 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 <u>covered drug, device, biological or medical supply</u> 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 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed or used.
19.	<b>Definition - Covered Drug, Device, Biological, or Medical Supply</b> § 1128G(e)(4) and (5) [42 U.S.C. § 1320a-	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 [SCHIP] (or a waiver of such a plan).

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	7g(e)(4) and (5)]	
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>applicable manufacturer</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>covered recipient</b> through a third party in connection with an activity or service in the case where the <b>applicable manufacturer</b> is unaware of the identity of the <b>covered recipient</b>.</p> <p>Reporting is not required for the Exclusions provided in section 1128G(e)(10)(B).</p>

Summary of Other Transparency Requirements		
TOPIC Section of Social Security Act [U.S. Code citation]		DESCRIPTION OF REQUIREMENT
1.	<b>Sec. 6001. Physician and Hospital Disclosures</b> § 1877(i)(1)(C) [42 U.S.C. § 1395nn(i)(1)(C)]	<p>Requires hospitals to:</p> <ul style="list-style-type: none"> <li>Submit annual reports to the Secretary [of HHS] containing a detailed description of each physician owner or investor (and any other owners or investors) of the hospital and the nature and extent of all ownership and investment interests. The Secretary [of HHS] will publish such information on the CMS website.</li> <li>Implement procedures requiring physician owners and investors to disclose to patients referred to the hospital the physician’s ownership or investment interest.</li> <li>Disclose the fact that the hospital is partially owned or invested in by physicians on the hospital’s public website and in any public advertising by the hospital.</li> <li>If the hospital admits a patient but does not have a physician on the premises during all hours in which the hospital will provide services to the patient, disclose to the patient, prior to admission, the limited physician availability.</li> </ul> <p>The Secretary [of HHS] must implement policies and procedures for the above requirements <b>within 18 months</b> of enactment – the time at which the disclosure requirements begin.</p>

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	<b>TOPIC</b> Section of Social Security Act [U.S. Code citation]	<b>DESCRIPTION OF REQUIREMENT</b>
2.	<b>Sec. 6003.</b> <b>Physician Disclosure Requirements for In-Office Ancillary Services</b> § 1877(b)(2) [42 U.S.C. § 1395nn(b)(2)]	<p>Requires that the regulations promulgated by the Secretary [of HHS] for the in-office ancillary services exception (under Sec. 1877(b)(2) of the SSA) include the following requirements for physicians who refer a patient for in-office radiology or imaging services:</p> <ul style="list-style-type: none"> <li>• Inform the patient in writing at the time of the referral that the patient may obtain such services from a person other than the in-office provider, and</li> <li>• Provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.</li> </ul> <p>Effective date: <b>January 1, 2010.</b></p>
3.	<b>Sec. 6004.</b> <b>Prescription Drug Sample Transparency</b> § 1128H [42 U.S.C. § 1320a–7h]	<p>Requires manufacturers and authorized distributors of record to submit to the Secretary [of HHS] by April 1 of each year (beginning with 2012) the following information: the identity and quantity of drug samples requested and distributed, aggregated by the practitioner making the request.</p> <p>Reporting requirements begin on <b>April 1, 2012.</b></p>
4.	<b>Sec. 6005.</b> <b>Pharmacy Benefit Managers Transparency Requirements</b> § 1150A [42 U.S.C. § 1320b–21a]	<p>Requires reporting by a health benefits plans or PBMs that manage prescription drug coverage under contract with:</p> <ul style="list-style-type: none"> <li>• A PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or</li> <li>• A qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act.</li> </ul> <p>Information to be reported to the Secretary [of HHS] includes:</p> <ul style="list-style-type: none"> <li>• The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type, that is paid by the health benefits plan or PBM under the contract</li> <li>• The aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.</li> <li>• The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed</li> </ul> <p>PBMs also required to report the above information to the plan with which the PBM is under contract.</p> <p>No implementation date specified – reporting shall be “at such times, and in such form and manner, as the Secretary [of HHS] shall specify.”</p>
5.	<b>Sec. 6101.</b> <b>Nursing Homes – Required Disclosure of Ownership and Additional Disclosable</b>	<p>Requires nursing facilities and skilled nursing facilities to disclose information related to:</p> <ul style="list-style-type: none"> <li>• Entities or individuals with ownership or control interests in the facility;</li> <li>• Members of the facility’s governing body;</li> <li>• Officers, directors, and other managing employees;</li> <li>• Individuals or entities that exercise operational, financial, or managerial control</li> </ul>



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	<b>Parties Information</b> § 1124(c) [42 U.S.C. § 1320a-3(c)]	<p>over a facility;</p> <ul style="list-style-type: none"> <li>• Individuals or entities that lease or sublease the real property to the facility; and</li> <li>• Individuals or entities that provide management or administrative services, management or clinical consulting, or accounting or financial services to the facility.</li> </ul> <p><b>Beginning immediately</b>, nursing facilities and skilled nursing facilities must keep and have available the above information until reporting regulations are implemented and the Secretary [of HHS] has made the reported information publicly available. The Secretary [of HHS] must issue final regulations on the reporting requirements <b>within two years</b>. Not later than 1 year after implementation of the final regulations, the Secretary [of HHS] must make the reported information publicly available.</p>
6.	<b>Sec. 6106.</b> <b>Nursing Homes – Ensuring Staffing Accountability</b> § 1128I(g) [42 U.S.C. § 1320a-7i(g)]	<p>Requires nursing facilities to electronically submit to the Secretary [of HHS] direct care staffing information based on payroll and other verifiable and auditable data in a uniform format. Such information shall</p> <ul style="list-style-type: none"> <li>• Specify the category of work a certified employee performs (such as whether the employee is an RN, LPN, etc.)</li> <li>• Include resident census data and information on resident case mix;</li> <li>• Include a regular reporting schedule; and</li> <li>• Include information on employee turnover and tenure and on the hours of care provided by each category of certified employees per resident per day.</li> </ul> <p>The Secretary [of HHS] shall implement reporting requirements <b>within 2 years</b>. Reported information will be included in the Nursing Home Compare Website established pursuant to Sec. 6103 (Sec. 1819(i) of the SSA).</p>