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U.S. SUNSHINE REGULATORY & STATUTORY PROVISIONS

CMS Regulations for U.S. Sunshine

CMS released its long-awaited final rule on February 1, 2013 (published in the *Federal Register* on February 8, 2013, at 78 Fed. Reg. 9458), over a year after the proposed rule was published on December 14, 2011.

	Citation (Final Rule)	Statute	Proposed Rule	Final Rule
1.	**Effective Date of Reporting Requirement** 42 C.F.R. §§ 403.904(a)(2), 403.908(a) 78 Fed. Reg. 9522, 9526 (preamble discussion at 9459–9460)	42 U.S.C. § 1320a–7h(a)(1)(A) Beginning March 31, 2013, and on the 90th day of each calendar year thereafter (i.e., March 31), any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient) shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information regarding any payments or transfers of value for the preceding calendar year.	Applicable manufacturers and applicable group purchasing organizations must begin to report the data to CMS by March 31, 2013.	Applicable manufacturers and applicable group purchasing organizations **must begin to collect the required data on August 1, 2013**, and **report the data to CMS by March 31, 2014**.
	Procedures for Electronic Submission of Reports			
2.	**Registration** 42 C.F.R. § 403.908(c) 78 Fed. Reg. 9526 (preamble discussion at 9496–9497, 9509)	N/A	Any applicable manufacturer or applicable group purchasing organization that is required to report under this provision must register with CMS before March 31, 2013. During registration, applicable manufacturers and applicable group purchasing organizations	The following are required to report under this subpart and must register with CMS **within 90 days of the end of the calendar year for which a report is required**: 1. Applicable manufacturers that have reportable payments or other transfers of value, ownership, or investment interests, or both 2. Applicable group purchasing organizations that have

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			must name a point of contact with appropriate contact information.	reportable ownership or investment interests During registration, applicable manufacturers and applicable group purchasing organizations must name **two points of contact** (a primary and backup) with appropriate contact information. Applicable manufacturers that have reportable payments or other transfers of value that are **submitted through a consolidated report by another applicable manufacturer will still be required to register with CMS**.
3.	**Consolidated Reporting** 42 C.F.R. § 403.908(d)(1) 78 Fed. Reg. 9526 (preamble discussion at 9464)	N/A	1. An applicable manufacturer under paragraph (1) of the definition of ''applicable manufacturer'' in § 403.902 and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of ''applicable manufacturer'' may, but are not required to, file a consolidated report of payments or other transfers of value to covered recipients, and physician ownership or investment interests. 2. 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. It is up to the discretion of the applicable manufacturer and entity (or entities) under common ownership whether or not specific payments need to be identified to the entity that provided the payment.	1. An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities. 2. An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests. 3. If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, **and the report must identify the specific entity that provided each payment.** 4. **A single payment or other transfer of value reported in a consolidated report must only be reported once by one**

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			3. If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported. • in the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and • only once by one applicable manufacturer.	**applicable manufacturer.** 5. **The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.**
4.	**Errors and Omissions** 42 C.F.R. § 403.908(h) 78 Fed. Reg. 9527 (preamble discussion at 9502–9503, 9510)	N/A	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 **immediately upon discovery** of the error or omission.	Finalized as proposed.
5.	**Attestation** 42 C.F.R. § 403.908(e) 78 Fed. Reg. 9526	N/A	Each report, including any subsequent corrections to a filed report, must include a certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance	Each report submission, including any subsequent changes or corrections to a filed report, must include an **attestation** at the time of submission to be considered. The attestation wording was finalized as proposed. The applicable manufacturer and applicable

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	(preamble discussion at 9497–9498, 9509)		Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.	group purchasing organizations may designate the officer to sign the attestation. Applicable manufacturers that have reportable payments or other transfers of value that are **submitted through a consolidated report by another applicable manufacturer** will be required to register with CMS but **will not be required to attest.** Therefore, applicable manufacturers considering submitting a consolidated report must fully consider the ramifications, particularly the applicable **manufacturer actually attesting on behalf of all entities included in the consolidated report.** Applicable manufacturers for which **covered drugs, devices, biologicals, or medical supplies represent less than 10 percent of total (gross) revenue** for the preceding year that have payments or other transfers of value to report **must attest** that less than 10 percent of total (gross) revenue in the immediately preceding year came from covered drugs, devices, biologicals, or medical supplies.
6.	**45-Day Review Period to Allow for Error Correction** 42 C.F.R. § 403.908 (g) 78 Fed. Reg. 9526–9527 (preamble discussion at 9501–9503, 9510)	42 U.S.C. §§ 1320a–7h(c)(1)(C)(ix), (D) (C) Public availability. Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning	Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45 days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public. 1. Notification: CMS will notify the applicable manufacturers, applicable group	Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors will have an opportunity to review and submit corrections to the information submitted for a period of 45 days before CMS makes the information available to the public. **If no data is disputed, the data will be finalized for publication after the close of the annual 45-day review and correction period**. 1. Notification: 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. 2. Data Verification: **Once registered**, an applicable

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	thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that, (ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public. (D) Clarification of time period for review and corrections. In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available	purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review. 2. Data Verification: 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. 3. Certification: 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. 4. Data Disputes: 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	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. 3. Certification: 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. 4. Data Disputes: **In the event that a transaction is disputed during the 45-day review and correction period, it will be flagged as disputed within the CMS system with electronic notification going to the applicable manufacturer or applicable group purchasing organization that submitted the data. Subsequent to the 45-day review and correction period, applicable manufacturers and applicable group purchasing organizations will be provided with a 15-day resolution period to resolve disputes. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day resolution period will be captured in the initial publication of the data for the reporting period. Corrections to the data can continue to be made after the 15-day resolution period, but the public data will not be updated until the following year. If the dispute is not resolved by the end of the 15-day resolution period, CMS will show the data as disputed but will include in the public reports the applicable manufacturer's or applicable group purchasing organization's original attested data. The parties may continue to work to reach resolution and update the data,**

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		to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).	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.	**but the public data will not be updated until the following year.**
	Reporting Payments or Other Transfers of Value			
7.	**General Rule** 42 C.F.R. § 403.904(a)(1) 78 Fed. Reg. 9522	42 U.S.C. § 1320a–7h(a)(1)(A) On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit reports to the Secretary [of HHS], in such electronic form as the Secretary shall require.	An applicable manufacturer must report the following to CMS on an annual basis: • Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer)	An applicable manufacturer must report the following to CMS on an annual basis: • **Direct and indirect** payments or other transfers of value provided by the applicable manufacturer to a covered recipient **during the preceding calendar year** • **Direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year**
8.	**Limitations**	N/A	N/A	1. **Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or**

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42 C.F.R. § 403.904(b) 78 Fed. Reg. 9522 (preamble discussion at 9462–9464)			**medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.** 2. **Entities that meet the definition of an applicable manufacturer because they are under common ownership with a manufacturer and provide assistance or support in the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support.** 3. **Applicable manufacturers that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.** 4. **Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply, except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity; do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or**

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				medical supply; and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.
9.	**Information That Must Be Reported Regarding Payments of Value** 42 C.F.R. § 403.904 (c) 78 Fed. Reg. 9522–9523 (preamble discussion at 9472–9482)	42 U.S.C. § 1320a–7h(a)(1)(A)(i)-(viii) An applicable manufacturer must report the following information with respect to the preceding calendar year of any payment or other transfer of value to a covered recipient: 1. The name of the covered recipient. 2. The business address of the covered recipient (and if the covered recipient is a physician, the specialty and National Provider Identifier of the covered recipient). 3. The amount of the payment or other transfer of value. 4. The dates on which the payment or other transfer of value was	An applicable manufacturer must report the following information with respect to the preceding calendar year of any payment or other transfer of value to a covered recipient: 1. The name of the covered recipient. 2. 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 payment or transfer of value must be disclosed in the name of that covered recipient. 3. The business address of the covered recipient, including street address, suite or office number (if applicable), city, state, and zip code. 4. If the covered recipient is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient. 5. The amount of the payment or other transfer of value. 6. The dates on which the payment or other transfer of value was provided to the covered recipient. 7. A description of the form of the payment or other transfer of value, indicated as: • Cash or cash equivalent	An applicable manufacturer must report the following information with respect to the preceding calendar year of any payment or other transfer of value to a covered recipient: 1. The name of the covered recipient. 2. 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 payment or transfer of value must be disclosed in the name of that covered recipient. 3. The business address of the covered recipient, including street address, suite or office number (if applicable), city, state, and zip code. 4. If the covered recipient is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient. 5. **If the covered recipient is a physician, state professional license number(s) for at least one state where the physician maintains a license and the state in which the license is held.** 6. The amount of the payment or other transfer of value. 7. The dates on which the payment or other transfer of value was provided to the covered recipient. 8. A description of the form of the payment or other transfer of value, indicated as: • Cash or cash equivalent • In-kind items or services

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	provided to the covered recipient. 5. A description of the form of the payment or other transfer of value, indicated as: • Cash or cash equivalent • In-kind items or services • Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment • Any other form of payment or other transfer of value 6. A description of the nature of the payment or other transfer of value, indicated as: • Consulting fees • Compensation for services other than consulting • Honoraria • Gift • Entertainment	• In-kind items or services • Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment. 8. A description of the nature of the payment or other transfer of value, indicated as: • Consulting fees • Compensation for services other than consulting • Honoraria • Gift • Entertainment • Food and beverage • Travel and lodging • Education • Research • Charitable contribution • Royalty or license • Current or prospective ownership or investment interest • Compensation for serving as faculty or as a speaker for a medical education program • Grant • Other 9. Indication of whether the payment or other transfer of value is subject to delayed publication as outlined in section 23. The absence of this indication in the report will	• Stock, a stock option, or other ownership interest • Dividend, profit, or other return on investment 9. A description of the nature of the payment or other transfer of value, indicated as: • Consulting fee • Compensation for services other than consulting, **including serving as faculty or as a speaker at an event other than a continuing education program** • Honoraria • Gift • Entertainment • Food and beverage • Travel and lodging **(including the specified destinations)** • Education • Research • Charitable contribution • Royalty or license • Current or prospective ownership or investment interest • **Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program** • **Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program** • Grant • **Space rental or facility fees (teaching hospitals only)** 10. Indication of whether the payment or other transfer of value is

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		• Food • Travel • Education • Research • Charitable contribution • Royalty or license • Current or prospective ownership or investment interest • Compensation for serving as faculty or as a speaker for a CME program • Grant • Any other nature of the payment or transfer of value	result in CMS posting all payments publicly in the first year of public reporting. 10. Indication of whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined within § 403.902) in the applicable manufacturer.	subject to delayed publication as outlined in section 23. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting. 11. Indication of whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined within § 403.902) in the applicable manufacturer.
10	**Special Rules for the Reporting of Information Related to Covered Drug, Device, Biological, or Medical Supply** 42 C.F.R. § 403.904 (c) (8) 78 Fed. Reg. 9523 (preamble discussion at 9474–9475)	42 U.S.C. § 1320a–7h(a)(1)(A)(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the applicable manufacturer also must provide the name of that	If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the applicable manufacturer must also provide the name under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, the applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological, or	1. If the payment or other transfer of value is related to a covered drug, device, biological, or medical supply, the applicable manufacturer must provide the name(s) of the related covered drugs, devices, biologicals, or medical supplies. **Applicable manufacturers may report up to five covered drugs, devices, biologicals, or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were**

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	covered drug, device, biological, or medical supply.	medical supply for each payment or other transfer of value.	**most closely related to the payment or other transfer of value.** • **Drugs and biologicals: Applicable manufacturers must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.** • **Devices and medical supplies: Applicable manufacturers must report at least one of the following:** – **The name under which the device or medical supply is or was marketed** – **The therapeutic area or product category for the device or medical supply** 2. **If the payment or other transfer of value is not related to a covered drug, device, biological, or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate "non-covered product."** 3. **If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate "none."** 4. **If the payment or other transfer of value is related to at least one covered drug, device, biological, or medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological, or medical supply (as required) and may indicate "non-covered products" in addition.**

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11	**Payments to Third Parties** 42 C.F.R. § 403.904 (c) (10) 78 Fed. Reg. 9527 (preamble discussion at 9488–9492, 9517)	42 U.S.C. § 1320a–7h(a)(1)(B) 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 disclose that payment or other transfer of value under the name of the covered recipient.	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 **disclose that payment or other transfer of value** 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.	1. If the payment or other transfer of value was provided to a third party at the request of, or designated on behalf of, a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient. 2. This payment must also include information related to the actual recipient receiving the value from the payment. If it is an entity, the name of the entity should be included. If the payment was made to an individual, the word "individual" should be included in the data for this payment. 3. **If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.**
12	**Special Rules for Research Payments** 42 C.F.R. § 403.904 (f) 78 Fed. Reg. 9524 (preamble discussion at 9482–9482)	42 U.S.C. § 1320a–7h(a)(1)(A)(viii) An applicable manufacturer also must report any other categories of information regarding the payment or other transfer of value that the Secretary [of HHS] determines appropriate.	Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research. 1. **Direct research:** 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). • Direct research payments must be reported individually under the name(s) and NPI(s) (if applicable) of the covered recipient. The total must	**All payments or other transfers of value made in connection with an activity that meets the definition of "research" and that are subject to a written agreement, a research protocol, or both must be reported under these special rules.** **Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value and must include the following information (in lieu of the information required by § 403.904(c)):**

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		indicate the amount the covered recipient received. • Direct research payments made to a teaching hospital must be reported under the name of the teaching hospital. 2. **Indirect research:** 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). • 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. • 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).	1. **Name of the research institution, individual, or entity receiving the payment or other transfer of value** 2. **If paid to a physician covered recipient,** • **the name of the covered recipient;** • **National Provider Identifier;** • **state professional license number(s) for at least one state where the physician maintains a license and the state in which the license is held;** • **specialty; and** • **the business address of the covered recipient** 3. **If paid to a teaching hospital covered recipient,** • **the name of the covered recipient; and** • **the business address of the teaching hospital** 4. **If paid to a non-covered recipient (such as a non-teaching hospital or clinic),** • **the name of the entity; and** • **the primary business address of the entity** 5. **Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both** 6. **Name of the research study** 7. **Name of any related covered drugs, devices, biologicals, or medical supplies and, for drugs and biologicals, the relevant National Drug Code, if any** 8. **Information about each physician covered recipient principal investigator, if applicable, including:** • **The name of the covered recipient** • **National Provider Identifier** • **State professional license number(s) for at least one**

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			3. **Physician Payments:** For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value. 4. **Requirements:** All payments or other transfers of value designated as research (direct or indirect) must be subject to a written agreement and research protocol.	**state where the physician maintains a license and the state in which the license is held** • **Specialty** • **The business address of the covered recipient** 9. **Contextual information for research (optional)** 10. **ClinicalTrials.gov identifier (optional)** 11. **Pre-clinical studies (before any human studies have begun) only require the following information:** • **Research entity name** • **Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both** • **Information about each physician covered recipient principal investigator, if applicable, including:** – **The name of the covered recipient** – **National Provider Identifier** – **State professional license number(s) for at least one state where the physician maintains a license and the state in which the license is held** – **Specialty** – **The business address of the covered recipient**
13	**Exclusions from Reporting—Payments and Transfers of Value under $10** 42 C.F.R. § 403.904	42 U.S.C. § 1320a–7h(e)(10)(B) An applicable manufacturer shall not be required to submit information with	1. For CY 2012, transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year. 2. For CY 2013 and subsequent calendar	1. **For CY 2013**, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year. 2. **For CY 2014** and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar

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	(i)(2) 78 Fed. Reg. 9525 (preamble discussion at 9485–9486)	respect to the following: • A transfer of anything the value of which is less than $10, unless the aggregate amount to a covered recipient 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	years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (f)(2)(i) of this section must be increased by the same percentage as the 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.	amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the 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. **CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.** 3. **Payments or other transfers of value less than $10 in CY 2013 (or less than the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance with paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.** 4. **When reporting payments or other transfers of value under the $10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.**
14	**Exclusions from Reporting** 42 C.F.R. § 403.904 (i)	42 U.S.C. § 1320a–7h(e)(10)(B) An applicable manufacturer shall not be required to	The following types of payments or other transfers of value are excluded from the reporting requirements specified in this section: 1. Transfers of value made indirectly to a	The following are excluded from the reporting requirements specified in this section: 1. Indirect payments or other transfers of value **(as defined in § 403.902)**, where the applicable manufacturer is unaware of the

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78 Fed. Reg. 9524–9525 (preamble discussion at 9484–9488)	submit information with respect to the following: • Product samples that are not intended to be sold and are intended for patient use • Educational materials that directly benefit patients or are intended for patient use • The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient • Items or services provided under a contractual warranty, 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 • A transfer of anything of value to a covered recipient when the covered recipient is a	covered recipient through a third party 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. 2. [See above row for payments under $10.] 3. Product samples that are not intended to be sold and are intended for patient use. 4. Educational materials that directly benefit patients or are intended for patient use. 5. The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient. 6. Items or services provided under a contractual warranty, 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. 7. A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient. 8. Discounts, including rebates. 9. In-kind items used for the provision of charity care. 10. A dividend or other profit distribution from, or ownership or investment interest in, a	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 **during the reporting year or by the end of the second quarter of the following reporting year.** 2. [See above row for payments under $10.] 3. Product samples, **including coupons and vouchers that can be used by a patient to obtain samples**, which are not intended to be sold and are intended for patient use. 4. Educational materials and items that directly benefit patients or are intended to be used by or with patients, **including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.** 5. The loan of a covered device **or a device under development or the provision of a limited quantity of medical supplies for a short-term trial period**, not to exceed a loan period of 90 days **or a quantity of 90 days of average daily use**, to permit evaluation of the **device or medical supply** by the covered recipient. 6. Items or services provided under a contractual warranty (including service or maintenance agreements), **whether or not the warranty period has expired**, 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. 7. A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, **research subject, or participant in data collection for research** and is not acting in the professional capacity of a covered recipient. 8. Discounts, including rebates.

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	patient and not acting in the professional capacity of a covered recipient • Discounts (including rebates) • In-kind items used for the provision of charity care • A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund • In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of healthcare to employees under the plan • In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical	publicly traded security or mutual fund. 11. In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of healthcare to employees under the plan. 12. In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional. 13. 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.	9. In-kind items used for the provision of charity care. 10. A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded **security** or mutual fund. 11. In the case of an applicable manufacturer who offers a self-insured plan or **directly reimburses for healthcare expenses**, payments for the provision of healthcare to employees **and their families**. 12. In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional. 13. 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 an administrative proceeding, **legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.** 14. **A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.**

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		professional • 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		
	Physician Ownership and Investment Interest			
15	**General Rule** 42 C.F.R. § 403.906 (a) 78 Fed. Reg. 9525	42 U.S.C. § 1320a–7h(a)(2) Beginning March 31, 2013, and on the 90th day of each calendar year thereafter (i.e., March 31), any applicable manufacturer or applicable group purchasing organization 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	Any applicable manufacturer or applicable group purchasing organization must report to CMS on an annual basis all ownership or investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding year.	Finalized as proposed.

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		security or mutual fund) held by a physician (or an immediate family member of such physician) in the applicable manufacturer or applicable group purchasing organization during the preceding year.		
16	**Information That Must Be Reported Regarding Ownership or Investment Interest** 42 C.F.R. § 403.906 (b) 78 Fed. Reg. 9525–9526 (preamble discussion at 9495–9496)	42 U.S.C. § 1320a–7h(a)(2) An applicable manufacturer or applicable group purchasing organization must report the following information with respect to the preceding calendar year of any ownership or investment interest held by a physician in the applicable manufacturer or applicable group purchasing organization: 1. The dollar amount invested by each physician. 2. The value and terms of each ownership or investment interest. 3. Any payment or other transfer of value provided to a physician holding such ownership	Reports on physician ownership or investment interests must include the following information: 1. The name of the physician and whether the ownership or investment interest is held by an immediate family member of the physician. 2. The business address of the physician, including street address, suite or office number (if applicable), city, state, and zip code. 3. The physician owner's specialty and National Provider Identifier (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. 4. The dollar amount invested by each physician or immediate family member. 5. The value and terms of each ownership or investment interest. 6. For any payment or other transfer of value provided to a physician holding such ownership or investment interest (or to an	Reports on physician ownership or investment interests must include the following information: 1. The name of the physician **(as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply),** and **an indication of** whether the ownership or investment interest was held by the physician or an immediate family member of the physician. 2. The **primary** business address of the physician, including street address, suite or office number (if applicable), city, state, and zip code. 3. The following information, **regardless of whether the ownership or investment interest is held by an immediate family member of the physician**: (i) **the physician owner's specialty**, (ii) National Provider Identifier (if applicable **and as listed in NPPES**), **and** (iii) **state professional license number(s) (for at least one state where the physician maintains a license) and the state(s) in which the license is held**. 4. The dollar amount invested by each physician or immediate family member. 5. The value and terms of each ownership or investment interest. 6. **Direct and indirect** payments or other transfers of value

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		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). 4. Any other information regarding the ownership or investment interest that the Secretary [of HHS] determines appropriate.	entity or individual at the request of or designated on behalf of the physician), report the information required under proposed 42 C.F.R. § 403.904 (b).	provided to a physician holding an ownership or investment interest (or to **a third party** at the request of or designated **by the applicable manufacturer or applicable group purchasing organization** on behalf of a physician **owner or investor**) must be reported **in accordance with the requirements for reporting payments or other transfers of value** in 42 C.F.R. § 403.904(c) through (i).
			Penalties	
17	**Failure to Report** 42 C.F.R. § 403.912 (a) 78 Fed. Reg. 9527 (preamble discussion at 9506–9507)	42 U.S.C. § 1320a–7h(b)(1) Failure to submit the information required above may result in a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil monetary penalties imposed	1. Any applicable manufacturer or applicable group purchasing organization that fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported. 2. The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization under this subpart	1. Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely. 2. The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization **(regardless of whether the applicable manufacturer was a part of a consolidated report)** with respect to failures to report in an annual submission of information will not exceed $150,000.

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		with respect to each annual submission shall not exceed $150,000.	with respect to each annual submission of information will not exceed $150,000.	
18	**Knowing Failure to Report** 42 C.F.R. § 403.912 (b) 78 Fed. Reg. 9527 (preamble discussion at 9506–9507)	42 U.S.C. § 1320a–7h(b)(2) A knowing failure to submit the information required above may result in a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil monetary penalties imposed for knowing failures to report with respect to each annual submission shall not exceed $1,000,000.	1. Any applicable manufacturer or applicable group purchasing organization that knowingly fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported. 2. The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization for knowing failures to report with respect to each annual submission shall not exceed $1,000,000.	1. Any applicable manufacturer or applicable group purchasing organization that knowingly fails to timely, accurately, or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely. 2. The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization **(regardless of whether the applicable manufacturer was a part of a consolidated report)** with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000.
19	**Total Annual Civil Monetary Penalties** 42 C.F.R. § 403.912 (c) 78 Fed. Reg. 9528 (preamble discussion at 9506–9507)	N/A	N/A	**The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are** 1. **aggregated separately; and** 2. **subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of $1,150,000.**
20	**Records Retention**	N/A	Applicable manufacturers and applicable group	Finalized as proposed.

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	42 C.F.R. § 403.912 (e)(1) [42 C.F.R. § 403.912 (d)(1) in proposed rule] 78 Fed. Reg. 9528 (preamble discussion at 9507–9508)		purchasing organizations must maintain all books, contracts, records, documents, and other evidence 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 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.	
21	**Audits** 42 C.F.R. § 403.912 (e)(2) 78 Fed. Reg. 9528 (preamble discussion at 9506–9507)	N/A	HHS, CMS, OIG, or their designees may audit, inspect, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to accurately and completely submit information in a timely manner. The record retention and audit requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.	Finalized as proposed.
	Public Availability of Information			
22	**Public Availability of Information** Discussed in preamble only at 78 Fed. Reg. 9503–9504	42 U.S.C. § 1320a–7h(c)(1)(C) No later than September 30, 2013, and on June 30 of	No later than September 30, 2013, and on June 30 of each calendar year thereafter, the information required to be submitted will be made available to the public through an Internet website that 1. is searchable and in a format that is clear	Finalized as proposed.

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	each calendar year thereafter, the information required to be submitted will be made available to the public through an Internet website that 1. is searchable and in a format that is clear and understandable; 2. contains information that is presented by • the name of the applicable manufacturer or applicable group purchasing organization, • the name of the covered recipient, • the business address of the covered recipient, • the specialty of the covered recipient, • the value of the payment or other transfer of value, • the date on which the payment or other transfer of value was made to	and understandable; 2. contains the following information for reporting received that is related to payments or other transfers of value to covered recipients: • the name of the applicable manufacturer or applicable group purchasing organization, • the name of the covered recipient, • the business street address of the covered recipient, • the specialty of the covered recipient (physician only), • the value of the payment or other transfer of value, • the date on which the payment or other transfer of value was made to the covered recipient, • the form of payment or other transfer of value, • the nature of the payment or other transfer of value, • the name of the covered drug, device, biological, or medical supply, and • the name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly 3. contains the following information for reporting received that is related to	

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	the covered recipient, • the form of payment or other transfer of value, • the nature of the payment or other transfer of value, and • the name of the covered drug, device, biological, or medical supply 3. can be easily aggregated and downloaded; 4. describes any enforcement action taken, including civil monetary penalties; 5. contains background information on industry-physician relationships; 6. contains any other information the Secretary [of HHS] determines would be helpful to the average consumer; 7. does not contain the National Provider Identifier of the covered	physician ownership and investment interest: • the name of the applicable manufacturer or applicable group purchasing organization, • the name of the physician owner, • the business street address of the physician owner, • the specialty of the physician owner, • the data to designate whether the ownership or investment interest is held by the physician or an immediate family member of the physician, • the dollar amount invested, • the value and terms of each ownership or investment interest, and • the data related to any payment or other transfer of value provided to the physician owner, including: – the amount of payment or other transfer of value – the date of payment or other transfer of value – the form of payment or other transfer of value – the nature of payment or other transfer of value – the name of the covered drug, device, biological, or medical supply	

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		recipient; and 8. provides the applicable manufacturer, applicable group purchasing organization, or covered recipient 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. 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.	4. can be easily aggregated and downloaded; 5. describes any enforcement action taken, including civil monetary penalties; 6. contains background information on industry-physician relationships; 7. does not contain the National Provider Identifier of the covered recipient; 8. contains publication of information on payments or other transfers of value that were granted delayed reporting; and 9. clearly states 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.	
23	**Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations**	42 U.S.C. § 1320a–7h(c)(1)(E) In the case of information submitted with respect to a payment or other transfer of value made pursuant to a product research or	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, payments may be delayed from publication on the website. Publication of a payment or other transfer of value is delayed when made in	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, payments may be delayed from publication on the website. 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

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42 C.F.R. § 403.910 78 Fed. Reg. 9527 (preamble discussion at 9504–9506)	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 clinical investigation 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 date of the approval or clearance of the covered drug, device, biological, or medical supply by the FDA; or • four calendar years after the date such payment or other transfer of value was made.	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 as 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. Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of • the date of the approval, licensure, or clearance of the covered drug, device, biological, or medical supply by the FDA; or • four calendar years after the date the payment or other transfer of value was made. 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. 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	supply as well as clinical investigations regarding a new drug, device, biological, or medical supply. The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient. The rest of the proposed rule related to delayed publication was finalized as proposed.

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			pending. 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. 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.	
	Preemption of State Laws			
24	**General Rule** 42 C.F.R. § 403.914 (a) 78 Fed. Reg. 9528 (preamble discussion at 9508–9509)	42 U.S.C. § 1320a–7h(d)(3) Effective January 1, 2012, these transparency provisions will preempt any law or regulation of a state that requires an applicable manufacturer to disclose or report the type of information reported hereunder for payments or other transfers of value provided by the applicable manufacturer to a covered recipient. **Exception:** These transparency provisions do not preempt any law or	In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, 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, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart. Note that a state law may require information other than that required under this provision, including items listed below as exclusions.	Finalized as proposed.

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		regulation of a state that requires the disclosure or reporting of information • that is not required to be disclosed by these transparency provisions; • that is expressly excluded under 1128G(e)(10)(B) [see Row 14 above on exclusions]; or • by any person or entity other than an applicable manufacturer or covered recipient. The state preemption provisions are not to be construed to limit the discovery or admissibility of information in a criminal, civil, or administrative proceeding.		
25	**Information Collected for Public Health Purposes** 42 C.F.R. § 403.914 (a) 78 Fed. Reg. 9528 (preamble discussion	42 U.S.C. § 1320a–7h(d)(3) These transparency provisions do not preempt any law or regulation of a state that requires the disclosure or reporting of	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 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.	Finalized as proposed.

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	at 9508–9509)	information to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.		
	Reports to Congress and the States			
26	**Annual Reports** Discussed only in the preamble at 78 Fed. Reg. 9508	42 U.S.C. § 1320a–7h(d)(1)-(2) No later than April 1, 2013 (and on April 1 each year thereafter), the Secretary [of HHS] must submit a report to Congress 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. No later than September 30, 2013 (and on June 30 each year thereafter), the Secretary must submit a report to the states that summarizes the information	CMS is required to submit a report to Congress annually by April 1, beginning in 2013. Since CMS will not receive data for the prior year until the 90th day of each year, the data submitted that year will not be ready for the April 1 report. Instead, CMS proposed to report to Congress the information submitted by applicable manufacturers and applicable group purchasing organizations during the preceding year. CMS is required to report to states annually by September 30, 2013, and June 30 for each year thereafter. Since these reports are due later in the year, CMS proposed that the reports would include data collected during the previous calendar year that was submitted in the current year.	In the preamble to the final rule, CMS finalized its proposals for submitting reports to Congress and the states, as described in the preamble to the proposed rule. **CMS will submit its first report to Congress on April 1, 2015, for data collected in the preceding calendar year.**

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	CITATION (FINAL RULE)	STATUTE	PROPOSED RULE	FINAL RULE
		submitted for the preceding year with respect to covered recipients in the state.		
		Definitions		
27	**Applicable Group Purchasing Organization** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9493)	42 U.S.C. § 1320a–7h(e)(1) A group purchasing organization that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States or in a territory, possession, or commonwealth of the United States.	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.	An entity that 1. **operates in 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, but not solely for use by the entity itself.
28	**Applicable Manufacturer** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9460–9464)	42 U.S.C. § 1320a–7h(e)(2) A manufacturer of a covered drug, device, biological, or medical supply, which is operating in the United States or in a territory, possession, or commonwealth of the United States.	An entity that is 1. engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States or in a territory, possession, or commonwealth of the United States; or 2. under common ownership 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	An entity **that is operating in the United States** and that falls within one of the following categories: 1. An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, **but not if such covered drug, device, biological, or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological, or medical supply**. 2. An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation,

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	CITATION (FINAL RULE)	STATUTE	PROPOSED RULE	FINAL RULE
			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.	propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.
29	**Assistance and Support** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9463–9464)	N/A	N/A	**Providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.**
30	**Charity Care** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9486–9487)	N/A	Services provided by a covered recipient specifically for a patient who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.	Services provided by a covered recipient specifically for a patient who is unable to pay for such services **or for whom payment would be a significant hardship**, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.
31	**Charitable Contribution** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9478)	N/A	Includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986.	Includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, **which is not provided in exchange for any goods, items, or services**.
32	**Clinical Investigation** 42 C.F.R. § 403.902 78 Fed. Reg. 9521	42 U.S.C. § 1320a–7h(e)(3) Any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or	Any experiment involving one (1) or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.	Any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, **biological, or medical supply** is administered, dispensed, or used.

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	CITATION (FINAL RULE)	STATUTE	PROPOSED RULE	FINAL RULE
		device is administered, dispensed, or used.		
33	**Common Ownership** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9463–9465)	N/A	Entities that are owned, in whole or in part, by the same individual, individuals, entity, or entities, directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.	Refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly **own five percent or more total ownership of two entities**. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.
34	**Covered Device** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9460–9464)	42 U.S.C. § 1320a–7h(e)(4) Any device for which payment is available under Title XVIII [42 U.S.C.S. §§ 1395 et seq.] or a state plan under Title XIX or XXI [42 U.S.C.S. §§ 1396 et seq. or §§ 1397aa et seq.] (or a waiver of such a plan).	Any device for which payment is available under Title XVIII [Medicare] or under a state plan under Title XIX [Medicaid] or XXI [SCHIP] (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, require premarket approval by or premarket notification to the FDA.	Any device for which payment is available under Title XVIII of the Act [Medicare] or under a state plan under Title XIX [Medicaid] or XXI [SCHIP] of the Act (or a waiver of such plan), either separately (such as through a fee schedule) **or as part of a bundled payment** (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that, by law, requires premarket approval by or premarket notification to the FDA.
35	**Covered Drug, Device, Biological, or Medical Supply** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9465–9466)	42 U.S.C. § 1320a–7h(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 [SCHIP] (or a waiver of such a plan).	Any drug, device, biological, or medical supply for which payment is available under Title XVIII [Medicare] or under a state plan under Title XIX [Medicaid] or XXI [SCHIP] (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	Any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act [Medicare] or under a state plan under Title XIX [Medicaid] or XXI [SCHIP] of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) **or as part of a bundled payment** (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) **and that is of the type that in the case of a** • drug or biological, by law, requires a prescription to be dispensed; or • device (including a medical supply that is a device), by law,

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			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, require premarket approval by or premarket notification to the FDA.	requires premarket approval by or premarket notification to the FDA.
36	**Covered Recipient** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9466–9468)	42 U.S.C. § 1320a–7h(e)(6) • A physician (not including a physician employed by an applicable manufacturer). • 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. • A teaching hospital.	1. A physician, but not including a physician employed by an applicable manufacturer; or 2. A teaching hospital, which is any institution that received a payment under § 1886(d)(5)(B) (IME), 1886(h) (GME), or 1886(s) (psychiatric hospitals IME) during the last calendar year for which such information is available.	1. Any physician, except for a physician who is a **bona fide** employee of the applicable manufacturer **that is reporting the payment**; or 2. A teaching hospital, which is any institution that received a payment under § 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.
37	**Employee** 42 C.F.R. § 403.902 78 Fed. Reg. 9521 (preamble discussion at 9467–9468)	N/A	An individual who is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for	Finalized as proposed.

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			purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).	
38	**Immediate Family Member** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9493)	N/A	1. Spouse 2. Natural or adoptive parent, child, or sibling 3. Stepparent, stepchild, stepbrother, or stepsister 4. Father-, mother-, daughter-, son-, brother-, or sister-in-law 5. Grandparent or grandchild 6. Spouse of a grandparent or grandchild	Finalized as proposed.
39	**Indirect Payments or Other Transfers of Value** 78 Fed. Reg. 9522 (preamble discussion at 948–9492)	N/A	N/A	**Payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).**
40	**Know, Knowing, or Knowingly** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9506)	N/A	A person, with respect to information, • has actual knowledge of the information; • acts in deliberate ignorance of the truth or falsity of the information; or • acts in reckless disregard of the truth or falsity of the information; and • requires no proof of a specific intent to defraud.	Finalized as proposed.
41	**Operating in the**	N/A	N/A	**An entity**

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	CITATION (FINAL RULE)	STATUTE	PROPOSED RULE	FINAL RULE
	United States 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9460–9461)			1. **has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or** 2. **otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally authorized agent.**
42	**Ownership or Investment Interest** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9494–9495)	N/A	1. Includes, but is not limited to • stock or stock option(s) (other than those received as compensation, until they are exercised); • partnership share(s); • limited liability company membership(s); and • loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue 2. May be direct or indirect and through debt, equity, or other means 3. Must not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act, nor any of the following: • 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	1. Includes, but is not limited to • stock or stock option(s) (other than those received as compensation, until they are exercised); • partnership share(s); • limited liability company membership(s); and • loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue 2. May be direct or indirect and through debt, equity, or other means 3. **Exceptions:** The following are not ownership or investment interests: • An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act • 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

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			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 • Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity • An unsecured loan subordinated to a credit facility	• Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity • An unsecured loan subordinated to a credit facility • **An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest**
43	**Payment or Other Transfer of Value** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9470)	42 U.S.C. § 1320a–7h(e)(10) A transfer of anything of value, but does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient. Reporting is not required for the exclusions provided in section 1128G(e)(10)(B).	N/A	**A transfer of anything of value.**

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	Citation (Final Rule)	Statute	Proposed Rule	Final Rule
44	**Physician** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9466–9467)	42 U.S.C. § 1320a–7h(e)(6) 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.	Has the same meaning given that term in section 1861(r) of the [Social Security] Act (includes a doctor of medicine or osteopathy, a doctor of podiatric medicine, a doctor of optometry, and a chiropractor).	Finalized as proposed.
45	**Related to a Covered Drug, Device, Biological, or Medical Supply** 42 C.F.R. § 403.902 78 Fed. Reg. 9522	N/A	N/A	**Means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.**
46	**Research** 42 C.F.R. § 403.902 78 Fed. Reg. 9522 (preamble discussion at 9482–9483)	N/A	N/A	**Includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.**
47	**Third Party** 42 C.F.R. § 403.902 78 Fed. Reg. 9522	N/A	N/A	**Another individual or entity, regardless of whether such individual or entity is operating in the United States.**