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CMS Publishes Final Sunshine Act Rule; Data Collection to Begin on August 1, 2013

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The long-awaited final rule (the Final Rule) implementing the Physician Payments Sunshine Act (Sunshine Act) has arrived at the Federal Register. It amends key definitions and adds new terms; retains broad reporting provisions but includes new limitations; exempts certain continuing medical education (CME) payments from disclosure; and includes additional reporting guidance.

The Sunshine Act requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (Manufacturers) to collect and report payments and other transfers of value to physicians and teaching hospitals. These requirements apply if a Manufacturer sells or distributes at least one covered drug, device, biologic, or medical supply (Covered Product). The Sunshine Act also requires Manufacturers and Group Purchasing Organizations (GPOs) to disclose ownership or investment interests held by physicians or their immediate family members.

Most importantly, the Final Rule requires Manufacturers and GPOs to begin collecting the required data on August 1, 2013 and to report the remaining calendar year 2013 data to the Centers for Medicare & Medicaid Services (CMS) by March 31, 2014.

The delay in publication of the Final Rule is well documented. CMS published the Proposed Rule in December 2011 and left many questions unanswered, as explained in our analysis of the Proposed Rule previously published in BNA's Health Care Fraud Report. It therefore comes as no surprise that CMS received more than 300 comments on the Proposed Rule. While awaiting publication of the Final Rule, Manufacturers and GPOs remained in the dark about many operational and implementation details and thus could not fully implement processes to comply with the Sunshine Act's data collection and reporting requirements.

The Final Rule provides Manufacturers and GPOs with long-awaited guidance in many areas and differs from the Proposed Rule in several key respects. Mintz Levin has prepared the following chart that summarizes the differences between the Proposed Rule and the Final Rule.

Physician Payments Sunshine Act – Comparison of Selected Provisions of Proposed Rule to Final Rule

Reference	Proposed Rule	Final Rule	Change?
Definitions (selected sections)			
§ 403.902 - Applicable Group Purchasing Organization	Applicable group purchasing organization means 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.	Applicable group purchasing organization means 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.	Yes Incorporates the newly defined term "operating in the United States."
§ 403.902 - Applicable Manufacturer	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 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.	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, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.	Yes Clarifies that a wholesaler or distributor that does not hold title to a Covered Product is not an "applicable manufacturer."

Reference	Proposed Rule	Final Rule	Change?
§ 403.902 – Charitable Contribution	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.	Yes
§ 403.902 – Charity Care	Services provided by a covered recipient 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 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.	Yes
§ 403.902 – Common Ownership	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 5 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.	Yes Creates a five percent threshold for common ownership, which is a term used in the definition of "applicable manufacturer."
§ 403.902 – Covered Device	Any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (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 Food and Drug Administration.	Any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI 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 Food and Drug Administration (FDA).	No substantive change

Reference	Proposed Rule	Final Rule	Change?
§ 403.902 – Covered drug, device, biological medical supply	Any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.	Any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI 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 which is of the type that in the case of a-- (1) Drug or biological, by law, requires a prescription to be dispensed; or (2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.	Yes Clarifies that payment is "available" through a fee schedule or formulary, or as part of a bundled payment. *A covered drug, device, biological, medical supply is referred to as a "Covered Product" throughout this document.*
§ 403.902 – Covered Recipient	(1) Any physician, except for a physician who is an employee (as defined in section 1877(h)(2) of the Act) of an applicable manufacturer; 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.	(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.	Yes Exempts only physicians who are "bona fide" employees of an applicable manufacturer.
§ 403.902 – Indirect payments or other transfers of value	N/A	Refer to 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	Yes Adds this newly defined term, which appears in the general rule on disclosure (§ 403.904).

Reference	Proposed Rule	Final Rule	Change?
		whole or in part, to a covered recipient(s) (or a physician owner or investor).	
§ 403.902 – Operating in the United States	N/A	Means that an entity-- (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.	Yes Adds new defined term.
§ 403.902 – Ownership or investment interest	(1) Includes, but is not limited to the following: (i) Stock, stock option(s) (other than those received as compensation, until they are exercised). (ii) Partnership share(s); (iii) Limited liability company membership(s). (iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a potion of that property or revenue. (2) May be direct or indirect and through debt, equity or other means. (3) Exceptions: (i) ownership or investment interests in a publicly traded security or mutual fund (ii) an interest arising from a retirement plan offered by the manufacturer or GPO to physician or physician's immediate family member through employment with that manufacturer or GPO (iii) stock options or convertible securities received as compensation, until converted to equity (iv) an unsecured loan subordinated to a	The Final Rule includes an additional exception: 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.	Yes Adds an exception for ownership or investment interests of which the applicable manufacturer or applicable group purchasing organization is unaware.

Reference	Proposed Rule	Final Rule	Change?
	credit facility		
§ 403.902 – Physician	Same meaning given that term in section 1861(r) of the Act.	Same meaning given that term in section 1861(r) of the Act.	No
§ 403.902 – Related to a covered drug, device, biological, or medical supply	N/A	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.	Yes Adds this newly defined term, which is used in the limitations on reporting (§ 403.904(b)).
§ 403.902 – Research	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.	Yes Adds this newly defined term, which is used in disclosure requirement (§ 403.904(f)).
§ 403.902 – Third Party	N/A	Another individual or entity, regardless of whether such individual or entity is operating in the United States.	Yes Adds new defined term.
Reports of Payments or Other Transfers of Value (selected sections)			
§ 403.904(a) – General rule	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) must be reported to CMS by the applicable manufacturer on an annual basis.	(1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and 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, must be reported by the applicable manufacturer to CMS on an annual basis. (2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.	Yes Incorporates newly defined terms "indirect payments or other transfers of value" and "third party." Establishes that data collection must begin on August 1, 2013.
§ 403.904(b) – Limitations [Final]	N/A	Certain limitations on reporting apply in the following circumstances: (1) Applicable manufacturers for whom	Yes

Reference	Proposed Rule	Final Rule	Change?
		total (gross) revenues from covered drugs, devices, biologicals, or 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) Applicable manufacturers under paragraph (2) of the definition in §403.902 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 to an applicable manufacturer under paragraph (1) of the definition. (3) Applicable manufacturers under either paragraph (1) or (2) of the definition in §403.902 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. . . . (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 medical supply, and are not involved in the sale, marketing, or	

Reference	Proposed Rule	Final Rule	Change?
		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.	
§ 403.904(b) – Required information to report [Proposed] **§ 403.904(c) – Required information to report [Final]**	A report must contain all of the following information for each payment or other transfer of value: (1) Name of the covered recipient. 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. (2) Business address of the covered recipient . . . (3) In the case of a covered recipient who is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient. (4) Amount of each payment or other transfer of value to the covered recipient. (5) Date of each payment or transfer of value to the covered recipient. (6) Form of each payment or other transfer of value, as described in paragraph (c) of this section. (7) Nature of each payment or other transfer of value, as described in paragraph (d) of this section.	A report must contain all of the following information for each payment or other transfer of value: (1) Name of the covered recipient. For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply). (2) Address of the covered recipient . . . (3) Identifiers for physician covered recipients. In the case of a covered recipient who is a physician, the following identifiers: (i) The specialty. (ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one. (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) Amount of payment or other transfer of value. . . . (5) Date of payment or transfer of value.	Yes Changes the requirements for the report in several ways.

Reference	Proposed Rule	Final Rule	Change?
	(8) If a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value. (9) The applicable manufacturer must indicate that a payment or other transfer of value is subject to delayed publication, if the payment or other transfer of value is made under any of the following arrangements: (i) In accordance with a product research or development agreement for services furnished in connection with 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. (ii) In connection with a clinical investigation regarding a new drug, device, biological, or medical supply. (10) If the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other individual or entity that receives the payment or other transfer of value. (11) Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest	The date of each payment or other transfer of value. *** (6) Form of payment or transfer of value. The form of each payment or other transfer of value, as described in paragraph (d) of this section. (7) Nature of payment or transfer of value. The nature of each payment or other transfer of value, as described in paragraph (e) of this section. (8) Related covered drug, device, biological or medical supply. The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. *** (9) Eligibility for delayed publication. Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in §403.910. (10) Payments to third parties. . . . (11) Payments or transfers of value to physician owners or investors. Must indicate whether the payment or other transfer of value was provided to a	

Reference	Proposed Rule	Final Rule	Change?
	(as defined § 403.902) in the applicable manufacturer.	physician or the immediate family of the physician who holds an ownership or investment interest (as defined §403.902) in the applicable manufacturer. (12) Additional information or context for payment or transfer of value. May provide a statement with additional context for the payment or other transfer of value.	
§ 403.904(c) – Reporting the form of payment or other transfer of value [Proposed] **§ 403.904(d) – Reporting the form of payment or other transfer of value [Final]**	Manufacturers must indicate the form of payment or transfer of value using one of the following descriptions: (1) Cash or cash equivalent. (2) In-kind items or services. (3) Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.	Manufacturers must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms: (1) Cash or cash equivalent. (2) In-kind items or services. (3) Stock, stock option, or any other ownership interest. (4) Dividend, profit or other return on investment.	Yes Requires reporting of form of separable parts of payments or transfers of value, with dividends and stocks qualifying as separate "forms."
§ 403.904(d)(2) – Reporting the nature of the payment or other transfer of value/Rules for categorizing natures of payment [Proposed] **§ 403.904(d)(2) – Reporting the nature of the payment or other transfer of**	Manufacturers must indicate the nature of payment or transfer of value using one of the following mutually exclusive descriptions: (1) Consulting Fee (2) Compensation for Services Other than Consulting (3) Honoraria (4) Gift (5) Entertainment (6) Food and Beverage (7) Travel and Lodging (8) Education (9) Research (10) Charitable Contribution (11) Royalty or License (12) Current or Prospective Ownership or	Manufacturers must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the following mutually exclusive descriptions: (i) Consulting fee. (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program. (iii) Honoraria. (iv) Gift. (v) Entertainment. (vi) Food and beverage. (vii) Travel and lodging (including the specified destinations).	Yes Mandates reporting on the nature of separable parts of payments or transfers of value. Clarifying that compensation for services includes serving as faculty or a speaker at non-CME events. Creates two new, separate categories specifically addressing speaking or serving as faculty at unaccredited/non-certified CME programs and accredited/certified CME programs.

Reference	Proposed Rule	Final Rule	Change?
value/Rules for categorizing natures of payment [Final]	Investment Interests (13) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program (14) Grant (15) Other	(viii) Education. (ix) Research. (x) Charitable contribution. (xi) Royalty or license. (xii) Current or prospective ownership or investment interest. (xiii) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program. (xiv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program. (xv) Grant. (xvi) Space rental or facility fees (teaching hospital only).	Adds a category for space rental or facility fees (teaching hospitals only). Deletes the category "Other."
§ 403.904(e) – Special rules for research payments [Proposed] **§ 403.904(f) – Special rules for research payments [Final]**	(1) Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research. (i) Direct Research. A payment or other transfer of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity). (ii) Indirect Research. A payment or other transfer 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). (2) Payments and other transfers of value designated as research must be subject to a written agreement and research protocol.	All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules. (1) 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)): (i) Name of the research institution, individual or entity receiving the payment or other transfer of value. *** (ii) Total amount of the research payment, including all research-related costs for	Yes Expands scope of reporting obligation.

Reference	Proposed Rule	Final Rule	Change?
	Indirect research must be reported individually under the name(s) and NPI(s) of the principle investigator; total amounts paid to institutions must be reported for each principle investigator. Direct research must be reported individually under the names(s) and NPI(s) of the covered recipient. (3) If payment is made to a teaching hospital, the payment to the teaching hospital must be reported as follows: (i) Direct research under the name of the teaching hospital. (ii) Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s). (4) For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.	activities outlined in a written agreement, research protocol, or both. (iii) Name of the research study. (iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any. (v) Information about each physician covered recipient principal investigator (if applicable) . . . . (vi) Contextual information for research (optional). (vii) ClinicalTrials.gov identifier (optional). (2) For pre-clinical studies (before any human studies have begun), only report the following information: (i) Research entity name . . . (ii) Total amount of payment . . . (iii) Principal investigator(s)	
§ 403.904(g) – Special rules for payments or other transfers of value related to continuing education programs	N/A	(1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met: (i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following: (A) The Accreditation Council for Continuing Medical Education. (B) The American Academy of Family Physicians. (C) The American Dental Association's Continuing Education Recognition	Yes Creates an exclusion from reporting for compensation related to certain CME programs.

Reference	Proposed Rule	Final Rule	Change?
		Program. (D) The American Medical Association. (E) The American Osteopathic Association. (ii) The applicable manufacturer does not pay the covered recipient speaker directly. (iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program. (2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section. *** Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category "Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program."	
§ 403.904(h) – Special rules for reporting food and beverage	N/A	(1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered	Yes

Reference	Proposed Rule	Final Rule	Change?
		recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage. (2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.	
Exclusions from Reporting (selected sections)			
§ 403.904(f)(1) - Aware of identity [Proposed] **§ 403.904(i)(1) [Final]**	Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient; knowledge element is defined in § 403.902.	Indirect payments or other transfers of value (as defined in §403.902), where 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 during the reporting year or by the end of the second quarter of the following reporting year.	Yes Requires reporting of a payment if the applicable manufacturer becomes aware of the identity of covered recipient prior to the second quarter of the year following the reporting year.
§ 403.904(f)(2)(i) – De minimus [Proposed] **§ 403.904(i)(2)(i) [Final]**	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.	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.	No substantive change

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(f)(2)(ii) - De minimus [Proposed] **§ 403.904(i)(2)(ii) [Final]**	For CY 2013 and subsequent calendar years, . . . the dollar amounts specified in paragraph (f)(2)(i) of this paragraph 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.	For CY 2014 and subsequent calendar years . . . the dollar 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.	Yes States that CMS will publish the value of the de minimus amount 90 days before the beginning of the reporting year.
§ 403.904(i)(2)(iii) - De minimus [Final]	N/A	Payments or other transfers of value of less than $10 in CY 2013 . . . 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 . . . even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.	Yes
§ 403.904(f)(2)(iv) - $100 in the aggregate [Proposed] **§ 403.904(i)(2)(iv) [Final]**	N/A	When reporting payments or other transfers of value under the $10 threshold for CY 2013 . . . 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.	Yes
§ 403.904(f)(3) - Samples [Proposed] **§ 403.904(i)(3) [Final]**	Product samples that are not intended to be sold and are intended for patient use.	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.	Yes Clarified that exclusion for product samples includes coupons or vouchers to obtain samples.

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(f)(4) – Educational material [Proposed] **§ 403.904(i)(4) [Final]**	Educational materials that directly benefit patients or are intended for patient use.	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.	Yes Expands the exclusion to include an applicable manufacturer's services to educate patients.
§ 403.904(f)(5) – Loan of a device [Proposed] **§ 403.904(i)(5) [Final]**	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.	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.	Yes Expands the exclusion to cover devices under development and medical supplies, in addition to covered devices.
§ 403.904(f)(6) - Warranty [Proposed] **§ 403.904(i)(6) [Final]**	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.	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.	Yes Clarifies that the exclusion applies whether or not the warranty period has expired.
§ 403.904(f)(7) – Covered recipient as patient [Proposed] **§ 403.904(i)(7) [Final]**	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.	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 not acting in the professional capacity of a covered recipient.	Yes Expands the exclusion to include a covered recipient not acting in such professional capacity if he or she is a "research subject or participant in data collection for research."

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(f)(8) – Discounts [Proposed] **§ 403.904(i)(8) [Final]**	Discounts, including rebates.	Discounts, including rebates.	No
§ 403.904(f)(9) – Charity care [Proposed] **§ 403.904(i)(9) [Final]**	In-kind items used for the provision of charity care.	In-kind items used for the provision of charity care.	No
§ 403.904(f)(10) – Dividend or profit [Proposed] **§ 403.904(i)(10) [Final]**	A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.	A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.	No
§ 403.904(f)(11) – Self-insurance plan [Proposed] **§ 403.904(i)(11) [Final]**	In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.	In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.	Yes Applies the exclusion to an applicable manufacturer who directly reimburses healthcare expenses.

Reference	Proposed Rule	Final Rule	Change?
§ 403.904(f)(12) – Non-medical services [Proposed] **§ 403.904(i)(12) [Final]**	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.	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.	No
§ 403.904(f)(13) – Legal proceedings [Proposed] **§ 403.904(i)(13) [Final]**	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.	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.	Yes Expands the exclusion to include additional legal action.
§ 403.904(i)(14) – Personal relationship	N/A	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.	Yes
Reports of Physician Ownership and Investment Interests (selected sections)			
§ 403.906(a) – General rule	Manufacturers and GPOs must make an annual report to CMS of all ownership and investment interests of physicians or immediate family members of physicians during the preceding year.	(1) Manufacturers and GPOs must make an annual report to CMS of all ownership and investment interests of physicians or immediate family members of physicians during the preceding year. (2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.	Yes Clarifies that reporting for CY 2013 begins on August 1, 2013.
§ 403.906(b) – Identifying information	Reports must include: (1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician. (2) Business address of physician, including street address, suite or office number (if	Reports must include (regardless of whether the ownership or investment interest is held by an immediate family member of the physician): (1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the	Yes Clarifies reporting requirements and confirms that reports must be made regardless of whether the interest is held by an immediate family member of the physician.

Reference	Proposed Rule	Final Rule	Change?
	applicable), city, State, and ZIP code. (3) Specialty and NPI (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician's specialty and National Provider Identifier must be reported. (4) Dollar amount invested by each physician or immediate family member of the physician. (5) Value and terms of each ownership or investment interest. (6) If a payment or other transfer of value is provided to a physician owner or investor, the manufacturer or GPO must report the information requested in § 403.904(b) subject to the same reporting exclusions described in § 403.904(f).	physician. (2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code. (3) Specialty and NPI (if applicable), state professional license number(s) and state (for at least one state where the physician maintains a license). (4) Dollar amount invested by each physician or immediate family member of the physician. (5) Value and terms of each ownership or investment interest. (6) If a payment or other transfer of value is provided to a physician owner or investor or to a third party at the request of or designated by the applicable manufacturer or GPO on behalf of a physician owner or investor, the manufacturer or GPO must report the information as required in §403.904(c) through (i).	
Procedures for Electronic Submission of Reports (selected sections)			
§ 403.908(b) – General rules	Applicable manufacturers without reportable payments or transfers of value or reportable ownership or investment interests are not required to file a report.	Applicable manufacturers without reportable payments or transfers of value or reportable ownership or investment interests are not required to file a report.	No
§ 403.908(c) – Registration	Any applicable manufacturer or applicable group purchasing organization that is required to report under this subpart must register with CMS before March 31, 2013.	(1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, 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. (2) Applicable group purchasing	Yes Requires registration only if reporting is required.

Reference	Proposed Rule	Final Rule	Change?
		organizations that have reportable ownership or investment interests 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. ***	
§ 403.908(d)(1) – Consolidated reports	(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.	Applicable manufacturers may submit consolidated reports in certain cases, but are not required to do so.	Yes Provides flexibility for consolidated reports.
§ 403.908(f) – Assumptions document	N/A	Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.	Yes
§ 403.908(g)(1) - 45 day review period for review and correction; General Rule	CMS must allow a 45 day period for applicable manufacturers and GPOs, covered recipients, and physician owners or investors to review and correct information prior to the information being made public.	CMS must allow a 45 day period for applicable manufacturers and GPOs, covered recipients, and physician owners or investors to review and correct information prior to the information being made public.	No

Reference	Proposed Rule	Final Rule	Change?
§ 403.908(g)(2) – Notification	CMS notifies the applicable manufacturers and GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.	CMS notifies the applicable manufacturers and GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.	No
§ 403.908(g)(3)(i) – Process	An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view information reported specific to the party.	An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure website to view only the information reported specifically about itself.	Yes Clarifies that the applicable manufacturer views only its own information.
§ 403.908(g)(3)(ii) [Proposed] **§ 403.908(g)(3)(iii) [Final]**	If an applicable party agrees with the information reported, it may electronically certify that the information reported is accurate.	If an applicable party agrees with the information reported, it may electronically certify that the information reported is accurate.	No
§ 403.908(g)(3)(iv)	N/A	If a covered recipient or physician owner or investor disagrees with the information reported, it can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable GPO to be resolved between the parties.	Yes
§ 403.908(e) – Errors or omissions [Proposed] **§ 403.908(h) – Errors or omissions [Final]**	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.	(1) 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 confirmation of the error or omission. (2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the website at least once annually with corrected information.	Yes

Reference	Proposed Rule	Final Rule	Change?
Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations (selected sections)			
§ 403.910(a) – General rule	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 Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances: (1) 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. (2) Clinical investigations regarding a new drug, device, biological, or medical supply.	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 Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances: (1) 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. (2) Clinical investigations regarding a new drug, device, biological, or medical supply.	No
§ 403.910(c) – Date of publication	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 following: (1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration. (2) Four calendar years after the date the payment or other transfer of value was made.	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 following: (1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration. (2) Four calendar years after the date the payment or other transfer of value was made.	No

Reference	Proposed Rule	Final Rule	Change?
§ 403.910(d)(1) – Indication of eligibility	Manufacturers must indicate on the report whether a payment or other transfer of value is eligible for a delay in publication.	Manufacturers must indicate on the report whether a payment or other transfer of value is eligible for a delay in publication.	No
§ 403.910(d) – Notification of delayed publication [Proposed] **§ 403.910(d)(3) [Final]**	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.	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.	No
§ 403.910(d)(3) – Notification of FDA approval [Proposed] **§ 403.910(d)(4) [Final]**	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.	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.	No
§ 403.910(d)(4) – Publication [Proposed] **§ 403.910(d)(5) [Final]**	If, after 4 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.	If, after 4 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.	No
§ 403.910(e) – Confidentiality	N/A	Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under applicable Federal, State, or local law, until on or after the date on which the information made available to the public.	Yes

Reference	Proposed Rule	Final Rule	Change?
Penalties for Failure to Report (selected sections)			
§ 403.912(a) – Failure to report	Civil monetary penalty of not less than $1,000 and not more than $10,000 for each failure by a manufacturer to report a payment or other transfer of value or failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for each annual submission capped at $150,000.	Civil monetary penalty of not less than $1,000 and not more than $10,000 for each failure by a manufacturer to report a payment or other transfer of value or failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for each annual submission capped at $150,000.	No
§ 403.912(b) – Knowing failure to report	Civil monetary penalty of not less than $10,000 and not more than $100,000 each knowing failure by a manufacturer to report a payment or other transfer of value or knowing failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for knowing failures for each annual submission capped at $1,000,000.	Civil monetary penalty of not less than $10,000 and not more than $100,000 each knowing failure by a manufacturer to report a payment or other transfer of value or knowing failure of manufacturer or GPO to report physician ownership or investment interest; total penalties for knowing failures for each annual submission capped at $1,000,000.	No
§ 403.912(c) – Total annual civil monetary penalties [Final]	N/A	The penalties imposed for failures to report and knowing failures to report will be aggregated separately and are subject to separate aggregate totals, with a maximum combined annual total of $1,150,000.	Yes

Reference	Proposed Rule	Final Rule	Change?
§ 403.912(c) – Determinations regarding the amount of civil monetary penalties [Proposed] **§ 403.912(d) – Determinations regarding the amount of civil monetary penalties [Final]**	Factors to be considered in setting amount of CMP include: (1) The length of time the entity failed to report. (2) Amount of the unreported payment. (3) Level of culpability. (4) Nature and amount of information reported in error. (5) Degree of diligence exercised in correcting information reported in error.	Factors to be considered in setting amount of CMP include: (1) The length of time the entity failed to report. (2) Amount of the unreported payment. (3) Level of culpability. (4) Nature and amount of information reported in error. (5) Degree of diligence exercised in correcting information reported in error.	No
§ 403.912(d)(1) – Record retention and audits / Maintenance of Records [Proposed] **§ 403.912(e)(1) – Record retention and audits /Maintenance of Records[Final]**	Applicable manufacturers and GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable an audit of the applicable entity's compliance for at least 5 years after the publication of the information on CMS' Web site. HHS, CMS, or OIG may audit the records.	Applicable manufacturers and GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable an audit of the applicable entity's compliance for at least 5 years after the publication of the information on CMS' Web site. HHS, CMS, or OIG may audit the records.	No

Reference	Proposed Rule	Final Rule	Change?
§ 403.912(d)(2) – Record retention and audits / Audit [Proposed] **§ 403.912(e)(2) – Record retention and audits /Audit [Final]**	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 in accordance with the rules established under this subpart.	HHS, CMS, OIG or their designees may audit, inspect, investigate 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 timely, accurately or completely submit information in accordance with the rules established under this subpart.	No substantive change.
§ 403.912(g) – Notice, hearings, appeals, and collection	N/A	Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.	Yes
Preemption of State Laws			
§ 403.914(a) – General rule	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.	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.	No