HHS | Hart Health Strategies

Transparency Reports and Reporting of Physician Ownership/ Investment Interests

A Summary of the Final Rule

On February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) released the final rule regarding Transparency Reports and Reporting of Physician Ownership or Investment Interests (also known as the "Sunshine Rule"). This final rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals ("covered recipients"). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish applicable manufacturers' and applicable GPOs' submitted payment and ownership information on a public website. This final rule implements the requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act (the Act), at an estimated cost of approximately $269 million in the first year and $180 million annually thereafter.

The following summarizes key sections of the final rule that may be of interest to physicians, whereas sections deemed less applicable have been omitted. Page numbers referenced correlate to the display version of the rule found on the Federal Register website.

Executive Summary and Background (pg. 2)

Summary of the Major Provisions (pg. 3)

Transparency Reports (pg. 3). The final rule:

- Finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients;
- Provides definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply;
- Clarifies how applicable manufacturers should report and characterize payments or other transfers of value, including rules for research payments, and indirect payments provided to a covered recipient through a third party;
- Finalizes which payments or other transfers of value are excluded from the reporting requirements;
- Finalizes the requirements for applicable manufacturers and applicable GPOs to annually report information about certain ownership or investment interests held by physicians and the immediate family members of physicians in such entities, as well as payments and other transfers of value to such physicians;
- Details what constitutes an ownership or investment interest for purposes of the reporting requirements, and defines for whom they must be reported; and,
- Clarifies the content for the ownership or investment interest report.

Report Submission, Correction, and Publication (pg. 3). The final rule:

- Finalizes the processes and requirements for applicable manufacturers and applicable GPOs to submit their reports to CMS, including the specific data elements required to be included in the reports and the report format;
- Details the processes for the review, dispute, and correction period when applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors are provided the opportunity to review, dispute, and propose corrections to reported payments or other transfers of value, or ownership or investment interests, attributed to them;
- Clarifies the information to be included on the publicly available website, as well as the usability of the public

website; and,
- Provides details on the processes for reporting and publishing payments or other transfers of value, which are eligible for delayed publication.

Penalties (pg. 4). The rule includes details regarding the statutorily authorized civil monetary penalties for failure to report payments or other transfers of value, or physician ownership or investment interests, including clarification of the instances when the penalties will be imposed.

Annual Report (pg. 4). The rule finalizes the details of the annual reports to Congress and the States.

Relation to State Laws (pg. 4). The rule clarifies the statutory requirements for the pre-emption of State laws.

Summary of Costs and Benefits (pg. 4)

In light of public comments received, CMS anticipated that much of the total estimated burden of the final rule would fall on applicable manufacturers and applicable GPOs. CMS estimated that the total cost of these provisions would be approximately $269 million in the first year and $180 million annually thereafter. CMS has no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. According to CMS, increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships which can sometimes lead to increased health care costs. Additionally, increased transparency about the owners and investors in GPOs will allow purchasers to make better informed decisions and identify potential conflicts of interest with ordering physicians.

Provisions of the Final Rule and Analysis of and Responses to Public Comments (pg. 7)

CMS received approximately 373 timely public comments, most of which addressed provisions included in the proposed rule. Comments outside the scope of the proposed rule are addressed in the final rule. Throughout the final rule, time periods referenced in days are considered to be calendar days, unless otherwise noted.

Timing (pg. 8). The final rule was not published in time for applicable manufacturers and applicable GPOs to begin collecting the information required in section 1128G of the Acton January 1, 2012, as provided in the statute. Among other things, commenters were concerned with the length of time applicable manufacturers and applicable GPOs would be given following publication of the final rule before the data collection requirements begin. After consideration of the public comments received and given the timing of the final rule, CMS finalized that data collection will begin on August 1, 2013 and must be reported to the agency by March 31, 2014. There will be no retroactive reporting.

Transparency Reports (pg. 11). CMS finalized its decisions to collect separate reports from:

1. Applicable manufacturers on payments or other transfers of value to covered recipients, and
2. Applicable manufacturers and applicable GPOs concerning ownership and investment interests of physicians, and their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors.

Reports on Payments and Other Transfers of Value Under Section 1128G(a)(1) of the Act (pg. 12).

Applicable Manufacturer (pg. 12). CMS proposed to define applicable manufacturer as

- 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
- Under common ownership with an entity in the first paragraph of this definition, and 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 or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

In light of public comments, CMS revised the definition of applicable manufacturer by retaining the statutory phrase operating in the U.S., which the agency defined as having a physical location within the United States, or otherwise conducting activities within the U.S. or in a territory, possession, or commonwealth of the U.S. Therefore, entities based outside the U.S. that do have operations in the U.S. are subject to the reporting requirements. Entities that have operations in the U.S. are not permitted to circumvent the reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the U.S.

Entities that only manufacture raw materials or components, which are not themselves covered products, will not be required to report unless they are under common ownership with an applicable manufacturer and assist such manufacturer with the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply.

Entities such as hospitals, hospital-based pharmacies and laboratories that manufacture a covered product solely for use by or within the entity itself or by an entity's own patients are excluded.

The definition of applicable manufacturer does not include pharmacies, including compounding pharmacies, that meet all of the following conditions: (1) maintain establishments that comply with applicable local laws regulating the practice of pharmacy; (2) regularly engage in dispensing prescription drugs or devices upon prescriptions from licensed practitioners in the course of their professional practice; and (3) do not produce, prepare, propagate, compound, or convert drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail to individual patients.

Distributors and wholesalers (which include re-packagers, re-labelers, and kit assemblers) that hold the title to a covered drug, device, biological or medical supply meet the definition of an applicable manufacturer for the purpose of this rule. Wholesalers or distributors that do not hold the title of a covered product will not be subject to the reporting requirements, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological, or medical supply. An applicable manufacturer that has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor or wholesaler to covered recipients, since these will be reported by the distributor or wholesaler. However, in the event that the applicable manufacturer makes payments or other transfers of value related to the product independently from the distributor or wholesaler (or through the distributor or wholesaler as a third party), then the applicable manufacturer would have to report these payments or other transfers of value.

Limitations to the Definition of Applicable Manufacturer (pg. 17). Commenters requested clarification on the reporting requirements for situations when the license-holder is not the manufacturer or the manufacturing process is contracted out. They recommended that an entity that manufactures a covered product under contract, but does not market or distribute the product and is not an applicable manufacturer otherwise, does not meet the definition and does not need to report.

For the contracted entity conducting the actual manufacturing, CMS believes that these entities fit into the definition of applicable manufacturer since they are actually manufacturing a covered product and clearly are "engaged in the production, preparation, propagation, compounding, or conversion" of a product. Therefore, CMS finalized that entities that manufacture any covered product are applicable manufacturers, even if the manufacturer does not hold the FDA approval, licensure, or clearance.

In addition, if an applicable manufacturer does not manufacture a covered drug, device, biological, or medical supply except pursuant to a written agreement to manufacture the covered product for another entity, does not hold the FDA approval, licensure or clearance for the product, and is not involved in the sale, marketing or distribution of the product,

then the manufacturer is only required to report payments or other transfers of value related to the covered product.

If an applicable manufacturer has this business arrangement for some products and also manufactures at least one covered product that does not meet these criteria, then the applicable manufacturer must report all payments or other transfers of value subject to the reporting requirements.

No payment or other transfer of value should be reported more than one time by a single entity.

CMS clarified the agency's position in §403.904(b)(1) to allow applicable manufacturers with less than 10 percent of total (gross) revenues from covered drugs, devices, biologicals or medical supplies during the previous fiscal year to report only payments or other transfers of value specifically related to covered drugs, devices, biologicals or medical supplies. The 10 percent threshold should be calculated based on the company's total (gross) annual revenue. Applicable manufacturers with less than 10 percent of total (gross) revenue from covered products during the previous year that have payments or other transfers of value to report must register with CMS and must attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data. CMS selected a 10 percent threshold based on the public comments that it received suggesting a range from 5 to 10 percent; CMS chose the higher percentage in order to reduce the reporting burden on a greater number of entities.

When an applicable manufacturer who did not previously have any other covered products becomes subject to the data collection and reporting requirements, CMS will allow an applicable manufacturer a grace period of 180 days to begin complying with the rule.

Common Ownership (pg. 22). CMS finalized the 5 percent ownership threshold for common ownership. CMS also defined "assistance and support" as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. An entity under common ownership that only aids the applicable manufacturer with human resources administrative functions would not be deemed necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of covered products, since human resources functions are not directly involved with any of these manufacturing processes. Entities under common ownership that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product should not have to report all payments or other transfers of value that the entities provide to covered recipients, and §403.904(b)(2) of this final rule states that they only need to report payments or other transfers of value that are related to covered products.

With regard to applicable manufacturers that have separate operating divisions that only produce non-covered products and do not meet the definition of providing "assistance and support," CMS believes that such divisions only need to report payments or other transfers of value that are related to a covered drug, device, biological or medical supply as stated in §403.904(b)(3). CMS believes that the vast majority of payments or other transfers of value will not be related to covered products. To prevent applicable manufacturers from diverting payments through these divisions in order to avoid the reporting requirements, CMS finalized that all payments or other transfers of value made by these divisions that are related to covered products must be reported. This includes payments or other transfers of value made directly by the operating division, as well as payments or other transfers of value made indirectly by the applicable manufacturer through the separate operating division, as the latter payments are required to be reported as indirect payments or other transfers of value.

CMS clarified in §403.908(d) that applicable manufacturers under paragraph 1 (see above) of the definition that are under common ownership with separate entities that are also applicable manufacturers under paragraph 1 may, but are not required to, file a consolidated report for all of the entities. Applicable manufacturers under paragraph 1 of the definition of applicable manufacturer and an entity (or entities) under common ownership with such manufacturer under paragraph 2 (see above) of the definition also may, but are not required to, file a consolidated report. If multiple applicable manufacturers (under paragraph 1 and/or 2 of the definition) submit a consolidated report, the agency requiring the report must provide information specified by CMS to identify each applicable manufacturer and entity (or

entities) under common ownership that the report covers. Applicable manufacturers submitting consolidated reports must specify on an individual payment line which entity made which discrete payment or other transfer of value. All covered recipients included in the report must be individually, uniquely and consistently identified. That is, the same individual, if present on multiple payment lines within the same report, must have the same unique identifiers for all occurrences within the report.

Covered Drug, Device, Biological, or Medical Supply (pg. 29). CMS finalized its general definition for "covered drug, device, biological, or medical supply" as: 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 (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a bundled payment (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). Drugs and biologicals that are considered "over-the-counter" (OTC) are excluded, as are many Class I devices and certain Class II devices, which are exempt from premarket notification requirements under 21 U.S.C. 360(l) or (m), such as tongue depressors and elastic bandages.

CMS revised the definition to clarify that a covered drug, device, biological or medical supply is one for which payment is available under Medicare, Medicaid or CHIP **and** which requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). The definition is not intended to include products that require premarket approval or premarket notification, but that are regulated by the FDA solely as a food.

Covered Recipients (pg. 35). Despite public comments, CMS would not expand the definition of covered recipient to include other provider types (such as nurse practitioners) nor would it limit the definition to exclude those clearly intended in the statutory definition. CMS recognized it would not be able to fully capture financial relationships between industry and prescribers, specifically non-physician prescribers such as nurse practitioners. However, to the extent that applicable manufacturers make payments or other transfers of value to non-physician prescribers to be passed through to a physician, they would be indirect payments to the physician and would have to be reported under the name of the physician.

CMS maintains that the definition hinges on whether a physician is "legally authorized" to practice, so all physicians (including all providers types listed in the statutory definition) that have a current license to practice will be considered covered recipients. Payments or other transfers of value to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic) will not be required to be reported for purposes of this regulation.

CMS did not agree that that the term "physician" should be limited to those enrolled in Medicare, and believes such an interpretation would be contrary to the language of the statute.

CMS did not agree that it would be possible to implement an “opt-out” system, and believes that such a system would be overly burdensome for both CMS and applicable manufacturers to track who has opted out and ensure that no payments or other transfers of value are made to those individuals. CMS stated that a physician who wants to opt out should simply refuse all payments or other transfers of value from manufacturers, and will, accordingly, not be included on the public website (unless they hold ownership or investment interests in an applicable manufacturer or applicable GPO).

CMS clarified the definition of covered recipient to ensure that only bona fide employment relationships are included in the employee exclusion. Regarding employees of agents of the applicable manufacturer, CMS does not intend these individuals to be included in the exception since they are not employees of the applicable manufacturer. However, as discussed in the section on indirect payments (section II.B.1.k of this final rule), CMS does not believe that payments or other transfers of value to legal agents of an applicable manufacturer that happen to have physicians on staff constitutes a payment or other transfer of value for the purposes of this rule.

CMS noted it would unable to adopt a bright-line policy that all board members or medical directors, as well as prospective employees and retirees, are (or are not) bona fide employees for purposes of the reporting exclusion. CMS

believes that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act, which defines employee by referencing common law rules used to determine the employer-employee relationship for Internal Revenue Service purposes, will require a case-specific analysis.

With respect to teaching hospitals, CMS agreed that payments to non-healthcare departments of universities affiliated with teaching hospitals should not be included in reporting requirements. However, any payments or other transfers of value made through these departments to a covered recipient as indirect payments or other transfers of value must be reported as required for indirect payments.

Identification of Covered Recipients (pg. 41)

Identification of Physicians (pg. 42). CMS reiterated that reporting a physician-covered recipient's NPI is a statutory requirement, so the agency does not have flexibility to waive the requirement. In addition, CMS believes it is reasonable for the applicable manufacturer to bear responsibility for determining a physician-covered recipient's NPI (or lack thereof). Applicable manufacturers should be able to demonstrate that they made a good faith effort to obtain an NPI for the physician, which among other things, may include specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk. Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year, as the NPPES is updated continually. If an applicable manufacturer cannot determine an NPI for a physician covered recipient, or a physician does not have an NPI, CMS stated that the NPI field may be left blank to indicate that the applicable manufacturer could not identify an NPI for the physician covered recipient. However, if CMS determines that a physician covered recipient does have an NPI, it may inform the applicable manufacturer and require the applicable manufacturer to re-submit the data including the NPI and re-attest to the updated data. Additionally, not reporting an NPI for physician-covered recipients that do have an NPI will be considered inaccurate reporting, which may be subject to penalties.

CMS does not believe it can require physicians to disclose their NPI to applicable manufacturers when requested; however, the agency strongly encourages physicians to provide this information because it is essential for matching payments or other transfers of value to physicians accurately.

CMS reiterated that only one individual NPI (not a group NPI) may be reported for each physician, and that applicable manufacturers should use the NPI listed in NPPES, if a dispute arises. Also as required by statute, physician-covered recipient's NPIs will not be included on the public website.

CMS also finalized that that applicable manufacturers must report the State(s) and appropriate State professional license number(s) for at least one (but multiple will be accepted) State where the physician maintains a license for all physician covered recipients, regardless of whether the applicable manufacturer has identified an NPI for the physician covered recipient or not.

Despite public requests, CMS will not make available a physician covered recipient list, which the agency notes will be difficult to maintain and invariably include mistakes and inaccuracies.

Identification of Teaching Hospitals (pg. 48). CMS agreed that the teaching hospital list would be useful for applicable manufacturers and appreciates the comments making suggestions for how to improve the list. CMS will publish the list once annually and make it available publicly and for download at least 90 days before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection. Applicable manufacturers can rely on the list for the entirety of the data collection year. The list will include all hospitals that CMS had recorded as receiving a payment under one of the defined Medicare direct GME or IME programs. The list will include hospital TINs to provide more specific information on hospitals with complex corporate identities.

Payments or Other Transfers of Value (pg. 49)

CMS interprets value as the discernible economic value on the open market in the U.S., but agrees that applicable manufacturers should be allowed flexibility to determine value, so the agency does not plan to create numerous rules for calculating value. Rather, CMS has outlined a few guidelines to help manufacturers.

1. Payments or other transfers of value that do not have a "discernible" economic value for the covered recipient specifically, but nevertheless have a discernible economic value generally, must be reported.
2. Even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported.
3. When calculating value CMS believes that all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value.
4. All applicable manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value. The methodology used and assumptions made by the applicable manufacturer may be included in the applicable manufacturer's voluntary assumptions document.

CMS also finalized that payments provided to a group or practice (or multiple covered recipients generally) should be attributed to the individual physician covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

Payments provided to one covered recipient, but directed by the applicable manufacturer to another specific covered recipient, should be reported in name of the covered recipient that ultimately received the payment because the intermediate covered recipient was merely passing through the payment. In addition, a payment provided directly to a physician covered recipient should be reported in the name of the physician, regardless of whether the physician is an employee of a teaching hospital, since the payment was provided to the physician and not the teaching hospital. In order to prevent double counting, payments provided in these circumstances should not also be reported in the name of the intermediate covered recipient. If the payment or other transfer of value was not passed through in its entirety, then the applicable manufacturer should report separately the portion of the payment or other transfer of value retained by the teaching hospital covered recipient and the portion passed through to the physician covered recipient. If the payment or other transfer of value was not passed through at all, the applicable manufacturer should report it in its entirety in the name of the teaching hospital.

CMS did not agree to set a limit for the total amount a physician can receive annually, as the statute does not afford CMS this authority, nor does it limit or ban them in any way. This is a transparency initiative, and inclusion on the public website does not indicate that the relationships are necessarily improper or illegal.

Applicable manufacturers must report, in the name of the covered recipient, all payments or other transfers of value made at the request of or designated on behalf of a covered recipient, as well as the name of the entity that received the payment or other transfer of value. In the event that a payment was provided to an individual, at the request of or designated on behalf of a covered recipient, the individual's name does not need to be reported. Instead, the applicable manufacturer should report simply "individual" in the field for entity paid.

With respect to providing entities receiving payments or other transfers of value at the request of or designated on behalf of a covered recipient (as a third-party recipient) the opportunity to review and correct the information, CMS stated that it does not believe there is a viable method for administering it. The agency said it will not have any information on the entities beyond their name, and, therefore, will not be able to match an entity across applicable manufacturers. More importantly, since the entities will not be readily identifiable groups or individuals (such as physicians), the agency will have no means to validate the identity of an individual signing on to the website and stating that he or she is from a specific entity. CMS notes that a covered recipient will be able to review these payments or other transfers of value sufficiently since they should be aware of the payment or other transfer of value made at their request or designated on their behalf.

CMS decided to only require reporting and publication of the name of entities (and not individuals) that received payments or other transfers of value at the request of or designated on behalf of covered recipients, which should alleviate some of the concerns regarding review and correction because personal payments to an individual will not be made public on the website. CMS finalized that review and correction for entities, which receive a payment at the request of or designated on behalf of a covered recipient, will be done by the covered recipient, rather than the entity.

CMS provided general guidelines and information on how it intends to interpret the phrases "at the request of" and "designated on behalf of." Specifically, if a covered recipient directs that an applicable manufacturer provide a payment or other transfer of value to a specific entity or individual, rather than receiving it personally, then the payment is being made "at the request" of such covered recipient and must be reported as described in this section (under the name of the covered recipient, but also including the name of the entity paid or "individual," in the case of an individual). If a covered recipient decides to neither accept the payment or other transfer of value nor request that it be directed to another individual or entity, then the payment or other transfer of value that was offered by the applicable manufacturer does not need to be reported.

In addition, CMS interprets "designated on behalf of a covered recipient" as when a covered recipient does not receive a payment or other transfer of value, but the applicable manufacturer provides the payment or other transfer of value to another entity or individual in the name of the covered recipient. CMS encourages covered recipients to make very clear to applicable manufacturers whether they would like their waived fee to be paid to another individual or entity.

Payment and Other Transfer of Value Report Content (pg. 59)

Name (pg. 59). Applicable manufacturers must report the middle initial of a physician covered recipient as listed in NPPES, but will not be penalized for leaving the field blank if it is not available in NPPES or if the physician does not have a middle name. In order to ensure that physician covered recipients are appropriately matched across applicable manufacturers and to their own data during the review and correction period, CMS will require applicable manufacturers to report a physician covered recipient's name as listed in NPPES.

Business Address (pg. 60). CMS finalized its proposal to require the primary practice location address to be reported as the business address. CMS realizes that a physician can be associated with multiple addresses, but it believes that primary practice location is the most recognizable to consumers. Applicable manufacturers do not need to use NPPES when reporting addresses, but they are welcome to do so. CMS will not penalize applicable manufacturers for providing the incorrect address, as long as applicable manufacturer reports a legitimate business address for the covered recipient. CMS will continue to require reporting of full street business address.

Specialty and NPI (pg. 62). Applicable manufacturers may use their internal information when reporting specialty. However, the NPPES" provider taxonomy" list should be used as the list of accepted specialties since consistency in the names of reported specialties is important for facilitating aggregation of the data. However, the NPPES list does include the nine recognized ADA specialties. When reporting specialty, applicable manufacturers should list both the specialty name and code to ensure consistency. Applicable manufacturers need only provide a single specialty.

Date of Payment (pg. 63). CMS finalized that applicable manufacturers have the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. CMS will allow flexibility for what specific date to report for a nature of payment category. CMS also believes that the methodology employed should be consistent within a single nature of payment category. For example, for all flights, applicable manufacturers should report dates in a consistent manner (such as the flight date or ticket purchase date).

CMS also noted that the aggregated payments should not cross years, so for payments, which span multiple years, the amount paid in a given year must be reported for that reporting year. Similarly, the date of payment methodology should not be used to move payments from one reporting year to another.

Applicable manufacturers are encouraged to include information on the methods they used for reporting date of payment or other transfer of value in their assumptions document. When reporting the date of payment for bundled small payments (as described in §403.904(i)(2)(iv)), applicable manufacturers should report the date of payment as the date of the first small payment or other transfer of value made to the covered recipient.

Context (pg. 65). CMS agreed that information on the context of a payment or other transfer of value could be useful in helping the public better understand the relationships between the industry and covered recipients, and helping covered recipients when reviewing the payments or other transfers of value. CMS does not want this contextual information to overwhelm users or significantly increase the data reported, so will limit the amount of data that can be

reported in that field, but per Section 403.904(c)(12), will allow applicable manufacturers to provide brief contextual information for each payment or other transfer of value, but does not require them to do so.

Related Covered Drug, Device, Biological or Medical Supply (pg. 66). CMS finalized that applicable manufacturers must report a related product name for all payments or transfers of value, unless the payment or other transfer of value is not related to a covered product. Applicable manufacturers are not required to report the name of associated non-covered products since this may be misleading to consumers and would provide information that is beyond the goal of the statute. However, CMS believes it will be useful to know the extent of payments or other transfers of value that are not associated with any product or not associated with a covered product. As such, the final rule directs applicable manufacturers to fill in associated product fields as appropriate. Therefore, if the payment or other transfer of value is not related to at least one covered product, then applicable manufacturers should report "none." If the payment or other transfer of value is related to a specific product, which is not a covered product, then applicable manufacturers are to report "non-covered product." If the payment or other transfer of value is related to at least one covered product, as well as at least one non-covered product, then applicable manufacturers must report the covered products by name (as required), and may include non-covered products in one of the fields for reporting associated product.

CMS finalized that applicable manufacturers may report up to five related covered products for each interaction. If the interaction was related to more than five products, an applicable manufacturer should report the five products, which were most closely related to the payment or other transfer of value. When aggregating payments or other transfers of value by product, CMS will not represent a single interaction related to multiple products as multiple interactions. CMS does not agree that the applicable manufacturer should report the percentage of the interaction dedicated to each product, as this will be burdensome to the applicable manufacturers and would not be beneficial to consumers.

For drugs and biologicals, CMS finalized that applicable manufacturers must report the market name of the product and must include the NDC (if any). If a market name is not yet available, applicable manufacturers should use the name registered on clinicaltrials.gov. If there is no NDC available for a product, it does not have to be reported. For devices and medical supplies, §403.904(c)(8)(ii) allows reporting of either the name under which the device or medical supply is marketed, or the therapeutic area or product category.

Form of Payment and Nature of Payment (pg. 71). The statute requires reporting on both the form and nature of payment for each payment or transfer of value made by an applicable manufacturer to a covered recipient. The statute includes the following form of payment categories:

- Cash or a cash equivalent.
- In-kind items or services.
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.
- Any other form of payment or other transfer of value.

The statute includes the following nature of payment categories:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel (including the specified destinations)
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest

- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grant
- Any other nature of the payment or other transfer of value

CMS finalized in the rule that the categories within both the form of payment and the nature of payment should be defined as distinct from one another. Additionally, if a payment or other transfer of value for an activity is associated with multiple categories, such as travel to a meeting under a consulting contract, the travel expenses should remain distinct from the consulting fee expenses and both categories would need to be reported to accurately describe the relationship.

For lump sum payments or other transfers of value, CMS finalized that the applicable manufacturer break out the distinct parts of the payment that fall into multiple categories for both form of payment and nature of payment.

CMS finalized these provisions, as it believes flexibility in the reporting requirements is important to aid applicable manufacturers with different systems. CMS also agreed that if a payment could fit within multiple possible categories, applicable manufacturers should have flexibility to select the category that best described the payment, in accordance with their own documented methodology.

Form of Payment (pg. 77)

CMS finalized its proposal to break the category of "stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment" category into two categories, but otherwise will not be adding any additional categories to form of payment.

Nature of Payment (pg. 78)

Applicable manufacturers are required to report all payments or other transfers of value, unless they specifically fall within an exception. CMS believes precise definitions could make these descriptors less useful and could make reporting more challenging for applicable manufacturers. Similarly, CMS does not believe it should rank the payment/transfer categories and indicate some as more desirable or beneficial than others. As such, applicable manufacturers should select the most appropriate description. In the interest of consistency and to enhance of the usefulness of the data, CMS provided some additional explanations for the categories. CMS only added categories for those recommendations that it believes cannot be described by existing nature of payment categories. CMS will add "space rental and facilities fees" as a nature of payment category under its authority in section 1128G(a)(1)(A)(vi)(XV) of the Act, but will not add "appearing as an author for a ghostwritten article."

Charitable Contributions (pg. 81). CMS believes that the "charitable contribution" nature of payment category should be used only in situations when an applicable manufacturer makes a payment or other transfer of value to a charity on behalf of a covered recipient and not in exchange for any service or benefit.

Food and Beverage (pg. 83). For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), CMS will require applicable manufacturers to report the per person cost (not the per covered recipient cost) of the food or beverage for each covered recipient who actually partakes in the meals (that is, actually ate or drank a portion of the offerings). If the per person cost exceeds the minimum threshold amount, then the applicable manufacturer must report the food or beverage as a payment or other transfer of value for each covered recipient who actually participated in the group meal by eating or drinking a food or beverage item.

Regarding meals that are dropped off at a covered recipient's office (for example, by a sales representative) and other meals where the attendees are not controlled or selected by the applicable manufacturer, CMS believes that these situations nevertheless constitute payments or other transfers of value to a covered recipient, so they must be reported. Applicable manufacturers are responsible for keeping track of food and beverages provided to covered recipients and must use the same attribution method for all meals as described previously regardless of whether the manufacturer's representative remained in the office for the entire meal.

CMS finalized that food and beverage provided at conferences in settings where it would be difficult to establish the identities of people partaking in the food do not need to be reported. However, CMS does not intend this to apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish identity of the attendees.

Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program (pg. 88). While CMS agrees that given the title of this nature of payment category, which was set out in the statute itself, should not include compensation for accredited or certified continuing education payments, CMS does believe that all payments to physicians for serving as speakers at an accredited or certified continuing education program should be granted a blanket exclusion. Therefore, CMS has added an additional nature of payment category for serving as a faculty or speaker at an accredited or certified continuing education event. This new category, named "compensation for serving as faculty or as a speaker for an accredited or certified continuing education event," includes all accredited or certified continuing education payments that are not excluded by the conditions set forth in. CMS also renamed the category for direct compensation to include speaking engagements at unaccredited and non-certified continuing education events. The new title "compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program" includes all other instances when an applicable manufacturer provides compensation to a covered recipient for serving as a speaker or faculty at an unaccredited and non-certified education event, regardless of whether the payment was provided directly or indirectly. The nature of payment category for "compensation for services other than consulting" now explicitly includes payments or other transfers of value for speaking engagements that are not for continuing education.

Other (pg. 91). CMS omitted the "other" category from the nature of payment categories.

Other Nature of Payment Categories (pg. 92). CMS provided additional information for applicable manufacturers when considering the categories below.

- ***Consulting Fees (pg. 92).*** Intended to include fees paid by an applicable manufacturer to a covered recipient for services traditionally viewed as consulting services.
- ***Compensation for Services Other than Consulting (pg. 92).*** Intended to capture compensation for activities or services that are not traditionally considered consulting services, but are provided by a covered recipient to an applicable manufacturer.
- ***Honoria (pg. 93).*** Honoraria are distinguishable from "compensation for services other than consulting" in that they are generally provided for services for which custom prohibits a price from being set.
- ***Gift (pg. 93).*** Will often include anything provided to a covered recipient that does not fit into another category, such as a small trinket.
- ***Entertainment (pg. 93).*** Intended to include, but is not limited to, attendance at recreational, cultural, sporting or other events that would generally have a cost.
- ***Travel and Lodging (pg. 93).*** Includes travel, including any means of transportation, as well as lodging. The destination, including City, State and country must be reported.
- ***Education (pg. 93).*** Includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a profession. CMS does not intend to capture the attendees at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer (as opposed to payments for speakers at such events); however, CMS believes that any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these events must be reported under the appropriate nature of payment categories.
- ***Royalty or License (pg. 94).*** Includes, but is not limited to, the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes.
- ***Current or Prospective Ownership or Investment Interests (pg. 94).*** Includes ownership or investment interests currently held by the covered recipient, as well as ownership interests or investment that the covered recipient has not yet exercised.
- ***Grant (pg. 94).*** Refers to payments to covered recipients in support of a specific cause or activity.

Nature of Payment Categories (pg. 95). The nature of payment categories finalized are as follows:

- 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

Assumptions Document (pg. 96). CMS finalized the voluntary submission of an assumptions document. Applicable manufacturers may include in the assumptions document assumptions and methodologies other than only those employed when classifying nature of payment categories. Applicable GPOs reporting under section 1128G(a)(2) of the Act may also submit an assumptions document. The assumptions document may include the applicable GPO's assumptions when categorizing nature of payment categories for any information submitted on payments or other transfers of value provided to physician owners or investors (as required in section 1128G(a)(2)(C) of the Act) or any other assumptions or methodologies the applicable GPO wishes to include. The contents of the assumptions document will not be made public, nor will it be provided to covered recipients, by CMS. However, applicable manufacturers may provide their assumptions document to covered recipients upon the request of covered recipients independently from CMS.

CMS carefully reviews the assumptions documents to determine whether it needs to publish more detailed guidance to assist applicable manufacturers in classifying the nature of payment categories, or other assumptions or methodologies included in the assumptions document. Additionally, CMS intends to provide assistance to applicable manufacturers to help classify payments or other transfers of value and hopes that such guidance will be useful. CMS does not intend to use the assumptions document for prosecution, but acknowledges that the reporting based on the assumptions would be open to prosecution. Other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO.

Research (pg. 99)

Scope of Research (pg. 99).

CMS decided to define research based on the Public Health Service Act definition of research in 42 CFR 50.603; this definition defines research as: "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."

CMS finalized that payments reported as research should be made in connection with an activity that meets the definition. CMS finalized that if a payment falls within the nature of payment category for research, it only needs to be

subject to a written agreement or contract or a research protocol. This may include an unbroken chain of agreements (instead of a single agreement between the applicable manufacturer and the covered recipient), which link the applicable manufacturer with the covered recipient because CMS understands that many applicable manufacturers use other entities such as contract research organizations (CROs) (as defined in 21 CFR 312.3(b)), or site management organizations (SMOs) to manage their clinical research activities.

Regarding reporting of research-related payments, which do not meet the definition of research, applicable manufacturers should report using the other categories available.

CMS believes that any payments related to the definition of research discussed previously should be reportable and does not believe it should further limit the scope of research payments to be reported. CMS will require reporting of research payments to PIs who meet the definition of "physician," even if they do not regularly treat patients.

Material transfers (such as provision of a protein) to a researcher for discovery collaboration does not need to be reported when not part of a commercial or marketing plan and precedes the development of a new product. CMS believes for the purposes of this regulation that due to the early stage of the research process, the transferred material does not have independent value.

Reporting Research Payment (pg. 103). CMS finalized that applicable manufacturers must report research payments separately in a different template, since CMS will be requiring the reporting of modified information. Applicable manufacturers will not be responsible for indicating whether a payment was direct or indirect. CMS adopted a procedure similar to the process outlined in many of the comments, where a single research payment is reported once and includes the entity paid, as well as the name of the principal investigator(s). Applicable manufacturers must report each research payment once as a single interaction. They must report the name of the individual or entity (regardless of whether it is a covered recipient) that received the payment for the research services, as well as the principal investigator(s). When reporting the entity or individual that received the payment, CMS intends for the applicable manufacturer to report the entity or individual that received the payment, either directly from the applicable manufacturer or indirectly through a CRO or SMO. CMS believes that the recipient of the payment could include individual principal investigators, teaching hospitals, nonteaching hospitals or clinics. CMS intends for the principal investigator(s) to include the individual(s) conducting the research or providing the services on behalf of the research institution. The same identifying information will be required to be reported for each PI meeting the definition of covered recipient.

Applicable manufacturers shall be required to report the following for each research-related payment that ultimately is paid, in whole or in part, to a covered recipient (physician or teaching hospital):

- Name of research institution/other entity or individual receiving payment (regardless of whether a covered recipient)
  ++ If paid directly to a physician covered recipient, list the individual's name, NPI, State professional license number(s) and associated State names for at least one State where the physician maintains a professional license, specialty, and primary business address of the physician(s)
  ++ If paid directly to a teaching hospital covered recipient, list name and primary business address of the teaching hospital
  ++ If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list name and primary business address of the entity.
- Total amount of research payment
- Name of study
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value) and NDC (if any).
- Principal investigator(s) (including name, NPI, State professional license number(s) and associated States for at least one State where the physician maintains a professional license, specialty, and primary business address)
- Context of research (optional)

- ClinicalTrials.gov identifier (optional)

Reporting this information for each research payment will better capture the nature of the research relationship, creating a simpler reporting mechanism for the applicable manufacturers to report payments and allowing end users a more accurate understanding of the relationship. The study name will provide information on the research topics, but CMS has also included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research.

CMS will allow applicable manufacturers to provide the ClinicalTrials.gov Identifier to allow consumers the ability to obtain more information on the study from ClinicalTrials.gov. However, CMS recognizes that not all research studies will be posted on ClinicalTrials.gov, so this category will be optional. This represents the information required to be reported for each research-related payment or other transfer of value, but the agency may identify other optional fields, such as information on publications related to the research, in order to provide additional information and background on the public website.

For pre-clinical research, CMS finalized slightly modified reporting requirements since such early stage research is often not connected to a specific product. CMS intends pre-clinical research to include laboratory and animal research that is carried out prior to beginning any studies in humans, including FDA's defined phases of investigation. For pre-clinical research, applicable manufacturers only have to report the name of the research institution, principal investigator(s) (including name, NPI, State professional license number(s), specialty and business address), and the total amount of the payment, so they do not need to report an associated product, or study name.

CMS finalized guidelines for what should be included in the total research payment amount. The amount should include the aggregated amount of any payments for services included in the written agreement/research protocol, such as costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.

The payment amount should not include any payments for activities, which are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research, such as payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately. Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment. Meals and travel should be reported separately (under the food and travel nature of payment categories) unless included in written agreement or research protocol and paid for through the large research contract.

CMS does not intend for applicable manufacturers to be required to itemize each research payment since they are usually large payments obligated to general administration of the study and the applicable manufacturer may not be aware of the daily activities. Additionally, CMS does not require the reporting of payments to non-covered recipients that are not passed on to covered recipients.

When reporting research payments, CMS acknowledges that research payments are generally different than other payments and may not represent a payment to the covered recipient. For physician-covered recipients whom are paid by a third party and not directly by the manufacturer, CMS will list research studies separately from all other payments provided to the covered recipient. For teaching hospitals, CMS will publish all research payments, which went to the hospital as a research institution. These will be listed separately from other payments to the hospital, but will include both the study amount and study name.

Exclusions (pg. 110)

Despite public comments, CMS did not agree that it had the statutory authority to add exclusions beyond what was outlined in the statute. CMS finalized its policy that the exclusions will be defined by their dictionary definitions, but CMS plans to provide additional clarification.

Existing Personal Relationships (pg. 111). CMS does not intend existing personal relationships to be reported and has finalized that as such.

Payments or Other Transfer of Value of Less Than $10 (pg. 111). Small payments or other transfers of value, which the statute defines as payments or other transfers of value less than $10, do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100. Given the timing of this final rule, CMS decided to begin increasing the de minimis thresholds for reporting in CY 2014, and retain the statutory de minimis thresholds ($10 and $100) for reporting in CY 2013. Applicable manufacturers should be prepared to collect data and report using these thresholds for CY 2013.

CMS finalized that applicable manufacturers have flexibility in reporting small payments. They may either report them individually or bundled with other small payments or other transfers of value in the same nature of payment category, as long as applicable manufacturers are reporting consistently and clearly indicating the method they are using. CMS agreed that the de minimis thresholds should not change within a reporting year and will be constant for the entire year. CMS will report the new de minimis value with the reporting template for the next reporting year.

CMS provided additional guidelines expanding the proposed rule and will finalize that these guidelines will apply to conference and similar events, as well as events open to the public. At events open to the public, CMS agrees that it will be extremely difficult for applicable manufacturer to identify physician-covered recipients. Therefore, CMS will finalize that small incidental items that are under $10 (such as pens and note pads) that are provided at large-scale conferences and similar large-scale events will be exempted from the reporting requirements, including the need to track them for aggregation purposes.

Payments or other transfers of value of $10 or more (for CY 2013) need to be tracked and reported even when provided at large-scale conferences or similar events. CMS believes that if an applicable manufacturer is handing out an item above the threshold, they should be able to track who received the payment since it is a more significant transfer.

CMS will not provide a standard template for reporting by entities that organize and oversee events and conferences. These event and conference vendors are not applicable manufacturers, so CMS does not believe it should have any contact with them or impose requirements on them.

Educational Materials that Directly Benefit Patients or are Intended for Patient Use (pg. 115). CMS agreed that patient education "materials" should be interpreted somewhat more broadly for purposes of the exclusion. A device manufacturer may give a physician an anatomical model to help explain to patients how a procedure would work, and this would fall within the exclusion. Overhead expenses, such as printing and time, should be included in the exclusion as long as they are directly related to the development of the materials, which directly benefit patients or are intended for patient use.

CMS finalizes that educational materials provided to covered recipients for their own education, but that do not "directly" benefit patients, do not fall within the exclusion and are therefore subject to the reporting requirements.

Discounts and Rebates (pg. 117). CMS finalized that discounts and rebates for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to covered recipients are excluded from reporting under section 1128G(e)(10)(B)(vii) of the Act.

In-kind Items for the Provision of Charity Care (pg. 117). CMS intends this exclusion to include in-kind items given to covered recipients to provide care to patients who are unable to pay, or for whom payment would be a significant hardship. CMS does not intend applicable manufacturers to be responsible for tracking each individual item provided to a covered recipient to ensure it is provided to a patient unable to pay. CMS believes it is sufficient for the applicable

manufacturer and covered recipient to agree in writing that the covered recipient will use the in-kind items only for charity care.

CMS finalized that only in-kind items will be included in the exclusion, which does not include financial support for charitable covered recipients. While CMS recognizes that some payments made to charitable third parties may at some point indirectly benefit a covered recipient, these payments or other transfers of value should be reported based on the reporting requirements for indirect payments or other transfers of value. Charitable contributions made directly to or intended for a covered recipient should be reported as a charitable contribution.

Products Samples (pg. 119). Any drug, device, biological or medical supply provided as a sample to a covered recipient that is intended for use by patients will be included in the exclusion. As long as single use or disposable devices, demonstration devices or evaluation equipment provided to a covered recipient are intended for patient use, they will be included in the exclusion. Products used for research studies should be included as a part of the larger research payment.

CMS finalized that all coupons and vouchers for the applicable manufacturer's products that are intended for patient use to defray the costs of covered drugs, devices, biologicals or medical supplies will be included in this exclusion category.

CMS does not believe the applicable manufacturer should be responsible for tracking what actually happens to samples. Instead, CMS believes that as long as the applicable manufacturer and covered recipient agree in writing that the products will be provided to patients, which is commonplace in the industry, the provision of samples can be excluded.

Short Term Loans (pg. 121). CMS finalized that this exclusion may include loans for covered devices, as well as those under development. CMS finalized that this will also include a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days. CMS does not believe that applicable manufacturers should be allowed to provide an unlimited supply of these products and still fall within the exclusion, so the agency is establishing a 90-day supply as the limit. If an applicable manufacturer provides a specific disposable or single use device for more than 90 days (even if provided over multiple dates), the products provided beyond the 90-day supply will be subject to the reporting requirements.

For a single product the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days were consecutive. In the event that the loan of a non-disposable device exceeds 90 days (for the entire calendar year), the applicable manufacturer should start reporting as if the loan began on day 91. If a device is purchased within 90 days, the applicable manufacturer does not need to report the loan since the loan was less than 90 days.

Contractual Warranty (pg. 122). CMS finalized that as long as the contract warranty specified the terms prior to expiration and the terms do not change, then the exclusions may extend to items and services provided outside the expiration period. CMS finalized that items and services provided under a contractual service or maintenance agreement will also be subject to the exclusion.

Covered Recipient Acting as a Patient (pg. 124). CMS agreed that covered recipients participating as a subject (and not in a professional capacity) in a research study is the same as being a patient and, should be included in the exclusion.

Provision of Healthcare (pg. 124). CMS finalized that this category encompasses other situations, beyond a self-insured plan, when an applicable manufacturer makes a payment to a covered recipient as part of healthcare services provided to the manufacturer's employees or their family, such as at an on-site clinic or at a health fair.

Nonmedical Professional (Pg. 125). Section 1128G(e)(10)(B)(xi) of the Act excludes "in the case of a covered recipient who is a licensed nonmedical professional, a transfer of anything of value to the covered recipient if the transfer is solely for the non-medical professional services of such licensed nonmedical professional."

Civil or Criminal Action or Administrative Proceeding (pg. 125). CMS finalized that other specific legal relationships will

be included in the exclusion. CMS believes that there are numerous legal proceedings that require physician involvement and it plans to exclude all of them in order to allow for clear, consistent reporting requirements for applicable manufacturers, covered recipients, and consumers.

Indirect Payments or Other Transfers of Value through a Third Party (pg. 126)

CMS does not agree that all indirect payments or other transfers of value should be excluded from the reporting requirements. Excluding from the reporting requirements all payments made through a third party would create a significant loophole by allowing manufacturers to funnel payments through a third party and not report them; such a loophole would significantly undermine the intent of the reporting requirements. CMS does not believe that it has statutory authority to carve out otherwise reportable indirect payments made through particular third parties, such as medical professional societies.

CMS provided for the purposes of these regulations a definition of "indirect payments or other transfers of value" in §403.902. The definition states that an indirect payment or other transfer of value is one that an applicable manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient. For example, if an applicable manufacturer provided an unrestricted donation to a physician professional organization to use at the organization's discretion, and the organization chose to use the donation to make grants to physicians, those grants would not constitute "indirect payments" because the applicable manufacturer did not require, instruct, or direct the organization to use the donation for grants to physicians. The physician professional association could have used the donation for another purpose at its discretion. In this situation, the applicable manufacturer would not be required to report the donation, even if a portion of the payment or other transfer of value was ultimately provided to a covered recipient as a grant (or some other type of payment or other transfer of value). However, if an applicable manufacturer gave money to a medical professional society earmarked for the purpose of funding awards or grants for physicians, the awards or grants would constitute indirect payments to covered recipients and would be subject to the reporting requirements.

CMS finalized its proposed definition that an applicable manufacturer is "unaware" if it does not know the identity of a covered recipient, and that "know" means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity. If a payment meets the definition of an indirect payment or other transfer of value in §403.902, then the payment can only be excluded from the reporting requirements if the applicable manufacturer did not "know" the identity of the covered recipient, as defined in §403.902. CMS clarified that, for purposes of this rule only, it will not consider an applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity in situations when the reason a payment or other transfer of value is being made through a third party is that the identity of the covered recipient remains anonymous. CMS' intention with this definition is to prevent applicable manufacturers from directing payments to a discrete set of covered recipients whose identities the manufacturer may not actually know, but could easily ascertain. CMS does not require reporting of every payment that an applicable manufacturer makes through a third party that is ultimately provided to a covered recipient; rather, the intent is to require reporting of indirect payments where applicable manufacturers know or should know the identity of the covered recipients who receive them.

CMS finalized that for the purposes of this exclusion, an applicable manufacturer must be unaware of the identity of a covered recipient during the reporting year and the second quarter of the subsequent year following the transfer of the payment from the third party to the covered recipient. Therefore, if an applicable manufacturer becomes aware of the identity of a covered recipient on or before June 30th of the year following the year in which the payment is made by the third party to the covered recipient, then the payment or other transfer of value must be reported.

CMS does not believe it is necessary to significantly change the reporting requirements for indirect payments. Applicable manufacturers will need to work with the third parties through which they make payments to covered recipients to ensure that the third parties are taking the appropriate steps to track the indirect payments.

CMS clarified that when multiple applicable manufacturers provide a payment or other transfer of value to a covered recipient through a third party, the agency intends to allow for flexibility because the agency wants to ensure that no

payment or other transfer of value is captured twice. Applicable manufacturers and third parties may work together to determine the best method for reporting the payment or other transfers of value, as long as the payment or other transfer of value gets reported.

CMS agreed that industry support for accredited or certified continuing education is a unique relationship. The accrediting and certifying bodies, including ACCME, AOA, AMA, AAFP, and ADA CERP, and the industry standards for commercial support, create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content. However, CMS believes that even with this separation, the sponsor may still influence the selection of faculty by offering suggestions to the accredited or certified continuing education provider; although the continuing education provider may not be required to follow these suggestions, CMS believes that it may often be impossible to distinguish when a suggestion is influential and when it is not.

CMS finalized at §403.904(g)(1) that an indirect payment made to a speaker at a continuing education program is not an indirect payment or other transfer of value for the purposes of this rule and, therefore, does not need to be reported, when all of the following conditions are met: (1) the program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP; (2) the applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and (3) the applicable manufacturer does not directly pay the covered recipient speaker. CMS believes that when applicable manufacturers suggest speakers, they are directing or targeting their funding to the speakers, so these payments will be considered indirect payments for purposes of this rule.

Conversely, when they do not suggest speakers, they are allowing the continuing education provider full discretion over the CME programming, so the payment or other transfer of value will not be considered an indirect payment for purposes of these reporting requirements.

Since industry support of CME programs that meets all three requirements discussed previously will not be considered indirect payments or other transfers of value for the purposes of reporting, the awareness standards for indirect payments are not applicable to such support. Applicable manufacturers will not be responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for continuing education events. However, as explained in the discussion of the nature of payment categories, payments or other transfers of value associated with attendance of an event (such as travel and meals) must be reported as required.

With regard to unaccredited and non-certified education, this type of education program does not require the same safeguards as an accredited and certified program, and therefore payments or transfers of value should be reported as required for any other payment or other transfer of value. If the payment or other transfer of value is made indirectly, it will be subject to the same reporting requirements for all indirect payments. The details for how to report both accredited or certified, and unaccredited or non-certified continuing education payments or other transfers of value are discussed in section II.B.1.h. of the final rule, dedicated to nature of payment categories.

CMS believes that payments made in connection with prescriber education required by REMS should be reportable on the same basis as other education payments. For example, if a sponsor directs the choice of a program speaker, or pays for covered recipients' meals or transportation to a REMS educational program, such payments would be reportable. However, applicable manufacturers are not required to report the provision of written materials that have been approved by FDA for distribution to physicians, such as Dear Healthcare Provider letters. Other REMS educational materials may be excluded if they fall within the exclusion for materials intended for patient use described in §403.904(i)(4).

Reports on Physician Ownership and Investment Interests under Section 1128G(a)(2) of the Act (pg. 141)

CMS does not agree that applicable GPOs are required to report under section 1128G(a)(1) of the Act. Applicable GPOs are not mentioned in section 1128G(a)(1) at all, indicating that Congress did not intend for them to be subject to the requirements of that section. Additionally, other sections of the statute, such as the definition of payment or other

transfer of value (section 1128G(e)(10) of the Act), only refer to applicable manufacturers when discussing payments or other transfers of value separately from ownership of investment interests.

Reporting Entities (pg. 142)

Applicable Manufacturers (pg. 143). Section 1128G(a)(2) of the Act includes applicable manufacturers as defined for section 1128G(a)(1) of the Act, as entities subject to the reporting requirements in section 1128G(a)(2) of the Act.

Applicable Group Purchasing Organizations (pg. 143). CMS did not agree with commenters to change the definition to include additional physician-owned distributors (PODs), and therefore, CMS is not going to remove the word "group" from the definition.

Physician Owners or Investors (pg. 145)

CMS finalized its proposal that the requirement to report physician ownership and investment interests includes any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO. A physician is defined as having the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice. Ownership and investment interests of immediate family members of physicians must also be reported under this provision, and CMS has defined immediate family member as:

- Spouse
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-, mother-, daughter-, son-, brother-, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

CMS agreed that applicable manufacturers and applicable GPOs should not report the name and relationship of immediate family members of physicians holding ownership or investment interests in such entities. CMS agreed that applicable manufacturers and applicable GPOs may report a specific ownership or investment interest in aggregate across multiple family members, and therefore, reported interests can be aggregated across multiple immediate family members. Applicable manufacturers and applicable GPOs can only aggregate interests when multiple immediate family members have ownership or investment interests with the same terms (as reported pursuant to §403.906(b)(5)) and the value reported includes the total value of all the immediate family member's interests.

Ownership of Investment Interests (pg. 149)

CMS does not agree that applicable manufacturers and applicable GPOs should only report direct ownership or investment interests, and believes that "any ownership or investment interest" encompasses both direct and indirect interests, since indirect ownership or investment interests are also true interests. CMS finalized the recommendation that aligns with the physician self-referral rule in that applicable manufacturers and applicable GPOs will not have to report ownership or investment interests held by physicians or their immediate family members if they did not know about such interests. CMS finalized that applicable manufacturers and applicable GPOs do not have to report indirect ownership or investment interests held by physicians or immediate family members of physicians about which they do not know (as defined for the purposes of this rule).

CMS believes that stock options before they are exercised are traditionally considered compensation, rather than an ownership or investment interest, so it does not believe that the agency should require them to be reported as held ownership or investment interests. Rather, stock options will need to be reported when granted under sections 1128G(a)(1) and 1128G(a)(2)(C) of the Act as a payment or other transfer of value.

Physician Ownership or Investment Reports Content (pg. 152)

CMS finalized these provisions to align with the reporting requirements for payments or other transfers of value reports to the extent the requirements overlap. For example, applicable manufacturers and applicable GPOs should report both physician NPI and State professional license number(s) for at least one State where the physician maintains a license (including the name of the applicable State) to ensure that the agency is able to attribute ownership and investment interests to the appropriate physician. Similarly, requirements for reporting name, primary business address and specialty should also be the same as described for reporting payments or other transfers of value. Finally, as described in the section on the assumptions document, both applicable manufacturers and applicable GPOs may submit an assumptions document including information on their assumptions and methodologies when reporting payments or other transfers of value, or ownership or investment interests.

Applicable manufacturers must report all payments or other transfers of value to covered recipients and physician owners or investors, including the provision of ownership and investment interests. In the event that a physician receives an ownership or investment interest in a given year, an applicable manufacturer should report it as a payment or other transfer of value (under section 1128G(a)(1) of the Act), as well as a standing ownership or investment interest (under section 1128G(a)(2) of the Act).

An individual may be both a covered recipient and a physician owner or investor, so an applicable manufacturer should only report a payment or other transfer of value once, regardless of whether the individual is a covered recipient, a physician owner or investor, or both. The payment or other transfer of value and all the additional required information must be reported in the "payments or other transfers of value" reporting template; however for physician owners or investor (regardless of whether the physician is a covered recipient) the applicable manufacturer should mark that that payment or other transfer of value was provided to a physician owner or investor.

Report Submission and Review (pg. 155)

Prior to Submission (pg. 156)

CMS finalized that it will not administer or manage a pre-submission review process and will not make it mandatory, but recommend that applicable manufacturers voluntarily provide covered recipients the opportunity to review the data prior to submission to CMS, but doing so is not mandatory. Because CMS is not requiring the review, it does not feel it is appropriate for it to prescribe the process and standardize it.

Report Submission (pg. 157)

CMS finalized that it would interpret "on" March 31, 2013 or the 90th of the each year thereafter as "by" March 31, 2013 or the 90th of each year thereafter and intend to allow applicable manufacturers and applicable GPOs to submit data prior to this date to provide applicable manufacturers and applicable GPOs with more flexibility for submission. Because of the publication date of this final rule, reports including 2013 data will not be due until March 31, 2014.

Registration (pg. 158). CMS believes that it does not need to require all entities that meet the definition of applicable manufacturer or applicable GPO to register and finalized the position as proposed. Because the statute only requires the reporting of payments or other transfers of value, CMS will not require action by entities without payments or other transfers of value to report. All applicable manufacturers with payments or other transfers of value to report under paragraph 1 of the definition must register individually, regardless of whether they intend to be part of a consolidated report being submitted by another applicable manufacturer.

Applicable manufacturers that are submitting data as a part of a consolidated report under another applicable manufacturer may indicate during registration that they intend to be part of the consolidated report to be submitted by another applicable manufacturer, allowing CMS to approximate the number of consolidated reports to anticipate. As stated in the applicable manufacturer section, the reporting entity submitting a consolidated report must indicate all the applicable manufacturers for which it is reporting. Similarly, applicable manufacturers that are reporting separately must each register individually.

CMS finalized that applicable manufacturers and applicable GPOs must indicate two points of contact when they register

to allow for a primary and backup point of contact for each reporting entity. In order to ensure that the points of contact are up to date in the CMS system, applicable manufacturers and applicable GPOs will be able to change them as appropriate (subject to CMS user security protocols).

CMS finalized that applicable manufacturers or applicable GPOs with payments or other transfers of value to report must register prior to the deadline for data submission for data for the preceding calendar year for every annual reporting cycle. CMS intends applicable manufacturers and applicable GPOs to register sufficiently prior to the deadline in order to allow registration to be completed appropriately. Applicable manufacturers or applicable GPOs will be able to choose to submit the data immediately after completing the registration process successfully. CMS will open the registration process at the beginning of the calendar year, giving applicable manufacturers and applicable GPOs time to register and submit their data; however, CMS may open registration earlier to allow additional time.

File Format (pg. 160). CMS agrees that it should provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting. CMS will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, CMS will comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which CMS will publish the list of teaching hospitals.

Per the statute, CMS will only allow submission of a single report consisting of the entire reporting period (for example CY 2014). CMS will only be collecting and staging data for public posting in accordance with annual submissions, and will not be accepting ongoing or quarterly submissions. CMS believes that not only is annual publication sufficient for end users, but also allows for a single review and dispute period prior to publicly publishing the data, which is operationally easier for all parties. In addition, submission extensions will not be granted.

After receiving all the submitted data, CMS will need to process all the data to aggregate across manufacturers and applicable GPOs and provide a single review and dispute period to correct submitted data prior to public posting. Late data will be considered failure to report and may be subject to penalties. Applicable manufacturers and applicable GPOs should not aggregate any payments or other transfers of value, or ownership or investment interests (except as described for small payments or other transfers of value). All reported transactions must be at the individual payment or other transfer of value, or ownership or investment interest level and do not intend applicable manufacturers or applicable GPOs to organize or group specific transactions. CMS agrees that it should create an electronic system for accepting the data. CMS plans to publish additional information along with greater detail on the submission process.

Attestation Process (pg. 163). Applicable manufacturers and applicable GPOs can and should be confident that the data is accurate. CMS notes that the penalties are significantly less for unknowing errors, so the statute provides safeguards for unexpected errors. CMS understands that applicable manufacturers and applicable GPOs may have different business structures, and does not want to confine applicable manufacturers and applicable GPOs with regard to which officers must attest, so it finalized that other officers will be allowed to attest, as designated by the company.

CMS also clarified the timing of the attestation requirement, noting that applicable manufacturers and applicable GPOs must provide an attestation for their data at the time of original submission for it to be considered submitted; however, they will also be required to provide an attestation any time the data is changed or updated. The most recent data for which there is an attestation will be considered the official data submission from the applicable manufacturer or applicable GPO. Data without such attestation will not be considered an official submission for purposes of reporting under section 1128G of the Act. CMS believes this may alleviate some of the concerns of applicable manufacturers regarding the difficulty in knowing whether the data submitted originally will be appropriately amended during the review and correction period.

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, as a part of the attestation process, must attest that less than ten percent of total (gross) revenue in the immediately

preceding year came from covered drugs, devices, biological, or medical supplies. For consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. 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.

Accordingly, CMS encourages applicable manufacturers considering submitting a consolidated report to fully consider the ramifications of doing so, particularly the applicable manufacturer actually attesting on behalf of all the entities included in the consolidated report.

Report Content (pg. 165)

CMS outlined the fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests. The asterisks indicate the additional information that CMS will require under the discretion provided by the statute.

For each payment and other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Covered recipient's --
  ++ Name (for physicians only, provide name as listed in NPPES, including first and last name, and middle initial and suffix (if applicable));
  ++ Specialty (for physicians only);
  ++ Primary business street address (practice location);
  ++ NPI (for physicians only, as listed in NPPES);
  ++ State professional license number(s) for at least one State where the physician maintains a license, including the applicable State where the license(s) is held;*
- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drug, device, biological, or medical supply, as applicable.
- NDCs of related covered drugs and biologicals, if any.*
- Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly.*
- Whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the applicable manufacturer (Yes or No response).
- Statement providing additional context for the payment or other transfer of value (optional).*

For each research-related payment or other transfer of value, the following information is required:

- Applicable manufacturer's name.
- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of related covered drug, device, biological or medical supply (same requirements as for all payments or other transfers of value).
- NDCs of related covered drugs and biologicals, if any.*
- Principal investigator(s) (including name (as listed in NPPES), NPI (as listed in NPPES), State professional license number(s) for at least one State where the physician maintains a license including the applicable State where the license(s) is held , specialty and primary business address).
- Context of research (optional).

- ClinicalTrials.gov identifier (optional).
- Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation (Yes or No response).

For each physician ownership or investment interest, the following information is required:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's --
  ++ Name (as listed in NPPES, including first and last name, middle initial, and suffix (if applicable));
  ++ Specialty;
  ++ Primary business street address (practice location);
  ++ NPI (as listed in NPPES);
  ++ State professional license number for at least one State where the physician maintains a license including the applicable State where the license(s) is held;* and
- Whether the ownership or investment interest is held by the physician, or an immediate family member of the physician.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.
- Any payments or other transfers of value provided to the physician owner or investor, including the following (applicable manufacturers should report this information with their other payments or other transfers of value, and indicate that the covered recipient is a physician investor or owner):
  ++ Amount of payment or other transfer of value in U.S. dollars.
  ++ Date of payment or other transfer of value.
  ++ Form of payment or other transfer of value.
  ++ Nature of payment or other transfer of value.
  ++ Name(s) of related covered drugs, devices, biologicals, or medical supplies.
  ++ NDCs of related covered drugs and biologicals, if any.*
  ++ Name of entity that received the payment or other transfer of value, if not provided to the physician owner or investor directly.*
  ++ Statement providing additional context for the payment or other transfer of value (optional).*

45-Day Review Period for Applicable Manufacturers, Applicable GPOs, Covered Recipients, and Physician Owners or Investors (pg. 169)

Notification of Review and Correction Period (pg. 169). CMS will notify physicians and teaching hospitals, as proposed, using email list serves, online postings (including both on the CMS website and the Federal Register) and directly (likely by email) to any physicians or teaching hospitals that have registered with CMS ahead of time. CMS recommends that all covered recipients and physician owners or investors register. Although registration is not mandatory for these entities, in order for covered recipients to be able to review the data attributed to them, they will be required to register so CMS can appropriately match them to their data. CMS will work with physician professional societies and provide the information to applicable manufacturers and applicable GPOs to provide voluntarily to covered recipients and physician owners or investors.

CMS may not provide ongoing notifications to covered recipients or physician owners or investors for data submitted on their behalf outside of the formal period (such as in response to a dispute). CMS will only provide for one formal review and correction period prior to the publication of that year's data.

Length of Review and Correction Period (pg. 172). CMS finalized a 45-day review and correction period, during which covered recipients and physician owners and investors may register and then sign into the CMS secure website and review the data submitted by applicable manufacturers and applicable GPOs on their behalf and choose to dispute certain payments or other transfers of value, or ownership of investment interests. As soon as a dispute is initiated, applicable manufacturers or applicable GPOs may begin resolving the dispute and correcting the data. Following the end

of the review and correction period, applicable manufacturers and applicable GPOs will have an additional 15 days to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. Disputes submitted earlier in the review and correction period will have more time to be resolved, and CMS encourages covered recipients and physician owners and investors to register with the CMS system, review their data and if necessary, initiate disputes as soon as possible within the 45-day review and correction period to maximize the likelihood of successful resolution and accurate data available for publication. There is no limit to the number of times a particular transaction can be reviewed and disputed.

CMS finalized its proposal of facilitating the process on a CMS-secure website. CMS is working to develop a system to allow secure registration, data submission, data review and submission of corrections processes. Applicable manufacturers and applicable GPOs will only be able to access and review the data they submitted or that was submitted for them within a consolidated report submitted by another covered entity; covered recipients and physician owners and investors will only be granted access to data regarding payments or other transfers of value and/or ownership or investment interests submitted on their behalf.

CMS plans to employ a system that will allow for secure user identification and authorization, and plans to allow physicians and teaching hospitals to register prior to the start of the annual formal review and correction period to establish their profile, allowing them immediate access to the information at the beginning of the formal review and correction period. The secure user-based authentication will require that the actual individual register and interact with the system to ensure the utmost security of the data.

CMS did not agree that more than 2 years of data should be available for review and correction. CMS believes that the data should be finalized and no longer open to disputes and updates after a certain time period. CMS believes that allowing only the review of the previous year's data (submitted in that year) provides covered recipients and physician owners and investors sufficient time to review and, if necessary, correct disputes.

CMS agrees that all data from the previous reporting year, including data granted delayed publication should be available for review during the review and correction period following the reporting year. CMS intends to provide additional information and guidance on the reporting requirements and timing of data review and correction to help applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors understand how transactions should be reported.

Dispute Resolution (pg. 177). CMS believes that it does have a responsibility to facilitate the capability for correcting the data and resolving disputes among the parties, but maintains that the agency should not be actively engaged in mediating dispute resolutions. CMS plans to provide the opportunity for covered recipients, or physician owners or inventors to review and correct the data submitted on their behalf. CMS also plans to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.

If a covered recipient or physician owner or investor decides to initiate a dispute, the applicable manufacturer or applicable GPO and physician or teaching hospital will be responsible for resolving the dispute, after which the applicable manufacturer or applicable GPO will be responsible for submitting corrected data and re-attesting to the new data by the end of the 15-day resolution period. If a dispute cannot be resolved in this time, the parties may and should continue to work to reach resolution and update the data. However, CMS will continue to move forward with publishing the original and attested data, but will mark it as disputed.

If an applicable manufacturer or applicable GPO submits updated data to resolve dispute(s), the applicable manufacturer or applicable GPO must re-attest to the timeliness, accuracy, and completeness of the data, as required during the original data submission. If an applicable manufacturer or applicable GPO does not update its data at the end of the correction period, then its original attestation will be used.

CMS believes that Congress intended any disputes identified to be resolved; however, CMS does recognize that there

may be situations when the cost of initiating and resolving a dispute may not be worth the potential benefits. CMS intends to monitor the volume and terms of disputes and resolutions, and plans to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits.

CMS finalized that on the public website, payments or other transfers of value or ownership or investment interests that cannot be resolved by the end of the 15-day resolution period will be marked as "disputed," but the applicable manufacturer's or applicable GPO's most recent attested data subject to the dispute will be the only account of the information published. Publishing the most recent attested account by the applicable manufacturer or applicable GPO (rather than the corrected account provided by the covered recipient or physician owner or investor during the review and correction period) is appropriate because applicable manufacturers and applicable GPOs are responsible for collecting, reporting, and attesting to the accuracy of the information and are subject to penalties for failure to report.

CMS agrees that it has a responsibility to allow for updates to the data more frequently than once a year during the formal 45-day review and correction period and 15-day resolution period, particularly given the short time period for the data to be reviewed and updated. CMS notes that some disputes will not be resolved in time for updated data to be included in the public data release for that reporting year, but will be resolved and require changes thereafter. These should not be incorrectly listed on the website for a whole year, when they have in fact been resolved. Nevertheless, CMS believes that it does not have the resources to make continual changes to the website and should not be required to continually update the data. CMS will update the current and a previous year's data at least once annually, beyond the initial data publication following the submission of the data.

CMS believes that covered recipients, and physician owners or investors, should be allowed to review and dispute the contents of the public website throughout the year. After registering with the CMS system, physicians and teaching hospitals, and physician owners and investors may sign in to the system to review or dispute officially submitted and attested transactions any time during the year. However, any disputes and subsequent updates initiated and resolved outside the 45-day review and correction period and 15-day resolution period may not be reflected on the public website until the next update of the data.

CMS believes that covered recipients and physician owners or investors should use the CMS review and correction processes to report errors and begin to resolve them with applicable manufacturers and applicable GPOs as quickly as possible. It will be the responsibility of the applicable manufacturer or applicable GPO that submitted and attested to the data to submit any updates, including errors and omissions, immediately after confirming that an update is needed or an error needs to be corrected; failure to do so may be considered incomplete reporting and may give rise to penalties.

Public Availability (pg. 186)

CMS agrees that stakeholder input is essential to the success of the public website, and the agency plans to engage stakeholders regarding the content of the website, since CMS recognizes that stakeholders and the public must be a part of the development process. CMS agrees that it is important that the final website is user-friendly and provide accurate and understandable information to the public. CMS believes it is important that it have flexibility to make changes to the website as they are identified, so it has not discussed specific details in the final rule. CMS will release additional data and work with the public as part of it education and outreach efforts.

CMS agrees that both the information included and capabilities of the website are extremely important. CMS plans to ensure that the public website accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions. In addition, CMS plans to provide information to stakeholders regarding the data submission, review, dispute, dispute resolution and other applicable operational processes. As proposed, the website will clearly state that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. CMS plans to provide Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.

CMS is cognizant that the website will include a significant amount of information and are considering the best way to provide sufficient context without overwhelming the consumer. CMS plans to aggregate the data submitted and publish the data on a website that is searchable across multiple fields and available for downloads. CMS plans to establish mechanisms for researchers who may want information that is not publicly available. CMS plans to provide opportunities to download the data that support researchers, as well as consumers, since CMS believes that research on this information is an important benefit of any transparency initiative.

Data Elements (pg. 190)

CMS finalized the data elements that would be available on the public website. As required by statute, a physician's NPI will not be published on the public website. The asterisks indicate the additional information that CMS will publish under the discretion provided by the statute.

As required in section 1128G(c)(1)(C)(ii) of the Act, at a minimum the following information on payments and other transfers of value would be included on the public website in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's name.
- Covered recipient's--
  ++ Name;
  ++ Specialty (physician only); and
  ++ Primary business street address (practice location).
- Amount of payment or other transfer of value in U.S. dollars.
- Date of payment or other transfer of value.
- Form of payment or other transfer of value.
- Nature of payment or other transfer of value.
- Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
- NDCs of related covered drugs and biologicals, if any.*
- Name of the entity that received the payment or other transfer of value, if not provided to the covered recipient directly.
- Statement providing additional context for the payment or other transfer of value (optional).*

For research payments or other transfers of value, at a minimum the following research related information will be available on the public website:

- Name of research institution/entity receiving payment.
- Total amount of research payment.
- Name of study.
- Name(s) of the related covered drugs, devices, biologicals or medical supplies.
- NDCs of related covered drugs and biologicals, if any.*
- Principal investigator(s) (including name, specialty and primary business address).
- Context of research.
- ClinicalTrials.gov identifier (optional).

For physician ownership and investment interests, at a minimum the following information would be included on the public website in a format that is searchable, downloadable, understandable, and able to be aggregated:

- Applicable manufacturer's or applicable GPO's name.
- Physician owner or investor's--
  ++ Name;
  ++ Specialty; and

++ Primary business street address.

- Whether the ownership or investment interest is held by the physician or an immediate family member of the physician.
- Dollar amount invested.
- Value and terms of each ownership or investment interest.
- Any payment or other transfer of value provided to the physician owner or investor, including:
  ++ Amount of payment or other transfer of value in U.S. dollars.
  ++ Date of payment or other transfer of value.
  ++ Form of payment or other transfer of value.
  ++ Nature of payment or other transfer of value.
  ++ Name(s) of the related covered drugs, devices, biologicals, or medical supplies, as applicable.
  ++ NDCs of related covered drugs and biologicals, if any.*
  ++ Name of the entity that received the payment or other transfer of value, if not provided to the physician directly.
  ++ Statement providing additional context for the payment or other transfer of value (optional).*

Delayed Publication for Payments Made Under Product Research or Development Agreement and Clinical Investigations (pg. 192)

CMS clarified that all payments or other transfers of value that are related to research, as defined in §403.902, and are made pursuant to a written research agreement for research related to new products will be granted a delay. Payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation." Given the broad scope of the statutory definition of "clinical investigation," CMS believes this includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies). CMS also amended the regulatory definition to include biologicals and medical supplies, as well as drugs and devices, since all product types should be treated similarly.

For purposes of determining eligibility for delayed publication under section 1128G(c)(1)(E) of the Act, new generic products will be considered new products, including drugs receiving approval under an Abbreviated New Drug Application, and devices under the 510(k) process.

CMS does not believe that the statute grants it the ability to grant delays for payment types other than research. A payment or other transfer of value can only be granted delayed publication if the payment meets the definition of research and could be reported under the "research" nature of payment category. Any related payments or other transfers of value that would not be reported as a part of the research nature of payment category, pursuant to the discussion in section II.B.1.i. of the final rule, will not be granted delayed publication.

CMS believes Congress clearly intended that all payments should be included on the public website, even if a product never received FDA approval, licensure or clearance.

Process for Reporting payments or Other Transfers of Value Granted Delayed Publication (pg. 197)

If a manufacturer does not indicate that a payment or other transfer of value is eligible for delayed publication, it will be published immediately on the next publication date.

Despite concerns raised by commenters, CMS believes that allowing applicable manufacturers to report in a different manner and allowing special considerations for certain research payments or other transfers of value makes the reporting requirements significantly more complicated. CMS does not intend applicable manufacturers to provide research protocols or other such agreements to CMS for verification.

Information reported by applicable manufacturers that is subject to delayed publication under section 1128G(c)(1)(E) of the Act shall be considered confidential and shall not be subject to disclosure under 5 U.S.C. 552, or any other similar

Federal, State or local law, until after the date on which the information is made available to the public via publication on the website.

Penalties (pg. 200)

CMS finalized its proposal that a civil monetary penalty (CMP) may be imposed for failure to report information in a timely, accurate, or complete manner. This includes failure to report timely or accurately an entire transaction, as well as failure to report timely or accurately certain fields related to a transaction.

To clarify this, CMS revised the regulation text in 42 CFR 402.105 to include the same text regarding reporting in a timely, accurate, or complete manner. CMS revised the regulation text at §402.105 and §403.912 to clarify that 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. CMS clarified that the procedures in 42 CFR 402 subpart A and subpart B will apply with regard to imposition, appeal, and collection of CMPs.

CMS will require applicable manufacturers and applicable GPOs to attest the timeliness, accuracy, and completeness of their original submission to CMS prior to the review and correction period. CMS does not intend that errors corrected during the review and correction, and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith. Applicable manufacturers and applicable GPOs will be required to re-attest after the submission of updated or new data. Outside this period, any errors or omissions will be considered failures to report timely, accurately, or completely, and will be subject to penalties. Additionally, both CMS and the HHS OIG are authorized to impose CMPs and both agencies will have the ability to investigate failures to report timely, accurately or completely.

For consolidated reports, the applicable manufacturer that submitted the consolidated report will be required to attest on behalf of all the entities included in the consolidated report. Therefore, the applicable manufacturer actually submitting the consolidated report and signing the attestation will be subject to the maximum penalties (based on unknowing and knowing failures to report) for each individual applicable manufacturer included in the consolidated report. Because the applicable manufacturer submitting the consolidated report is the entity attesting to the data, CMS believes it is fair that it be subject to the CMPs for each applicable manufacturer included in the consolidated report.

CMS finalized the retention requirements of five years as proposed. CMS noted that the requirements set forth in this final rule are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable GPOs to retain and allow access to records.

Annual Reports (pg. 206)

CMS is required to submit annual reports to the Congress and the States. The Report to Congress is due annually on April 1st, beginning April 1, 2013, and shall include aggregated information on each applicable manufacturer and applicable GPO submitted during the preceding calendar year, as well as any enforcement action taken and any penalties paid. CMS must report information submitted during the previous year to States annually by September 30, 2013 and June 30 for each year thereafter.

CMS agreed that the annual Congressional report should include summary statistics on the annual aggregate totals across applicable manufacturers and applicable GPOs, and that inclusion of the aggregate total of payments or other transfers of value would be useful for oversight of the program. Therefore, CMS will include this information in its annual Congressional report. CMS did not include specific details in the final rule regarding this, in order to allow the agency the flexibility to include and present information as appropriate. CMS plans to work closely with other Federal agencies, since it recognizes that other agencies are involved in similar activities. However, the purpose of this program is not to prosecute reporting entities, but to promote transparency.

CMS finalized that the Report to Congress will be submitted annually on April 1st, beginning April 1, 2015, and will include aggregated information submitted by each applicable manufacturer and applicable GPO submitted during the

preceding calendar year (that is, data collected in CY 2013 and submitted in March of 2014), as well as any enforcement actions taken and any penalties paid.

Relation to State Laws (pg. 209)

CMS understands that the delay in publication of the rule implementing section 1128G of the Act, which was to be published by October 1, 2011, has led to uncertainty regarding when preemption actually becomes effective. CMS urges manufacturers to continue to report under State or local disclosure laws until the requirements under the Federal rule take effect.

CMS provided some additional guidelines to clarify the preemption requirements, but noted that preemption determinations will need to be analyzed on a case-by-case basis. Specifically, CMS interprets "type of information" for purposes of the preemption clause at 1128G(d)(3)(A) of the Act, to refer to the categories of information for each payments or other transfer of value required to be reported under the statute at 1128G(a)(1)(A)(i) through (viii) of the Act and §403.904(c) of the regulations.

State and local entities may require reporting of non-required categories of information for payments or other transfers of value reported to CMS, which are not required under Federal law, such as categories excluded by Federal law.

States and localities may require reporting of payments or other transfers of value not required to be reported at all under the Federal law, such as the reporting of payments to non-covered recipients or by non-applicable manufacturers.

If a Federal, State or local government agency seeks to collect information reportable under this regulation for public health and/or oversight purposes and specifically needs the information for a purpose other than transparency, then such collection will not be preempted. However, if the purpose of the collection does not meet this exception and in actuality seeks to achieve the same transparency goal as the collection required under section 1128G of the Act, CMS believes such a collection would be preempted, and the States or localities can obtain the information they want from the Federal program.

CMS finalized the proposed discussion of public health agencies. CMS intends such agencies to include those that are charged with preventing or controlling disease, injury or disability and/or with conducting oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.